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Enhancement of the REACH requirements for (imported) articles

Options for improvement of the chemicals regulation

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Enhancement of the REACH requirements for (imported) articles

Options for improvement of the chemicals regulation

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Abstract

The study investigates how modifications of the REACH and CLP Regulations can contribute to a better protection of human health and the environment against impacts caused by substances of very high concern (SVHC) in articles.

The first part of the report is a legal opinion analysing the conformity with World Trade Organization WTO law (especially TBT Agreement) of an expansion of the REACH provisions concerning authorisation of SVHC to those substances present in articles imported from countries outside the EEA. The study concludes that an extended authorisation requirement which also covers imported articles with "very high concern" components is compatible with international trade laws. Whether an extension of the authorisation requirement is the paramount recommendable regulatory option did not fall within the scope of this study.

Additionally, the second part of the report (chapter 6) discusses how information and communication on SVHC in articles can be improved. Several practical options are suggested in this respect. These options refer to communication requirements under Art. 33 REACH (standardised communication format for articles, labelling of SVHC in articles, communication of further substances), obligations for substances in articles pursuant Art. 7 REACH and regarding registration of substances on their own, clarification of the reference point for the 0.1 threshold for SVHC in articles stipulated by Art.7 and Art. 33 and a register for articles containing SVHC.

A draft version of the study report was discussed with representatives from competent authorities, science, stakeholders from companies and trade associations as well as environment and consumer protection organisations at workshops on 7 July 2014 in Berlin and on 9 October 2014 in Brussels.

Kurzbeschreibung

Die Studie untersucht, welche Anpassungen des originären Stoffrechts (REACH-VO und CLP-VO) einen Beitrag leisten können, die Umwelt und die menschliche Gesundheit besser vor Belastungen durch besonders besorgniserregende Stoffe (SVHC) in Erzeugnissen zu schützen.

Kern der Studie ist ein Rechtsgutachten. Es geht der Frage nach, ob eine erweiterte Zulassungspflicht für SVHC, die in aus Drittstaaten importierten Erzeugnissen enthalten sind, mit den Vorgaben des Rechts der Welthandelsorganisation WTO (v. a. TBT-Übereinkommen) vereinbar ist. Als Ergebnis der Prüfung lässt sich festhalten, dass eine erweiterte Zulassungspflicht, die auch importierte Erzeugnisse mit „besonders besorgniserregenden" Inhaltsstoffen erfasst, mit dem Welthandelsrecht vereinbar ist. Gegenstand der Studie war nicht die Frage, ob dies eine vorrangig zu empfehlende Gestaltungsoption darstellt.

Ergänzend erörtert Kapitel 6, wie man Information und Kommunikation bezüglich SVHC in Erzeugnissen verbessern könnte. Diskutierte Optionen beziehen sich auf die Kommunikationspflichten gemäß Art. 33 REACH (standardisiertes Kommunikationsformat für Erzeugnisse, Kennzeichnungsplicht von SVHC in Erzeugnissen, Kommunikation weiterer Stoffe), auf die Registrierungspflicht von Stoffen als solchen oder in Erzeugnissen, auf die Klarstellung des Bezugspunktes der 0,1% Schwelle für SVHC im Erzeugnis und auf die Schaffung eines Registers für SVHC-haltige Erzeugnisse.

Die Entwurfsfassung der Studie war Gegenstand eines Fachgesprächs am 7. Juli 2014 in Berlin sowie eines „Policy Workshops" am 9. Oktober 2014 in Brüssel; beteiligt waren jeweils Vertreter der zuständigen Behörden, der Wissenschaft sowie von Stakeholdern aus Unternehmen und Industrieverbänden, aber auch Umwelt- und Verbraucherorganisationen.

Overview

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List of Abbreviations

A	year
Art.	Article
BVerwG	Bundesverwaltungsgericht (German Federal Administrative Court)
CFR	Charter of Fundamental Rights of the European Union
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or Toxic for reproduction
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EDC	Endocrine Disrupting Chemical
EEA	European Economic Area
EGC	General Court (of the European Union)
GATT	WTO General Agreement on Tariffs and Trade
GHS	Global Harmonised System of Classification and Labelling of Chemicals
ICJ	International Court of Justice
ITLOS	International Tribunal for the Law of the Sea
OR	Only representative
OSPAR Convention	The Convention for the Protection of the marine Environment of the North-East Atlantic
PBT	Persistent, Bioaccumulative and Toxic
POP	Persistent Organic Pollutant
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SVHC	Substance of Very High Concern
t	ton/tonnes
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TFEU	Treaty of the Functioning of the European Union
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
VCLT	Vienna Convention on the law of treaties
vPvB	very Persistent and very Bioaccumulative
WTO	World Trade Organization

0 Summary

0.1 Scope and key results

How may the requirements of the European Chemicals Legislation REACH (EG) No 1907/2006 regarding (imported) articles be enhanced? Especially if they contain substances of very high concern (SVHC)? This is the central question of this study which seeks to better bring to bear the aim formulated in the Treaty of the Functioning of the European Union as well as in Art. 1(1) REACH to ensure a high level of protection of human health and the environment.

The REACH Regulation introduces two key innovations: the registration of chemical substances and the authorisation regime for SVHC. In each case special arrangements for imported articles have to be considered. The authorisation regime only applies to SVHC used in Europe. It follows that articles (such as furniture, textiles, toys, DVDs, books, kitchen appliances and other electronic devices, vehicles, insulation materials etc.) produced in the European Economic Area may not contain these substances unless an authorisation was granted for the specific use. In effect, REACH treats European articles more strictly. Such discrimination can lead to SVHC entering the European market as part of imported articles, burdening human health and the environment.

The first part of the report examines whether an extension of the authorisation requirement to SVHC present in imported articles may close this protection gap in accordance with the specifications of WTO world trade law (chapters 2-5). This takes the form of a legal assessment of a regulatory option. A recommendation as to whether this or another option, e.g. REACH restrictions, is preferable, is not included in this study.

In the second part of the report (chapter 6), deficiencies in REACH and its implementation regarding SVHC in articles are described. This refers to the registration and notification of these substances and to the communication on SVHC (within the supply chains and to consumers). Seven regulatory options are described which can help to strengthen the existing weak points. With the aim to achieve a high level of protection for human health and the environment facing SVHC in articles. These options refer to communication requirements under Art. 33 REACH (standardised communication format for articles, labelling of SVHC in articles, communication of further substances), obligations for substances in articles pursuant Art. 7 REACH and regarding registration of substances on their own, clarification of the reference point for the 0.1 threshold stipulated by Art.7 and Art. 33 and a register for articles containing SVHC.

The study concludes that an extended authorisation requirement which also covers imported articles with “very high concern” ingredients is compatible with international trade laws. Measured by the standards of the WTO dispute settlement practice, this would neither violate the principles of national treatment and most-favoured nation treatment set out in 2.1 TBT Agreement. Also, such regulation would not constitute an unnecessary obstacle to trade within the meaning of Art. 2.2. TBT, since the extended authorisation requirement would pursue a legitimate objective covered by the regulatory autonomy of the EU. Furthermore, the regulation would not be more trade-restrictive than necessary.

As regards the seven additional regulatory options, a uniform communication format for articles (regulatory option 1) would to a large extend support the correct implementation of the REACH communication requirements regarding SVHC. It can be implemented without change of the existing legal framework.

In addition, the clarification of the information requirements for the registered use (option 5) is a second specification of REACH that can be implemented within the existing legal framework and which might contribute significantly to the achievement of the aims of REACH.

Furthermore, clarification that the 0.1 % threshold (above which SVHC contained in articles have to be notified and communicated) refers to the component (regulatory option 6), and not to the overall article, would help to obtain additional information which would facilitate the replacement of SVHC in articles.

Major changes are also expected from the extension of communication requirements to other substances (regulatory option 3). It supports industrial and professional actors as well as consumers, who want be informed about problematic substances in articles or who want to use less problematic articles. The examination of this option is foreseen by REACH in a review clause.

Finally substantial additional information for actors in the supply chain and consumers can also be expected from the labelling obligation for articles containing SVHC (regulatory option 2) and a register for articles containing SVHC (regulatory option 7). A register involves, however, considerable additional efforts for producers and importers of articles and the operator of the register. It has to be clarified whether both regulatory options shall be implemented in parallel or just one of them. A standardised communication format (regulatory option 1) should be part of both options.

The following sections concisely summarise the main assessment steps.

0.2 Extended authorisation requirement for SVHC in imported articles

Art. 57(a) – (f) REACH specify the SVHC criteria. These include CMR substances with carcinogenic (a) or cell mutagenic (b) properties as well as substances toxic to reproduction (c); PBTs that are persistent, bioaccumulative and toxic (d); vPvBs that are very persistent and very bioaccumulative (e); and substances "for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e)".

For CMR substances which account for the majority of the identified SVHC, scientific evidence of the hazard potential is provided (Classification Category 1A and 1B); substances which are only suspected to have CMR properties (Cat. 2) do not fall under Art. 57 lit. (a) – (c). The toxicity of PBT substances may be based on several grounds such as harmful effects on aquatic organisms, toxicity to certain target organs as well as CMR properties. Regarding the latter, reproductive toxic effects can also be based on suspected properties (Cat. 2). Other substances of equivalent concern include, for example, substances with hormonal effects (EDCs) or allergenic properties. Usually threshold levels cannot be derived for carcinogenic, mutagenic, PBT and vPvB substances, i.e. in these cases a fixed concentration below which adverse effects can be excluded cannot be determined.

Following Art. 56(1) REACH a "manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV," unless the respective actor attained an authorisation for the corresponding use or this use is exempt from the authorisation requirement. However, REACH regulates only the use of SVHC within the European Economic Area (EEA). Whenever the producer of an article incorporates the substance outside the EEA, Art. 56(1) does not apply. An article may therefore be imported into the EEA subject to the requirements of Art. 7 REACH. "Domestic" producers of articles are thus subject to stricter requirements than those which produce "abroad".

To overcome this regulatory gap an alternative solution would be to adjust the regulation text so that the effect of the authorisation requirement is expressly extended to SVHC in imported articles. For this purpose Art. 56 REACH could be modified to the extent that Paragraph 1 also covers the import of an Annex XIV-substance when incorporated into articles.

0.2.1 Applicable law and scope of the assessment

The proposed modification would treat imported articles like domestic articles: articles containing one or more substances listed in Annex XIV REACH may not be imported, unless a specific authorisation is granted or the use is exempted from the authorisation requirement. In this case, the prohibition and the lifting of the ban as a result of an authorisation decision form one measure. This measure could constitute a "non-tariff trade barrier" with regard to the international trade of goods. To this end the Agreement on Technical Barriers to Trade (TBT) provides the relevant legal specifications for the WTO-legal assessment; the extended authorisation requirement is a "technical regulation" in terms of TBT. Furthermore, in the interpretation of the TBT Agreement in accordance with the WTO dispute settlement practice, the provisions of the GATT Agreement (General Agreement on Tariffs and Trade) and the SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures) should be referred to some degree.

According to the WTO dispute settlement practice and the literature on TBT, the central requirements of the Agreement particularly result from Art. 2.1 with respect to the principles of national treatment and most-favoured nation treatment and from Art. 2.2 TBT concerning the prohibition of unnecessary obstacles to international trade. These provisions formulate independent requirements that must be examined independently. It follows that, as in the case of a violation of Art. 2.1, due to the discriminatory effect of a technical regulation, this can be justified in overall terms by virtue of Art. 2.2.

0.2.2 National treatment and most-favoured nation treatment (Art. 2.1 TBT)

The technical regulation of an extended authorisation requirement would violate Art. 2.1 TBT, if it treats imported products less favourably than products of the same kind ("like products") which were produced within the EEA or another third country.

Product "likeness". In order to determine whether the domestic and the imported articles are "like products" the following product pair has to be assessed:

> Article A, produced in the EEA and not containing any SVHC,
> and article B, produced in a third country and containing one or more Annex XIV SVHC.

From the standards established by WTO case law, it follows that articles with SVHC and articles without SVHC may often be "like products" in terms of Art. 2.1 TBT.

- On the one hand, articles with SVHC frequently pose a certain "general risk" to humans or the environment which is due to the exposure in the product life cycle that is in practice hardly avoidable. Similar products without SVHC do not pose corresponding risks, indicating as a result that the two products are not regarded as "like products" in this way.
- On the other hand, potential end-uses will, except in special cases, be identical for both products in principle. Moreover, data on consumer tastes and habits shows that consumers in the EEA do not consistently prefer products without SVHC; rather, relevant market segments are likely to exist in which consumers perceive the compared articles as substitutable. This may result in individual cases where there is evidence in favour of the likeness of the products.

However, it should be stressed that the question of likeness can only be answered conclusively by examining specific product examples; depending on the type and function of an article, the specific characteristics of the SVHC used and their integration in the article. If the products are not regarded as alike, the technical regulation may not violate Art. 2.1 TBT and the Art. 2.1 test would thus be completed.

"Treatment no less favourable" test. Regarding the extent to which the analysed pair of articles may be "like products", it needs to be tested whether the technical regulation treats imported articles less favourably than like domestic articles or imported like articles of other origin (principles of national treatment and most-favoured-nation treatment). An extended authorisation requirement would by design and structure treat imported articles the same as domestic articles. Thus there is no de jure discrimination of imported SVHC-articles vis-à-vis domestic SVHC-free articles. Moreover, the extended authorisation requirement would not cause a de facto discrimination; but even if one assumes for individual cases that the specific composition of the substances on Annex XIV or the necessity of an establishment in the community may detrimentally impact the competitive opportunities of imported products, this effect would be due to legitimate regulatory distinctions.

So as a result the extended authorisation requirement is compatible with Article 2.1 TBT.

0.2.3 Unnecessary obstacles to international trade (Art. 2.2 TBT)

Art. 2.2 TBT bars technical regulations that are more trade-restrictive than necessary to fulfil a legitimate objective. Since the extended authorisation requirement is trade-restrictive (non-tariff barrier) the question is whether the regulation is also more trade-restrictive than necessary. This includes a three-fold examination of whether the regulation pursues a legitimate objective, whether it is appropriate to fulfil such objective and whether it is more trade-restrictive than necessary to fulfil the objective, taking account of the risks non-fulfilment would create.

Legitimate objective. With the objective of a high level of protection of human health and the environment, the extended authorisation requirement follows a legitimate objective in terms of Art. 2.2 TBT.

Appropriateness. The extended authorisation requirement prevents SVHC from entering the EEA marked as part of imported articles. The regulation reduces thus the exposure of human health and the environment to "very high concern" substances. It is therefore "as written and applied" appropriate to achieve its legitimate objective.

Necessity. Art. 2.2 TBT provides that technical regulations may not be more trade-restrictive than necessary. In order to examine whether the intrusiveness of a given technical regulation is necessary, a "relational analysis" of

- the specific trade restrictions due to the regulation;
- the legitimate objective and the contribution of the regulation to fulfil this objective; and
- the risks that non-fulfilment would create

has to be performed. Typically, the analysis also includes

- a comparison with possible alternative measures that may be reasonably available and less trade-restrictive than the technical regulation.

Since the first steps of the analysis have already been taken, only the last two steps are summarised below.

Risks of non-fulfilment. Art. 2.2 Sentence 4 TBT gives clues as to how the negative effects can be determined that can be expected if the objectives of the technical regulation cannot be fulfilled; however, the risk assessment steps provided therein are not mandatory. The Appellate Body adds that the comparison with possible alternative regulatory options "should be made in the light of the nature of the risks at issue and the gravity of the consequences that would arise from non-fulfilment of the legitimate objective". The technical regulation of an extended authorisation requirement aims to reduce and avoid the exposure of humans and the environment to SVHC listed in Annex XIV. The risks posed by SVHC thus have to be examined.

This includes both procedural and substantive considerations. From a procedural point of view an assessment is necessary whether the risk assessment provided for in the extended authorisation requirement is appropriate to determine risks in terms of Art. 2.2(4) TBT. From a substantive point of view the importance which the TBT Agreement ascribes to these risks needs to be considered.

Procedural view. As the TBT Agreement lacks the relevant context to examine the risk assessment one might refer to the respective requirements set out in the Agreement on Sanitary and Phytosanitary Measures (SPS) and relevant case law. On this basis the conclusion can be drawn that the risk assessment in accordance with the extended authorisation requirement conforms to the requirements of the SPS Agreement. By implementation of the risk-ratio model and qualitative risk characterisation methods in the application for authorisation and its review, the technical regulation ensures the assessment of the risks in each application of SVHC in an article. This is especially true with regard to those SVHC for which effect thresholds can be derived. But even in relation to cases in which methodological challenges will not allow an unambiguous assignment of causality, the Appellate Body lowers the relevant threshold for the determination of potential adverse effects down to a level ("whether those adverse effects could ever occur") that the technical regulation meets.

Substantive view. In the *EC – Asbestos* case, the European Community showed that asbestos can cause various forms of cancer. Given the relevance of the identified risk, its possible consequences, and the objective of the import ban ("halt the spread of this risk"), the WTO dispute settlement organs held the strict regulatory measure is compliant with the requirements of the General Agreement on Tariffs and Trade (GATT) – especially because it was not possible to derive effect thresholds.

Most SVHC – namely those designated in Art. 57(a) to (d) and partially Art. 57(f) – is a scientifically proven hazard potential immanent which – as is the case with asbestos – is (also) based on internationally harmonised classification criteria according to GHS. In the event of exposure, the hazard potential of these substances – under German law – may establish a situation of danger in the legal sense, against which the state is even obliged to take preventing measures. As regards these substances, the "nature of risks" and "gravity of the consequences" are therefore – in light of the purpose of the technical regulation –to be rated as of similar high concern compared to the situation in *EC – Asbestos*. Strong evidence for the necessity of the technical regulation can be derived from this.

However, the extended authorisation requirement also builds selectively on SVHC whose hazard potential involves, to some extent, scientific uncertainty. This includes PBTs "suspected" of human reproductive toxicity (Category 2), vPvB and possibly specific substances determined on the grounds of Art. 57(f). The risks posed by these substances would therefore – in principle despite release – be located below the danger threshold; a regulatory approach to these substances is thus to be classified as a precautionary measure. Thus, it has to be examined how a technical regulation which is also an expression of the precautionary principle must be evaluated in terms of Art. 2.2 TBT.

The question is whether the "nature of the risks" and "gravity of the consequences" posed by the latter mentioned "precaution group" of SVHC – in the light of the purpose of the regulation – may justify the trade-restricting effect of the technical regulation. The TBT Agreement itself gives no information as to whether a precautionary approach is admissible. However, relevance of the precautionary principle could be derived from international environmental law, the requirements of which according to Art. 31(3)(c) of the Vienna Convention on the law of treaties "shall be taken into account" when interpreting an international treaty such as the TBT Agreement. International law does not contain a "horizontal" clause making the applicability of

the precautionary principle mandatory; a conclusive determination of whether the principle has attained a customary international law binding status is also not yet possible. However, there are increasing indications that such a status exists. Detached from this discussion the wide distribution of the precautionary principle also shows that it is of prominent importance at international level and especially in the chemicals legislation.

Measured by the principles the Appellate Body formulated in *US – Shrimp*, the normative content of precaution therefore is also noteworthy for the interpretation of Article 2.2 TBT. The subject of the mentioned decision is the interpretation of Art. XX(g) GATT (conservation of exhaustible natural resources) that has to be done according to the Appellate Body in the light of the current concerns of the community of states. With recourse to different binding and non-binding sources of international law (e.g. Agenda 21) the Chamber expands the justifications of Art. XX(g) GATT by way of an "evolutionary" interpretation which takes into account the international law developments. It follows from this and from the international importance of precaution that the principle at least informs the interpretation of the environmental and health protection-related justifications under 2.2 TBT – which are systematically related to Art. XX(g) GATT – when a tested technical regulation is (partly) based on this principle.

The majority of the identified SVHC are CMR substances with a proven hazard potential. Regulatory measures against these substances are hence – in the case of relevant exposure – not within the sphere of precaution, but rather danger prevention. However, to some extent the extended authorisation requirement is also linked to risk situations under uncertainty; but even in these cases it is directed against irreversible and serious damage. Also, derivation of effect thresholds is often not possible, harmful effects therefore have to be expected at low and lowest concentrations already. Thus, the technical regulation acts exactly in the scope of application of Principle 15 of the United Nations' Rio Declaration. Especially with regard to the chemicals group of persistent substances with a high potential of accumulation the precautionary principle gains additional significance through concrete international legal requirements (e.g. POP Convention). The risks associated with the "precaution categories" of Art. 57 REACH are therefore by no means insignificant. This is particularly true because neither TBT nor the Appellate Body requires a minimum amount for a risk to be detected.

Furthermore, the legitimate objective of the extended authorisation requirement is to ensure a high level of protection for human health and the environment. The SVHC criteria addressed by the technical regulation are an expression of this level of protection, the adoption of which – according to an evolutionary interpretation of Art. 2.2 TBT in the light of the requirements of the precautionary principle – is covered by the regulatory autonomy of the Member States of the Agreement. A non-fulfilment of the normative goals would therefore cause unacceptable risks, also in the case of the "precaution group" of SVHC. This again speaks for the necessity of the technical regulation.

Possible alternative measures. There are no means available which on the one hand constitute a less intrusive trade-restriction and on the other hand make an equal – or higher – contribution to the legitimate objective. This applies especially in the case of the restriction mechanism already available in the REACH framework (Art. 67 et seq. REACH). Authorisation requirements are available for certain hazard potentials of (prioritised) substances while restrictions require the knowledge of a concrete "unacceptable risk" and might thus not achieve the same degree of risk reduction. However, if the intervention threshold of the restriction would be lowered accordingly (hazard as a trigger), the restriction would be stricter and the authorisation requirement which provides for a permit reservation would be the milder means.

Conclusion: relational analysis. The extended authorisation requirement as a "technical regulation" within the meaning of the TBT Agreement is directed at imported products

containing substances of very high concern (SVHC) that are listed in Annex XIV. It aims to prevent the risks posed by these substances. All these substances exhibit a scientifically proven hazard potential. The risks linked to the substances may trigger the state's obligation to prevent dangers as well as to take precautionary measures; in both cases the presumption of risk is linked to actual evidence of possible (or probable) damage.

The analysis shows that the technical regulation is likely to make a significant contribution to its purposes which are legitimate objectives under Art. 2.2 TBT. As no possible alternative means are available, the overall view of these facts leads to the conclusion that the extended authorisation requirement (prohibition with permit reservation) is not more trade-restrictive than necessary in terms of Art. 2.2 TBT.

0.2.4 Conclusion: extended authorisation

In summary, the regulatory option of an extended authorisation requirement is consistent with world trade law. It would not violate the principles of national treatment and most-favoured nation treatment according to Art. 2.1 TBT. Moreover, the regulation would not constitute an unnecessary obstacle to international trade within the meaning of Art. 2.2. TBT.

0.3 Further regulatory options to achieve the protection objectives of REACH for articles containing SVHC

In addition to the extended authorisation requirement further amendments or clarifications of the REACH Regulation have been investigated in the present study. The following regulatory options can contribute to reach the protection aims of REACH (high protection level for human health and the environment). An explicit prioritisation of the different options did not fall within the scope of this study.

0.3.1 Standardised communication format for articles (regulatory option 1)

The implementation of a standardised communication format for (substances in) articles helps to ensure that the information that is necessary to achieve the protection goals will actually be communicated. A major weakness of the current practice - the limitation of the communication regarding REACH Art. 33 to the mere indication of the names of the SVHC - can be overcome by this. Beside the name of the substance information on the concentration, the total quantity, the hazardous properties, the specific location inside the article and the safe use and disposal should be given.

Standardisation can help to enable suppliers to provide responses about SVHC in articles more quickly within the 45-day period prescribed. Furthermore some of the information is necessary to calculate the total concentration or the total quantity in a complex article which is not possible without the knowledge of the concentration or the quantity in the components (see also regulatory option 6). A standardised communication format would also facilitate the enforcement of Art. 33.

A legal option to implement the standardised communication format for articles in REACH is to implement a new Annex "Standardised communication format for articles". Such an amendment is covered by the current legal content of Art. 33(1) REACH. A further step could be the requirement for suppliers to answer information requests according to Art. 33(2) REACH even in the case that the article does not contain a SVHC. This clarification would support the existing information requirements under REACH.

0.3.2 Labelling for SVHC in articles (regulatory option 2)

Currently, the supplier is granted a period of 45 days to reply to requests about SVHC in his articles. This is considered to be not sufficiently practical. Mandatory labelling for SVHC in articles would ensure that industrial and professional users and consumers are directly informed. This would facilitate the choice in favour of articles that are free of these substances, which increases the pressure to offer articles without SVHC. This approach, too, could make a significant contribution to achieving the protection goals associated with the communication on SVHC.

As on the packaging of the article rarely more than the name of a SVHC can be stated it is recommendable that additional information can be found in the internet. It is reasonable to use also in this case the standardised communication format to ensure completeness of information (see regulatory option 1).

There are several options to implement an obligatory labelling for articles containing SVHC. One is to implement it in the CLP Regulation. However, a precondition for the option is that criteria for the classification and labelling of PBT and vPvB are introduced to the CLP Regulation which should be preferably harmonised on the international level. Moreover, the scope of articles covered by Art. 4(8) CLP Regulation needs to be extended. An alternative option is to introduce the labelling obligation for articles containing SVHC in Art. 33 REACH. In this place it would directly amend the existing communication requirements for the substances of the candidate list. Another regulatory option is to enact a separate regulation with a cross-product obligatory labelling for all articles containing SVHC.

The implementation of an obligatory labelling for articles containing SVHC does not contradict WTO rules. The option is compatible with the principle of national treatment and most-favoured nation treatment according to Art. 2.1 TBT Agreement. It is not an unjustified obstacle according to Art. 2.2 TBT. In addition, it is compatible with the freedom to conduct a business, as protected in the Charter of Fundamental Rights of the European Union. Even though the labelling violates the fundamental freedom of enterprises to conduct a business this can be justified on the ground of the protection of human health and the environment.

0.3.3 Extension of the communication requirements to other substances (regulatory option 3)

The extension of the communication requirements of Art. 33 REACH to other substances will be examined by the European Commission until June 2019, as stipulated in Art 138(8) REACH. The communication requirements could not exclusively focus on the SVHC criteria, but also have regard to other hazardous characteristics (e.g. CMR substances Category 2, sensitisers, long term effects on aquatic organisms). In addition, substances could be included for which reduction objectives exist in other legislations (e.g. Water Framework Directive, Biocide regulation). Such an amendment would provide professional and private users of the articles with a higher degree of information and also allow a better coordination of the different areas of substance regulation. This extension of the communication requirements is not covered by the present legal text of REACH. It requires a change of the legal text.

For the time being, it is most important to bring all substances with SVHC properties to the candidate list. If it appears that the inclusion of substances with a harmonised CMR classification Cat. 1A or 1B is quite lengthy, the possible scenarios to automatically include these substances in the list on the basis of such a harmonised classification should be examined. The fast inclusion of all substances with SVHC properties in the candidate list would increase the effectivity of the existing regulation.

0.3.4 Registration obligation for unintended releases (regulatory option 4)

An extension of the registration obligations of producers and importers of articles in Art. 7(1) to inadvertent release and to cases where a release cannot be precluded will most likely have little practical effect. It can be assumed that the substance producer in the vast majority of cases will already - at least formally - have complied with the requirements regarding the use of the substance in an article in his registration. In these cases, Art. 7(6) REACH waives all obligations for producers/ importers of articles pursuant to Art. 7(1) – and thus also possible extensions of these obligations. It is important that for the registration of the use of a substance in an article information with enough details is given in the registration – this is at present not the case (see regulatory option 5).

0.3.5 Information requirements for a registered use (regulatory option 5)

A closer definition of the registration requirements as to information on the use of a substance in an article would probably significantly enhance the exposure scenarios in the registration dossiers. This applies not only to SVHC included in the candidate list, but also to other substances. Essential for this purpose is information regarding the concentration of the substances in the articles, data on migration and release rates (which often are material specific) as well as changes over time in this respect. Furthermore, the registered uses should not be too broad and unspecific. As a result, this would increase the informative value of exposure scenarios for the protection of consumers and the environment, but also for occupational safety in industrial and professional settings in which articles are used, since these scenarios have hitherto been of little relevance. Furthermore, the possibility to waive the registration or notification of SVHC in articles because their use is already registered (Art. 7(6)) would be limited.

0.3.6 Component as reference point for the 0.1% threshold (regulatory option 6)

If the concentration of SVHC in an article is above 0.1%, this information has to be communicated in the supply chain according to Art. 33 and notified to ECHA according to Art. 7(2). In the opinion of the authors the current legal framework of REACH requires that the component is considered to be the appropriate reference of the 0.1 % threshold and not the entire article; thus REACH does not need to be amended. However, as there are other opinions, the question of the correct reference point for the threshold is to be decided by a case in front of the European Court of Justice at present. Should the court rule that the component is the correct reference point for the 0.1 % threshold and not the entire article it is recommended to clarify this by amending Art. 7 and Art. 33 REACH. The clarification of this reference point is of crucial importance for ensuring - also for complex articles - that the regulatory purpose of Art. 33 and Art. 7(2) REACH will be achieved. This can be illustrated with an example. If for example a SVHC is present in the knobs of end-cutting pliers, the concentration of this SVHC in the whole tool can be below the concentration threshold of 0.1 % - although the user of the tool has direct skin contact with the SVHC. If the reference point is the component (in this example the knob), the danger of such a loss of information does not occur. A further argument in favour of the component as reference point is, that the information for the component should already be available – due to the placing on the market of the component. Therefore it is possible to make use of existing information (as long as the component has been produced in the EU).

0.3.7 Register for articles containing SVHC (regulatory option 7)

A register for articles containing SVHC promotes greater transparency with regard to the presence of SVHC in specific articles and thus supports ECHA and national authorities. This

information could be used to prioritise follow-up measures on SVHC. European consumers as well as industrial and professional users of articles might use the register to have overview of the current situation of SVHC in articles.

It might make sense to discuss the possibility of either to implement the labelling obligation for articles containing SVHC (see regulatory option 2) or to implement a register for such articles. Labelling obligations make it possible that the consumer can see immediately at the point of sale whether an article contains SVHC. On the other hand, the overview on SVHC in all articles of different producers is an important advantage of a register. Nevertheless it requires to build up and maintain an appropriate infrastructure. The requirement to develop a standardised communication format could be linked to the notification obligation for a register of articles containing SVHC. Irrespective of the register, this option has already been recommended further above. However, the importance of this regulatory option also depends on whether articles containing SVHC will remain on the market in significant amounts in future or if their market share will decrease due to other measures – for example the rapid inclusion of all relevant SVHC in Annex XIV REACH in combination with an extended authorisation requirement.

As described above, such a register is connected with a detailed notification requirement. It includes and combines information on substances, article names and commercial names (including all variations of an article). This is not covered by the existing legal text of REACH.

0 Zusammenfassung

0.1 Gegenstand und zentrale Ergebnisse

Wie lassen sich die Regelungen für (Import-)Erzeugnisse in der Europäischen Chemikalienverordnung REACH (EG) Nr. 1907/2006 stärken, vor allem, wenn die Erzeugnisse besonders besorgniserregende Stoffe enthalten? Diese Frage steht im Mittelpunkt der vorliegenden Studie, die darauf gerichtet ist, das primärrechtlich im Vertrag über die Arbeitsweise der Europäischen Union (AEUV) vorgegebene und auch in Art. 1 Abs. 1 REACH verankerte Ziel eines „hohen Schutzniveaus für die menschliche Gesundheit und die Umwelt" besser zum Tragen zu bringen.

Die REACH-Verordnung bringt zwei zentrale Neuerungen: Die Registrierungspflicht für chemische Stoffe und das Zulassungsregime für besonders besorgniserregende Stoffe (engl.: substances of very high concern – „SVHC"). Die Ausgestaltung dieser Mechanismen enthält jedoch Sonderregelungen für importierte Erzeugnisse. So gilt das Zulassungsregime nur für SVHC, die in Europa verwendet werden. Daraus folgt, dass im Europäischen Wirtschaftsraum hergestellte Erzeugnisse (unter den Begriff fallen z. B. Möbel, Textilien, Spielzeug, Bücher, Küchengeräte und andere elektronische Geräte, Fahrzeuge, Dämmplatten) diese Stoffe nicht enthalten dürfen, es sei denn, eine spezifische, extra zu beantragende Zulassung wurde für diese Verwendung erteilt. Aus Drittstaaten eingeführte Erzeugnisse dürfen diese Stoffe hingegen weiterhin enthalten. REACH behandelt europäische Erzeugnisse somit strenger als importierte Erzeugnisse. Diese Ungleichbehandlung kann dazu führen, das SVHC als Bestandteil von Import-Produkten auf den Markt gelangen und in der Folge Mensch und Umwelt belasten.

Der erste Teil des Berichts untersucht, ob sich diese Schutzlücke über eine Ausweitung des Zulassungserfordernisses auf SVHC in Import-Produkten im Einklang mit den Vorgaben des Welthandelsrechts der WTO schließen lässt (Kapitel 2 – 5). Dabei handelt es sich um die rechtliche Beurteilung einer Regulierungsoption (Rechtsgutachten). Eine Empfehlung, davon Gebrauch zu machen ist ebenso wenig Gegenstand der Untersuchung wie die Frage, ob diese Option anderen Optionen, etwa dem Rückgriff auf Beschränkungen nach REACH, vorzuziehen ist.

Der zweite Teil des Berichts (Kapitel 6) widmet sich weiteren Regelungsdefiziten im Hinblick auf SVHC in Erzeugnissen sowie der Kommunikation zu SVHC-haltigen Erzeugnissen in den Herstellungsketten und gegenüber Verbraucherinnen und Verbrauchern. Anhand von sieben Gestaltungsoptionen wird diskutiert, wie sich diese Lücken schließen lassen, um ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt bei SVHC-haltigen Erzeugnissen zu gewährleisten. Diese Optionen beziehen sich auf die Kommunikationspflichten gemäß Art. 33 REACH (standardisiertes Kommunikationsformat für Erzeugnisse, Kennzeichnungspflicht von SVHC in Erzeugnissen, Kommunikation weiterer Stoffe), auf die Pflichten gemäß Art. 7 REACH zu Stoffen in Erzeugnissen und bei der Stoffregistrierung, auf die Klarstellung des Bezugspunktes der 0,1% Schwelle für SVHC in Erzeugnissen und auf die Schaffung eines Registers für SVHC-haltige Erzeugnisse.

Als Ergebnis der Prüfung lässt sich festhalten, dass eine *erweiterte Zulassungspflicht*, die auch importierte Erzeugnisse mit „besonders besorgniserregenden" Inhaltsstoffen erfasst, mit dem Welthandelsrecht vereinbar ist. Nach den Maßstäben der WTO-Streitbeilegungspraxis liegt darin weder ein Verstoß gegen das Gebot der Inländergleichbehandlung noch gegen das der Meistbegünstigung nach Art. 2.1 des TBT-Übereinkommens. Auch ein ungerechtfertigtes Handelshindernis im Sinne von Art. 2.2. TBT ist darin nicht zu sehen, denn die EU würde mit einer solchen Erweiterung der Zulassungspflicht ein legitimes, von der Regelungsautonomie gedecktes Ziel verfolgen; zugleich reicht die Einschränkung des Welthandels auch nicht weiter als zur Erreichung des Ziels erforderlich.

Die Prüfung weiterer Gestaltungsoptionen für Erzeugnisse kommt zu dem Ergebnis, dass ein *standardisiertes Kommunikationsformat* für SVHC in Erzeugnissen erheblich dazu beitragen würde, die bestehenden Kommunikationspflichten korrekt umzusetzen.

Ebenso wäre die Klarstellung der *Informationsanforderungen an die registrierte Verwendung* eine Konkretisierung von REACH, die im bestehenden Rechtsrahmen umgesetzt werden könnte und die Erreichung der Schutzziele von REACH in signifikantem Maß unterstützen würde.

Auch der *Bezug der 0,1%-Schwelle*, ab der SVHC-haltige Erzeugnisse angemeldet bzw. kommuniziert werden müssen, auf das Teilerzeugnis und nicht auf das Gesamterzeugnis, hätte einen erheblichen Informationsgewinn zur Folge, der den Ersatz von SVHC erleichtern würde.

Von der *Ausdehnung der Kommunikationspflichten* auf weitere Stoffe wären ebenfalls große Änderungen zu erwarten. Sie würde industrielle und gewerbliche Akteure ebenso wie Verbraucherinnen und Verbraucher unterstützen, die sich über die Inhaltstoffe von Erzeugnissen informieren oder gezielt problemstoff-ärmere Erzeugnisse einsetzen wollen. Die Prüfung dieser Option ist in einer Review-Klausel von REACH vorgesehen.

Zuletzt wären von der *Kennzeichnungspflicht für SVHC-haltige Erzeugnisse* und einem *Register für SVHC-haltige Erzeugnisse* in erheblichen Maß Informationsgewinne für die Akteure in der Herstellungskette sowie die Verbraucherinnen und Verbraucher zu erwarten. Letzteres wäre jedoch auch mit deutlichem zusätzlichem Aufwand für Hersteller und Importeure der Erzeugnisse sowie den Betreiber des Registers verbunden. Ob beide Optionen nebeneinander oder nur eine von beiden umgesetzt werden sollte, wäre zu klären. Bei beiden Gestaltungsoptionen sollte auf ein standardisiertes Kommunikationsformat zurückgegriffen werden (siehe oben).

Die folgenden Abschnitte fassen die wesentlichen Untersuchungsschritte in knapper Form zusammen.

0.2 Ausweitung der Zulassungspflicht auf SVHC in importieren Erzeugnissen

Art. 57 lit. a – f REACH definiert die SVHC-Kriterien. Hierzu zählen CMR-Stoffe, die karzinogene (lit. a), keimzellmutagene (lit. b) oder reproduktionstoxische Eigenschaften aufweisen (lit. c), PBTs (persistente, bioakkumulierbare und toxische Stoffe, lit. d), vPvBs (sehr persistente und sehr bioakkumulierbare Stoffe, lit. e); sowie gemäß lit. f Stoffe, „die nach wissenschaftlichen Erkenntnissen wahrscheinlich schwerwiegende Wirkungen auf die menschliche Gesundheit oder auf die Umwelt haben, die ebenso besorgniserregend sind“ wie die zuvor genannten Eigenschaften.

Bei den CMR-Stoffen, die bislang der Gros der identifizierten SVHC ausmachen, ist der wissenschaftliche Nachweis des Gefährdungspotentials erbracht (Einstufungskategorien 1A und 1B); Verdachtsstoffe (Kat. 2) sind den Kriterien aus Art. 57 lit. a – c nicht zugänglich. Für den Nachweis der Toxizität von PBT-Stoffen existieren verschiedene Begründungsmöglichkeiten: Neben einer schädlichen Wirkung für Gewässerorganismen kann es sich um eine toxische Wirkung auf bestimmte Zielorgane oder um eine CMR-Eigenschaft handeln. Hinsichtlich reproduktionstoxischer Wirkungen lässt sich dabei ebenfalls auf die Verdachtskategorie 2 abstellen. Zu den ebenso besorgniserregenden Stoffen können beispielsweise Stoffe mit hormonellen Wirkungen (EDCs) oder allergisierenden Eigenschaften gehören. Bei den krebserzeugenden, mutagenen, PBT und vPvB-Stoffen handelt es sich in der Regel um Stoffe ohne Wirkschwellen, d.h. es kann keine Konzentration festgelegt werden, unterhalb derer schädliche Wirkungen ausgeschlossen werden können.

Gemäß Art. 56 Abs. 1 REACH darf ein „Hersteller, Importeur oder nachgeschalteter Anwender einen Stoff, der in Anhang XIV aufgenommen wurde, nicht zur Verwendung in Verkehr bringen

und nicht selbst verwenden," es sei denn, der jeweilige Akteur besitzt eine Zulassung für die entsprechende Verwendung („Verbot mit Erlaubnisvorbehalt") oder diese ist vom Zulassungserfordernis ausgenommen. REACH regelt aber nur die Verwendung von SVHC innerhalb des Europäischen Wirtschaftsraums (EWR). Bringt ein Produzent diese Stoffe außerhalb des EWR in ein Erzeugnis ein, greift Art. 56 Abs. 1 nicht. So hergestellte Erzeugnisse dürfen unter den Voraussetzungen von Art. 7 REACH in den EWR importiert werden. „Inländische" Produzenten von Erzeugnissen unterliegen damit strengeren Vorgaben als solche, die im „Ausland" produzieren. Darin liegt – gemessen an den Zielen der REACH-Verordnung – nicht nur eine Schutzlücke, sondern auch eine „Diskriminierung" inländischer Erzeugnishersteller.

Die identifizierte Schutzlücke im Hinblick auf importiere Erzeugnisse ließe sich schließen, indem man die Wirkung des Zulassungserfordernisses ausdrücklich auch auf SVHC in eingeführten Erzeugnissen erstreckt. Zu diesem Zweck wäre Art. 56 Abs. 1 REACH so zu ändern, dass auch die Einfuhr eines in Anhang XIV bezeichneten Stoffs in Erzeugnissen erfasst ist.

0.2.1 Anwendbares WTO-Recht und Prüfumfang

Mit der Änderung würden importierte Erzeugnisse genauso behandelt wie im EWR hergestellte: Erzeugnisse, die einen oder mehrere für diese Verwendung zulassungspflichtige Stoffe enthalten, dürfen nicht eingeführt werden, es sei denn, dass dafür eine Zulassung erteilt wurde. Dabei bilden das Verbot und die infolge einer Zulassungsentscheidung gestattete Ausnahme davon gemeinsam eine Maßnahme. Diese stellt ein „nicht-tarifäres Handelshemmnis" im Hinblick auf den internationalen Warenverkehr dar. Eine diesbezügliche WTO-rechtliche Beurteilung erfolgt anhand der Vorgaben des Agreement on Technical Barriers to Trade (TBT-Übereinkommen), da es sich bei der erweiterten Zulassungspflicht um eine „technische Vorschrift" i. S. v. TBT handelt. Zusätzlich ist bei der Auslegung des TBT-Übereinkommens entsprechend der WTO-Streitbeilegungspraxis teils auf die Bestimmungen des GATT-Überkommens (General Agreement on Tariffs and Trade) sowie des SPS-Übereinkommens (Agreement on Sanitary and Phytosanitary Measures) zurückzugreifen.

Gemäß der WTO-Streitbeilegungspraxis sowie der Literatur zum TBT ergeben sich die zentralen Anforderungen des TBT-Übereinkommens insbesondere aus dessen Art. 2.1 bezüglich der Gebote der Inländergleichbehandlung und Meistbegünstigung sowie aus Art. 2.2 TBT bezüglich des Verbots von ungerechtfertigten Handelsbeschränkungen. Die Vorschriften formulieren jeweils eigenständige Anforderungen, die unabhängig voneinander zu untersuchen sind. Daraus folgt, dass etwa auch im Falle eines Verstoßes gegen Art. 2.1, aufgrund der diskriminierenden Wirkung einer technischen Vorschrift, diese insgesamt gerechtfertigt sein kann i. S. v. Art. 2.2.

0.2.2 Inländergleichbehandlung und Meistbegünstigung nach Art. 2.1 TBT

Ein Verstoß gegen Art. 2.1 TBT wäre zu bejahen, wenn die technische Vorschrift einer erweiterten Zulassungspflicht Produkte aus Drittstaaten weniger günstig behandelt als gleichartige Produkte aus dem EWR oder aus anderen Drittstaaten.

Warengleichheit. Um zu klären, ob es sich bei dem inländischen und dem ausländischen Erzeugnis um „gleichartige Produkte" handelt, ist von folgendem Vergleichspaar auszugehen:

Erzeugnis A, das in der EU produziert wird und keine SVHC aus Anhang XIV enthält, und Erzeugnis B, das in einem Drittstaat produziert wird und SVHC aus Anhang XIV enthält.

Aus den in der WTO-Streitbeilegungspraxis entwickelten Maßstäben ergibt sich, dass es sich bei Erzeugnissen mit SVHC und Erzeugnissen ohne SVHC oftmals um gleichartige Produkte i. S. v. Art. 2.1 TBT handeln kann:

- Zwar geht von Erzeugnissen mit SVHC regelmäßig ein „generelles Risiko“ für Mensch und Umwelt aus, das zurückzuführen ist auf die in der Praxis kaum vermeidbare Exposition im Produktlebensweg, während von ähnlichen Erzeugnissen ohne SVHC keine entsprechenden Risiken ausgehen. Hieraus folgt ein Indiz für die Ungleichartigkeit der Waren.
- Hingegen dürften die möglichen Endnutzungen grundsätzlich, außer in besonderen Fällen, bei beiden Erzeugnissen identisch sein. Insbesondere sind aber auch die Verbraucherpräferenzen im EWR nicht durchgängig so gelagert, dass Konsumentinnen und Konsumenten Produkte ohne SVHC präferieren; vielmehr dürften relevante Marktsegmente bestehen, in denen die zu vergleichenden Erzeugnisse in der Verbraucherwahrnehmung als austauschbar gelten. Hieraus können sich im Einzelfall Indizien ergeben, die für die Gleichartigkeit der Erzeugnisse sprechen.

Allerdings ist die Frage der Warengleichheit letztlich nur anhand von konkreten Produktbeispielen abschließend zu beantworten, d. h. abhängig von Art und Funktion eines Erzeugnisses, den konkreten Eigenschaften der genutzten SVHC und deren Einbindung in das Erzeugnis. Kommt die likeness-Prüfung zu dem Ergebnis, dass die Gleichartigkeit zu verneinen ist, dann lässt sich bereits an dieser Stelle feststellen, dass eine Zulassungspflicht für Stoffe in importierten Erzeugnissen mit Art. 2.1 TBT vereinbar ist.

Diskriminierung aufgrund der erweiterten Zulassung. Soweit die Erzeugnisse des Vergleichspaars gleiche Waren darstellen, bleibt weiterhin zu klären, ob die technische Vorschrift ausländische Erzeugnisse weniger günstiger behandelt als gleichartige inländische oder andere gleichartige ausländische Erzeugnisse (Gebote der Inländergleichbehandlung und Meistbegünstigung). Die erweiterte Zulassungspflicht behandelt nach ihrem Wortlaut aus dem EWR oder aus Drittstaaten stammende Erzeugnisse unterschiedslos. Eine de iure-Diskriminierung scheidet damit aus. Darüber hinaus führt die erweiterte Zulassungspflicht für Akteure aus Drittstaaten auch nicht zu einer de facto-Diskriminierung. Selbst dann, wenn man für einzelne Fälle annimmt, dass etwa die konkrete Zusammenstellung der Substanzen auf Anhang XIV oder die Erforderlichkeit eines Unternehmenssitzes in der Gemeinschaft die Wettbewerbsbedingungen von Import-Produkten nachteilig beeinflussen könnten, so wäre dieser Effekt nicht Ausdruck einer willkürlichen Diskriminierung, sondern auf legitime Unterscheidungskriterien zurückzuführen.

Im Ergebnis ist die erweiterte Zulassungspflicht daher vereinbar mit Art. 2.1 TBT.

0.2.3 Ungerechtfertigtes Handelshindernis nach Art. 2.2 TBT

Art. 2.2 TBT verbietet technische Vorschriften, die handelsrestriktiver als erforderlich sind, um ein legitimes Ziel zu erfüllen. Da die erweiterte Zulassungspflicht handelsrestriktiv i. S. d. Norm ist (technischer Mindeststandard/nicht-tarifäres Handelshindernis) läge ein Verstoß gegen Art. 2.2 TBT vor, wenn die Vorschrift zugleich übermäßig handelsrestriktiv ist. Hierzu ist zu untersuchen, ob sie einen legitimen Zweck verfolgt, ob sie geeignet ist, diesen Zweck zu erreichen und ob sie handelsrestriktiver als für die Zielerfüllung erforderlich ist; unter Berücksichtigung der Risiken, die mit einer Zielverfehlung verbunden sind.

Legitimes Regelungsziel. Mit dem Ziel eines hohen Schutzniveaus für die menschliche Gesundheit und die Umwelt (Art. 1 Abs. 1 REACH), welches die erweiterte Zulassungspflicht für importierte Erzeugnissen anstrebt, verfolgt diese einen legitimen Zweck i. S. v. Art 2.2 TBT.

Beitrag zur Zielerreichung (Geeignetheit). Die erweiterte Zulassungspflicht verhindert, dass SVHC als Bestandteil von Erzeugnissen auf den EWR-Markt gelangen. Damit verhindert sie, dass Mensch und Umwelt mit besonders besorgniserregenden Stoffen in Kontakt kommen. Die Vorschrift ist mithin „as written and applied“ insgesamt geeignet, ihre Ziele zu erreichen.

Erforderlichkeit. Art. 2.2 TBT fordert, dass eine technische Vorschrift nicht handelsrestriktiver ist als zur Erreichung der Ziele erforderlich. Welche Eingriffsintensität dabei im Einzelfall als erforderlich angesehen werden kann, ist Gegenstand einer Analyse, welche

- die konkreten Handelsrestriktionen aufgrund der technischen Vorschrift
- die Frage nach dem legitimen Ziel und des Zielbeitrags der Vorschrift
- das Risiko verknüpft mit einer Nichterfüllung dieses Ziels
- die Erhältlichkeit alternativer Regelungsoptionen, die realistischerweise in Betracht kommen und einen geringeren Eingriff in den Handel darstellen

in Beziehung zueinander setzt.

Da die ersten Analyseschritte bereits absolviert sind, ist nachfolgend nur auf die letzten beiden Schritte einzugehen.

Risiken verbunden mit einer Nichterfüllung des Ziels. Art. 2.2 Satz 4 TBT gibt Hinweise darauf, wie die negativen Wirkungen, mit denen zu rechnen ist, wenn sich die Ziele der technischen Vorschrift nicht erreichen lassen, zu ermitteln sind; wobei das dort beschriebene „Risk Assessment" keine zwingend durchzuführenden Prüfschritte vorsieht. Das WTO-Berufungsgremium ergänzt, dass der Vergleich einer infrage stehenden technischen Vorschrift mit alternativen Regelungsoptionen „im Licht der Natur der betrachteten Risiken und der Schwere der Konsequenzen, die aus einer Nichterfüllung des legitimes Ziels resultieren würden" zu erfolgen hat. Die technische Vorschrift einer erweiterten Zulassungspflicht zielt darauf ab, die Exposition des Menschen und der Umwelt gegenüber zulassungspflichtigen Stoffen zu vermeiden oder zu vermindern. Zu untersuchen ist also, welche Risiken von diesen Stoffen ausgehen. Zu betrachten sind dabei sowohl prozedurale als auch materielle Implikationen. Aus prozeduraler Sicht ist zu klären, ob das Risk Assessment im Rahmen der technischen Vorschrift geeignet ist, Risiken i.S.v. Art. 2.2 Satz 4 TBT zu ermitteln. Daraufhin ist unter materiellen Gesichtspunkten zu prüfen, welche Bedeutung TBT den von SVHC ausgehenden Risiken beimisst.

Prozedurale Sicht. Weil es im TBT-Kontext an Vorgaben an das Risk Assessment mangelt, ist auf die Anforderungen des SPS-Übereinkommens bezüglich gesundheitspolizeilicher und pflanzenschutzrechtlicher Maßnahmen sowie der hierzu ergangenen Spruchpraxis der WTO-Streitbeilegungsorgane abzustellen. Hierbei zeigt sich, dass das Risk Assessment gemäß der technischen Vorschrift mit diesen Anforderungen im Einklang steht. Über die Umsetzung des Risiko-Quotienten-Modells bzw. qualitativer Risikobeschreibungen im Rahmen der Zulassungsantragstellung und -prüfung ist sichergestellt, dass in Bezug auf jede SVHC-Anwendung in einem Erzeugnis die spezifischen Risiken ermittelt und bewertet werden. Dies gilt insbesondere im Hinblick auf diejenigen SVHC, zu denen sich Wirkschwellen ableiten lassen. Aber auch in Bezug auf Fälle, in denen es aus methodischen Gründen nicht möglich ist, eine eindeutige Zuordnung von Kausalitäten vorzunehmen, senkt der Appellate Body die maßgebliche Schwelle für den Nachweis einer potentiellen Schädigung auf ein Maß herab („whether those adverse effects could ever occur"), dessen Voraussetzungen hier erfüllt sind.

Materielle Sicht. Im *EC – Asbestos*-Fall wiesen die Europäischen Gemeinschaften nach, dass Asbest verschiedene Formen von Krebs verursachen kann. Angesichts der Erheblichkeit des identifizierten Risikos, dessen möglicher Folgen sowie der Zielsetzung des Importbanns („halt the spread of this risk"), sahen die WTO-Streitbeilegungsorgane die strenge regulatorische Maßnahme als vereinbar an mit den Vorgaben des allgemeinen Zoll- und Handelsabkommens GATT – gerade auch, weil es nicht gelang Wirkschwellen abzuleiten.

Den meisten SVHC (Art. 57 lit. a bis d sowie teilweise lit. f) ist ein wissenschaftlich nachgewiesenes Gefährdungspotential immanent, das – wie im Falle von Asbest – auf international harmonisierten Einstufungskriterien gemäß GHS beruht. Bezüglich dieser Stoffe

kann im Falle einer Exposition – nach deutschem Recht – sogar eine Gefahr im juristischen Sinne vorliegen, gegen die eine staatliche Abwehrpflicht besteht. Die „Natur der Risiken" und die „Schwere der Konsequenzen" sind – im Licht der Zielsetzung der technischen Vorschrift („hohes Schutzniveau") – hier folglich als ähnlich besorgniserregend einzustufen, wie sich die Situation in *EC – Asbestos* darstellte. Dies gilt zugleich als starkes Indiz für die Erforderlichkeit der technischen Vorschrift.

Jedoch knüpft die erweiterte Zulassungspflicht punktuell auch an SVHC an, deren Gefährdungspotential zu einem gewissen Grad durch eine wissenschaftliche Ungewissheit gekennzeichnet ist: Dies betrifft PBTs, die „vermutlich reproduktionstoxisch" sind (Reproduktionstoxizität Kat. 2), vPvBs sowie ggf. SVHC nach Art. 57 lit. f. Das von diesen Substanzen ausgehende Risiko wäre – grundsätzlich trotz Freisetzung – nach gegenwärtigem Kenntnisstand unterhalb der Gefahrenschwelle angesiedelt; ein regulatorisches Vorgehen gegen diese Stoffe folglich als Vorsorgemaßnahme einzuordnen. Daher ist zu klären, wie eine technische Vorschrift, die auch eine Ausprägung des Vorsorgegrundsatzes darstellt, am Maßstab von Art. 2.2 TBT zu beurteilen ist.

Fraglich ist also, ob die von der zuletzt genannten „vorsorgeorientierten" SVHC-Gruppe ausgehende „Natur der Risiken" und „Schwere der Konsequenzen" – im Licht der Zielsetzung der Vorschrift – die handelshemmende Wirkung der technischen Vorschrift rechtfertigen können. Das TBT-Übereinkommen enthält keine Vorgaben über die Zulässigkeit von Vorsorgemaßnahmen. Die Beachtlichkeit des Vorsorgegrundsatzes kann sich aber auch aus dem Völkerrecht ergeben – dessen Bestimmungen sind gemäß Art. 31 Abs. 3 lit. c des Wiener Übereinkommens über das Recht der Verträge bei der Auslegung eines Vertrags – wie dem TBT-Übereinkommen – „in gleicher Weise" zu berücksichtigen wie die eigentlichen Vertragsklauseln. Zwar existiert keine völkerrechtliche „Querschnittsklausel", aus der eine verbindliche Anwendbarkeit des Vorsorgegrundsatzes folgt; auch lässt sich nicht abschließend beurteilen, ob dieser mittlerweile einen völkergewohnheitsrechtlichen Verbindlichkeitsstatus aufweist. Jedenfalls mehren sich aber die Anhaltspunkte, die auf die Existenz eines solchen Status schließen lassen. Losgelöst von dieser Diskussion zeigt sich die herausragende Bedeutung des Vorsorgegrundsatzes zudem an dessen völkerrechtlichen Verbreitungsgrad, gerade auch im internationalen Chemikalienrecht.

Legt man als Maßstab die Spruchpraxis des WTO-Berufungsgremiums in *US – Shrimp* an, ist der normative Gehalt der Vorsorge daher auch beachtlich bei der Auslegung von Art. 2.2 TBT. Gegenstand der genannten Entscheidung war die Auslegung von Art. XX(g) GATT zur Erhaltung der Umwelt, die laut Berufungsgremium im Licht der aktuellen Besorgnisse der Staatengemeinschaft zu erfolgen hat. Unter Rückgriff auf unterschiedliche verbindliche und unverbindliche Völkerrechtsquellen (z. B. Agenda 21) weitet der Spruchkörper den Rechtfertigungstatbestand aus Art. XX(g) GATT im Wege einer „evolutiven" Auslegung, welche die völkerrechtlichen Entwicklungen berücksichtigt. Hieraus und aus der völkerrechtlichen Bedeutung der Vorsorge folgt, dass bei der Auslegung der umwelt- und gesundheitsschutzbezogenen Rechtfertigungstatbestände des regelungssystematisch verwandten Art. 2.2 TBT der Vorsorgegrundsatz zumindest „informierend" heranzuziehen ist, wenn eine zu prüfende technische Vorschrift sich (teilweise) auf diesen Grundsatz stützt.

Bei der Mehrzahl der identifizierten SVHC handelt es sich um CMR-Stoffe mit nachgewiesenem Gefährdungspotential. Ein regulatorisches Vorgehen gegen diese Stoffe ist – bei einer relevanten Exposition – folglich nicht dem Bereich der Vorsorge, sondern der Gefahrenabwehr zuzuordnen. Allerdings knüpft die erweiterte Zulassungspflicht teils ebenfalls an Risiko-Situationen unter Ungewissheit an; auch in diesen Fällen richtet sie sich aber gegen irreversible und scherwiegende Schädigungen. Damit agiert die technische Vorschrift genau im Anwendungsspektrum von Grundsatz 15 der Rio-Erklärung der Vereinten Nationen. Oftmals lassen sich zudem keine Wirkschwellen bestimmen, so dass auch geringe und geringste

Konzentrationen bereits schädigende Effekte hervorrufen können. Gerade hinsichtlich der Stoffgruppe der langlebigen Substanzen mit hohem Anreicherungspotential erhält der Vorsorgegrundsatz zudem zusätzliche Tragweite über konkrete völkerrechtliche Vorgaben (z. B. POP-Konvention). Die Risiken durch die vorsorgeorientierte SVHC-Gruppe sind daher keineswegs unerheblich. Dies gilt vor allem auch deshalb, weil weder TBT noch das WTO-Berufungsgremium eine Mindesthöhe für ein nachzuweisendes Risiko voraussetzen.

Weiterhin besteht das legitime Ziel der erweiterten Zulassungspflicht darin, ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt sicherzustellen. Die von der technischen Vorschrift adressierten SVHC-Kriterien sind Ausdruck dieses Zielniveaus, dessen Festlegung – gemäß einer „evolutiven" Auslegung von Art. 2.2 TBT im Licht der Maßgaben des Vorsorgegrundsatzes – von der Regelungsautonomie der Mitgliedstaaten des Übereinkommens gedeckt ist. Eine Nichterfüllung der normativen Ziele würde daher auch im Falle der vorsorgeorientierten SVHC-Gruppe inakzeptable Risiken verursachen, was erneut für die Erforderlichkeit der technischen Vorschrift spricht.

Alternative Gestaltungsoptionen. Es sind keine Regelungsoptionen verfügbar, die bei gleicher Zielerreichung einen geringeren Eingriff in die Handelsaktivitäten von Erzeugnisproduzenten darstellen. Insbesondere ist die Beschränkung nach Art. 67 ff. REACH in ihrer gegenwärtigen Ausgestaltung (erstens) nicht geeignet, denselben Grad an Risikominderung zu erreichen, weil die Zulassung bereits an das Gefährdungspotential der (priorisierten) SVHC anknüpft, während Beschränkungen nur im Hinblick auf ein konkretes „unannehmbares Risiko" erlassen werden können. Würde man aber die Eingriffsschwelle der Beschränkung entsprechend absenken, so ergäbe sich hieraus (zweitens) mangels Erlaubnisvorbehalt keine mildere, die Warenverkehrsfreiheit weniger belastende Option.

Ergebnis zur Erforderlichkeitsprüfung. Die erweiterte Zulassungspflicht als „technische Vorschrift" im Sinne des TBT-Übereinkommens betrifft importierte Erzeugnisse mit besonders besorgniserregenden Stoffen, die in Anhang XIV gelistet sind. Sie zielt darauf ab, Risiken zu begegnen, die von diesen Stoffen ausgehen. Allen diesen Stoffen ist ein wissenschaftlich nachgewiesenes Gefährdungspotential immanent. Die technische Vorschrift wird mithin nur auf solche Stoffe angewandt, die aufgrund ihrer besonders besorgniserregenden Eigenschaften im Falle der Exposition auch ein erhebliches Risiko für die menschliche Gesundheit und die Umwelt darstellen, welches zu minimieren sich – je nach Erheblichkeit im Einzelfall – aus dem Gebot der Gefahrenabwehr oder dem Grundsatz der Vorsorge ergibt. Zu den SVHC können karzinogene genauso wie persistente, bioakkumulierbare und toxische Stoffe zählen – auf diese Weise kommt das spezifische Schutzniveau der Vorschrift zum Ausdruck, welches individuell zu definieren jedem Mitglied des TBT-Übereinkommens im Rahmen seiner Regelungsautonomie zusteht. Ließe sich das Ziel der Vorschrift – zunächst die reduzierte Exposition gegenüber SVHC, in letzter Konsequenz aber ein vollständiger phase-out der entsprechenden Stoffe – nicht verwirklichen, wären mithin inakzeptable Risiken die Folge.

Die Analyse zeigt, dass die technische Vorschrift geeignet ist, einen Beitrag zu Ihrem gemäß Art. 2.2 TBT legitimen Zweck zu leisten. Da weiterhin keine Regelungsalternativen verfügbar sind, die bei gleicher Zielerreichung einen geringeren Eingriff in die Handelsaktivitäten bewirken, gelangt man zu dem Ergebnis, dass das erweiterte Zulassungserfordernis (Verbot mit Erlaubnisvorbehalt) nicht handelsrestriktiver als erforderlich und damit insgesamt verhältnismäßig i. S. v. Art. 2.2 TBT ist.

0.2.4 Ergebnis zu einer Ausweitung der Zulassungspflicht

Zusammenfassend lässt sich festhalten, dass die Regelungsoption einer erweiterten Zulassungspflicht mit dem Welthandelsrecht vereinbar ist. Darin läge weder ein Verstoß gegen

das Gebot der Inländergleichbehandlung noch gegen das der Meistbegünstigung nach Art. 2.1 TBT. Auch ein ungerechtfertigtes Handelshindernis im Sinne von Art. 2.2. TBT liegt nicht vor.

0.3 Weitere Gestaltungsoptionen zur Erreichung des Schutzziels bei SVHC-haltigen Erzeugnissen

Neben einer Ausdehnung der Zulassungspflicht auf SVHC in Erzeugnissen sind in der vorliegenden Studie weitere Änderungen oder Klarstellungen der REACH-Verordnung für Erzeugnisse geprüft worden. Die folgenden Gestaltungsoptionen können zur Erreichung des Schutzziels – hohes Schutzniveau für die menschliche Gesundheit und die Umwelt - beitragen. Eine ausdrückliche Priorisierung der Optionen lag außerhalb des Untersuchungsrahmens der Studie.

0.3.1 Standardisiertes Kommunikationsformat für Erzeugnisse (Gestaltungsoption 1)

Durch die Aufnahme eines standardisierten Kommunikationsformates für Erzeugnisse kann sichergestellt werden, dass alle erforderlichen Informationen, die zum Erreichen der Schutzziele notwendig sind, auch tatsächlich mitgeteilt werden. Ein wesentlicher Schwachpunkt der derzeitigen Praxis – die Beschränkung der Kommunikation nach Art. 33 REACH auf die bloße Mitteilung der Namen der SVHC – kann dadurch überwunden werden. Neben dem Namen des Stoffes sollten u.a. Angaben zu dessen Konzentration, Gesamtmenge, gefährlichen Eigenschaften, genauem Ort sowie zur sicheren Verwendung einschließlich Entsorgung gemacht werden.

Standardisierung kann dazu beitragen, dass die Verantwortlichen Anfragen zu SVHC-Stoffen in Erzeugnissen innerhalb der 45-Tage-Frist schneller beantworten. Zudem sind manche der Informationen notwendig, um innerhalb der Lieferkette die Gesamtmenge- bzw. Gesamtkonzentration in komplexen Erzeugnissen zu berechnen, da dies ohne Kenntnis der Menge oder Konzentration in den Teilerzeugnissen nicht möglich ist (siehe hierzu auch Gestaltungsoption 6). Auch die behördliche Überwachung des Art. 33 würde durch konkrete Vorgaben erleichtert.

Die rechtsverbindliche Festlegung, welche Daten in einem standardisierten Kommunikationsformat enthalten sein sollen, könnte durch die Einführung eines neuen Anhangs in REACH „Standardisiertes Kommunikationsformat für Erzeugnisse“ erfolgen. Eine weitere Präzisierung, die ebenfalls zur konsequenteren Umsetzung der bestehenden Auskunftsrechte unter REACH beitragen würde, wäre die Pflicht für die Lieferanten, auf Anfragen auch dann zu antworten, wenn die Erzeugnisse keine SVHC enthalten.

0.3.2 Kennzeichnungspflicht für SVHC in Erzeugnissen (Gestaltungsoption 2)

Derzeit hat der Lieferant 45 Tage Zeit, Anfragen zu SVHC in seinen Erzeugnissen zu beantworten. Dies ist nicht praxisgerecht. Eine Kennzeichnungspflicht für SVHC in Erzeugnissen würde eine direkte Information der Anwender bzw. Verbraucherinnen und Verbraucher sicherstellen. Dies würde die Entscheidung zugunsten von Erzeugnissen erleichtern, die frei von diesen Stoffen sind. Der Druck, Erzeugnisse ohne SVHC-Stoffe anzubieten, würde steigen. Auch diese Möglichkeit könnte einen bedeutenden Beitrag zum Erreichen der Schutzziele leisten, die mit der Kommunikation zu SVHC verbunden sind. Da auf dem Erzeugnis selbst wahrscheinlich kaum mehr als der Name des SVHC angegeben werden kann, wäre zudem zu empfehlen, dass weiterführende Informationen woanders abgerufen / nachgesehen werden können. Für diese Informationen wäre es dann sinnvoll, sie in einem standardisierten Format aufzubereiten, um ihre Vollständigkeit zu gewährleisten (siehe Gestaltungsoption 1).

Die Kennzeichnungspflicht könnte an verschiedenen Regelungsorten verankert werden. So bietet sich aus rechtssystematischen Gründen die Einführung einer Kennzeichnungspflicht für SVHC-haltige Erzeugnisse in der CLP-Verordnung an. Allerdings würde dies voraussetzen, dass Merkmale für die Einstufung und Kennzeichnung von Stoffen als PBT und vPvB in die CLP-Verordnung aufgenommen werden – und möglichst international abgestimmt sind. Ferner müssten die von der CLP-Verordnung erfassten Erzeugnisse in Art. 4 (8) iVm Anhang I CLP-Verordnung um SVHC-haltige Erzeugnisse erweitert werden. Als weiterer Regelungsort für eine Kennzeichnungspflicht käme Art. 33 REACH in Frage. Sie würde dort direkt an die bestehenden Kommunikationsanforderungen für die Stoffe der Kandidatenliste anschließen. Und schließlich könnte auch eine neue produktübergreifende Regelung für eine Kennzeichnungspflicht eingeführt werden.

Die Einführung einer Kennzeichnungspflicht für SVHC-haltige Erzeugnisse verstößt nicht gegen WTO-Recht. Sie ist mit den Prinzipien der Inländergleichbehandlung und der Meistbegünstigung nach Art. 2.1 TBT-Übereinkommen vereinbar und ist nicht als ungerechtfertigtes Handelshemmnis nach Art. 2.2 TBT zu bewerten. Weiterhin ist die Kennzeichnungspflicht mit der in Art. 16 Grundrechte-Charta der Europäischen Union geschützten unternehmerischen Freiheit vereinbar. Zwar wird in das Grundrecht der unternehmerischen Freiheit eingegriffen, aber dieser Eingriff ist durch den vorbeugenden Schutz der Gesundheit und der Umwelt gerechtfertigt.

0.3.3 Ausdehnung der Kommunikationspflichten des Art. 33 auf weitere Stoffe (Gestaltungsoption 3)

Für die Ausdehnung der Kommunikationspflichten des Art. 33 auf weitere Stoffe – über die SVHC der Kandidatenliste hinaus – besteht nach Art. 138 Abs. 8 REACH bis zum 1.Juni 2019 ein Prüfauftrag an die EU-Kommission. Die Kommunikationspflichten könnten sich nicht nur an den SVHC-Kriterien orientieren, sondern auch weitere Gefährlichkeitsmerkmale (z.B. CMR-Kategorie 2, sensibilisierend, chronisch gewässergefährdend) einbeziehen sowie Stoffe, für die es unter anderen Regelungen Minderungsziele gibt (z.B. im Wasserecht oder für Biozide). Dies würde zu einem Informationsgewinn für professionelle und private Nutzer und Nutzerinnen der Erzeugnisse führen und eine bessere Abstimmung verschiedener Gebiete der Chemikalienregulierung erlauben. Die Ausdehnung der Kommunikationspflicht in Art. 33 REACH auf weitere Stoffe wird vom derzeitigen Rechtsrahmen nicht abgedeckt und erfordert eine Änderung des Rechtstextes.

In Bezug auf die bereits unter REACH bestehende Kommunikationspflicht von Stoffen mit SVHC-Eigenschaften sollte im Vordergrund stehen, dass alle Stoffe, die tatsächlich besonders besorgniserregend sind, auch auf die Kandidatenliste für die Zulassungspflicht genommen werden. Sollte die Aufnahme von Stoffen mit einer harmonisierten CMR-Einstufung der Kategorie 1A oder 1B langwierig sein, ist zu prüfen, welche Möglichkeiten einer automatischen Übernahme in die Liste aufgrund einer solchen harmonisierten Einstufung bestehen. Die schnelle Aufnahme aller Stoffe mit SVHC-Eigenschaften auf die Kandidatenliste würde die Effektivität der bestehenden Regelung erhöhen. Eine Wechselwirkung dieser Gestaltungsoptionen mit den anderen Gestaltungsoptionen besteht nicht.

0.3.4 Registrierungspflicht für unbeabsichtigte Freisetzung (Gestaltungsoption 4)

Eine Ausdehnung der Registrierungspflichten für Produzenten bzw. Importeure von Erzeugnissen auf eine unbeabsichtigte bzw. nicht-ausgeschlossene Freisetzung von Stoffen in Art. 7 Abs. 1 wird wahrscheinlich ohne große Auswirkungen in der Praxis bleiben. Es kann davon ausgegangen werden, dass in der großen Mehrzahl der Fälle bereits der Stoffhersteller in seiner Registrierung

die Verwendung des Stoffes in einem Erzeugnis – zumindest formal – abgedeckt hat. Art. 7 Abs. 6 REACH hebt in diesen Fällen die Verpflichtungen aus Art. 7 Abs. 1 für den Produzenten/Importeur des Erzeugnisses auf – und damit auch eventuelle Erweiterungen dieser Pflichten. Wichtig ist jedoch, dass die Registrierung der Verwendung des Stoffes im Erzeugnis ausreichend präzise eingegrenzt und mit ausreichend genauen Informationen hinterlegt ist, was bislang nicht der Fall ist (siehe Gestaltungsoption 5).

0.3.5 Informationsanforderungen für eine registrierte Verwendung (Gestaltungsoption 5)

Werden die Informationsanforderungen an die Registrierung der Stoffverwendung in einem Erzeugnis präzisiert, wird dies wahrscheinlich zu einer bedeutenden Verbesserung der Expositionsszenarien in den Registrierungsdossiers führen. Nicht nur bei SVHC der Kandidatenliste, sondern auch bei anderen Stoffen. Hierfür erforderlich sind Aussagen zum Gehalt im Produkt, zur (materialspezifischen) Migrations- und Freisetzungsmöglichkeit, und zu deren zeitlichem Verlauf. Auch dürfen die registrierten Verwendungen nicht zu allgemein und unspezifisch sein. Dadurch würde die derzeit geringe Aussagekraft der Expositionsszenarien für den Verbraucher- und den Umweltschutz, aber auch für den Arbeitsschutz bei industriellen und gewerblichen Anwendern von Erzeugnissen erhöht. Weiterhin würde durch eine genauere Beschreibung der registrierten Verwendungen die nach Art. 7 Abs. 6 gegebene Möglichkeit eingeschränkt, auf die Registrierung oder Anmeldung von SVHC in Erzeugnissen zu verzichten.

0.3.6 Bezug der 0,1%-Schwelle auf das Teilerzeugnis (Gestaltungsoption 6)

Beträgt die Konzentration von SVHC mehr als 0,1% im Erzeugnis, muss diese Information nach Art. 33 in der Lieferkette kommuniziert und nach Art. 7 Abs. 2 an die ECHA mitgeteilt werden. Die Auffassung, dass sich die 0,1%-Schwelle nicht auf das Gesamterzeugnis, sondern auf das Teilerzeugnis bezieht, und sich dies aus dem Gesetzeswortlaut von REACH ergibt – also keine Änderung des Gesetzeswortlauts erfordert – liegt derzeit dem EuGH zur Entscheidung vor. Die Klarstellung dieses Bezugspunktes ist von hoher Bedeutung, um auch bei komplexen Erzeugnissen sicher zu stellen, dass das in Art.33 und Art. 7 Abs. 2 REACH angesprochene Schutzziel von REACH erreicht wird.

Ein Beispiel kann dies illustrieren: Wenn ein SVHC nur in den Griffen eines Werkzeugs vorhanden ist, kann dessen Konzentration im Gesamterzeugnis ggf. unterhalb der Mengenschwelle für die Kommunikation liegen, obwohl der Nutzer des Werkzeugs direkten Hautkontakt damit hat. Wird als Bezugspunkt das Teilerzeugnis gewählt, besteht die Gefahr eines solchen Informationsverlustes nicht. Für den Bezugspunkt des Teilerzeugnisses spricht zudem, dass die Informationen auf dieser Ebene bereits für die Vermarktung des Teilerzeugnisses vorliegen müssen und somit auf vorhandene Informationen zurückgegriffen werden kann.

Sollte das Gericht zum Ergebnis kommen, dass der Bezugspunkt für die 0,1%-Schwelle nicht das Erzeugnis, sondern das Teilerzeugnis ist, müsste der Text in Art. 7 und Art. 33 nicht unbedingt geändert werden, eine klarstellende Änderungen wäre jedoch empfehlenswert. Eine Wechselwirkung dieser Gestaltungsoptionen mit den anderen Gestaltungsoptionen besteht nicht.

0.3.7 Register für SVHC-haltige Erzeugnisse (Gestaltungsoption 7)

Ein Register für SVHC-haltige Erzeugnisse würde der ECHA und den nationalen Behörden mehr Transparenz geben zum Vorliegen von SVHC in konkreten Produkten. Behörden könnten diese Informationen nutzen, um weitere Maßnahmen zu SVHC zu (de-)priorisieren. Europäischen Konsumentinnen und Konsumenten würde ein Register einen schnellen und aktuellen Überblick

zu SVHC in Erzeugnissen geben, ebenso industriellen und gewerblichen Anwendern von Erzeugnissen.

Ob ein Register für SVHC-Erzeugnisse oder eine Kennzeichnungspflicht für diese Erzeugnisse (siehe Gestaltungsoption 2) eingeführt werden sollte, ist zu diskutieren. Mit der Kennzeichnungspflicht können Verbraucherinnen und Verbraucher unmittelbar beim Kauf erkennen, ob SVHC im Erzeugnis enthalten sind. Der Vorteil eines Registers liegt insbesondere im herstellerübergreifenden Überblick über SVHC-haltige Erzeugnisse, es setzt jedoch die Schaffung und Pflege einer entsprechenden Infrastruktur voraus. Mit der Meldepflicht für ein Erzeugnisregister kann die Vorgabe eines einheitlichen Kommunikationsformates verknüpft werden – eine Gestaltungsoption, die weiter oben bereits losgelöst vom Register empfohlen wurde (siehe Gestaltungsoption 1). Zuletzt hängt die Bedeutung dieser Gestaltungsoption auch davon ab, ob es in Zukunft noch größere Anteile SVHC-haltiger Erzeugnisse auf dem Markt gibt oder ob diese aufgrund anderer Maßnahmen – beispielsweise der raschen Aufnahme aller relevanten SVHC in den Anhang XIV REACH und der Erweiterung der Zulassungspflicht – nur noch selten vorkommen.

Eine so umfassende Meldepflicht sowie Erfassung und Verknüpfung von Stoffinformationen mit Produkt- und Handelsnamens (einschließlich aller Produktvarianten) wie sie in einem Register für SVHC-haltige Erzeugnisse angedacht ist, wird vom geltenden Rechtsrahmen in REACH nicht abgedeckt.

1 Introduction

A "high level of protection of human health and the environment" is the objective of European primary legislation, laid down in the TFEU.[1] Secondary legislation, such as the REACH Regulation,[2] aims at the same level of protection. However, a closer look at the provisions of REACH unveils deficits as regards the regulation of hazardous substances in articles. This study examines regulatory options to strengthen REACH[3] in order to address these deficits.

In this respect, special attention is given to imported articles. According to the REACH authorisation scheme, articles containing substances of very high concern (SVHC) included in Annex XIV may be imported into the EEA[4] while a European producer of the same article is not allowed to use that substance.[5] In terms of the aims stipulated in Art. 1(1), (3) REACH, this constitutes a protection gap and moreover, this "discriminates" against domestic producers of articles. An expansion of the authorisation provisions to those SVHC present in articles imported from countries outside the EEA has to be in line with the legal standards of international trade law (chapters 1-5).

First of all, the requirements of international (environmental) law, which also inform the interpretation of WTO law, are to be outlined (section 1.1). These provide the normative framework to assess the legislative purposes of the REACH regulation (section 1.2) as well. Subsequently, the role of the precautionary principle within the REACH authorisation scheme[6] will be analysed. This classification is crucial for the legal assessment of an extended authorisation obligation concerning SVHC present in imported articles against the requirements of WTO law. Chapter 2 outlines the approach of this assessment to be found in chapters 3-5.

Beyond the problem of imported articles, several other legal issues concerning the REACH provisions on substances in articles arise (chapter 6). These include:

- REACH does not require a standardised communication format for the circulate information on SVHC.
- With respect to articles containing SVHC, there is no requirement to provide information on the presence of SVHC on the article itself or its packaging.
- It is not clear to which definition of "article" the information obligations pursuant to Art. 7(2) and Art. 33 REACH refer. There is some debate as to whether the required threshold value refers to the entire (finished) product or to parts which have been assembled to the final product (once an article, always an article, "O5A-approach").

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1 Consolidated Version of the Treaty of the Functioning of the European Union, 2012 OJ C 326/47.

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 OJ L 396/1.

3 This also includes an examination of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, 2008 OJ L 353/1.

4 The European Economic Area includes the EU-28 plus Iceland, Liechtenstein and Norway.

5 Art. 56(1), (2) REACH. Only in cases where the provisions of Annex XIV contain specific exemptions a European producer of an article is allowed to use the substance.

6 An overview can be found at *Hermann/Ingerowski* 2011, *Bergkamp/Herbatschek* 2013, para. 4.154 et seq.

Against this background chapter 6 assesses the following options for improvements:

- Communication obligations under REACH Art. 33 (section 6.2);
- Registration obligations under REACH Art. 7 (section 6.3);
- Clarification of the reference point of the 0.1% threshold in Art. 7 and Art. 33 REACH (section 6.4);
- Creating a register for articles containing SVHC (section 6.5).

With regard to the REACH objective of a high level of protection for human health and the environment a wide range of regulatory options to enhance the provisions on articles containing SVHC are discussed in this study.

1.1 International law context to prevent substance-related risks

To protect human health and the environment against substance-related risks is not solely the task of the European REACH Regulation. On the international level a number of declarations action programs and agreements are committed to the same goal. This provides orientation as to which international law standards are to be applied to assess trade policies of the European Union.

The Stockholm Conference of 1972 is seen as the starting point for the development of international environmental law[7] since it included the protection of the natural environment of man to the agenda of international law.[8] The United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992 where 178 states signed on a number of mainly environmental and developmental agreements is considered the next major milestone. The signatory states committed to the overarching objective of sustainable development and formulated in the "Rio Declaration"[9] several political principles whose adherence is intended to contribute to this vision. Central to the subject of this study at hand is the principle 15 concerning the "precautionary approach":

> "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

In addition, the international community agreed with the "Agenda 21" on an ambitious action program[10] that serves to flesh out the Rio Declaration and at the same time, integrates various international activities[11] of supranational actors (FAO, ILO, OECD, UNEP and WHO[12]).[13] Later, in 2002 in Johannesburg the international community adopted the Implementation Plan of the World Summit on Sustainable Development. The signatory states declared to achieve "by 2020, that chemicals are used and produced in ways that lead to the minimization of significant

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7 United Nations Conference on the Human Environment, June 1972 in Stockholm.

8 *v. Heinegg* 2003, para. 5 et seq.; *id.* 2014, § 50, para. 5 et seq.; cf. further developments *Sands/Peel* 2012, pp. 218 et seq., *Proelß* 2010, para. 92 et seq.

9 Rio Declaration on Environment and Development.

10 *United Nations* 1992.

11 Overview at *Warning/Winter* 2004, pp. 247 et seq.

12 Food and Agriculture Organization (FAO), International Labour Organization (ILO), Organization for Economic Co-operation and Development (OECD), United Nations Environment Programme (UNEP), World Health Organization (WHO). The International Programme on Chemical Safety (IPCS) combines the global activities of the various organizations.

13 *Warning/Winter* 2004, p. 242, *Führ* 2013, para. 22.

adverse effects on human health and the environment, […] taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration". [14] This was affirmed by the international community once again at the World Summit in 2012.[15]

Agenda 21 devoted its 19th chapter to the subject of chemical safety and defines six program areas that concern the advanced and accelerated international assessment of chemical hazards as well as the harmonisation of classification and labelling of chemicals.[16] The latter program area refers to the Global Harmonised System of Classification and Labelling of Chemicals (GHS),[17] which has been implemented by 67 states[18] to date using different[19] instruments. Another area is devoted to risk reduction programs. This explicitly includes measures such as

> "the phasing out or banning of chemicals that pose unreasonable and otherwise unmanageable risks to human health and the environment and of those that are toxic, persistent and bio-accumulative and whose use cannot be adequately controlled."[20]

Under this impression, in 2001 the Stockholm Convention on persistent organic pollutants ("POP") was drawn up, providing restriction measures regarding the production, use and release of specific substances.[21] Pursuant to its Art. 1 "[m]indful of the precautionary approach as set forth in Principle 15 of the Rio Declaration […], the objective of this Convention is to protect human health and the environment from [POP]".[22] In order to list a new substance in one of the Convention's annexes, the Conference of the Parties shall decide "in a precautionary manner" while taking due account of "any scientific uncertainty".[23] According to *Sands* and *Peel* the "Convention increasingly moves to regulate POPs whose toxicity is not uniformly accepted".[24] Meanwhile 179 countries have ratified the Convention.[25]

There are also provisions of international law on the protection of the maritime area, many of which implement the precautionary principle in terms of risk prevention.[26] For example, in Art. 3 of the OSPAR Convention the Contracting Parties commit to taking all possible steps to prevent and eliminate pollution from land-based sources, that is point and diffuse sources on land from which substances reach the maritime area by water, through the air, or directly from the coast. According to Annex I Art. 3(a) these measures include, listed first, to reduce and phase out substances that are toxic, persistent and liable to bioaccumulate ("PBT"-Substances). Thereby, as stipulated by Art. 2(2)(a), the Contracting Parties apply the precautionary principle

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14 *United Nations* 2002, para 23. To achieve the ambitious so-called Johannesburg-goal, in 2006 under the title 'Strategic Approach to International Chemicals Management' (SAICM) a specific policy agenda was adopted, see the Dubai Declaration on International Chemicals Management at *SAICM* 2006, pp. 6 et seq.

15 *United Nations* 2012, para. 213.

16 *Vereinte Nationen* 1992, para 19.4.

17 *Warning/Winter* 2004, pp. 256 et seq.

18 Cf. http://www.unece.org/trans/danger/publi/ghs/implementation_e.html (10.6.2014). In Europe GHS was implemented by the CLP Regulation (fn. 3).

19 Binding regulations, recommendations, codes and guidelines.

20 *United Nations* 1992, para 19.44, 19.49.

21 Cf. the UNECE Aarhus Protocol on Persistent Organic Pollutants (POP) as well as the UNEP Rotterdam convention on certain hazardous chemicals and pesticides in international trade, both from 1998.

22 Cf. Recitals 8, 9 POP-Convention.

23 Art. 8(9) POP-Convention.

24 *Sands/Peel* 2012, p. 526.

25 As of June 2014, cf. http://chm.pops.int/Countries/StatusofRatifications/tabid/252/Default.aspx#a-note-1 (10.6.2014).

26 *WBGU* 2013, p. 85.

> "by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances […] introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, […] even when there is no conclusive evidence of a causal relationship between the inputs and the effects".

With the Declarations of Rio and Johannesburg, Agenda 21 and other principles, declarations and resolutions[27] international law is spanning - although the documents referred to unfold no direct legal force[28] - the operational framework of the international chemical legislation, into which the national as well as supranational regulatory activities fit.[29]

In addition, there are some binding multilateral agreements[30] that regulate the production and application of certain substances of concern. Moreover, GHS provides an internationally consented standard with regard to the classification and identification of substance-related risks.

As a result, international law has not only established the objective to protect human health and the environment from substance-related risks. Instead, by providing the precautionary approach it defines a level of protection which legitimates actions to prevent "serious or irreversible damage" - even if the perceived damage is not subject to scientific certainty.

1.2 Legislative objectives of REACH and of the authorisation regime

According to Art. 1(1) REACH[31] the primary goal of REACH is to ensure a high level of protection.[32] The European Commission's White Paper "Strategy for a future Chemicals Policy" from 2001 already identifies the protection of human health and the environment as the main objective of what was later to become the REACH system, while at the same time avoiding unnecessary barriers to trade and discrimination against imported substances and articles.[33]

In order to achieve its protection objectives the Regulation "is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment".[34] This means, as recital 16 stipulates, that the protective goods are not adversely affected "under reasonably foreseeable conditions" – this is the standard by which the industry has to align its self-responsibility and which REACH operationalises through the duty to "adequately control" substance-related risks.[35]

At the same time, the high level of protection objective serves the overriding goal of a sustainable development (Recitals 3, 131) and is to be considered in the context of the

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27 Overview at *Sands/Peel* 2012, *Proelß* 2010, *v. Heinegg* 2014, § 49.

28 Instead the documents constitute so-called "soft law".

29 *Warning/Winter* 2004, pp. 241 et seq. observe approaches to a "global chemicals regulation".

30 Overview at *Sands/Peel* 2012, pp. 521 et seq.

31 The Regulation's aim "is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."

32 EGC, judgment of 7.3.2013, case T-93/10, not yet published, para. 116 – Bilbaína de Alquitranes and others v ECHA.

33 *European Commission* 2001, pp. 7 et seq.

34 First sentence of Art. 1(3) REACH.

35 *Führ* 2011, chapter 8, para. 69 et seq.

aforementioned United Nations' Johannesburg Plan implementation (Recital 4). Furthermore, REACH is the EU's contribution to the "SAICM" (Recital 6).[36]

According to Art. 1(3) sentence 2 the REACH provisions "are underpinned by the precautionary principle." The White Paper designates this as "fundamental" to ensure the striven high level of protection.[37] In REACH the precautionary principle is laid down as a structural or guiding principle which, while not being directly applicable,[38] bears some meaning whenever provisions build on the concept of risk.[39] In practice this means, for instance, that in the presence of conflicting information on the hazards of a substance, the risk assessment must be conducted on the basis of those data associated with the greatest concern.[40] The shifting of responsibility to the manufacturers and downstream users including, as part of the registration process, the submission of data on the properties of substances and the adequate control of risks is also seen as an expression of the precautionary principle.[41]

As regards particularly problematic substances, this approach relying on self-responsibility[42] of the actors, however, is deemed insufficient by the legislator. For such substances REACH offers specific mechanisms of governmental risk regulation.[43] Pursuant to Art. 55 et seq. REACH, certain "substances of very high concern" (SVHC) may become subject to the authorisation regime, the aim of which is to replace SVHC successively by suitable alternative substances or technologies.[44] Whenever a substance is identified as SVHC and listed in Annex XIV REACH, a manufacturer, importer or downstream user must not place the substance on the market or use it themselves, unless certain conditions are met. The authorisation scheme thus establishes a use specific ban with permit reservation; by applying for authorisation actors may (temporarily) overcome the barrier of the ban. For this they must, prior to the placing on the market or usage, prove that the risks posed by the substance use are adequately controlled or that the socio-economic benefits outweigh the risks. Due to this reversal of the burden of proof and since the approval obligation is triggered by the substance-inherent hazards, without in any case taking full account of the actual exposure-related risk, the authorisation regime is another expression of the precautionary principle, much like the mere idea of substitution of SVHC.[45]

In addition, substances posing an "an unacceptable risk to human health or the environment" may become subject to general restrictions (Art. 67 et seq. REACH).[46] These are designed as prohibitions which – as opposed to the authorisation – do not provide a permit reservation. Instead, restrictions often contain article-specific or application-specific exceptions or limit values.

Finally, a further aim of the Regulation[47] is to grant EU citizens access to "information about chemicals to which they may be exposed, in order to allow them to make informed decisions

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36 *European Commission* 2009a, p. 8. Cf. fn. 14 as regards SAICM.

37 *European Commission* 2001, p. 5, cf. *Appel* 2003, p. 167, *Calliess/Lais* 2005.

38 *Rehbinder* 2012, chapter 3, para. 17, 22.

39 *Rehbinder* 2012, chapter 11, para. 17, *id*. 2008, Art. 1, para. 29.

40 *European Commission* 2007, p. 3.

41 *v. Holleben/Schmidt* 2002, p. 534. *Calliess/Lais* 2005, p. 296, *Hansen/Carlsen/Tickner* 2007, p. 399, *Kogan* 2012, pp. 8, 39.

42 Cf. *Führ* 2003, p. 43 et seq., *Führ* 2011, chapter 1, para. 47 et seq., *Rehbinder* 2008, Art. 1, para. 20 et seq.

43 C.f. Recital 86 REACH.

44 Cf. Recitals 69 et seq.

45 Likewise *Hansen/Carlsen/Tickner* 2007, p. 400, *Rehbinder* 2008, Art. 1, para. 11, 34 et seq., *Führ* 2011, chapter 1, para. 46.

46 Cf. section 2.1.3 for a comparison of the mechanisms of restriction and authorisation.

47 Although not explicitly designated as such in Art. 1, cf. *Fischer* 2005.

about their use of chemicals" (Recital 117 REACH). Consumers are entitled to gain information related to SVHC contained in articles (Art. 33(2), Recital 56).[48]

1.3 Legal classification of the authorisation regime

Art. 55 et seq. REACH allow a substance to be subjected to an authorisation requirement due to their inherent properties (hazard potential) without prior determination of the exposure-related risk due to the actual application of the substance.[49] The authorisation mechanism may therefore in principle – in terms of its instrumental configuration – be located within the sphere of precautionary measures. However, this legal doctrinal classification needs to be separated from the question of the extent to which the authorisation - from a substantive point of view – also regulates a hazard potential, which lacks "full scientific certainty" as set forth in Principle 15 of the Rio Declaration. It is therefore necessary to classify the risks of SVHC. To this end, first of all, the concepts of hazard potential, risk, danger and risk potential must be differentiated.

1.3.1 Definition of terms: hazard potential, risk, danger and risk potential

In terms of environment and health, the term "risk" usually refers to the potential harm to an object or interest protected by law.[50] From a legal point of view, one can differentiate between situations in which one speaks of a "danger" and those in the area of the precautionary principle, in which a mere "risk potential" has been identified. Beyond this, there is also the area of "residual risk".

Risk is characterised by a two-fold uncertainty with respect to the occurrence of an event (1st order uncertainty) and its specific effects and resulting consequences (2nd order uncertainty):[51] whether a situation causes the risk of damage to human health or the environment, can only be determined with an appropriate (natural sciences and engineering) expertise in the context of a risk assessment. It is then the task of the law to normatively evaluate an identified risk (risk evaluation) and assign it the required legal consequence (risk management).

The substance-specific risk assessment is typically based on the risk-ratio model.[52] REACH also puts forward this four-fold concept:

> "(1) *Hazard identification* means identifying the biological, chemical or physical agents that may have adverse effects …
>
> (2) *Hazard characterisation* consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity …
>
> (3) *Appraisal of exposure* consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study …

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48 This aspect is reiterated by the legislative purpose of the CLP Regulation: CLP aims to "ensure proper and comprehensive information provision to consumers on the hazards and safe use of chemicals" (Recital 41).

49 Before the listing of a SVHC on Annex XIV the substance-related risk is indeed considered, using distribution (application) and the volumes as a proxy (cf. Art. 58(3) REACH). Consideration is, however, given rather to the "general" risk of the substance in the EEA and not to the specific risk posed by the substance in a specific application. Cf. section 4.4.1.1.1.

50 *Roßnagel* 1994, para. 163, *SRU* 1999, para. 50 et seq.

51 *Führ* 2014, para. 45 et seq.

52 Since its publication in 1983 the model has served as a risk assessment standard, c.f. *NRC* 1983, *van Leeuwen* 2007, p. 16, *Kleihauer/Führ/Hommen* et al. 2013, p. 4.

> (4) *Risk characterisation* corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and of the severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding [components] and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process.[53]"

Steps (1) and (2) serve to derive the hazard potential, steps (3) and (4) incorporate the exposure-related risk as well. To determine the hazard potential, REACH provides a standard procedure to identify, by means of quantitative analysis, the dose (concentration)-response (effect) relationship. If a no-effect threshold cannot be derived, however, the effects have to be deduced by using a semi-quantitative or qualitative analysis.[54] For instance, carcinogenicity is one of the properties often not eligible for the deduction of threshold values.[55] Specific uncertainties are inherent to all process steps of the risk-ratio model and finally coalesce in the risk characterisation.[56]

In the legal sense, one refers to the term "danger" in situations – or with regard to risks – in which, after an unhindered course of events, with reasonable probability harm to a protected object is expected.[57] Under German law, in such a situation an unconditional duty to avert the danger arises; the choice of means, however, is still to be assessed against the principle of proportionality.[58] The term "danger" is relative and situational; damage intensity and probability of occurrence are therefore mutually affected in the sense of an "opposite proportionality":[59] the requirements of the probability are lower when a particularly large loss or damage to a particularly sensitive legal interest is possible.[60] Conversely, a hazard potential of a substance does not automatically result in a danger as understood here if by appropriate risk management measures – reduction or avoidance of exposure – the probability of occurrence of the potentially damaging event (1st order uncertainty) can be sufficiently lowered.[61]

However, various situations are conceivable in which a risk may not be classified as danger and an assignment to the area of the residual risk would be inadequate as well. Such situations are within the scope of precaution whereby

> "also such possibly damaging events have to be considered, the only reason they not be excluded is because, according to current knowledge specific causal relationships can be neither affirmed nor denied, and to that extent no danger, but only a suspicion of danger or a "risk potential" exists"[62]

A risk potential may exist when there are "potential adverse environmental effects, a merely possible link between emissions and damage occurrence or a general risk concern".[63] The

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53 *European Commission* 2000, p. 33, quoted after EGC, judgment of 9.9.2011, case T-257/07, ECR II-5827, para. 72 – France v Commission *(numbering and emphasis by the authors)*.

54 Cf. Annex I, Section 6.5 REACH, *Kleihauer* 2011, para. 13, 47 et seq.

55 *ECHA* 2009, p. 54.

56 There are four different categories of uncertainty factors which embody the uncertainty of 1st and 2nd order, c.f. *van Leeuwen* 2007, p. 22 with further references; c.f. *NRC* 1983, pp. 11 et seq. *European Commission* 2000, p. 17, *ECHA* 2012a.

57 *Denninger* 2012, Rn. 39.

58 *Rehbinder* 2012, chapter 3, para. 24.

59 *Rehbinder* 2012, chapter 3, para. 25.

60 *Köck* 1999, p. 16 with further references. For the limitations of that formula c.f. *Kleihauer* 1998, pp. 35 et seq.

61 *Di Fabio* 1994, p. 146, *Merenyi* 2011, chapter 4, para. 8.

62 BVerwG, judgment of 19.12.1985, 7 C 65/82, NVwZ 1986, 208 (212) – Wyhl *(authors' translation)*.

63 BVerwG, judgment of 11.12.2003, 7 C 19/02, NVwZ 2004, 610 (611) *(authors' translation)*.

German Federal Administrative Court (BVerwG) classifies the possible adverse effect associated with the fabrication of ultrafine metal and ceramic powder ("nanopowders") a risk potential which is to minimise by way of precaution.[64] In order to identify a risk potential, there is no prerequisite to build upon reliable empirical evidence; thus recourse is permitted on theoretical considerations.[65] However, reference to a purely hypothetical risk is not sufficient but rather a certain relation to reality is needed in order to avoid a "precaution out of the blue"[66]. The German Advisory Council on the Environment (SRU) defines risk potential as "the theoretical – yet as opposed to pure speculation being based on scientific plausibility reasons - initial concern, which is, however, only little empirically solidified or attestable".[67]

In the chemicals context, risk is therefore always composed of a substance's inherent hazard potential and substance-related exposure. When there is a relevant exposure of a substance with proven hazard potential, the risk has to be regarded as a danger. A risk that is attributable to the release of a substance with an uncertain hazard potential has to be qualified as a risk potential. The following sections examine the extent to which SVHC can be assigned to these categories.

1.3.2 Appreciation of the SVHC-criteria in the light of the categories

A substance has to fulfil the criteria specified by Art. 57(a) - (f) to be identified as substance of very high concern (SVHC). This includes CMR substances (carcinogenic, mutagenic or toxic for reproduction), PBT substances (persistent, bioaccumulative and toxic), or vPvB substances (very persistent and very bioaccumulative) as well as substances under Art. 57(f) "for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those" other mentioned categories of substances.

The following subsections examine, to what extent SVHC and their associated hazard potentials and risks can be assigned to the categories developed in section 1.3.1.

1.3.2.1 CMR substances

Substances identified pursuant to Art. 57(a) – (c) have to fulfil classification criteria for substances that are carcinogenic, mutagenic or toxic for reproduction, Categories 1A or 1B as specified in the CLP Regulation.[68] These criteria are globally harmonised through the GHS.[69] In part, regulatory action against substances with CMR properties is therefore classified as a prevention of identified dangers.[70] Meanwhile, classification according to GHS even includes cases that are only "suspected" of CMR-related toxic effects (Category 2)[71] – these substances, however, are excluded from identification on the grounds of Art. 57(a) - (c). SVHC with CMR properties therefore exhibit severe hazard potentials with an increased realisation potential. Moreover, for carcinogenic and mutagenic substances – as opposed to substances that are toxic

64 BVerwG, judgment of 11.12.2003, 7 C 19/02, NVwZ 2004, 610 (611) referring to § 5(1) No. 2 BImSchG.

65 BVerwG, judgment of 19.12.1985, 7 C 65/82, NVwZ 1986, 208 (212).

66 *Ossenbühl* 1986, p. 166.

67 *SRU* 2011, para. 33 with further references *(authors' translation)*.

68 Annex I, Sections 3.5-3.7 CLP.

69 C.f. section 1.1.

70 *SRU* 2004, para 1031, *Köck* 2009, p. 196.

71 *United Nations* 2013, p. 162 for "Suspected of causing genetic defects", p. 167 for "Suspected human carcinogens", p. 178 for "Suspected human reproductive toxicants"; c.f. the corresponding Category 2 classifications according to Annex I, Section 3 CLP.

for reproduction – often no threshold values may be derived. In these cases a substance may develop its toxic potential to an organism after receiving a single molecule.

1.3.2.2 PBT substances

In international law the Agenda 21 had already postulated the gradual phase-out of PBTs in 1992; the OSPAR Convention contains corresponding duties.[72] Furthermore, states such as Canada, Japan and the U.S. also pursue "protective policies" towards PBT substances. At least in Japan these are designed instrumentally in a manner comparable with REACH.[73]

The particularity of persistent and bioaccumulative substances is – as is also true for vPvBs – that threshold values are not an adequate indicator of risk[74] because the common risk assessment methodology is not designed to evaluate p- and b-properties, but linked solely to the standard endpoints reflected in several (eco-) toxic effects.[75]

PBTs determined according to Art. 57(d) have to meet the criteria set out in Annex XIII REACH. The substance's toxicity may be based on several (eco)toxic effects, the criteria of which are mostly based on GHS standards: this is at least true for substances exhibiting the properties mentioned in Sections 1.1.3(b) (CMR substances) and (c)(substances with specific target organ toxicity) of Annex XIII.[76] As far as classification is based on lit. (b) (toxic for reproduction), the SVHC-status is also eligible for "suspected" hazardous properties.

Furthermore, pursuant to Annex XIII, Section 1.1.3(a) the (eco)toxicity of a PBT substance can be proven if its long-term NOEC[77] or EC10[78] for marine or freshwater organisms is less than 0.01 mg/l. Although not referring to harmonised GHS criteria, these values still only meet the concerns that international law formulates in order to protect waters and water organisms from PBTs. Overall, the documentation requirements to prove the toxicity of PBTs stipulated by REACH are more stringent, compared with the requirements of the POP-Convention and the POP-Protocol, which do not contain clearly defined criteria for toxicity.[79]

The indicators set out in Annex XIII for the persistence of substances, on the other hand, are almost similar to the requirements of the POP-Convention and the POP-Protocol. Moreover, the OSPAR Convention provides requirements on the identification of PBTs that are less stringent overall.[80]

1.3.2.3 vPvB substances

The determination of vPvB substances in accordance with Art. 57(e) is (so far) not based on harmonised GHS criteria. Instead, referring to "[e]xperience at international level" Recital 76

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72 C.f. section 1.1.

73 *Abelkop/Bergkamp/Brooks* et al. 2013, pp. 70 et seq.

74 A substance may show no or low toxicity with respect to the standard endpoints but still produce yet unknown undesirable reactions (see, for example, the case of chlorofluorocarbons, so-called CFCs).

75 Toxicity due to bioaccumulative properties of the food chain is to some extent captured by the model, since a threshold for "secondary poisoning" is provided only for "B"-substances. The threshold level itself, however, follows the standard procedure and is thus based on toxic effects alone.

76 C.f. the analogous classification criteria at *United Nations* 2013, pp. 201 et seq.

77 NOEC: No-observed effect concentration.

78 EC: Effective Concentration. EC10 describes the concentration exerting an effect on 10% of the test organisms.

79 *Moermond/Janssen/de Knecht* et al. 2011, p. 368.

80 *Moermond/Janssen/de Knecht* et al. 2011, p. 368.

REACH suggests a substance with very high persistence and very high bioaccumulation potential is also of very high concern. Indeed, the following aspects support this rating.

In several respects the properties of vPvB substances are similar to the properties of the group of persistent organic pollutants which are regulated by binding international law (POP-Convention and POP–Protocol). The main difference between these groups of substances is that with regard to POP there is also evidence[81] of toxicity.[82] Another condition for a substance to be identified as POP is the potential for long-range transport; a quality often shown by vPvBs, too, though this does not belong to the Annex XIII criteria. The indicators to determine bioaccumulation in the international law sources are identical with the vB criteria in Annex XIII, Section 1.2.2.[83] Thus, as regards this criterion an international harmonisation can be observed.

Besides vPvB properties may also unfold adverse effects on humans and the environment; however, these are difficult to predict, which is especially true in respect of potential long-range transport and sensitive organisms in remote regions exposed to different environmental conditions.[84] Furthermore it is, for scientific reasons, not adequate to determine effect thresholds for these substances.[85]

VPvBs are determined independently from adverse effects because no impact models or sometimes even ideas about possible damage exist.[86] Instead, high concern follows because

> "Persistence, mobility and the non-natural state extremely expand the possibilities for high exposures and adverse effects in a variety of contexts. They increase the potential exposure immeasurably and are an indication of high interference rates and the fact that emissions are not reversible." [87]

Due to the lack of certainty about the harmful effects of vPvB properties a regulation addressing these properties can be dogmatically attributed to the area of precaution.[88] At the same time, however, it is not a "precaution into the blue" as the technical regulation requires the scientific evidence of increased persistence (vP) as well as increased bioaccumulation (vB), proven by reference to objective criteria stipulated in Annex XIII. Moreover, the regulation takes place exactly in the field of application of principle 15 of the Rio Declaration since without adequate control of vPvBs "serious or irreversible damage" might occur.[89]

Finally, the practical relevance of the vPvBs should not be overestimated: of the 155 identified SVHC (as of November 2014) only six exclusively meet the criteria of Art. 57(e).

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81 C.f. section 1.1 for signs of developments to open the POP status for substances with lower evidence base.

82 *Klöpffer* 2012, pp. 17 et seq.

83 *Moermond/Janssen/de Knecht* et al. 2011, p. 368.

84 *Zarfl/Matthies* 2013, p. 7 m.w.N., *European Commission* 2003, pp. 15 et seq.

85 C.f. section 1.3.2.2.

86 *v. Gleich/Pade/Wigger* 2013, p. 19.

87 *v. Gleich/Pade/Wigger* 2013, p. 19 *(authors' translation)*; *Løkke* 2006, p. 346.

88 *Løkke* 2006, p. 347, *Zarfl/Matthies* 2013, p. 7 with further references, *v. Gleich/Pade/Wigger* 2013, p. 19.

89 Even critics of an overemphasis of the precautionary approach compliment the REACH test specifications for being suitable for identifying the "chemical of concern" Henicosafluoroundecanoic Acid as vPvB substance, *Abelkop/Bergkamp/Brooks* et al. 2013, pp. 31 et seq.

1.3.2.4 Substances with equivalent level of concern

Art. 57(f) allows the SVHC-identification of substances

> "— such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e)".

Art. 57(f) opens the authorisation regime for other classes of substances, i.e. those of equivalent concern in respect of which no adequate evaluation criteria were available at the time of the adoption of REACH (such as endocrine disruptors[90]) as well as PBT or vPvB substances that do not meet the conditions laid down in Annex XIII REACH criteria.[91] However, SVHC determinations in accordance with this standard must be based on "scientific evidence of probable serious effects" which are comparable to the effects of the other SVHC categories. Thus, building upon mere speculation or assumptions is excluded. Even the mere possibility of serious effects is ruled out, but it depends on the science-based probability. In particular, endocrine disruptors (EDC) belong to the (small) group of the SVHC exclusively[92] picked on the grounds of "equivalent concern".[93] Their hazard potential is widely recognised: even certain regulators from third countries[94] base their product policies on the identification of a substance as EDC in accordance with Art. 57(f) REACH.

Furthermore, an Art. 57(f) classification may also be founded on GHS criteria: three of the previously identified SVHC[95] cause respiratory sensitisation and thus a hazard class according to CLP and GHS.[96] This is justified by ECHA with concerns equivalent to CMRs.[97] This practice shows that the clause is also permeable for hazard classes which were known at the time REACH was adopted and were still not included in the SVHC criteria of Art. 57.

A SVHC determination under Art. 57(f) may, however, be based on precautionary considerations if, for example, substances are identified as PBT or vPvB that do not meet the conditions laid down in Annex XIII REACH. The revision of Annex XIII in 2011, however, significantly reduces the importance of PBT and vPvB that do not meet such criteria. Moreover, an identification of substances as SVHC on this basis has not yet been undertaken.[98]

1.3.2.5 Specification of the hazard potential of SVHC

A scientifically reasoned hazard potential can be derived with respect to all SVHC classes of Art. 57 REACH. This is especially true for CMR and PBT substances and usually also for substances

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90 C.f. henceforth *Damstra/Barlow/Bergman* et al. (WHO) 2012.

91 *Ingerowski* 2010, p. 232 with further references.

92 In addition, cadmium sulphide and cadmium, for example, are determined as SVHC because of their carcinogenicity and also because of properties with equivalent concern.

93 E.g. 4-(1,1,3,3-tetramethylbutyl)phenol, 4-tert-octylphenol,

94 E.g. California's Safer Consumer Products Regulation (SCPR), in effect since 1.10.2013, shall set incentives for companies to substitute problematic substances used in articles with safer alternatives. Pursuant to § 69502.2 a) SCPR EDCs identified under Art. 59 REACH are among the candidate substances to the Regulation.

95 So-called HHPA: Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride and trans-cyclohexane-1,2-dicarboxylic anhydride.

96 Annex I, Section 3.4 CLP, *United Nations* 2013, pp. 149 et seq.

97 Among other things, against this argument a lawsuit filed by Hitachi Chemical Europe is directed. The firm aims at establishing the inadmissibility of SVHC-identification of the substances, 2013 OJ C 129/26.

98 An attempt in this direction (Triclorbenzole; still under the old Annex XIII) was unsuccessful.

of "equivalent concern". The identification of CMRs and respiratory tract sensitising substances may be based on legal classifications, where each hazard presents itself as "officially certified".[99] The same applies for PBTs whose toxicity results from criteria specified in Annex XIII, Section 1.1.3(b) and (c). In addition, the EU Member States and the European Commission commit themselves to working towards the inclusion of Annex XIII PBT and vPvB criteria in the classification canon of the United Nations.[100] Where authorisation is required for these mentioned SVHC categories, it is – with a view to the substance properties – not an instrument of precaution.

Where authorisation is required for PBTs only suspected toxic to reproduction as well as for vPvBs whose hazard potential cannot be proved due to the methodological complexity, however, it is – with a view to the inherent scientific uncertainty – considered an action within the meaning of the precautionary principle.[101]

However, within precaution-oriented regulation there is an incremental gradation in the degree of scientific uncertainty, which can be more or less pronounced. To that effect, an example for a high degree of uncertainty can be found in the EU Regulation on cosmetic products:[102] the hazard potential of nanomaterials[103] is to a large extent unknown[104], probably for that very reason[105] a cosmetic product containing nanomaterials shall – prior to being placed on the market – be notified which also includes submission of a toxicological profile of the nanomaterial.[106] Here, special obligations are addressed to the general property of being at the nanoscale – and thus irrespective of the knowledge on any hazard potential (e.g. CMR properties); rather, the starting point is the scientific uncertainty about the hazard potential.

In doing so, the degree of uncertainty is much higher compared to the "precaution categories" of Art. 57 REACH since even the determination of "suspected" PBTs because of their Category 2 toxicity to reproduction requires "some evidence from humans or experimental animals, […] of an adverse effect on sexual function and fertility, or on development, [while] the evidence is not sufficiently convincing to place the substance in Category 1." As a result there is some scientific evidence which is not sufficiently conclusive for a sound classification. As regards vPvB scientific evidence of increased persistence and bioaccumulation is even provided in any case.

This comparison shows that in terms of the hazard potential even within the substantive scope of precaution, gradations concerning the detection of possible damage can be established, while Art. 57 REACH ensures a more substantiated hazard suspicion.

1.3.2.6 Procedures and transparency

Finally, the procedures to identify SVHC and to include them in Annex XIV ensure a high degree of transparency. Prior to each final decision there is a public consultation giving interested actors such as companies, associations as well as scientists or private persons the opportunity to

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99 C.f. Art. 59(2) Sentence 2 and 59(3) Sentence 2 REACH.

100 Art. 53(2) CLP.

101 This may also apply to substances determined on the grounds of Art. 57(f).

102 Regulation (EG) No 1223/2009 of 30 November 2009 on cosmetic products, 2009 OJ L 342/59.

103 Commission Recommendation of 18 October 2011 on the definition of nanomaterial - 2011/696/EU, 2011 OJ L 275/38.

104 *Krug/Wick* 2011, p. 13, *SRU* 2011, para.*3.

105 Recital 30 Regulation on cosmetic products.

106 Cf. for the regulation of nanomaterials in the EU cosmetics legislation *Schenten* 2012, pp. 41 et seq.

submit incriminating or exculpatory evidence regarding the substance.[107] This way, the internationally available scientific expertise should be mobilised to inform regulatory decisions regarding SVHC.

1.3.3 Conclusion regarding the legal classification

The identification of SVHC is linked primarily to the substance-specific hazard potential determined by the process steps (1) and (2) of the risk-ratio model. However, to determine the specific risk posed by a substance, according to the risk-ratio model additional process steps (step 3: exposition and step 4: risk chracterisation) need to be carried out (section 1.3.1).

In addition, it needs to be considered that for certain uses of SVHC in articles, exposure to the applied substances during the product life cycle is scarcely avoidable due to material properties.[108] This inevitably leads to an exposure of protected goods, even if it is not yet possible to specify exactly where and to what extent. The use of SVHC in articles therefore carries an "intrinsic" risk.

Before a SVHC is included in Annex XIV the substance-related risk which results from the general dispersive use – i.e. the applications – and the quantities produced or used are considered. This consideration is, however, rather geared to the "general" risk caused by the substance within the EEA.

The specific risk posed by the substance in a specific application will only be examined within the consideration of authorisation applications.[109] The steps of establishing the authorisation obligation are thus considered a tool of precaution,[110] but is also based on a general consideration of the substance-related risk.

Such an instrument of "preventive" control is, however, not illegitimate per se; rather, globally there are countless examples about plant- or product-specific approval or authorisation reservations, based on comparable hazard (or risk) assessments.[111] One of the purposes of such regulations is that the actor who potentially causes a risk relating to, for example, a substance also bears the burden of proof with regard to its safe use, since she or he has the most detailed risk knowledge. The mere instrumental configuration thus appears unproblematic from a WTO law perspective.[112] The WTO dispute settlement bodies dealt with regulations that were designed as approval or authorisation process, respectively. In these cases, procedural requirements were not the matter of the dispute, but the criteria triggering the substantive obligations.[113]

It is therefore crucial that the risks posed by the subject matter of the authorisation, i.e. the articles with SVHC, legitimise such a regulatory control. Important, therefore, is whether and to what extent the specific risks (or rather, the hazard potentials underlying the risks) are attributable to the field of precaution.

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107 Art. 59(4), Art. 58(4) REACH. C. f. http://echa.europa.eu/about-us/partners-and-networks/stakeholders (6.2.2014).

108 C.f. section 3.1.2.1.

109 The legal assessment in section 4.4.1.1.1 will return to these issues.

110 See section 1.2 f.

111 *OECD* 2010, c.f. the examples at *Nordlander/Simon/Pearson* 2010, p. 250.

112 *SRU* 2004, para. 1047 et seq.

113 Panel Report WT/DS291-93/R of 29.09.2006 (EC – Biotech Products), para. 7.1353, 7.1693.

To establish an authorisation requirement, proof of the substance's inherent hazard potential is to be provided by the state actors; to this end, the requirements are defined quite strictly.[114] All SVHC categories are subject to high requirements for the scientific evidence. As concerns the determined degree of hazard potential two groups of SVHC can be differentiated:

- On the one hand, there are CMRs, most PBTs and basically substances of "equivalent concern" under Art. 57(f). To this end, the identified hazard reaches an intensity which, in combination with an exposure-related risk, presents a danger in the legal sense.
- On the other hand, there are Cat. 2 reprotoxic PBTs and vPvB, the hazards of which are scientifically uncertain. The risk of such substances would – in principle despite release – be located below the danger threshold; their regulatory control, therefore, is to be classified as a precautionary measure.

At the same time, with regard to the second group, the example of nanomaterials in the Cosmetics Regulation illustrates how far precautionary-based control can reach: without any specific knowledge of toxicological properties this regulation addresses a general risk potential posed by nanoscale materials and is thus predominantly triggered by scientific uncertainty.

In contrast, REACH stipulates – also in the case of SVHC of the "precaution group" - requirements regarding the scientific evidence of the hazard potential. The authorisation obligation does not, therefore, apply when there is uncertainty about the risk-related factors,[115] but only if there is concrete and verifiable scientific evidence of a hazard potential.

Moreover, for an evaluation of the risks posed by SVHC, it needs to be taken into account that frequently no effect thresholds can be derived. It follows that – once released – especially with regard to CMR substances already receiving a single molecule may activate the toxic potential. Finally, the majority of identified SVHC meet more than one of the criteria mentioned in Art. 57 REACH at the same time, resulting in an increased hazard potential.[116]

1.4 Problem situation and examination requirements in terms of SVHC in articles

Substances as defined in Art. 3 No. 1 are the immediate regulatory subject matter of REACH.[117] Mixtures composed of two or more substances and articles are only indirect regulatory objects, as the requirements of REACH apply only to the substances contained in them.[118] Examples of mixtures are ink, paints and glazes.

Art. 3 No. 3 defines article as "object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition". In contrast to substances and mixtures, the function of a product is determined by its physical appearance and not by its chemical composition.[119] Consequently, most products used in private homes such as furniture, textiles, toys, DVDs, books, kitchen appliances and electronic devices are covered by the term "article".[120]

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114 *Rehbinder* 2012, chapter 11, para. 100, *Raupach* 2011, p. 62.

115 For this reason, some of the literature does not classify the authorisation requirement as a precaution tool, *Ingerowski* 2010, p. 337.

116 For an overview, see *Wurbs* 2014, p. 11.

117 REACH is supplemented by the CLP Regulation which pursues the same objectives and whose article-related provisions in turn are linked to REACH, c.f. Art. 4(2) CLP; *Koch* 2011, para. 14.

118 *Merenyi* 2011, chapter 3, para. 3, *Raupach* 2011, p. 69.

119 *Merenyi* 2011, chapter 3, para. 76 et seq., 80.

120 *ECHA* 2011, p. 23.

Until the final steps of the adoption of REACH the provisions relating to articles were highly controversial - not least in view of the already then virulent debate on the "WTO-compatibility".[121] Following the adoption of the Regulation the voices that spell out a WTO incompatibility of the Regulation such provisions became clearly less perceptible. For instance, the current report "Foreign Trade Barriers" by the Office of the United States Trade Representative (USTR) does not mention the EU chemicals legislation.[122] At the same time, from the consumer's perspective the idea seems to prevail that products that have been manufactured within the scope of the REACH Regulation were safer than imported products.[123]

However, the question of WTO compatibility may arise again when the scope of the article-related REACH provisions is enhanced. Regulatory activities in this respect may address, in particular, imported articles containing[124] SVHC and thus substances that are particularly relevant for the protection of human health and the environment.

2 Extension of the authorisation requirement on SVHC in imported articles

Following Art. 56(1) REACH a "manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, " unless the respective actor attained an authorisation for the corresponding use or this use is exempt from the authorisation requirements.

However, REACH regulates only the use of SVHC within the EEA. Whenever the producer of an article incorporates the substance outside the EEA, Art. 56(1) does not apply. An article may therefore be imported into the EEA subject to the requirements of Art. 7 REACH.[125] "Domestic" producers of articles are thus subject to stricter requirements than those which are produced "abroad". In view of the hazard potential associated with SVHC, even the demand for "consistency of the legal system" raises the question of whether a uniform (i.e., irrespective of origin) level of protection must be ensured with regard to articles containing these substances. Against this background, the subsequent sections of this report analyse what regulatory options are available to extend the legal effect of Annex XIV on SVHC in imported articles.

2.1 Available regulatory options

One regulatory option would be to make use of the restriction procedure already provided for in REACH (section 2.1.1). Another option would be to modify the prevailing authorisation scheme (section 2.1.2).

2.1.1 Restriction procedure approach

According to Art. 68(1) REACH "[w]hen there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis" the European Commission may adopt or

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121 C.f. *Führ* 2011, chapter 1, para. 97, *Rehbinder* 2012, chapter 11, para. 61 as well as on the one side *Palmer* 2004 and on the other *Bronckers* 2004.

122 Office of the United States Trade Representative (USTR) [Ambassador Demetrios Marantis], 2013 National Trade Estimate Report on Foreign Trade Barriers; Washington, D.C.

123 "Half (49%) of Europeans have the view that products manufactured in the EU contain safer chemical substances than products imported from countries outside the EU", *TNS Political & Social* 2013, p. 54.

124 The legal opinion thus focuses on cases in which SVHC are contained in the article and were not already chemically converted during the manufacturing process, c.f. examples in *BDI* 2014.

125 C.f. section 6.3.

amend restrictions.[126] Pursuant to Art. 67(1) a "substance on its own, in a mixture or in an article […] shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction". Restrictions may therefore also apply to imported articles containing restricted substances.

For this reason, the legislator codified in Art. 69(2) that SVHC from Annex XIV may become subject to restrictions to the extent these substances are parts of articles:

> "After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV."

In order to expand the legal effect of Annex XIV on SVHC in imported articles, there is thus an option under the applicable law to adopt appropriate restrictions after Art. 69(2) REACH. This is also reflected in Art. 58(6) REACH.

However, this requires ECHA to prepare an Annex XV dossier, while only after the "sunset date" as specified in Art. 58(1)(c)(i) REACH the agency shall begin to determine whether the use of that substance in articles poses a risk to human health or the environment "that is not adequately controlled." In the light of Art. 58(6) REACH it should, however, also be possible to start preparations of a restriction dossier before the sunset date since, according to current legislation, with regard to SVHC in imported products no risk reduction is expected when the authorisation requirement takes effect.

In addition, the time consuming procedure set out in Art 69-73 is to be passed through.

As a result, a restriction would constitute a ban on the placing on the market which would, however, only come into effect at a later date after a further process. Furthermore, there would be no possibility to remove the ban in order to use the substance in articles by applying for authorisation.

An additional regulatory option follows from Art. 68(2) REACH which provides an accelerated restriction procedure for CMR substances of category 1A or 1B as such or, for example, in an article, as far as these could be used by consumers.

2.1.2 Modification of the authorisation procedure approach

An alternative solution would be to adjust the regulation text, so that the effect of the authorisation requirement is expressly extended to SVHC in imported articles. For this purpose Art. 56 REACH could be modified to the extent that Paragraph 1 also covers the import[127] of an Annex XIV substance when incorporated into articles, where this substance is present in these articles, e.g. in a certain concentration.

It should also be considered to adjust the requirements of Art. 7 and 33 REACH (c.f. chapter 6).

2.1.3 Comparative consideration of the regulatory options

The common purpose of the presented options is to find a regulatory response to the problems caused by substances of very high concern, including knowledge deficits.

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126 The Commission may also act on the proposal of a member state, Art. 69(4) REACH.

127 Art. 3 No. 10 REACH defines import as "the physical introduction into the customs territory of the Community".

2.1.3.1 Requirements and design

The options differ both in the requirements and in the design: subject to *restrictions* after Art. 69(2) REACH is a complete or partial – in any case, unconditional – prohibition to produce, to use or place on the market a given substance.[128] Prerequisite for a restriction is a sovereign ascertained "unacceptable risk" (Art. 68(1) REACH), which implies appropriate knowledge of the governmental bodies.[129] For inclusion in the list of substances subject to *authorisation*, however, the determination of a hazard potential is sufficient. But here the manufacturer may repeal the ban on the placing on the market by applying for an application-specific permission: to that end he or she needs to show that the risks of the application covered by Annex XIV are adequately controlled or that the socio-economic benefits of such application outweigh the risks.

If the manufacturer omits to apply for authorisation, both option scenarios would have the identical prohibitive effect, i.e. a ban on the placing on the market. The manufacturer has only to carry additional loads, if he or she decides to apply for an authorisation. But then it must be assumed that the benefits outweigh the costs required for the application procedure.

2.1.3.2 Criteria of proportionality

From the legal principle of proportionality (aptly referred to as "prohibition of disproportionate measures"), it follows that a regulation might restrict the fundamental freedoms and rights[130] only to the extent that is appropriate, necessary and, in an overall view of the end-means relation, not grossly unreasonable for achieving a defined objective.[131]

Which of the control options is the less intrusive means depends on the exact configuration of the mechanisms and the associated effects in a concrete situation. The reference point for the analysis is the respective regulatory objectives pursued.

Restrictions are only eligible when "unacceptable risks" exist and are therefore in principle limited to those uses known to pose a risk, while the authorisation requirement in its approach[132] is linked to the hazard potential of SVHC thus initially applies to all uses of the substance (provided these uses are not exempted in accordance with Art. 58(1)(e) REACH).

From the perspective of the free movement of goods, the intervention threshold is lower in the authorisation regime, which is compensated by the repeal option through a successful application for authorisation. In the restriction scheme the intervention threshold is higher, but the legal consequence is a strict ban on them being placed on the market.

However, the restriction could never be appropriate in the same manner to serve the legislative purpose in situations in which a hazard potential can be confirmed, but a final assessment of whether a risk is present is not possible (yet). If – in order to establish the similarity in terms of achieving the purposes – one would lower the intervention threshold accordingly (hazard as a trigger), the restriction would be stricter and the authorisation would be the milder means.

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128 Recital 23 REACH.

129 As regards restrictions under Art. 68(2) REACH risks are immanent since the option is only applicable to CMR substances of category 1A or 1B which could be used by consumers. Accordingly, an accelerated procedure is applied.

130 In the current case particularly the right to engage in work under Art. 15 of the Charter of the Fundamental Rights of the EU, 2007 OJ C 303/1.

131 International trade law formulates similar requirements. A regulation thus may not be more trade-restrictive than necessary to fulfil a legitimate objective, c.f. section 4.

132 Indeed, the prioritisation procedure for the inclusion of SVHC in Annex XIV after Art. 58(3) REACH also considers risk-based factors (inter alia "wide dispersive use" and "high volume").

In the light of the proportionality criteria, the restriction option is therefore not preferable because in its current form it is not appropriate in the same way. In lowering the threshold for intervention, the restriction is not a milder option and less stressful for the free movement of goods.

2.1.3.3 World trade legal legitimacy

If the legislator chooses the authorisation scheme, this affects aspects of international trade in goods. It is therefore necessary to consider whether this is consistent with the requirements of international trade and economic law, arising particularly from the WTO agreements.

2.2 Compatibility of the extended authorisation requirement with WTO law

In what follows, the compatibility of an extended REACH authorisation to SVHC in imported articles with WTO law is assessed. Section 2.2.1 makes some remarks as concerns the methodological approach of the legal opinion, sections 2.2.2 and 2.2.3 identify the applicable sources of law and give an overview of the required assessment.

2.2.1 Starting point of the assessment

The subject of this legal assessment is the extension of the authorisation requirement for substances of very high concern (SVHC) to SVHC in imported articles. In essence, it is to be assessed whether an extension of the legal effect of Annex XIV on SVHC in imported products (hereinafter: extended authorisation requirement) is compatible with the specifications of world trade law.

The starting point of the legal opinion is the assumption that the REACH system established in 2006 is essentially WTO-compliant. Although some non-European states expressed concerns in this respect[133], a formal dispute settlement procedure, however, has not yet been opened though this would have been possible since the end of 2006. Critics of REACH are very cautious about commenting on the merits of any dispute settlement procedure "against" REACH as well.[134] This is probably due, at least in part, to the fact that early in the design of the REACH system the legislator has already considered the WTO requirements, particularly the Agreement on technical barriers to trade (TBT).[135] Probably mainly in response to the international criticism, the adopted version of the regulation thus contains considerably milder conditions for the registration of substances in articles,[136] even if these were formulated origin-neutral a priori.

Regardless of WTO-compliance of REACH in principle, one has to take into account the doubts raised as to the legitimacy of individual aspects of the Regulation.[137] The assessment therefore needs to address these doubts to the extent that the relevant legal aspects relate to the extended authorisation requirement.

2.2.2 Applicable law

According to the extended authorisation requirement, articles containing one or more substances listed in Annex XIV REACH may not be imported unless a specific authorisation is

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133 WTO Director General, REPORT ON G-20 TRADE MEASURES, 31 May 2012, para. 32 et seq.

134 *Kogan* 2012, pp. 71 et seq.

135 *European Commission* 2001, pp. 7, 10, *European Commission* 2003, p. 6, more limiting *Gruszczynski* 2013.

136 *Orellana* 2006, pp. 26 et seq.

137 C.f. the overviews at *Kogan* 2012, pp. 7 et seq., *Gruszczynski* 2013.

granted or the use is exempted from the authorisation requirement.[138] In this case, the prohibition and the lifting of the ban as a result of the authorisation decision constitute one measure.[139] This measure constitutes a "non-tariff trade barrier" with regard to the international trade of goods. To this end, the legal requirements set out in the General Agreement on Tariffs and Trade (GATT), the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) need to be considered[140], all of which belong to Annex 1 A of the Agreement establishing the World Trade Organization.[141] The mentioned frameworks are multilateral agreements which are legally binding for all WTO members.[142]

The question thus arises of which framework formulates the requirements relevant for the extended authorisation. Firstly, therefore, the scope of the rather more specific SPS and TBT Agreements is to be examined. Depending on the result, the relation of the relevant set of rules to the rather general GATT Agreement is to be assessed in the next step.

2.2.2.1 SPS and TBT Agreements

TBT governs technical regulations while SPS governs sanitary or phytosanitary measures. Whenever a technical regulation serves as a sanitary or phytosanitary measure, its admissibility is subject to the requirements of SPS.[143] In that regard, SPS is lex specialis to TBT.[144]

2.2.2.1.1 SPS Agreement

Annex A No. 1 SPS defines sanitary or phytosanitary measures as follows:

> "Any measure applied:
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; …"

As mentioned in Annex A No. 1(b) SPS, the extended authorisation, too, serves to protect human life. However, it is not directed against "risks arising from additives, contaminants, toxins or disease-causing organisms in foods (…)" and therefore does not fulfill the second condition. The extended authorisation is thus not a SPS measure.[145]

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138 Applicant in the procedure can be one or more manufacturers of imported articles; but it is also possible that one or more manufacturers of the substance subject to authorisation apply for authorisation of the relevant use (Art. 62(2) and (3)). In the latter case the burden of article manufacturers established outside the Community would be significantly lower.

139 Appellate Body Report WT/DS135/AB/R of 12.3.2001 (EC – Asbestos), para. 63 et seq., c.f. *Burchardi* 2007, pp. 231 et seq.

140 *Stoll* 2012, para. 26 et seq., 37 et seq.

141 C.f. *Haltern* 2014, § 33, para. 78 et seq.

142 *Dolzer* 2010, para. 64.

143 Art. 1.5 TBT, Art. 1.4 SPS.

144 *Koebele* 2007, para. 9.

145 C.f., relating to the REACH registration procedure, *Tietje/Wolf* 2005, p. 10, *Quick* 2008, p. 135.

2.2.2.1.2 TBT Agreement

Annex 1 No. 1 TBT defines technical regulation as follows:

> "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

Building on this definition, the WTO Appellate Body differentiates three requirements which technical regulations have to meet:

> "First, the document must apply to an identifiable product or group of products. The identifiable product or group of products need not, however, be expressly identified in the document. Second, the document must lay down one or more characteristics of the product. These product characteristics may be intrinsic, or they may be related to the product. They may be prescribed or imposed in either a positive or a negative form. Third, compliance with the product characteristics must be mandatory."[146]

It is therefore necessary to assess whether the extended authorisation meets these requirements:

1. The regulation applies to an identifiable group of products, i.a. REACH articles including substances which are listed in Annex XIV REACH (at a specific fixed concentration).[147]
2. The regulation relates to the substances articles are composed of[148] and thus to the intrinsic characteristics of certain products.[149]
3. The regulation establishes a direct legal obligation as is emphasised by the specific language used ("A manufacturer, importer or downstream user shall not place [on the market]…").[150]

As a result, the extended authorisation requirement establishes a technical regulation in terms of Annex 1 No. 1 TBT.[151]

2.2.2.2 Priority between the TBT and the GATT Agreements

In principle, Member States have to apply cumulatively the WTO Agreements and simultaneously adhere to them.[152] TBT provides a differentiated regulatory scheme specifically directed at technical regulations, while the GATT, derived from the early days of the WTO era, focuses on the reduction of tariff barriers. The exact relation between TBT and GATT in the context of the examination of a certain regulation, however, is not yet fully understood; a specific ranking comparable to that between the TBT and SPS Agreements does not exist. Yet the 'general

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146 Appellate Body Report WT/DS231/AB/R v. 26.9.2002 (EC – Sardines), para. 176, Appellate Body, EC – Asbestos (fn. 139), para. 66-70.

147 C.f. Appellate Body, EC – Asbestos (fn. 139), para. 70.

148 The regulation complies with Art. 2.8 TBT as well, because, although it provides requirements on the quality of products, it makes no requirements as how to reach it, c.f. *Tamiotti* 2007, para. 53 et seq.

149 Appellate Body, EC – Asbestos (fn. 139), para. 67. A prohibition of asbestos fibers as such does not itself determine product characteristics, but rather does the prohibition of products containing asbestos, ibid. para. 171.

150 Appellate Body, EC – Asbestos (fn. 139), para. 68.

151 A corresponding interpretation is also established in view of the mechanism of the REACH registration, c.f. *Tietje/Wolf* 2005, p. 10, *Harrell* 2006, pp. 511 et seq., *Quick* 2008, p. 139, *Kogan* 2012, p. 5 et seq., 32 et seq., apparently relating to the overall regulatory system *European Commission* 2001. Different opinion: *Winter* 2005.

152 Appellate Body Report WT/DS98/AB/R of 14.12.1999 (Korea – Dairy), para. 74, c.f. *Graf Vitzthum* 2010, para. 154 et seq.

interpretative note to Annex 1A' provides hints as to the applicable law in situations where more than one Agreement applies:

"In the event of conflict between a provision of the [GATT] 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the World Trade Organization [...], the provision of the other agreement shall prevail to the extent of the conflict."[153]

This note hints at the *lex specialis* status of TBT in a situation of conflict with the GATT. Furthermore, according to Art. 2.5 TBT, whenever a technical regulation serves one of the legitimate objectives explicitly mentioned by TBT, "it shall be rebuttably presumed not to create an unnecessary obstacle to international trade." From this it can also be deduced that the TBT Agreement – as far as the assessment of technical regulations is concerned – establishes lex specialis in relation to GATT.[154] Since the sentencing of the WTO dispute settlement bodies postulates a lex specialis priority,[155] the legal assessment of the extended authorisation is also based on the requirements of the TBT Agreement.[156]

The question as to whether TBT or GATT is applicable in the current case, however, is more of a theoretical one since, as shown in the table below, both Agreements emanate from the principles of national treatment and most-favoured nation treatment[157] and thus seek, in terms of the origin of goods, a non-discriminatory international trading system. In addition, both Agreements also allow for certain exceptions from these rules in favour of public interests such as human health and environmental.[158]

153 See http://www.wto.org/english/docs_e/legal_e/05-anx1a_e.htm.

154 *Wolfrum* 2007, para. 27 et seq. In this direction c.f. *Koebele* 2007, para. 3-5.

155 Panel Report WT/DS231/R of 29.5.2001 (EC – Sardines), para. 7.15 et seq. referring to Appellate Body Report WT/DS27/R of 25.9.1997 (EC — Bananas III), para. 204, Panel Report WT/DS135/R and Add1 of 5.4.2001 (EC — Asbestos), para. 8.16.

156 Accordingly various authors examine the REACH registration primarily in the light of TBT, see *Tietje/Wolf* 2005, p. 10, *Kogan* 2012, c.f. *Voon/Mitchell/Gascoigne* 2012, p. 6.

157 Goods imported from third countries may not be treated less favourably than domestic like goods or like goods from other third countries, *Dolzer* 2010, para. 19 et seq.

158 C.f. *Carlone* 2014 who argues that the Appellate Body, in interpreting Art. 2.1 TBT, developed a test comparable with the Art. XX GATT so-called *Chapeau* test. This contributes to a further alignment of the agreements.

Table 1: Comparison of the TBT and GATT requirements

Requirements of the TBT Agreement	Requirements of the GATT Agreement
National Treatment + Most-Favoured-Nation Treatment of like products	
Art. 2.1. Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.	**Art. III.4 Sentence 1 (National Treatment)** The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. **Art. I.1 (Most-Favoured-Nation Treatment)** [...] With respect to all matters referred to in paragraphs 2 and 4 of Article III, any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.
Prohibition of unnecessary trade restrictions and justification(s)	
Art. 2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products **Preamble (Recital 6)** Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;	**Art. XI.1 (General Elimination of Quantitative Restrictions)** No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party **Art. XIII.1 (Non-discriminatory Administration of Quantitative Restrictions)** No prohibition or restriction shall be applied by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation of any product destined for the territory of any other contracting party, unless the importation of the like product of all third countries or the exportation of the like product to all third countries is similarly prohibited or restricted. **Art. XX** Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health; [...] (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;

2.2.2.3 Additional sources of law: sentencing of WTO dispute settlement bodies

WTO procedural law provides for a two-instance proceeding in a case of dispute between member states concerning trade-restrictive measures. First, a panel constituted for each individual case decides on the WTO compatibility of a measure. Both parties may then appeal these decisions to the ever-composed and "quasi-judicial"[159] Appellate Body.[160] According to the latter, in principle, decisions[161] and "[i]nterpretations developed by panels and the Appellate Body in the course of dispute settlement proceedings are binding only on the parties to a particular dispute."[162] However, usually the Appellate Body follows its own sentencing and also expects corresponding behaviour of the panels.[163] Furthermore, to interpret the provisions of a certain Agreement the dispute bodies may also use case law from other agreements. The relevance of this practice will be discussed in the interpretation of the TBT Agreement below.

2.2.3 Scope of the TBT assessment

According to the WTO dispute settlement practice and the literature on TBT, the central requirements of the Agreement result in particular from Art. 2.1 with respect to the national treatment and most-favoured nation treatment and from Art. 2.2 TBT concerning the prohibition of unnecessary trade restrictions. Other relevant provisions relate to the introduction and application of technical regulation and are therefore not assessable *ex ante*.[164] Accordingly, the legal examination of the extended authorisation requirement focuses mainly on the legal criteria set out in Art. 2.1 and 2.2 TBT.[165] These formulate independent requirements that must be examined independently. It follows that, as in the case of a violation of Art. 2.1, due to the discriminatory effect of a technical regulation, this can be justified in overall terms by virtue of Art. 2.2.[166]

3 National treatment and most-favoured nation treatment (Art. 2.1 TBT)

It is to be examined whether the technical regulation discriminates against imported products and therefore violates Art. 2.1 TBT:

> "Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country."

Art. 2.1 clarifies that in terms of technical regulations, the GATT principles of national treatment and most-favoured nation treatment[167] are to be taken into account.[168]

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159 *Haltern* 2014, § 33, para. 151 et seq., *Appell/Bell* 2009, p. 1.

160 Art. 6 et seq., 17 Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU).

161 These decisions can be described as recommendations rather than judgments because they have yet to be adopted by the Dispute Settlement Body, c.f. Art. 16(9), Art. 17(14) DSU.

162 Appellate Body Report WT/DS406/AB/R of 4.4.2012 (US – Clove Cigarettes), para. 258.

163 *Haltern* 2014, § 33, para. 141, *Voon* 2012. There are also counter-examples, c.f. Panel, EC – Biotech Products (fn. 113), para. 7.2968–7.2929.

164 C.f., e.g. Art. 3 TBT.

165 But occasionally other requirements such as those of Art. 2.4 and 2.8 TBT also have to be addressed.

166 If a measure violates Art. 2.1 its discriminatory effect, however, must be eliminated in any case, c.f. with evidence from TBT case law *Voon/Mitchell/Gascoigne* 2012, p. 5; c.f. Appellate Body, EC – Asbestos (fn. 139), para. 115. Conversely, a provision allowed by Art. 2.1 may violate Art. 2.2 because only (the case law to) Art. 2.2 requires a comprehensive alternative test.

167 C.f. section 2.2.2.2.

A measure violates Art. 2.1 TBT if

- it is a technical regulation (in this case confirmed, c.f. section 2.2.2.1), and
- the products imported from third countries are "like" domestic products or other products imported from other third countries (section 3.1), and
- the products imported from third countries enjoy less favourable treatment than "like" domestic products or other products imported from other third countries (section 3.2).[169]

In interpreting Art. 2.1 TBT, the Appellate Body uses the GATT case law.[170]

3.1 "Likeness" analysis

The importing state may treat unlike products in a dissimilar way. The extended authorisation requirement for imported articles can therefore violate the world trade non-discrimination rule only if the domestic articles and the foreign articles are like products.

3.1.1 Identification of products to be compared

The extended authorisation requirement would apply to all products containing SVHC in Annex XIV.[171] The "article" term covers most products which are used in private households (section 1.4). There are 31 SVHC listed in Annex XIV[172] with the number of substances continuing to increase. Depending on the substance, a variety of products may be covered: e.g. the plasticiser DEHP market share of global plasticizer consumption in 2010 was at almost 54%.[173] Overall, the technical regulation may affect a large number of products and product groups.[174]

The "nature and extent of a competitive relationship between and among products" is the main criteria to determine their likeness.[175] The competitive relationship thus also informs the identification of the pair of products to be compared. In the constellation at hand the following pairing is considered:

> Article A, produced in the EEA and not containing any SVHC,
> and article B, produced in a third country and containing one or more Annex XIV SVHC.[176]

Section 3.1.2 analyses the likeness of these two products. The relevance of other product pairs will be discussed, too.

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168 Appellate Body Report WT/DS384, 386/AB/R of 29.6.2012 (US – COOL), para. 267, Appellate Body, US – Clove Cigarettes (fn. 162), para. 87, c.f. *Voon* 2012.

169 Appellate Body Report WT/DS381/AB/R of 16.5.2012 (US – Tuna II), para. 229, Appellate Body, US – Clove Cigarettes (fn. 162), para. 87.

170 Appellate Body, US – Clove Cigarettes (fn. 162), para. 99 et seq.: "We consider that, in interpreting Article 2.1 of the TBT Agreement, a panel should focus on the text of Article 2.1, read in the context of the TBT Agreement, including its preamble, and also consider other contextual elements, such as Article III:4 of the GATT 1994", Appellate Body, US – Tuna II (fn. 169), para. 214, Appellate Body, US – COOL (fn. 168), para. 269.

171 Exemptions from the authorisation requirement for certain uses remain out of consideration.

172 As of November 2014.

173 C.f. http://www.ceresana.com/de/marktstudien/additive/weichmacher/.

174 The case studies at *Nordic Council of Ministers* 2010, pp. 35 et seq.

175 Appellate Body, US – Clove Cigarettes (fn. 162), para. 104 et seq., 111, 136.

176 This approach – related to GMO in food – can be seen at *Burchardi* 2007, p. 331.

3.1.2 Assessment of the likeness criteria

In *EC – Asbestos,* the Appellate Body differentiates four general criteria to be considered in the likeness analysis:

> "(i) the properties, nature and quality of the products;
> (ii) the end-uses of the products;
> (iii) consumers' tastes and habits – more comprehensively termed consumers' perceptions and behaviour – in respect of the products; […]
> (iv) the tariff classification of the products."[177]

Additionally, the Appellate Body comments on the importance of a product's health risks under the likeness analysis. In its 2012 *US - Clove Cigarettes* decision, the Appellate Body summarises this aspect as follows:

> "[T]he Appellate Body found that, in examining whether products are like, panels must evaluate all relevant evidence, including evidence relating to the health risks associated with a product, which was the underlying concern of the challenged measure in that dispute. The Appellate Body found that such evidence would not be examined as a separate criterion but, rather, under the traditional "likeness" criteria. In particular, the Appellate Body stated that a product's health risks are relevant to the determination of the competitive relationship between products, and addressed health risks as part of the products' physical characteristics and of the tastes and habits of consumers. In respect of physical characteristics, the Appellate Body considered that a panel should examine fully the physical properties of products, in particular, those physical properties that are likely to influence the competitive relationship between products in the marketplace. These include those physical properties that make a product toxic or otherwise dangerous to health. In respect of consumer tastes and habits, the Appellate Body found that the health risks associated with a product could influence the preference of consumers."[178]

This case law developed in the scope of GATT also explicitly applies with regard to the consideration of health risks in the likeness analysis under Art. 2.1 TBT.[179]

Considering the different emphasis of criteria (i) - (iv) the Appellate Body notes that in cases where products are found to be "physically quite different", "in order to overcome this indication […], a higher burden is placed on complaining Members to establish that […] all of the evidence, taken together, demonstrates that the products are "like" anyway.[180] Furthermore, these criteria only establish a framework for the analysis and do not establish a closed catalogue but may rather be expanded or reduced according to the needs of the case at hand.[181]

3.1.2.1 The properties, nature and quality of the products

The physical properties of products and particularly those aspects likely to influence the competitive relationship must be fully examined.[182] This includes properties that make the product toxic or otherwise harmful.[183] As regards the likeness of chrysotile asbestos fibres and PCG fibres (manufactured from other materials), the Appellate Body concludes that the

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177 Appellate Body, EC – Asbestos (fn. 139), para. 101.

178 Appellate Body, US – Clove Cigarettes (fn. 162), para. 118 citing Appellate Body, EC – Asbestos (fn. 139), c.f. *Schmidt/Kahl* 2003, para. 94.

179 Appellate Body, US – Clove Cigarettes (fn. 162), para. 119. C.f. *Tietje/Wolf* 2005, p. 14.

180 Appellate Body, EC – Asbestos (fn. 139), para. 118.

181 Appellate Body, EC – Asbestos (fn. 139), para. 102, Panel Report WT/DS400, 401/R of 25.11.2013 (EC – Seal Products), para. 7.136.

182 Appellate Body, EC – Asbestos (fn. 139), para. 114.

183 Appellate Body, US – Clove Cigarettes (fn. 162), para. 118.

carcinogenicity caused by the particular combination of chrysotile fibres' molecular structure, chemical composition, and fibrillation capacity, constitutes a "defining aspect of the physical properties" as opposed to PCG fibres.[184] For the same reason, the presence of chrysotile asbestos fibres in a cement-based product constitutes "one principal and significant difference" compared to chrysotile-free products.[185]

Furthermore, the Body distinguishes two types of exposure-related risk: first, there is an increased risk for builders or private consumers ("DIY enthusiasts") due to the use of cement. In addition, generally there is a lower exposure of the general public caused by intensive and long-term asbestos mining and processing. Due to undetectable effect thresholds of the substance this latter exposure still constitutes a relevant risk.[186]

According to these criteria a SVHC and a substance with comparable functions but without any properties of very high concern differ in their molecular structure and chemical composition in a "defining" way as well as only in the former case there is an inherent hazard potential. The presence or non-presence of SVHC in articles may therefore – irrespective of the actual SVHC category[187] – constitute a significant distinctive feature connected with the differing risk profiles of the articles.

Since the technical regulation does not address the fabrication of SVHC – as opposed to the constellation in *EC – Asbestos* – exposure during such processes is not relevant for the determination of likeness. Instead, however, only the risk caused by the actual application of SVHC in a specific article is significant, the extent of which is determined by reference to the specific circumstances of the individual case (section 1.3.3). Nevertheless, some general statements regarding these risks can be taken because REACH does not concern individual custom-made items, but rather bulk commodity that can lead to a ubiquitous exposure of the population and the environment by SVHC. Thus, exposure to the SVHC is possible not only because of releases intended by the article producer (e.g. fragrances), but also due to an improper use of the product, due to material defects or damage during the product's use phase or due to its (improper) disposal. In addition, exposure can be caused by a material-related gradual and unintended release during the use phase.

Annex XIV contains, for example, various phthalates that are classified toxic to reproduction. These are used among other things as a plasticiser for PVC, with a release of phthalates not intended, but ultimately "not to prevent".[188] Affected household products include "floor coverings, synthetic leather, wallpaper, shower curtains, baby products, children's toys, packaging, shoes and sports and leisure items" as well as sheathing of cables and wires; for the outside there are additional applications.[189] Combined with the uptake of phthalates via contaminated food, these articles contribute to the ubiquitous exposure of the population, e.g.

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184 Appellate Body, EC – Asbestos (fn. 139), para. 114, 135.

185 Appellate Body, EC – Asbestos (fn. 139), para. 142, 128.

186 Panel, EC – Asbestos (fn. 155), para. 8.201 et seq., Appellate Body, EC – Asbestos (fn. 139), para. 128. This ubiquitous exposure of the population has also been recognized by Panel Report WT/DS332/R (Brazil – Retreaded Tyres) of 17.6.2007, para. 7.53 ff, 7.77, 7.82 et seq.

187 All categories referred to in Art. 57 REACH exhibit a certain hazard potential, c.f. section 1.3.1 et seq.

188 *Umweltbundesamt* 2007, p. 2.

189 *Umweltbundesamt* 2007, p. 3. At least in 2008, tested rubber boots for children contained phthalates in some alarming concentrations, c.f. *Öko-Test* 2008, pp. 176 et seq.

in Germany, but also in other industrial countries.[190] As a result "some of the children are charged so high with phthalates that potential health risks cannot be excluded."[191]

Furthermore, it can be assumed that a relevant proportion of SVHC which are used in plastics[192] may "slip" into the environment after the use phase, even if specific recycling systems exist. At least for some European countries it is assumed that, depending on article and system, a more than insignificant slip occurs, increasing the ubiquitous exposure of the population.[193]

In addition, with regard to many SVHC effect thresholds cannot be derived,[194] which was seen as an indication of a relevant risk in *EC – Asbestos*, while the absence of effect thresholds is not a prerequisite for assuming a ubiquitous risk.[195]

All these aspects suggest that at least in terms of a significant number of articles affected by the technical regulation the respective properties generally – i.e. irrespective of the actual case by case assessment – pose a risk which similar articles not containing any SVHC do not pose. In the light of the WTO dispute settlement practice, these risks are relevant for the determination of the products' likeness, because differences in this respect can significantly affect the competitive situation.

However, there are also SVHC articles conceivable that can be assumed to cause such a low risk that the latter would not suffice as a distinguishing feature compared to a similar article without SVHC. This could, for example, be the case in situations in which only a very low exposure that lies below the (known) effect thresholds seems possible.

3.1.2.2 The end-uses of the products

The second criterion focuses on whether the compared articles are capable of performing the same end-uses.[196] This determination is based on a general overview of all possible end-uses.[197]

Based on the assumption that the SVHC and non-SVHC in articles differ only in terms of their hazard potential, but otherwise achieve the same intended effect, no difference is expected concerning the end-uses.

However, according to the Appellate Body divergent properties can beget and limit the uses of products.[198] So, among the articles within the scope of REACH, product groups are conceivable which, depending on their chemical functionalisation, are not suitable for children or pregnant women; at the same time, there are no such restrictions for a comparable product without this functionalisation. In these cases, the compared articles would at least *also* have different end-uses, which in the light of the specific competitive situation would argue against likeness as discussed with regard to the meaning of Art. 2.1 TBT.

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190 Regarding phthalates in human biomonitoring c.f. http://www.umweltprobenbank.de/de/documents/selected_results/16425 (14.6.2014).

191 *Kolossa-Gehring* 2012 (*authors' translation*).

192 This applies for at least eight SVHC in Annex XIV.

193 *Mehlhart* 2014.

194 *Rehbinder* 2012, chapter 11, para. 103, *Hermann/Ingerowski* 2011, para. 46.

195 Panel, Brazil – Retreaded Tyres (fn. 186), para. 7.53 ff, 7.77, 7.82 et seq.

196 Appellate Body, US – Clove Cigarettes (fn. 162), para. 131.

197 Appellate Body, US – Clove Cigarettes (fn. 162), para. 128, Appellate Body, EC – Asbestos (fn. 139), para. 119. For the scope of the assessment see l.c. para. 137 et seq.

198 Appellate Body, EC – Asbestos (fn. 139), para. 102.

3.1.2.3 Consumer tastes and habits

The assessment of consumer's tastes and habits indicates the extent to which private and professional consumers are willing to substitute article A by article B in respect of the identified end-uses.[199] The examination includes the preferences of all relevant consumers who are to be defined via the market for the products at issue.[200] Likeness under this criterion does not mean that the products are substitutable for all consumers, rather it may suffice when the products are "highly substitutable for some consumers".[201] Moreover, products do not have to actually compete in the entire market or in a market segment that is most representative.[202]

The geographic scope of REACH defines the EEA as the potential market for the articles considered here. Regarding the socio-cultural 'imprint' of European consumers it is important that they are relatively – compared to consumers in the United States, for example – highly risk averse with respect to certain product types.[203] At the same time, however, even within the EEA there are consumers – for example residents of different Member States – who have different perceptions of risk.[204]

In terms of product properties the compared articles exhibit one significant difference, since only in one case is a function obtained by using one or more SVHC. The question therefore is to what extent this characteristic affects the preferences and habits of the relevant consumers.

In general, the demand for products that contain "problematic" chemicals is turning towards inherently safer substances in the medium to the longer term. Therefore, article producers develop a stronger preference only to process such safer substances whenever possible, and to communicate the increased safety as a special product quality to commercial, industrial and private customers. This development is not even limited to the EEA, but rather takes place in a global context. The Greenpeace "Detox" initiative, launched in July 2011, could be an example of such a development: in response to a study showing that Chinese suppliers of Western textile companies cause harmful concentrations of particular eco-toxic substances in the environment, Greenpeace called on the Western importers to stop incorporating PBTs, vPvBs, CMRs, endocrine disruptors and substances of equivalent concern – these are also the SVHC categories of Art. 57 REACH[205] – in their products. In November 2011, Adidas, C&A, H&M, NIKE and PUMA among others committed to banning these substances from their supply chains by 2020.[206] Walmart launched a similar program in 2014.[207] If multinational corporations for consumer products henceforth avoid the use of SVHC, this increases the pressure on competitors to adapt their behaviour accordingly. This development has to be attributed to some extent to the preferences of private consumers as ultimately NGOs such as Greenpeace pick up and combine the sometimes diffuse particular interests of consumers and articulate these towards players such as industry and politics.[208]

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199 Appellate Body, US – Clove Cigarettes (fn. 162), para. 127.

200 Appellate Body, US – Clove Cigarettes (fn. 162), para. 137.

201 Appellate Body, US – Clove Cigarettes (fn. 162), para. 142 referring to Appellate Body Report WT/DS396, DS403/AB/R of 21.12.2011 (Philippines – Distilled Spirits).

202 Appellate Body, US – Clove Cigarettes (fn. 162), para. 142 et seq. referring to Appellate Body Report WT/DS396, DS403/AB/R of 21.12.2011 (Philippines – Distilled Spirits).

203 C.f. *Scherzberg* 2005, pp. 4 et seq.

204 C.f. the sometimes serious differences as to which ingredients of products EU citizens check before purchase, *TNS Political & Social 2013*, p. 31; see also *Lofstedt* 2011 p. 164.

205 For EDC this applies as far as the substances can be deemed to be of "equivalent concern" according to 57(f).

206 C.f. http://www.roadmaptozero.com/(31.10.2014).

207 *Walmart* 2014.

208 *Ingerowski/Kölsch/Tschochohei* 2008, p. 22.

The assessment of product likeness as regards consumers' tastes and habits has to consider these particular risks as well.[209] First of all, it is to be determined in how far this aspect affects private consumers.

In *EC – Asbestos* the Appellate Body considers it likely that the presence of a known carcinogen in one of the products would have an influence on consumer tastes and habits regarding that product.[210] With respect to the products considered here, this conclusion would be true for articles containing SVHC classified carcinogenic according to Art. 57(a) REACH. However, nothing else should apply with respect to the other criteria of Art. 57, which (as the "Detox" example shows) not only European consumers reject. The human toxicity of asbestos relevant in *EC – Asbestos* is thus not the point. Instead all SVHC categories have a specific hazard potential not accepted by consumers who commonly do not differentiate substances according to whether, in the case of their release, they establish a situation of danger prevention or precaution. Consequently, it can be assumed that two articles, one of which contains SVHC, are not considered by the consumer as substitutable, and are therefore lacking a competitive relationship. This finding is likely to apply even regardless of the actual product risks since consumers often disapprove the mere presence of SVHC in articles.[211]

In the assessment of consumer tastes and habits all relevant consumer groups need to be considered. This raises the question of whether the above conclusion about the lack of a competitive relationship is applicable to all consumer segments. First of all, there will always be groups among consumers of the same socio-cultural background who are more and less risk averse or environmentally conscious, whether as a result of a conscious decision about choosing the cheapest product and thereby tacitly accepting the affiliated risk, or be it due to a simple lack of interest as regards potentially adverse effects of the consumed products.[212] Although it would be possible to determine more specific classes within consumer groups in the manner described, the Appellate Body does not require such a differentiation when it postulates the consideration of all relevant consumer groups. Rather, for example, in a case where a product is primarily directed at younger buyers one should also consider potential older buyers.[213] The fact that there are individual consumers who are not or less interested in product quality and safety, is therefore not the point.

Differentiations with respect to risk perception and environmental awareness can, however, be relevant in relation to the inhabitants of entire states of the EEA when compared with other EEA States.[214] Amongst the EU countries quite different environmental standards prevail, even if the objective of a high level of protection stipulated by the TFEU is binding for all Member States. As a result, a garment with vPvB, for example, might be considered substitutable compared with a vPvB-free garment in a Member State without high environmental standards, but in a Member State with rather high environmental standards this would not be the case. Products can be like if they are "highly substitutable for some consumers", while this finding does not have to refer to the overall market.[215] For this reason, numerous scenarios are possible in which the products of the examined pair - notwithstanding the stated development of global demand behavior

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209 Appellate Body, US – Clove Cigarettes (fn. 162), para. 120.

210 Appellate Body, EC – Asbestos (fn. 139), para. 130.

211 Provided that the consumers are aware of the substance's presence which in turn requires that the relevant information is accessible in a user-friendly manner (c.f. chapter 6).

212 Appellate Body, EC – Asbestos (fn. 139), para. 130 ("This influence may well vary").

213 Appellate Body, US – Clove Cigarettes (fn. 162), para. 136 et seq., c.f. *Singh* 2012, pp. 7 et seq.

214 C.f. fn. 204.

215 Appellate Body, US – Clove Cigarettes (fn. 162), para. 142 et seq. referring to Appellate Body Report WT/DS396, DS403/AB/R of 21.12.2011 (Philippines – Distilled Spirits).

(Detox) - are regarded as substitutable in terms of consumer preferences and habits, pointing at the products' likeness.

Furthermore, the preferences and habits of professional consumers need to be assessed. The compared articles are often processed by industrial users into other articles. In this situation, the producer prefers the product without SVHC because then it can more likely avoid certain risk management obligations stipulated by work protection law. Moreover, if the product is intended for sale to private customers, the SVHC-free product reduces the risk of civil liability claims.[216] These are substantial arguments that in the industrial consumer's view the products in the comparison pair are not substitutable. Moreover, industrial users, in general,need to consider the end users' preferences for security and quality,[217] while again the potentially differing situations in the EEA States need to be considered.[218]

3.1.2.4 Tariff classification of the products

Finally the Harmonized Commodity Description and Coding System (HS)[219] is tested in order to examine product likeness.[220] However, subject to an analysis of concrete product examples it appears highly unlikely that two articles receive separate HS entries depending on the whether SVHC are used or not.[221]

3.1.2.5 Alternative pair of products to be compared

In literature there are other approaches to identifying a relevant pair of products to analyse their likeness. As suggested by the relevant literature a comparison could be made of the following pair of products:

> Article A, manufactured in the EEA, including one or more SVHC listed in Annex XIV and whose use has been authorised and article B, manufactured outside the EEA, including the same SVHC without having an authorisation.[222]

In this case, as concerns the physical properties (dimensions, chemical composition etc.) the domestic and imported articles are like products that pose the same risk. Under this condition, however, the foreign manufacturer[223] would also receive authorisation without problems.

Meanwhile, the mere choice of the product pair seems improper. Instead, one has to agree with *Winter* who states that "the entire trade law control system would collapse if the trade restriction that is to be controlled could qualify a product as being not like".[224] Accordingly, a WTO Panel recently determined in the TBT context that seals, which have been caught as

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216 Appellate Body, EC – Asbestos (fn. 139), para. 122.

217 Appellate Body, EC – Asbestos (fn. 139), para. 122, Appellate Body, US – Clove Cigarettes (fn. 162), para. 120.

218 This result also applies to those consumers who use the products as part of their commercial business since they are in immediate contact with the product and committed to their private end-users as well.

219 http://unstats.un.org/unsd/tradekb/Knowledgebase/Harmonized-Commodity-Description-and-Coding-Systems-HS. The database with the existing product classifications can be found at http://www.foreign-trade.com/reference/hscode.htm.

220 Appellate Body, US – Clove Cigarettes (fn. 162), para. 159.

221 For instance, clove cigarettes and menthol cigarettes are listed under the same subheading 2402.20 which simply refers to "Cigarettes (Containing Tobacco)", c.f. http://www.foreign-trade.com/reference/hscode.cfm?code=2402, Appellate Body, US – Clove Cigarettes (fn. 162), para. 159.

222 C.f. this approach at *Tietje/Wolf* 2005, p. 13, *Kogan* 2012, pp. 34, 36.

223 In the event that the manufacturer is not established in the EEA, it needs to contract an only representative, c.f. section 3.2.3.2.

224 *Winter* 2005 *(authors' translation).*

required by a technical regulation and other seals, where this was not the case, are like products.[225]

Therefore, since no other relevant comparison pair is conceivable, the analysis in section 3.1.1 is presumed to allow for a final conclusion regarding the question of likeness.

3.1.3 Conclusion of the "likeness" analysis

The criteria (i) - (iv) are used to collect and classify relevant aspects in order to assess the likeness of two products in terms of Art. 2.1 TBT.[226] The likeness-analysis in this legal opinion, when applying the assessment criteria, needs to consider the substance-related risks.

With respect to their physical properties (i), articles with SVHC and articles without SVHC are regularly not like products. This is because products with SVHC, regardless of the actual risk in individual cases, often pose a certain "general risk" to humans or the environment due to the exposure in the product life cycle that is hardly avoidable in practice. At the same time, similar products without SVHC do not pose corresponding risks.[227]

On the other hand, evidence with respect to the other comparison criteria (ii) – (iv) might also indicate product likeness. Potential end-uses (ii) will except in special cases, be identical for both products in principle. Also it can be assumed that from the HS (iv) results no evidence of dislikeness as regards product categories. In terms of consumer preferences (iii) it is to check whether consumers in the EEA prefer products without SVHC. To this end it is possible that in particular cases there are relevant market segments in which the consumers perceive the compared products as substitutable.

However, whether products with and without SVHC are similar in terms of Art. 2.1 TBT can ultimately only be determined for concrete examples based on the specific circumstances of each case. For instance, certain garments for children with high proportions of CMR substances are likely to be considered non-substitutable with CMR-free garments across all EEA countries. In connection with the differing properties (risk profile), these products can thus be expected to be not like.Depending on the type and function of an article, the specific characteristics of the SVHC used and their integration in the article there are also product pairs conceivable that are "like" according to Art. 2.1 TBT. For this reason, the following section will examine whether the extended authorisation requirement treats imported products less favourably than domestic like products and like products from other third countries.

If the products are not like, the technical regulation may not violate Art. 2.1 TBT and the Art. 2.1 test would thus be completed.[228]

3.2 "Treatment no less favourable" test

To this end, the Art. III:4 GATT case law regarding less favourable treatment is also "instructive" within the scope of the TBT Agreement while the specific context of TBT needs to be

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225 Panel, EC – Seal Products (fn. 181), para. 7.137 et seq.

226 Appellate Body, EC – Asbestos (fn. 139), para. 102.

227 Consequently, there is a higher burden to show that products are still like in the overall view of all comparison criteria, Appellate Body, EC – Asbestos (fn. 139), para. 118.

228 Appellate Body, EC – Asbestos (fn. 139), para. 148. C.f. for the relation between Art. III:4 GATT and Art. 2.1 TBT section 3.2.

considered.[229] Hence from the "treatment no less favourable" obligation follows a prohibition of de jure as well as de facto discrimination based on the origin of a product.[230]

The wording of the extended authorisation treats articles originating from the EEA or from outside the EEA alike; there is therefore no de jure discrimination.[231] However, the regulation might still constitute a de facto discrimination against foreign products. It is thus to be examined whether the extended authorisation "modifies the conditions of competition in the market of the regulating Member to the detriment of the group of imported products vis-à-vis the group of like domestic products" or products imported from other third countries.[232]

3.2.1 Relevant products and groups of products

Art. 2.1 TBT refers to two discriminatory cases: less favourable treatment of an imported product vis-à-vis a like domestic product and less favourable treatment of an imported product vis-à-vis a like product imported from another third country.[233] The Appellate Body comments on the subject matter of assessment:

> "Article 2.1 requires panels to assess objectively, on the basis of the nature and extent of the competitive relationship between the products in the market of the regulating Member, the universe of domestic products that are like the products imported from the complaining Member."[234]

However, Art. 2.1 does not intend to test equal treatment of each individual domestic product with every single imported product; rather, groups of competing products are to be formed and the task is then to assess whether these groups of imported products are treated less favourably than the domestic products.[235]

3.2.2 Scope and benchmark for the assessment

The limits of de facto discrimination[236] have to be determined and it needs to be established whether any measure capable of causing directly or indirectly, actually or potentially negative effects on the competitive situation of foreign products falls under the non-discrimination rule.[237] Indeed, all detrimental impacts on the competitive opportunities of imported products, caused by the technical regulation, "may potentially be relevant" for the examination.[238] However, based on the definition of technical regulation in Annex 1 No. 1 TBT, the precise purpose of which is to distinguish products due to specific properties or production methods from other products, the Appellate Body also notes

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229 Appellate Body, US – Clove Cigarettes (fn. 162), para. 180. Conversely, the discrimination test developed in the Art. 2.1 TBT context does not fully apply to the analysis in the GATT context, c.f. Appellate Body Report WT/DS400-1/AB/R of 22.5.2014 (EC – Seal Products), para. 5.310 et seq. (c.f. fn. 241).

230 Appellate, US – Clove Cigarettes (fn. 162), para. 175, Appellate Body, US – COOL (fn. 168), para. 269, *Tamiotti* 2007, para. 13.

231 *SRU* 2004, para. 1040.

232 Appellate Body, US – Clove Cigarettes (fn. 162), para. 180, *Tamiotti* 2007, para. 12.

233 Appellate Body, US – COOL (fn. 168), para. 267, Appellate Body, US – Clove Cigarettes (fn. 162), para. 190.

234 Appellate Body, US – Clove Cigarettes (fn. 162), para. 192. C.f. Panel, EC – Seal Products (fn. 181), para. 7.150.

235 Appellate Body, US – Clove Cigarettes (fn. 162), para. 193 citing Appellate Body, EC – Asbestos (fn. 139), para. 100, c.f. *Voon/Mitchell/Gascoigne* 2012, p. 7.

236 C.f. Appellate Body, US – Tuna II (fn. 169), para. 225.

237 Formulation based on ECJ judgment of 11.7.1974, case 8/74, ECR 837, para. 5 – Dassonville.

238 Appellate Body, US – Tuna II (fn. 169), para. 225.

> "that Article 2.1 should not be read to mean that *any* distinction, in particular those that are based *exclusively* on particular product characteristics or their related processes and production methods, would *per se* accord less favourable treatment within the meaning of Article 2.1."[239]

The Body reaches the same conclusion by way of a systematic interpretation of Art. 2.1 and 2.2 TBT, taking into account the Agreement's preamble; because a ban on all trade obstacles on the grounds of Art. 2.1 would deprive Member States of their basic regulatory autonomy in terms of environmental and health protection and would also make Art. 2.2 obsolete.[240] Thus, even if the conditions of competition for the products of a foreign actor should be detrimentally affected compared with similar products of domestic actors, this impairment could be due to a legitimate regulatory distinction and altogether justified.[241]

The "treatment no less favourable" test in respect of possible de facto discriminations must be based on "the totality of facts and circumstances",[242] including "the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed."[243] All consequential impacts on the competition have to be examined, taking into account all relevant characteristics of the markets, including the actors operating there, their relative market shares, the preferences of consumers and the historical trade patterns.[244] If a provision does not (de jure) require a particular behaviour by operators in third countries, but in fact, by establishing certain conditions (e.g. compliance costs), provides incentives for these actors to behave in a disadvantageous manner (causing, for example, opportunity costs[245]), the rule may have the "practical effect" that imports are treated less favourably.[246] Indeed, even effects of the regulatory debate preceding the adoption of a technical regulation may be relevant for the examination.[247]

It has to be determined whether the extended authorisation requirement modifies the conditions of competition to the detriment of imported products vis-à-vis like domestic products or products imported from other third countries. If this is the case, the next question is whether any detrimental impact reflects discrimination in terms of Art. 2.1 TBT.[248]

3.2.3 Detrimental impacts on the conditions of competition

To evaluate whether the practical application of the technical regulation de facto causes detrimental impacts on the conditions of competition of imported products, all mechanisms of the regulation must be examined and various scenarios must also be taken into consideration. Two possible problem areas appear particularly relevant.

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239 Appellate Body, US – Clove Cigarettes (fn. 162), para. 169 (original emphasis), Appellate Body, US – Tuna II (fn. 169), para. 226, Appellate Body, US – COOL (fn. 168), para. 268.

240 Appellate Body, US – Clove Cigarettes (fn. 162), para. 171-174, 181, Appellate Body, US – COOL (fn. 168), para. 268, c.f. *Tietje/Wolf* 2005, pp. 18 et seq.

241 Appellate Body, US – Clove Cigarettes (fn. 162), para. 174 et seq., 181, Appellate Body, US – COOL (fn. 168), para. 340; this practice is a speciality in the TBT context which is not applied in the GATT context, Appellate Body, EC – Seal Products (fn. 229), para. 5.310 et seq.

242 Appellate Body, US – Clove Cigarettes (fn. 162), para. 206.

243 Appellate Body, US – Clove Cigarettes (fn. 162), para. 182, Appellate Body, US – Tuna II (fn. 169), para. 225.

244 Appellate Body, US – COOL (fn. 168), para. 269.

245 Appellate Body, US – COOL (fn. 168), para. 288.

246 Appellate Body, US – COOL (fn. 168), para. 288.

247 Appellate Body, US – Clove Cigarettes (fn. 162), para. 201, 206, *Kogan* 2012, p. 39 et seq.

248 Appellate Body, US – Tuna II (fn. 169), para. 231, Appellate Body, US – Clove Cigarettes (fn. 162), para. 215.

3.2.3.1 Problem area 1: origin of the SVHC concerned

The compatibility with Art. 2.1 TBT could be disputed if the authorisation requirements in practice only or predominantly affect article producers from third countries.[249] Such a situation could exist in cases in which a SVHC is included in Annex XIV, which has (as a product component) virtually no importance for suppliers on the intra-EEA market, but actors in third countries make up relevant marketing quantities. Other possible scenarios: an authorisation requirement applies only to specific uses, which are also relevant mainly for suppliers from third countries; and, substance X, predominantly used by foreign suppliers, is included in Annex XIV, while this is not the case with substance Y, which is of comparable concern and mainly used by companies operating within the EEA. In all these scenarios, one might assume that the competitive conditions for article producers from third countries are detrimentally modified.[250] Furthermore, the same scenarios could be applied to situations with an impairment of competitive opportunities between importers from various third countries.

While it is possible that such scenarios could selectively apply to individual SVHC in Annex XIV,[251] this would, however, not cast doubt on the Art. 2.1 compatibility of the technical regulation in itself; rather, only the individual case would be put to the test.[252] Also, it is not expected that the substances on Annex XIV are mainly substances which are exclusively or primarily used by product producers in third countries and thus putting a disproportionate burden on this actors. As a result, in as much as the "origin of SVHC" are concerned, the technical regulation does not modify the conditions of competition to the detriment of imported products.

3.2.3.2 Problem area 2: necessity of establishment in the Community

A company needs to be established within the community to place substances, mixtures or articles on the market. The same requirement would apply to obtaining the authorisation of the use of certain SVHC in an imported article. Companies without establishment in the Community would thus need an importer (Art. 3 No. 4 and 11 REACH) or an only representative ("OR", Art. 8) with establishment in the community to apply for authorisation. However, companies are not forced to contract one of the mentioned actors, unless they refuse establishment of an office in the community. It is a rule that applies to the entire REACH system – regardless of the technical regulation – and has been practiced since the regulation entered into force.

It could be argued that the competitive opportunities of foreign companies without establishment in the community are detrimentally impacted. The obligation to appoint an OR could increase the compliance costs of the foreign article producer and would thus have a negative impact on the cost structure of its products. In addition, there are no controlled standards regarding the requirements which an OR has to meet.[253]

At the same time, not in every case would it be preferable for article producers from third countries to act as REACH actors themselves, as the autonomous execution of the regulation's requirements can sometimes be more costly than appointing an OR for this purpose.[254] Because,

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249 A similar constellation can be found at Appellate Body, US – Clove Cigarettes (fn. 162), para. 213 et seq.

250 C.f. Appellate Body, US – Clove Cigarettes (fn. 162), para. 213 et seq.

251 According to *Postle/Holmes/Camboni* et al. 2012, p. 121 only little use within the EU is made with the respect to the Annex XIV-SVHC TCEP, diarsenic pentaoxide, lead chromate.

252 With a similar conclusion *SRU* 2004, para. 1048.

253 C.f.– from the perspective of the REACH registration procedure – *Kogan* 2012, pp. 45 et seq.; c.f. *Merenyi/von Bismarck* 2008, pp. 3 et seq.

254 With this being true especially in cases where article producers from third countries have only a small volume of trade in the EU.

according to information from market participants, OR offer their services at a low four-figure euro range. The additional costs would thus still be below the expenses arising in the event of a legal dispute from an obligation to engage a lawyer licensed in the country respective country.

Thus, there might again be individual cases in which the real cost burden resulting from the imposition of an establishment in the community and the relating available options (importer, OR) modify the conditions of competition to the detriment of imported products in terms of Art. 2.1 TBT. However, again, this would not compromise the Art. 2.1 compatibility of the technical regulation in itself.

3.2.3.3 Examination of a Discrimination according to Art. 2.1 TBT

With respect to both alleged 'problem areas' the examination shows that the extended authorisation requirement in itself does not modify the conditions of competition to the detriment of imported products. The technical regulation does not, therefore, violate Art. 2.1 TBT. However, starting from the opposite assumption, i.e. that the technical regulation detrimentally impacts the conditions of competition, this section – in the sense of a supplementary opinion – assesses whether this impact stems exclusively from legitimate regulatory distinctions or whether this impact "would constitute a means of arbitrary or unjustifiable discrimination" in terms of Art. 2.1 TBT.[255]

If there were a disproportionate listing of SVHC in Annex XIV, predominantly affecting the competitive conditions of suppliers from third countries, the temporary overloading could still be based on legitimate regulatory distinction criteria. First of all, the selection of SVHC for Annex XIV is based on considerations that are transparent for all stakeholders and according to which the origins of a substance – apart from the question of exposure – have no meaning (section 4.4.1.1.1). At the same time, the ECJ notes with respect to the field of environmental law that the legislator cannot solve all existing challenges for environment and health – e. g. the ubiquitous risks arising from certain hazardous substances – at once.[256] Similarly, the EGC reasoned as regards the identification of SVHC.[257] Furthermore, the delayed inclusion of SVHC in Annex XIV not least supports the workability and practicality as regards natural or legal persons, who have to prepare application files and take appropriate risk management measures.[258]

Thus, even if the technical regulation temporarily affected a disproportionate share of SVHC especially relevant for foreign articles, this would be justified by legitimate regulatory distinctions, provided there is no further evidence that the legislator deliberately chooses substances for inclusion in Annex XIV that are not used in domestic articles.

As regards the second alleged 'problem area' the legislator's intention to require establishment in the community needs to be appreciated. Generally, legal acts may not be served to actors from outside EU; the same applies for favourable legal acts. Moreover, the objectives of REACH and of the technical regulation can only be achieved if the provisions are linked with appropriate and effective enforcement mechanisms. The fact that article producers from third countries need a representative established in the community is necessary to ensure transparent structures in the case of violation of rules: the European intermediary is a prerequisite that the

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255 Appellate Body, US – Clove Cigarettes (fn. 162), para. 174 et seq., 181, Appellate Body, US – COOL (fn. 168), para. 340.

256 ECJ, judgment of 14.7.1998, case C-284/95, ECR I-4301 – Safety High Tech, c.f. *Winter* 2003, pp. 138 et seq.

257 EGC, judgment of 7.3.2013 (not yet published) - Rütgers Germany et al. / ECHA, para. 138, c.f. *Scheidmann* 2013, pp. 123 et seq.

258 Recital 77 REACH.

REACH requirements can be fully applied or, where appropriate, enforcing measures (e. g. criminal sanctions) can be taken.

Some argue that the Appellate Body in *US – COOL* and in *US – TUNA II* expands the Art. 2.1 TBT test by adding a kind of necessity test in terms of Art. XX GATT in order to determine whether any identified unequal treatment is based on legitimate distinction criteria.[259] To this end, the detrimental impacts would need to be assessed in the light of the normative purposes of the technical regulation and its degree of fulfillment of these purposes.[260] However, since the extended authorisation requirement aims at legitimate objectives in terms of the TBT Agreement and is moreover appropriate and necessary – all of which will be assessed in section 4.2 et seq. – the same conclusion can be drawn that the technical regulation does not constitute a means of arbitrary or unjustifiable discrimination in terms of Art. 2.1 TBT.

3.3 Conclusion regarding national treatment and most-favoured nation treatment

The assessment of Art. 2.1 TBT shows that in certain cases domestic SVHC-free articles and imported articles containing SVHC can be assumed like products.

However, the extended authorisation requirement would not de jure discriminate imported SVHC-articles vis-à-vis like domestic SVHC-free articles or articles imported from other third countries (principles of national treatment and most-favoured nation treatment). Moreover, the extended authorisation requirement would not cause a de facto discrimination. Even if one assumes for individual cases that the specific composition of the substances on Annex XIV or the necessity of an establishment in the community may detrimentally impact the competitive opportunities of imported products, this effect would be due to legitimate regulatory distinctions. So as a result the extended authorisation requirement is compatible with Article 2.1 TBT.[261]

4 Unnecessary obstacles to international trade (Art. 2.2 TBT)

Regardless of the test according to Art. 2.1 TBT, it is also necessary to consider whether the technical regulation constitutes an unnecessary obstacle to international trade under Art. 2.2 TBT.[262] Art. 2.2 TBT contains the following wording:

> "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products."

259 *Carlone* 2014, pp. 118 et seq., 127 et seq.

260 *Carlone* 2014, 127 et seq., 133 et seq.

261 With the same conclusion *SRU* 2004, para. 1043.

262 Thus, a technical regulation may violate Art. 2.1 and still be compliant with Art. 2.2 TBT. Section 2.2.3 already outlines the relation of the two provisions.

Recital 6 of the TBT Agreement's preamble contains additional specifications relevant for the interpretation of Art. 2.2 TBT:[263]

> "[N]o country should be prevented from taking measures necessary […] subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement[.]"

Art. 2.2 TBT bars unnecessary trade restrictions i.e. technical regulations that are more trade-restrictive than necessary to fulfil a legitimate objective. First of all, it has to be assessed whether the extended authorisation requirement is trade-restrictive (section 4.1). If this is the case, the next question will be whether the regulation is more trade-restrictive than necessary.[264] This includes a threefold examination of whether the regulation pursues a legitimate objective (section 4.2); whether it is appropriate to fulfil such objective (section 4.3); and whether it is more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create (section 4.4).

4.1 Trade restrictions caused by the technical regulation

In terms of Art. 2.2 TBT, restriction refers to something that has a limiting effect on trade.[265] The extended authorisation requirement bans the sale within the EEA of articles that contain SVHC listed in Annex XIV REACH, unless a use-specific authorisation was granted. The technical regulation thus provides for a standard, the non-compliance with which causes a barrier to market access. This constitutes a (non-tariff) barrier or obstacle to trade in terms of Art. 2.2 TBT;[266] while the extent to which the regulation is trade-restrictive and its actual effects on trade remain to be seen.[267]

When companies apply for authorisation they have to pay fees that differ according to company size. When a large enterprise[268] is the applicant and many uses are intended, incurring costs can easily reach approx. € 100,000 while micro enterprises sometimes pay only a tenth of this amount.[269] In addition, every application includes a chemical safety assessment for each intended use as well as an analysis of the available alternatives.[270] The total costs of the first successful application for authorisation of the phthalate DEHP[271] apparently have amounted to € 250,000 with a processing period of 15 months.[272] However, commentators regard this

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263 Appellate Body, US – Tuna II (fn. 169), para. 313, 316.

264 Panel Report WT/DS406/R of 2.9.2011 (US – Clove Cigarettes), para. 7.332.

265 Appellate Body, US – Tuna II (fn. 169), para. 319.

266 At the same time it is a "measure having equivalent effect" in relation to quantitative restrictions, c.f. *Haltern* 2014, § 33, para. 24 et seq.

267 Panel, EC – Seal Products (fn. 181), para. 7.426 et seq., *Kogan* 2012, p. 48.

268 This refers to companies whose figures lay above the figures specified for SME in Commission Recommendation 2003/361/EC.

269 Annex VI Commission implementing regulation (EU) No 254/2013.

270 C.f. the requirements in the application procedure section 4.4.1.1.1.

271 Summary of Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV, OJ. C 260, 9.8.2014, p. 10.

272 *Bulleid* 2014.

application process as rather "simple"; [273] estimates for more complicated situations are based on a total cost per application of € 500,000 to € 1 million.[274]

It is, however, the responsibility of manufacturers, downstream users and suppliers of a substance or article to ensure adequate control of substance-related risks (Art. 1(3) REACH). This needs to be documented in the registration dossier. The more risk-appropriate the actors have proceeded in the registration, the lower is, on the one hand, the probability that this particular use of a substance will be subjected to the authorisation regime. On the other hand, in the registration casethere is already a high-quality chemical safety assessment that supports the application (Art. 62(4)(d) REACH). Moreover, no distributor is obliged to apply for authorisation.

4.2 Legitimate objective

The regulatory purpose of the extended authorisation requirement has to be assessed and whether it is a legitimate objective in terms of Art. 2.2 TBT.[275] It can be determined by recourse to the text of the technical regulation, its "legislative history, and other evidence regarding the structure and operation of the measure."[276]

According to Art. 55 REACH, the specific purpose of the authorisation scheme is

> "to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. […]"

The provisions are thus supportive of the main objective of REACH, namely to "ensure a high level of protection of human health and the environment" (Art. 1(1) REACH) as well as to contribute to the overriding goal of a sustainable development which is agreed at UN level.[277] Even before the adoption of REACH, the European Commission noted in several notifications to the WTO (Art. 2.9.2 TBT) the main purpose of the Regulation is to ensure a high level of protection.[278] To fulfil this, the REACH provisions are based on the precautionary principle (Art. 1(3) Sentence 2 REACH), which is also reflected in the substitution target regarding SVHC and the instrumental configuration of the authorisation regime.[279]

Articles produced in the EEA are subject to the provisions to ensure the high level of protection, which also specifically regulate Annex XIV-SVHC present in articles. However, the achievable positive effects could be watered down due the fact that imported articles may contain SVHC without a requirement to apply for authorisation of such use. Specifically, the purpose of the technical regulation, therefore, is to extend the high level of protection on articles coming from third countries and thus to regulate imported products following the same rules that apply to domestic products: if an article producer demonstrates that the risks due to the SVHC are adequately controlled (or, if the socio-economic benefits outweigh the risks), he also obtains permission to use the substance. From a consumer protection perspective, precisely such use of

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273 *Bulleid* 2014.

274 *CSES* 2012a, p. 48 et seq.

275 Appellate Body, US – Tuna II (fn. 169), para. 314.

276 Appellate Body, US – Tuna II (fn. 169), para. 314.

277 Recitals 3 et seq. illustrate the international dimension, including the "Johannesburg goal" and the link to the "Strategic Approach to International Chemical Management" (SAICM).

278 Overview at *Kogan* 2012, p. 48 (l.c. endnote 569).

279 Section 1.2 elaborates on REACH's legislative objectives.

SVHC calls for increased security and transparency: averagely informed consumers, while according to their risk perception reacting sensitively on substances and mixtures, the properties and possible effects of which are difficult to assess for a layman, often do not assume an inherent damage potential of products.[280]

Sentence 3 of Art. 2.2 TBT lists several objectives assumed to be legitimate. It is a non-exhaustive list; objectives not included may therefore be legitimate, too. In what follows the legitimacy of the extended authorisation requirement's objectives have to be examined.

4.2.1 Health protection through risk reduction

Primarily, the extended authorisation requirement shall contribute to ensuring a high level of protection of human health: because of the hazard potential of SVHC the actors are assigned the burden of proof that the risks are adequately controlled. Moreover, these substances shall be gradually substituted by suitable alternative substances or technologies. As a result, the technical regulation aims to avoid and reduce exposure to SVHC.

Health protection is therefore the overall objective, which is also a legitimate purpose in accordance with Art. 2.2 Sentence 3 TBT. Furthermore, Recital 6 of the TBT Agreement's preamble confirms the right of the Member States to take measures, inter alia, to protect human health. This shall also be possible "at the levels [the country] considers appropriate". The Member States can therefore determine the level of protection with respect to certain legal goods, provided the other TBT requirements are complied with. As a result, from a combined reading of Art. 2.2 and Recital 6 TBT, it follows that the high level of protection of human health is a legitimate objective.

4.2.2 Environment protection through risk reduction

At the same time, the extended authorisation requirement aims to ensure a high level of protection of the environment by means of risk reduction. Art. 2.2 Sentence 3 and Recital 6 TBT also lists "animal or plant life or health, or the environment" as a legitimate objective, while the (entire) environment belongs to the legitimate protective goods as well.[281]

4.2.3 Sustainable development

The overall objective of the REACH instruments, namely to contribute to a sustainable development is enshrined in the Treaty of the WTO. The non-exhaustive list of legitimate objectives in Art. 2.2 TBT does not provide any reference in this respect. However, other treaties from the WTO set may also provide relevant information for the interpretation of Art. 2.2 TBT.[282] To this end, the Marrakesh Agreement Establishing the World Trade Organization, which is of special significance for the interpretation of WTO law, foresees in its first recital an "optimal use of the world's resources in accordance with the objective of sustainable development". This normative goal influences all the other WTO Agreements,[283] with sustainable development being a generally accepted regulatory purpose, also in the context of TBT. Regardless of the ongoing debate about the actual content and requirements of the guiding

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280 Indeed, according to a Eurobarometer survey only 2/3 of Europeans expect articles like toys or furniture to contain chemicals; whereas 38% assume this only to be probable, *TNS Political & Social* 2013, pp. 22 et seq.

281 C.f. the parallel provision in Art. 2.1 SPS which, beyond "human, animal or plant life or health", does not refer to the environment as a whole.

282 Appellate Body, US – Tuna II (fn. 169), para. 313.

283 Appellate Body Report WT/DS58/AB/R of 12.10.1998 (US — Shrimp), para. 129–131; C.f. *Hilf* 2000, p. 485

principle of sustainable development,[284] a general optimising imperative can be derived from the formulation in the Marrakesh Agreement ("optimal use") which may only be achieved by sophisticated instruments such as those required in REACH.

4.2.4 Conclusion regarding the legitimacy of objectives

With the objective of a high level of protection of human health and the environment the extended authorisation requirement, as well as the contribution to sustainable development therein, follows a legitimate objective in terms of Art. 2.2 TBT.

4.3 Appropriateness

Technical regulations have to be necessary to *fulfil* their legitimate objective indicating that the contribution of the extended authorisation requirement to its objectives has to be examined (appropriateness).

The Appellate Body interprets the term 'fulfil' as the "degree of contribution a technical regulation makes toward the achievement of the legitimate objective".[285] According to the Body this reading is also covered by Recital 6 TBT pursuant to which Member States are allowed to set a regulation's level of protection.

To what extent a technical regulation has to contribute to comply with Art. 2.2 TBT cannot be determined in abstract terms; rather, the answer to this question depends either explicitly or implicitly on the regulation "as written and applied"; including its development process and actual application.[286] The examination may be based on the "design, structure, and operation of the technical regulation" as well as on empirical data relating to its application.[287] In doing so, evidence for the degree of contribution may be of a qualitative nature.[288]

4.3.1 Contribution of the regulation ("as written") to the legitimate objectives

Focusing first of all on the degree of contribution "as written" the restrictive approach of the technical regulation has to be highlighted as the listing of a substance on Annex VI generally establishes a ban on the placing on the market (section 4.1).

Authorisations are issued on a temporary basis in accordance with Art. 60(8), (9)(e) REACH to provide an opportunity in the future to re-evaluate whether suitable alternative substances or technologies are available. Furthermore, authorisations pursuant to Art. 60(8), (9)(d) REACH "shall normally be" subject to specific conditions. Moreover, permission holders have to consider the specifications of Art. 60(10) REACH, according to which "[n]otwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible". Authorisations are therefore linked to a dynamic risk reduction requirement.

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284 C.f. *v. Hauff/Kleine* 2009.

285 Appellate Body, US – Tuna II (fn. 169), para. 315, Appellate Body, US – COOL (fn. 168), para. 373.

286 Appellate Body, US – COOL (fn. 168), para. 373, Appellate Body, US – Tuna II (fn. 169), para. 316 et seq.

287 Appellate Body, US – Tuna II (fn. 169), para. 317, Appellate Body, US – COOL (fn. 168), para. 373.

288 Appellate Body Report WT/DS332/AB/R of 3.12.2007 (Brazil — Retreaded Tyres), para. 145 et seq. citing Appellate Body, EC – Asbestos (fn. 139), para. 167.

4.3.2 Contribution of the regulation's application to the legitimate objectives

The contribution of the regulation's application to the legitimate objectives is to be examined. For this, reference is made to empirical data gathered in terms of the existing authorisation requirement de lege lata.

Under the so-called "REACH Review" which obliged the European Commission to examine comprehensively for the first time the implementation and impacts of REACH five years after the entry into force of the Regulation, a study investigated how the actors in the value chain react if one of "their" substances is included in Annex XIV: according to a company survey of 223 participants responded 116 (43.4%) with reformulations, 105 of 207 (44.1%) took the SVHC out of their portfolio, 105 of 223 (41.0%) requested substitutes from their suppliers, 57 of 200 (24.9%) initiated new substance developments and 89 of 183 (46.4%) "took no special action".[289]

As regards article producers in particular, very little empirical data is currently available from which the effects of the SVHC regulation can be derived. Another "REACH review" study points to three article producers (extent of sample unknown) whose products contain at least one SVHC, of which one producer indicates that his or her costs have increased (due to customer inquiries); two article producers indicate in each case that the demand for the relevant substances has fallen, that the supplier has taken the substance from the market or that the supplier has the substance replaced with a less hazardous substance.[290]

Although it is too early for a final assessment of the impact of the regulatory scheme regarding SVHC, the figures concerning the direct effects on producers and users, caused by the identification of a substance as a SVHC or its inclusion in Annex XIV, suggest that the incentive system established by REACH achieves the intended effects towards the regulatory purposes.[291] These results can also be transferred to the extended authorisation requirement. Because a very high number of imported products would be affected, a very significant contribution to risk reduction also in quantitative terms can be expected.

4.3.3 Conclusion regarding appropriateness

An appreciation of design and structure of the technical regulation, of initial empirical findings regarding the application of existing rules on SVHC, and of their practical effects, demonstrate that the extended authorisation requirement can make quite a significant contribution to reducing the risks from SVHC and therefore "as written and applied" is appropriate to achieving its ambitious goals. It therefore also fulfils its standard of a "high level of protection", since it neither formulates a minimum level of protection to be achieved nor does it aim at a "maximum achievable" protection.[292]

It is, however, not excluded that individual actors who are not authorisation holders substitute an Annex XIV substance with an alternative substance, the hazard potential of which is of equivalent concern compared to the substituted SVHC.[293] However, this may not cast doubt on the appropriateness of the technical regulation as such since public risk mitigation measures would otherwise largely be hard to justify, because comparable avoidance strategies may never be entirely anticipated and prevented. Additionally, REACH provides mechanisms for identifying such developments and for taking appropriate measures.

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289 *CSES* 2012b, p. 76.

290 *Postle/Holmes/Camboni* et al. 2012, p. 101.

291 With a similar conclusion: *Postle/Holmes/Camboni* et al. 2012, p. 121.

292 C.f. Appellate Body, Brazil — Retreaded Tyres (fn. 288), para. 144.

293 *Bergkamp/Herbatschek* 2014, p. 227.

4.4 Necessity

The first two sentences of Art. 2.2 TBT provide that technical regulations may not be more trade-restrictive than necessary. In order to examine whether the intrusiveness of a given technical regulation is necessary a "relational analysis" of

- the specific trade restrictions due to the regulation (section 4.1);
- the legitimate objective (section 4.2) and the contribution of the regulation to fulfill this objective (section 4.3); and
- the risks non-fulfilment would create

has to be performed.[294] Typically, the analysis also includes

- a comparison with possible alternative measures that may be reasonably available and less trade restrictive than the technical regulation.[295]

Since the first analysis steps are already completed, the next sections respond only to the last two steps.

4.4.1 Risks of non-fulfilment

The central question of this step in the analysis is how the risks posed by SVHC in articles – considered in the light of the technical regulation's legitimate objectives – are to be assessed in terms of Art. 2.2 TBT. Sentence 4 of the provision gives clues as to how the negative effects can be determined that can be expected if the objectives of the regulation cannot be fulfilled; while the risk assessment steps provided therein are not mandatory:

> "In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products."

The Appellate Body adds that the comparison with possible alternative regulatory options "should be made in the light of the nature of the risks at issue and the gravity of the consequences that would arise from non-fulfilment of the legitimate objective".[296] The technical regulation aims to reduce and avoid the exposure of humans and the environment to SVHC listed in Annex XIV. To determine the risks in case these goals are not fulfilled, the nature of the risks caused by SVHC is to be examined. This includes both procedural and substantive considerations. From a procedural point of view an assessment is necessary whether the risk assessment provided for in the extended authorisation requirement is appropriate to determine risks in terms of Art. 2.2(4) TBT. From a substantive point of view, one needs to consider the importance which the TBT agreement ascribes to these risks.

4.4.1.1 Procedural requirements

The extended authorisation requirement causes a ban on the placing on the market with regard to SVHC listed in Annex XIV that are present in imported articles, whereas producers may lift the ban if they successfully apply for the authorisation of such use. In this case, the prohibition and exception constitute one measure (technical regulation) in terms of the TBT Agreement.[297] Below the risk assessment as put into effect by the technical regulation has to be examined.

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294 Appellate Body, US – Tuna II (fn. 169), para. 318, Appellate Body, US – COOL (fn. 168), para. 374.

295 Appellate Body, US – Tuna II (fn. 169), para. 320.

296 Appellate Body, US – Tuna II (fn. 169), para. 321.

297 Appellate Body, EC – Asbestos (fn. 139), para. 63 et seq., c.f. *Burchardi* 2007, pp. 231 et seq.

4.4.1.1.1 Risk assessment in the context of the technical regulation

ECHA coordinates the temporal sequence in which the identified SVHC are included in Annex XIV. To this end, it recommends to the European Commission which substances should be treated as a priority. In accordance with Art. 58(3) REACH, these are usually substances that have certain characteristics (PBT or vPvB) or fulfil the criteria of "wide dispersive use" or "high volumes". For each priority substance the Agency issues a report including an analysis of known uses and potential releases.[298] This compilation serves to substantiate the prioritisation and to define the exact conditions for inclusion in Annex XIV pursuant to Art. 58(1). The report is based on the original Annex XV dossier for each substance,[299] other relevant scientific information and the information on specific use conditions provided to ECHA by article producers with respect to their notification obligations. These notifications relate exclusively to those applications where exposure to humans and the environment cannot be excluded.[300] Information collected by ECHA also serves to identify uses which should – pursuant to Art. 58(2) – be exempted from the authorisation requirement as existing legal provisions ensure adequate control. Before ECHA delivers its final recommendations, the collected information will be made available for comment for the "interested parties" in accordance with Article 58(4).[301] These are invited to submit information on possible exemptions under Art. 58(2), but can also communicate exculpatory information regarding the risks of a substance, thus delaying the inclusion in Annex XIV or possibly[302] even working towards the substance being permanently excluded from prioritisation.

From the steps towards the inclusion of a substance in Annex XIV it becomes apparent that this procedure not only reflects the substance inherent hazard potential but also considers the risk due to the SVHC in different ways: the "general" risks due to substance quantities and distribution rates in the EEA and also the use-specific risks. In addition, it can be assumed that ECHA identifies the most relevant areas of SVHC in articles in the prioritisation procedure. Yet, the intensity of this risk assessment depends initially on the available scientific data. Moreover, it cannot be excluded that substance uses other than those identified by ECHA exist which would also become subject to the authorisation requirement without at least a rudimentary consideration of the risks having been previously performed.

After inclusion of a substance in Annex XIV, it must not be used in articles after a certain "sunset date", unless the use is exempted from the authorisation requirement or the producer receives a use-specific[303] authorisation.[304]

In the authorisation process a "risk assessment" specific to the circumstances of each case – i.e. the risk due to the use of SVHC in a given product – is then made mandatory. For this purpose, according to Art. 62(4)(d) REACH, the applicant has to submit a chemical safety report (CSR)[305]

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298 So-called "technical report on: manufacture, import, export, uses, releases and alternatives".

299 This was drawn up by a Member State or the Agency to identify a substance as SVHC.

300 Art. 7(2) in conjunction with Art. 7(4)(e), Art. 7(3). This obligation exists already de lege lata for article producers from third countries, *Danish Chamber of Commerce* 2009, p. 17. After Art. 7(6) Art. 7 Para. (1) to (5) shall not apply to substances that have already been registered for that use.

301 C.f. section 1.3.2.6.

302 Currently there is a debate about whether Art. 59(1) REACH ("for eventual inclusion in Annex XIV") requires, in the long term at least, inclusion in any case, c.f. *European Commission* 2013, p. 72.

303 However, there are several reliefs: so REACH does not require that each producer submits a comprehensive application on its own, allowing for savings of transaction costs, c.f. Art. 62(3), Art. 63.

304 Art. 56(1)(a), (b).

305 Requirements are specified in Art. 14 in conjunction with Annex I REACH. Even if Art. 14(3), (4) does not explicitly mention substances identified according to Art. 57(f) (e.g. EDC) the obligation to prepare an exposure

for each substance use, including exposure assessment and risk characterisation. Pursuant to Art. 64(4) the Risk Assessment Committee, an independent panel of experts to ECHA (Art. 85(7))[306] reviews the application. This includes:

> "an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives".

The risk assessments performed rely on qualitative, semi-quantitative or qualitative analysis (section 1.3.1). Regarding SVHC for which effect thresholds can be derived, authorisation is granted in accordance with Art. 60(2) REACH if the applicant provides proof of adequate risk control, with the European Commission taking "into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision". Evidence of adequate control is provided when, according to Annex I, Section 6.4 REACH throughout the life cycle of the substance in use and for each exposure scenario the estimated exposure and concentration levels do not exceed the respective DNEL[307] or PNEC[308] values.[309] If this does not succeed, authorisation may also be granted if the applicant demonstrates that the socio-economic benefits outweigh the risks linked to the use and that no less concerning alternative substances and technologies are available. For substances without effect thresholds, as proof of adequate control cannot be provided,[310] pursuant to Art. 60(4) in conjunction with Art. 60(2) only the socio-economic "authorisation route" is available.

4.4.1.1.2 Consideration in the light of the TBT and the SPS Agreement

The question is first of all how the basic data and evaluation methods, based on which the identification of SVHC is performed, are to be evaluated in the light of Art. 2.2(4) TBT. Only a few references can be found in the WTO dispute settlement case law as to what is meant by "available scientific and technical information".[311] In particular, none of the dispute settlement bodies has yet developed criteria which information has to satisfy in terms of Art. 2.2. The requirements to be placed on the scientific evidence of risks are thus unclear.

One option would be to refer to the Appellate Body's decision in *EC – Asbestos*, not least of all because the Body refers to the principles of this decision when taking into account the importance of product risks in the likeness analysis under Art. 2.1 TBT. With regard to the requirements of the scientific justification of the risks against which the French ban on asbestos and asbestos-containing products was directed, the Appellate Body came to the following conclusion:

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assessment should also refer to these substances, otherwise an exhaustive description of the risk seems hardly possible, *Merenyi/Kleihauer/Führ* et al. 2011, p. 26.

306 C.f. http://echa.europa.eu/de/about-us/who-we-are/committee-for-risk-assessment (17.6.2014).

307 Derived No-Effect Level for effects toxic to humans.

308 Predicted No-Effect Concentration for ecotoxic effects.

309 C.f. *Kleihauer/Führ/Hommen* et al. 2013, pp. 4 et seq. In addition, "the likelihood and severity of an event occurring due to the physicochemical properties of the substance" has to be negligible.

310 E.g. regarding CMR substances without effect thresholds accommodation of a single molecule may already be sufficient to realise the existing hazard potential. For these substances, therefore, adequate control of risks cannot be proved scientifically.

311 However, some guidance can be found in Panel Report WT/DS381/R v. 15.9.2011 (US – Tuna II), para. 5.72.

> "[R]elating to "quantification" of the risk, we consider that, as with the SPS Agreement, there is no requirement under Article XX(b) of the GATT 1994 to quantify, as such, the risk to human life or health. A risk may be evaluated either in quantitative or qualitative terms."[312]

Hence it can be concluded that the alternatively applicable semi-quantitative or qualitative analysis in the identification of SVHC, in principle, is suitable to determine risks in terms of Art. 2.2 TBT.[313]

Apart from Art. 2.2(4) TBT neither the TBT Agreement nor the relevant case law contains requirements concerning the risk assessment. However, the Appellate Body also consults the other "covered agreements" in the interpretation of Art. 2.2 TBT.[314] This is consistent with the generally accepted rules of interpretation of international law.[315] A systematic comparison with the provisions of the SPS Agreement (section 2.2.2.1)[316], which provides more concrete guidelines to the risk assessment, is therefore appropriate. Also, the Appellate Body in *EC – Asbestos* refers to SPS; in another decision, this occurs explicitly in order to gain guidance on the interpretation of the TBT Agreement.[317] At the same time no immediate requirements for risk assessment in the context of TBT can be derived from the SPS provisions for risk assessments, due to the different negotiating histories and objectives[318] of the texts.

Art. 5.1 SPS provides the following wording:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

In addition, according to Art. 5.2 SPS "[i]n the assessment of risks, Members shall take into account available scientific evidence." Annex A No. 4 SPS contains two approaches to defining risk assessment:

> "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

While in the first alternative of Annex A No. 4 SPS, the probability of establishment or spread of a pest or disease and even the economic effects caused by a measure have to be evaluated, risk assessments pursuant to the second alternative are limited to the evaluation of the potential, i.e. possible[319] damaging effects due to the presence of noxa in food. If the extended authorisation requirement was also a SPS measure, it would thus need to comply with the second alternative due to the comparable nature of the risks concerned.

SPS does not contain any requirements for the risk assessment methodology.[320] However, a WTO panel deduced from the concept of risk assessment that an evaluation regarding hormones in

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312 Appellate Body, EC – Asbestos (fn. 139), para. 167 (*footnotes omitted).*

313 A skeptical view on this matter can be found in *Kogan* 2012, pp. 35-38.

314 Appellate Body, US – Tuna II (fn. 169), para. 313.

315 Art. 31 Vienna Convention on the Law of Treaties.

316 C.f. *Tietje/Wolf* 2005, pp. 22 et seq.

317 Appellate Body, US – Tuna II (fn. 169), para. 363; c.f. Panel, EC – Seal Products (fn. 181), para. 7.560 et seq.

318 C.f. *Zarrilli* 1999, p.8, *Rigod* 2013, pp. 507 et seq.

319 Appellate Body Report WT/DS26, 48/AB/R of 16.1.1998 (EC – Hormones), para. 184.

320 Appellate Body Report WT/DS245/AB/R of 26.11.2003 (Japan – Apples), para. 204.

meat products should include the following two steps: (1) identification of the adverse effects on human health caused by the presence of a substance in meat and, if adverse effects exist, (2) evaluation of the occurrence potential or possibility.[321] The Appellate Body approves of this approach.[322] Furthermore, the risk concept in principle requires that potential health effects are associated with a cause.[323] In accordance with Art 5.1 SPS, this requirement must, however, be interpreted "as appropriate to the circumstances". Thus, in individual cases, the cumulative effect of several substances can make it difficult to determine the actual cause-and-effect relationships. In these cases, only a connection between the studied noxa (against which the measure is directed) and the possibility of health damage has to be established. Proof of direct causal relationships or differentiations of individual damage contributions of various factors is not necessary.[324] In such cases, according to the Appellate Body "to examine the 'potential' for adverse effects is to ask whether those adverse effects could ever occur".[325] Risk assessment in accordance with Art. 5.1 SPS can furthermore be carried out both quantitatively and qualitatively,[326] and there is no *de minimis* threshold as to the minimum size of a detected risk. Finally, the risk assessment can be based on minority views in the scientific community[327] and also has to consider social contexts.[328]

This overview of the case law shows that the risk assessment in accordance with the extended authorisation requirement conforms to the requirements of the SPS Agreement. By implementation of the risk-ratio model and qualitative risk characterisation methods in the application for authorisation and its review, the technical regulation ensures the assessment of the risks in each application of SVHC in an article. This is especially true with regard to those SVHC for which effect thresholds can be derived. But even in relation to cases in which methodological challenges will not allow an unambiguous assignment of causality (e.g. PBT and vPvB), the Appellate Body lowers the relevant threshold for the determination of potential adverse effects down to a level ("whether those adverse effects could ever occur") that the technical regulation meets.

As far as international standards for risk assessment relating to specific products or product categories exist (e.g. for textiles), this would be taken into account in accordance with Art. 5.1 SPS. This becomes even more important as 2.4 TBT contains a parallel provision in regard to technical rules.[329]

While SPS requires by default that a specific risk assessment is performed, risks only have to be "taken into account" in accordance with the TBT Agreement.[330] Nevertheless, the technical

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321 Panel Report WT/DS26/R/USA of 18.8.1997 (EC – Hormones), para. 8.98.

322 "Although the utility of a two-step analysis may be debated, it does not appear to us to be substantially wrong", Appellate, EC – Hormones (fn. 319), para. 184.

323 Appellate Body, Japan – Apples (fn. 320), para. 202 (fn. 372).

324 Appellate Body Report WT/DS320/AB/R of 16.10.2008 (EC – Hormones; Continued Suspension), para. 562.

325 Appellate Body, EC – Hormones; Continued (fn. 324), para. 572.

326 *Arcuri* 2010 is skeptical as the Appellate Body "juggles" both concepts.

327 Appellate Body, EC – Hormones (fn. 319), para. 184-186, 194, c.f. *Eggers* 1998, pp. 149 et seq.

328 Appellate Body, EC – Hormones (fn. 319), para. 187: "the risk to be evaluated in a risk assessment under SPS Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist—the actual potential adverse effects on human health in the real world where people live and work and die", c.f. *Stoll/Strack* 2007, para. 34, *Shaw/Schwartz* 2005, p. 7.

329 Both Agreements provide for a consideration of standards only to the extent that these are compatible with each chosen level of protection of a measure or regulation. This follows from the wording of Art. 2.4 TBT and, as regards SPS, from the decision in Appellate Body, EC – Hormones; Continued (fn. 324), para. 685.

330 *Gruszczynski* 2013.

regulation meets the comprehensive SPS requirements for the risk assessment. This shows the significance of the risks determined and controlled under the technical regulation and at the same time gives evidence as to the significance of "the risks non-fulfilment would create" in terms of Art. 2.2 TBT. This in turn is an indication of the necessity of the technical regulation.[331]

4.4.1.2 Substantive requirements

The formulation "nature of the risks at issue and the gravity of the consequences"[332] makes necessary a substantive test of risks caused by SVHC.

4.4.1.2.1 Nature of the risks and gravity of the consequences

In the *EC – Asbestos* case, the European Community showed that asbestos can cause various forms of cancer. Given the relevance of the identified risk, its possible consequences, and the objective of the import ban ("halt the spread of this risk"), the WTO dispute settlement organs approved the strict regulatory measure, especially because it was not possible to derive effect thresholds.[333]

According to Annex I, Section 3.6 CLP asbestos is – analogous to the internationally harmonised GHS criteria – classified as carcinogen Category 1A and thus as a "hazardous" substance.[334] Carcinogenicity is also one of the criteria of Art. 57 REACH (Paragraph a) for the identification of SVHC. In addition, a substance may be determined as SVHC – and also listed in Annex XIV – due to other high concern properties. These include, in accordance with Art. 57(b) to (d) and partially Art. 57(f), more categories (also) based on a GHS harmonised classification as "hazardous". Section 0 provides that all these substances is a scientifically proven hazard potential immanent, which in the event of exposure may – under German law – establish a situation of danger in the legal sense, against which the state is even obliged to take preventing measures. As regards these substances, the "nature of risks" and "gravity of the consequences" are therefore (in light of the purpose of the technical regulation) to be rated as of similar high concern compared to the situation in *EC – Asbestos*.[335] Strong evidence can be derived thereof for the necessity of the technical regulation.

However, the extended authorisation requirement also builds selectively on SVHC whose hazard potential involves scientific uncertainty to some extent. This includes PBTs with reproductive toxicity Category 2, vPvB and possibly specific substances determined on the grounds of Art. 57(f). From a legal point of view, the risks posed by these substances would therefore – in principle despite release – be located below the danger threshold; a regulatory approach to these substances is thus to be classified as a precautionary measure (section 1.3.3). With respect to GATT it has been argued that recourse to the justifications for trade restricting measures provided for in Art. XX must also be allowed in regard to "scientifically substantiated suspicion facts" because only in this way is a preventive approach against these risks even possible.[336] Thus, the following sections analyse how a technical regulation which is also an expression of the precautionary principle must be evaluated in terms of Art. 2.2 TBT.

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331 A similar conclusion can be found in *SRU* 2004, para. 1048.

332 Appellate Body, US – Tuna II (fn. 169), para. 321.

333 Panel, EC – Asbestos (fn. 155), para. 8.201-8.204, Appellate Body, EC – Asbestos (fn. 139), para. 167 et seq.

334 Index No 650-013-00-6 of the harmonised classification and labelling of hazardous substances list in Annex VI CLP.

335 Though the "nature of the risks" and "gravity of the consequences" test has been developed after *EC – Asbestos*.

336 *Schmidt/Kahl* 2003, para. 120 *(authors' translation)*; *SRU* 2004, para. 1049 with further references.

4.4.1.2.2 Evaluation of the precautionary elements of the technical regulation

The TBT Agreement gives no information as to how a precautionary approach is legally assessed.[337] From this follows, first of all, that precautionary measures are not forbidden from the outset. In addition, one option is again to use the SPS Agreement for systematic comparison because several specifications of the agreement express a precautionary approach.[338] The key provision is in this regard Art. 5.7 SPS:[339]

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, […]. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

The provision allows Member States to adopt interim protective measures in cases where "relevant scientific evidence is insufficient". The latter condition is fulfilled if there is, at least to some extent, evidence which indicates possible risks, yet the available scientific data do not allow an adequate risk assessment to be performed in accordance with Art. 5.1 SPS in quantitative or qualitative terms.[340] This is the case when little or no reliable data are available as the basis for the assessment.[341] Art. 5.7 SPS therefore legitimates provisional measures in situations where a risk potential prevails.

To what extent these established standards of Art. 5.7 are applicable to the technical regulation of an extended authorisation requirement has to be examined. According to the criteria set out in Art. 57 REACH, the technical regulation requires that the hazard potential of a SVHC is known and it assumes that with respect to all SVHC categories, a risk assessment compliant with Art. 5.1 SPS can be performed.[342] Thus, the existing knowledge of risk goes beyond finding a risk potential in terms of Art. 5.7 SPS since – according to the knowledge-related incremental gradations on the precautionary spectrum - the latter involves by contrast a much higher degree of uncertainty. [343] Within the scope of the authorisation requirement, "insufficient scientific evidence" does not therefore exist. As a result, the authorisation requirement that, in principle,[344] applies indefinitely[345] would not be obliged to be a provisional measure, even within the scope of the SPS Agreement.

Even to the extent the authorisation requirement is applicable to PBTs with reproductive toxicity (Cat. 2) and vPvBs, this would thus not fall within the substantive scope of Art. 5.7 SPS. However, both SVHC classes mentioned are characterised by a specific degree of uncertainty as

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337 This is also true for its negotiation history, c.f. Committee on Trade and Environment und Committee on Technical Barriers to Trade Report WT/CTE/W/10, G/TBT/W/11.

338 Appellate Body, EC – Hormones (fn. 319), para. 124. *Prévost* 2005, pp. 2 et seq. does not entirely share this opinion.

339 *European Commission* 2000, pp. 11 et seq., *Kogan* 2004, p. 96, *Prévost* 2005, p. 13.

340 Appellate Body, Japan – Apples (fn. 320), para. 179, Appellate Body, EC – Hormones; Continued (fn. 324), Panel, EC – Biotech Products (fn. 113), para. 7.3237.

341 "The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence", see Appellate Body Report WT/DS245/AB/R of 26.11. 2003 (Japan – Apples), para. 184, *Charnovitz* 2007, para. 19, *Seibert-Fohr* 2007, Art. 2 SPS para. 26.

342 Nevertheless, the possibilities for determining causalities may be limited in part.

343 Cf. sections 1.3.2.5 and 1.3.3.

344 If SVHC no longer meet the criteria of Art. 57 they are removed again from Annex XIV according to Art. 58(8) REACH. In this case the authorisation requirement also ends.

345 A granted authorisation is subject to a general review, see Art. 60(8), Art. 61. However, the "provisional element" of Art. 5.7 SPS refers to the trade-restrictive effect of a measure and not its exemptions.

regards the hazard potential. To enable a conclusive evaluation of the technical regulation under TBT, the further assessment therefore presumes that the "precautionary categories" of Art. 57 REACH might be seen as precaution also from a WTO legal point of view.

Because the TBT Agreement does not contain any provisions regarding precaution, the evaluation of the precautionary elements of the technical regulation is based on an interpretation of Art. 2.2 in conjunction with Recital 6 TBT. Thereafter, Member States may not be prevented from taking measures to protect humans and the environment given these measures are not more trade-restrictive than necessary. Insights as to the range of this regulatory autonomy may possibly be found in the provisions of international environmental law.[346] Pursuant to Art. 31(3)(c) VCLT,[347] in interpreting a treaty – such as the TBT Agreement – international law "shall be taken into account, together with the context", i.a. the actual contract terms.[348] Also, the Appellate Body noted in one of its first decisions that WTO law is not in "clinical isolation" from international law.[349]

International environmental law thus has to be examined as to whether it provides specifications on the applicability or at least the legitimacy of the precautionary principle which can be significant in the interpretation of WTO law and specifically the TBT Agreement.

4.4.1.2.2.1 The precautionary principle in international law

International environmental law thus has to be examined to establish whether it provides specifications on the applicability or at least the legitimacy of the precautionary principle which can be significant in the interpretation of WTO law and specifically the TBT Agreement. Treaties, general principles of law and customary law have to be considered as the sources of law.[350]

Since the 1980s a variety of partially binding international environmental agreements[351] applies the precautionary principle or a precautionary approach.[352] However, this is undertaken by way of different formulations and instrumental configurations, so no universal understanding has already emerged regarding the content and scope of the principle itself.[353] Generally, the precautionary principle is a risk management tool.[354] On the basis of the tool, a state may (or possibly must) act within its abilities carefully and proactively on decisions regarding activities that may have a harmful effect on the environment or human health.[355] Internationally the precautionary principle in its somewhat "more focused" nature in Principle 15 of the Rio Declaration is also experiencing increasing recognition.[356] Thereafter protective measures to

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346 For the relevance of multilateral environmental agreements in the WTO treaty interpretation see *Panizzon/Arnold/Cottier* 2010, pp. 231 et seq.

347 Vienna Convention on the law of treaties.

348 C.f. *Graf Vitzthum* 2010, para. 114 et seq.

349 Appellate Body Report WT/DS2/AB/R of 29.4.1996 (US – Gasoline), p. 17, similar Appellate Body, US — Shrimp (fn. 283), para. 129 et seq.

350 Art. 38 ICJ Statute, c.f. *Graf Vitzthum* 2010, para. 113 et seq.

351 On a local level, e.g. in Germany and Sweden, this occurred in the 1970s, *Rehbinder* 1991, pp. 7, 183.

352 A selection: Vienna Convention for the Protection of the Ozone Layer in 1985, the Montreal Protocol of 1987, Framework Convention on Climate Change of the United Nations, Convention on Biological Diversity and the Convention for the Protection of the Marine Environment of the North-East Atlantic in 1992, the Cartagena Protocol on Biosafety of 2000, Stockholm POP Convention of 2001 etc.

353 *OECD* 1995, pp. 16 et seq., *Sands/Peel* 2012, pp. 217 et seq., 222.

354 *Atapattu* 2006, p. 283 with further references.

355 *Sands/Peel* 2012, p. 222.

356 *Sands/Peel* 2012, pp. 217 et seq., 222. As regards the Rio Declaration see already section 1.1.

prevent serious or irreversible damage can be taken without full scientific certainty about the *possible* extent of damage. This procedure is thus to be distinguished from the largely consented principle of preventive environmental protection, according to which states take preventive measures to guard against damage which is *likely* to occur on the basis of scientific knowledge.[357] To this end, in German legal doctrine a distinction is made between prevention against scientifically proven damages and precaution against risk potentials under uncertainty.[358]

At a regional level, e.g. in the European Union,[359] coherent legislation and case law have established a largely consolidated application practice with regard to the precautionary principle, including specific substantive and procedural requirements. This is not the case in international law. The constitutive elements of the precautionary principle within the meaning of Principle 15 include risk, damage and scientific uncertainty.[360] However, there is no general guidance on how to identify risks and calculate the damages.[361] What degree of scientific certainty is required or *vice versa*, how much scientific uncertainty is allowed to act on the basis of precaution, can also only be determined in each individual case and in view of the potential and possible extent of the damage. Also the question of the appropriate instrumental design of a measure cannot be answered abstractly. So, depending on the degree of concern, mere monitoring activities in relation to a potential damage may as well be an expression of precaution as a general reversal of the burden of proof to the extent actors from industry must prove that a product is safe prior to its sale.

Binding multilateral agreements with reference to precaution can be found, for example, in the chemical sector. To this end, mention has to be made of the international treaties concerning POP as well as the OSPAR Convention with the main topic of these texts being on persistent and bioaccumulative substances which are toxic (section 1.1). However, there is no international agreement that imposes, in a horizontal effective standard, the relevance of the precautionary principle in the interpretation of international treaties.

Alongside binding contracts "the general principles of law recognized by civilized nations" as well as "international custom, as evidence of a general practice accepted as law" are also applied in international law.[362] A general principle of law status of precaution appears a priori very unlikely as this applies rather to universal legal maxims such as the principle of good faith in the exercise of rights.[363]

The precautionary principle is thus to be examined as to whether it has a customary law status. This would require a similar use of the principle as a conscious and consistent practice by a representative number of states; the mere acknowledgment of the principle in "soft law" documents such as the Rio Declaration and Agenda 21, however, is not sufficient.[364] Widespread inclusion of the principle in international treaties as well as the increasing focus of state policies on precautionary practice can be interpreted as an indication of an increasing juridification of the principle. An evaluation of different state practices led in 2002 to the conclusion that "nowadays [that] the precautionary principle is a principle of customary international is much

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357 *Atapattu* 2006, p. 203, *Sands/Peel* 2012, pp. 201 et seq..

358 C.f. section 1.3.1.

359 *European Commission* 2000, *Appel* 2005, pp. 202 et seq.

360 Another element is the different possibilities of the states. These are, however, not relevant to the study.

361 *Atapattu* 2006, pp. 206 et seq.

362 Art. 38 ICJ Statute.

363 *Sands/Peel* 2012, pp. 117 et seq.

364 For the requirements see *v. Heinegg* 2003, para. 75, *id.* 2014, § 17, *Graf Vitzthum* 2010, para. 131 et seq.

better defensible than the contrary."[365] A WTO dispute settlement body last dealt with the principle's customary international law status in 2006.[366] However, the panel itself took no position in this regard,[367] but merely referred to the ongoing debate among legal scholars, practitioners, legislators and judges, and the fact that so far no international court or tribunal has taken a clear position on the legal status of precaution.[368] In the meantime, however, two international chambers have commented in this respect. While the International Court of Justice (ICJ) in 2010 noted, in a comparatively restrained manner, that the precautionary principle could be relevant with respect to the interpretation and application of the provisions of a bilateral treaty between two states,[369] the International Tribunal for the Law of the Sea (ITLOS) concludes in an "Advisory Opinion" of 2011 as follows:[370]

> "The Chamber observes that the precautionary approach has been incorporated into a growing number of international treaties and other instruments, many of which reflect the formulation of Principle 15 of the Rio Declaration. In the view of the Chamber, this has initiated a trend towards making this approach part of customary international law. This trend is clearly reinforced by the inclusion of the precautionary approach in the Regulations [at hand]. […] The statement in paragraph 164 of the ICJ Judgment in Pulp Mills […] may be read in light of article 31, paragraph 3(c), of the Vienna Convention, according to which the interpretation of a treaty should take into account not only the context but "any relevant rules of international law applicable in the relations between the parties".

According to first opinions expressed in the literature the ITLOS thus effectively recognised the customary international law[371] status of the precautionary principle within the meaning of the Rio Declaration.[372] Accordingly, *Sands* and *Peel*[373] assert:

> "There is certainly sufficient evidence of state practice to support the conclusion that the principle, as elaborated in Principle 15 of the Rio Declaration and various international conventions, has now received sufficiently broad support to allow a strong argument to be made that it reflects a principle of customary international law, and that within the context of the European Union[374] it has now achieved customary status, without prejudice to the precise consequences of its application in any given case. Although the ICJ and a WTO-Panel have declined that the principle has a customary international law status, the ITLOS […] has, in effect, reached that conclusion."

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365 *Trouwborst* 2002, Evolution and Status of the Precautionary Principle in International Law, p. 275, cited after *Atapattu* 2006,p. 286.

366 Panel, EC – Biotech Products (fn. 113).

367 As previously Appellate Body, EC – Hormones (fn. 319), para. 121 et seq.

368 Panel, EC – Biotech Products (fn. 113), para. 7.87 et seq. and cited literature in fn. 260 of the decision; c.f. *v. Heinegg* 2003, para. 81 et seq., *id.* 2014, § 50, para. 21 et seq., *Atapattu* 2006, pp. 281 et seq., 285, *Proelß* 2010, para. 114 et seq., *Appel* 2003, p. 173 with further references.

369 Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment, I.C.J. Reports 2010, p. 14, para. 164; c.f. *Kazhdan* 2011.

370 Seabed Dispute Chamber of the International Tribunal for the Law of the Sea, Advisory Opinion of 1.2.2011, Case No. 17, Responsibilities and Obligations of States sponsoring Persons and Entities with respect to Activities in the Area, para. 135. C.f. *Freestone* 2011.

371 Some voices, among which is the Appellate Body, EC – Hormones (fn. 319), para. 123, distinguish customary law status in international environmental law and more general in international law. However, this differentiation has no practical significance, *Atapattu* 2006, pp. 270 et seq.

372 *Sands/Peel* 2012, p. 228, *Jessen* 2012, p. 77, apparently *Freestone* 2011.

373 *Sands/Peel* 2012, p. 228.

374 As regards the „regional custom", c.f., *Sands/Peel* 2012, p. 117, *Bederman* 2010 (*footnote added*).

It can be concluded that the ITLOS notes an increasingly growing trend towards recognising precaution as part of customary international law, while the judges make no statement as to when this status is attained. Assuming, in accordance with the above-mentioned literature opinions, that the precautionary principle now belongs to the international canon of common law this would affect the interpretation of international treaties which, according to Art. 31(3)(c) VCLT, has to consider "[a]ny relevant rules of international law applicable in the relations between the parties".[375] The practical significance of this rule is, however, already limited by the fact that customary law standards are not mandatory for states who constantly and in a decisive manner object against the relevant legal rule.[376] This could mean, for example in a WTO dispute settlement procedure between the EU and a country that is considered a "persistent objector", that in doubt the former could not invoke the precautionary principle.

4.4.1.2.2.2 Consideration in the light of the TBT Agreement

The extended authorisation requirement is regularly linked to SVHC in respect of which there is scientific evidence of a hazard potential. With regard to these substances, the necessity of the technical regulation has already been *prima facie* confirmed (section 4.4.1.2.1). It is partly also linked to SVHC whose hazard potential involves scientific uncertainty (vPvBs, some reprotoxic PBTs). The "nature of the risks" and "gravity of the consequences" of these substances – in the light of the purpose of the regulation – thus have to be examined as to whether they may justify the trade-restricting effect of the technical regulation.[377] This could be the case if international environmental law provided for a certain relevance of the precautionary principle. International law does not contain a "horizontal" clause making the applicability of the principle mandatory; a conclusive determination of whether the principle has attained a customary international law binding status is also yet not possible. However, there are increasing indications that suggest the existence of such a status. Detached from this discussion, the overview in the previous section also shows the prominent importance which the precautionary principle has at international level and especially in the chemicals legislation.

Measured by the principles the Appellate Body formulated in *US – Shrimp*, the normative content of precaution therefore is also remarkable for the interpretation of Article 2.2 TBT.[378] The subject of this decision is the interpretation of Art. XX(g) GATT (conservation of exhaustible natural resources) that has to be done according to the Appellate Body in the light of the current concerns of the community.[379] With recourse to different binding and non-binding sources of international law (e.g. Agenda 21) the Chamber expands the justifications of Art. XX(g) GATT by way of an "evolutionary" interpretation which takes into account the international law developments.[380] It follows from this and from the international importance of precaution that the principle at least informs the interpretation of the environmental and health protection-

375 ITLOS 2011 (fn. 370).

376 *Bederman* 2010, p. 33 („protest loud and often"); regarding the "persistent objector" c.f. *Sands/Peel* 2012, pp. 116 et seq., *v. Heinegg* 2014, § 17, para. 25 et seq.

377 Art. 2.2 in conjunction with Recital 6 TBT, Appellate Body, US – Tuna II (fn. 169), para. 321, Appellate Body, EC – Asbestos (fn. 139), para. 167 et seq.

378 Similarly notes the *SRU* 2004, para. 126* that the „precautionary principle is now sufficiently enshrined in international law and can no longer be ignored in WTO/GATT decisions. Therefore, no fundamental legal hurdles may preclude any precaution-oriented substance control" *(authors' translation).*

379 Appellate Body, US — Shrimp (fn. 283), para. 130, Panel, EC – Biotech Products (fn. 113), para. 7.94.

380 Appellate Body, US — Shrimp (fn. 283), para. 129-131; c.f. as regards the meaning of the decision *Hilf* 2000, pp. 488 et seq., *van den Bossche/Schrijver/Faber* 2007, pp. 17, 99 et seq., *Panizzon/Arnold/Cottier* 2010, pp. 232 et seq.

related justifications under 2.2 TBT – which are systematically related to Art. XX(g) GATT – when a tested technical regulation is (partly) based on this principle.[381]

To some extent the extended authorisation requirement is linked to risk situations under uncertainty, but even in these cases it is directed against irreversible[382] and serious damage. The derivation of effect thresholds is often not possible; harmful effects therefore have to be expected at low and lowest concentrations already. Thus, the technical regulation acts exactly within the scope of application of Principle 15 of the Rio Declaration. Especially with regard to the chemical group of persistent substances with a high potential of enrichment the precautionary principle gains additional significance through concrete international legal requirements (e.g. POP Convention). With respect to the degree of certainty to be required, the technical regulation governs actual evidence-based risks, the relevance and negative consequences of which are set forth in a much more substantiated way than would be the case with regard to a control of mere "risk potentials" that would not be linked to empirically substantiated risks.[383] The risks associated with the precaution categories of Art. 57 REACH are therefore by no means insignificant.[384] This is particularly true because neither the TBT[385] nor the Appellate Body requires a minimum amount for a risk to be detected.[386]

Furthermore, the legitimate objective of the extended authorisation requirement is to ensure a high level of protection for human health and the environment by reducing the risks of SVHC.[387] The SVHC criteria addressed by the technical regulation are an expression of this level of protection, the adoption of which – according to an evolutionary interpretation of Art. 2.2 TBT in the light of the requirements of the precautionary principle – is covered by the regulatory autonomy of the Member States of the Agreement. A non-fulfilment of the normative goals would therefore – also in the case of the precaution categories of Art. 57 REACH – cause unacceptable risks. This again underscores the necessity of the technical regulation.

4.4.1.3 Conclusion regarding the risks of non-fulfilment

The necessity test with regard to the technical regulation has to consider "the nature of the risks at issue and the gravity of the consequences that would arise from non-fulfilment of the legitimate objective".[388] The TBT Agreement does not specify the risk assessment;[389] however, measured by the strict requirements in this respect of the SPS Agreement, the extended authorisation requirement meets these criteria. With respect to all SVHC categories scientific evidence of their hazard potential is available. The technical regulation is therefore only applicable to those substances which, because of their very high concern properties in the case

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381 Similar *SRU* 2004, para. 126*, 1049.

382 As regards the relevance of irreversibility c.f. Appellate Body, EC – Hormones (fn. 319), para. 124.

383 C.f. the example regarding nanomaterials in the EU cosmetics Regulation, section 1.3.2.5, as well as section 4.4.1.2.2 regarding the regulation of risk potentials in the SPS Agreement.

384 This is also supported by the preferences of private customers who are potentially the main buyers of the regulated articles and who reject articles with very high concern substances due to the inherent risks. As the Appellate Body has noted, risk assessment under SPS need to take into account those social contexts, Appellate Body, EC - Hormones (fn. 319), para. 187; c.f. the information in fn. 328. Furthermore, this case law has been used in the context of the interpretation of Art. 2.2 TBT, Panel, US - Tuna II (fn. 311), para. 7.650.

385 Canada's proposal during the TBT negotiations to link necessity to an "acceptable degree of risk" was not successful, see MTN.GNG/NG8/W/77, p. 2.

386 Appellate Body, EC – Hormones (fn. 319), para. 184-186, 194.

387 C.f. section 4.2.1.

388 Appellate Body, US – Tuna II (fn. 169), para. 321.

389 C.f. *Tietje/Wolf* 2005, p. 25, *Quick* 2008, p. 141.

of exposure, also pose a significant risk to human health and the environment. Depending on the hazard potential in the individual case this risk has to be reduced as a means of danger prevention or of precaution. Amongst SVHC are carcinogenic substances as well as persistent, bioaccumulative and toxic substances – this being an embodiment of the specific level of protection which each member of the TBT Agreement is entitled to define individually as part of its regulatory autonomy. A non-fulfilment of the regulation's objectives – first of all, the reduced exposure to SVHC, and ultimately a complete phase-out of the corresponding substances – would thus result in unacceptable risks.[390]

4.4.2 Possible alternative measures

The necessity test includes the assessment of possible alternative measures. Such a measure might be preferable compared to the extended authorisation requirement, if it

- represents a less intrusive trade-restriction,
- reaches an equal – or higher[391] – contribution to the legitimate objective and
- is reasonably available.[392]

Using these criteria some possible alternative measures are evaluated below.

4.4.2.1 Option 1: Restriction

As discussed in section 2.1.3, the restriction provided for in the legal framework is by no means as effective but less intrusive. Adopting restrictions on priority substances just because they have a specific hazard potential is not permitted. Furthermore, the introduction of such a restriction would lack a permit reservation and it would therefore not be less intrusive.

4.4.2.2 Option 2: Extension of information and communication obligations

An extension of the notification requirements regarding SVHC in articles might contribute to a better regulation of these substances. For instance a clarification in Art. 7(2) REACH as to which (part of an) article the stipulated concentration refers to would be conceivable (chapter 6). Furthermore, the conditions of Art. 7(5) REACH which must be met before ECHA may require submission of a registration dossier for substances in articles could be reduced.

These measures would indeed help to establish more transparency in terms of SVHC and thus indirectly contribute to the objectives of the technical regulation. One might therefore be inclined to ask whether the imperative effect of the authorisation requirement is necessary at all. Such considerations, however, ignore the fact that the empirically proven (section 4.2) incentive effects due to the SVHC status of a substance are less due to the conditions attached to the SVHC status in terms of information and communication requirements but are mainly based on the so-called "announcement effect" according to which the SVHC status of a substance signals its disappearance from the market in the foreseeable future due to an authorisation requirement (user perspective) or due to much more difficult marketing conditions (perspective of the substance manufacturer). Only in the overall context of the impending authorisation requirement can the identification of SVHC therefore achieve the intended effect.

The expected contribution of Option 2 to the legitimate objectives would therefore be much lower, so this is not a preferable alternative means in terms of Art. 2.2 TBT.

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390 Necessity is also confirmed by *SRU* 2004, para. 1050.

391 Panel, EC – Seal Products (fn. 181), para. 7.461.

392 Appellate Body, US – Tuna II (fn. 169), para. 320 et seq.

4.4.2.3 Option 3: Labelling requirement for imported articles SVHC

This option would not be an alternative means because it is once again to be expected that the achieved contribution to the objectives would remain below the high level of protection pursued by the technical regulation: the articles with SVHC components remain in this scenario – in the absence of an authorisation requirement without an examination of the risks – on the market and it is likely that many consumers would buy these products only because they are not aware of the label or cannot classify its meaning correctly.[393]

4.4.2.4 Conclusion regarding alternative measures

The Member States of the TBT Agreement are allowed to specify the level of protection that a technical regulation should achieve. Conversely, a violation of Article 2.2 TBT may not be derived from the fact that an available alternative means is less trade-intrusive given that this means is associated with a higher risk of non-fulfilment with regard to legitimate objective.[394] As no means is available with at least an equal contribution to the objectives, the technical regulation in this respect is also necessary within the meaning of Art. 2.2 TBT. Options 2 and 3 could meanwhile be suitable to support the extended authorisation requirement in terms of a comprehensive regulatory strategy.[395]

4.5 Conclusion: relational analysis

The extended authorisation requirement as a "technical regulation" within the meaning of the TBT Agreement is directed at imported products containing very high concern substances (SVHC) that are listed in Annex XIV. It aims to prevent the risks posed by these substances. All these substances exhibit a scientifically proven hazard potential. The risks linked to the substances may trigger the state's obligation to prevent dangers as well as to take precautionary measures while in both cases the presumption of risk is linked to actual evidence of possible (or probable) damage.

The analysis shows that the technical regulation is likely to make a contribution to its purposes which are legitimate objectives under Art. 2.2 TBT. This follows both from the technical regulation itself ("as written") as well as from the available empirical data, insofar as these make it possible to draw conclusions about the effectiveness of the existing authorisation regime.

The trade restrictions stemming from the technical regulation are further not inappropriate in relation to its legislative objectives. This follows from the fact that the procedure for inclusion of SVHC in Annex XIV is regularly accompanied[396] by a comprehensive benefit-cost-analysis in which the European Commission considers improvements to the environment and human health as well as the potential burden on economic operators.[397]

Moreover, there are no possible alternative means available which are less invasive in the trading activities from article producers and which contribute to the objectives at least to the same degree.

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393 One might consider, however, a labelling requirement for articles the SVHC of which have been authorised for use, c.f. section 6.2.1.3.2.

394 Panel, US – Tuna II (fn. 311), para. 7.467.

395 Appellate Body, Brazil — Retreaded Tyres (fn. 288), para. 211, c.f. chapter 6 for these options.

396 *European Commission* 2009b, p. 6.

397 *European Commission* 2009b, pp. 31 et seq.

The overall view of these facts therefore leads to the conclusion that the extended authorisation requirement (prohibition with permit reservation) is not more trade-restrictive than necessary in terms of Art. 2.2 TBT.

5 Conclusion: extended authorisation requirement on SVHC in imported products

In summary, the regulatory option of an extended authorisation requirement is consistent with world trade law. It would not violate the principles of national treatment and most-favored nation treatment according to Art. 2.1 TBT. Moreover, the regulation would not constitute an unnecessary trade restriction within the meaning of Art. 2.2. TBT.[398]

This result is also consistent with the key objectives of the WTO, which foresee free international commodity trading contributing to the improvement of living standards and quality of life and the protection of the environment. Precisely because of these goals trade may be subjected to certain restrictions.[399]

[398] C.f. section 2.2.3 regarding further TBT requirements concerning the implementation and application of a technical regulation.

[399] Recital 1 Marrakesh Agreement Establishing the World Trade Organization, c.f. *Winter* 2001, pp. 71 et seq., *Hilf* 2000.

6 Further options for regulating articles

While the focal point of the foregoing was the regulatory proposal of extending the authorisation requirement for SVHC to imported articles, this section will examine and review from a legal perspective more regulatory options which could be capable of strengthening the provisions in REACH on SVHC (and optionally other hazardous substances) in articles.

6.1 Assignment of tasks and procedure

The investigated regulatory options cover four main fields:

- Communication requirements under Art. 33 REACH (section 6.2);
- Obligations for substances in articles under Art. 7 of REACH and regarding registration of substances on their own (section 6.3);
- Clarification of the reference point of the 0.1 % threshold in Art. 7 and Art. 33 of REACH (section 6.4);
- Introduction of a register for articles containing SVHC (section 6.5).

As regards the first three areas, it is not only relevant to explore the option of extension of REACH, but rather to also investigate possibilities of clarifying and specifying existing requirements.

In the presentation of the additional regulatory options, as far as possible, a uniform structure will be applied for each of the four areas mentioned above:

In the first step, the background and the design of the examined regulatory option will be described under the following headings:

- Requirements under REACH;
- Overview of the state of implementation;
- Description of regulatory option: clarification, specification, extension.

The description of the regulatory option is completed by a first qualitative assessment exploring how the specific regulatory option can contribute to the achievement of the objectives set by REACH for SVHC. Worth mentioning here are the high level of protection of human health and the environment and the informed consumer decisions. Considerations on efforts and benefits of the regulatory options are included in this assessment, too.

In the second step for each regulatory option the necessary amendments are evaluated from a legal perspective. With regard to the concrete implementation of options, there are three possibilities:

- Amendments in implementing guidance,
- Implementing the option to an Annex of the legal text,
- Amend or introduce specific provisions in the legal text.

For every regulatory option the assessment analyses whether the amendment is covered by the current legal framework or needs substantial changes of the legal text. Concrete text proposals are not provided.

After having analysed each regulatory option, a comparison of the different options is given in section 6.6.

6.2 Communication requirements under Art. 33 REACH

REACH only contains few provisions with regard to the communication on substances of very high concern in articles. With regard to further hazardous properties of substances in articles, REACH gives no guidance at all. In the following, three measures which - in the light of the protection targets of the Regulation - are suitable for extending and optimising the communication on substances of very high concern and, if applicable, on further hazardous substances in articles, are presented and analysed below.

6.2.1 Background and description of the regulatory options

6.2.1.1 Requirements under REACH

With regard to the information transmission between economic actors in the value chain, Art. 33(1) REACH as it stands only provides that the supplier of an article containing a concentration above 0.1 % weight by weight of a SVHC which is included in the candidate list is obliged to "provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance."

According to Art. 33(2) REACH, the information requirement shall extend to consumers upon request. The information must be provided free of charge within 45 days of receipt of the request. The supplier, however, is not obliged to respond, if the product contains none of the SVHC in concentrations greater than 0.1 % of the article weight. This poses a problem. There appear to be two reasons for the absence of a reply: the product does not contain any SVHC, or the request was not processed.

The regulation text does not set out clearly what kind of information on the safe use of the article is sufficient. Above, no further details are provided as to the nature and the extent of this communication (unlike, for example, for registration dossiers, which must be prepared and transmitted using the IUCLID software (Art. 111 REACH) or regarding mixtures, for which the communication takes place in general with safety data sheets (Art. 31 REACH)).

According to Art. 33 REACH, the communication requirements for hazardous substances in articles relate and are limited to the SVHC included in the candidate list.

6.2.1.2 State of implementation

6.2.1.2.1 Communication along the supply chain according to Art. 33(1) REACH

Audits of law enforcement authorities[400] have shown that the flow of information about SVHC in articles along the supply chain is currently unsatisfactory in many cases. This is based on a number of reasons such as:

- Lack of administrative framework. According to the requirements in REACH, the information about SVHC in articles should be made available throughout the supply chain. Everyday practice, however, shows that is not the case. Especially in small and medium-sized enterprises, there is usually no systematic gathering and analysis of information about SVHC in purchased raw materials (here, "raw materials" is a collective term for anything that the company has purchased for their own production, including substances, mixtures, components or articles that have not undergone subsequent working or processing). This requires a corresponding in-house management system for a targeted, raw material specific

[400] *Wursthorn/Adebahr* 2013.

query in order to obtain the pertinent information from the supplier. Some of the very large industries have developed suitable internal working routines and a multi-level data documentation and processing system.[401] A uniform system, however, does not exist yet. Material data systems already in place were the starting point for expansion in order to meet the information requirements as stipulated in Art. 33 REACH. Obligations to provide information as defined in Art. 33 REACH are structurally similar to information requirements stipulated by other regulations, such as the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). In part, these regulations have been in force for a much longer period than REACH. To meet the information obligations resulting therefrom, companies have developed a number of industry-specific information and communication systems.[402] However, only few industry sectors have established a standardised structured system throughout the sector (especially the automotive sector and the electrics and electronics sector). Most of the companies applying such tools use a tool which has been specifically developed for their own enterprise.

- Insufficient reliability of information. Plausibility checks of the responses received are required depending on the reliability of the supplier. In some cases it may be necessary to carry out specially adjusted analytics on substances that are suspected - despite information to the contrary on the part of the supplier – to be contained in the purchased raw materials. This presupposes knowledge of those SVHC included in the candidate list, which are of particular importance to the enterprise.
- Safety data sheet exclusively for substances and mixtures. For SVHC substances as such, the supplier shall pass on a safety data sheet pointing to the fact that the substance concerned is a substance of very high concern. With regard to mixtures as well, the safety data sheet shall indicate whether any substance of very high concern is contained in a concentration above 0.1 % weight by weight.[403] The provision of a safety data sheet on the part of the supplier is not mandatory for articles (see below). However, suppliers are required to inform their costumers if the delivered articles contain SVHC in a concentration exceeding 0.1 % weight by weight.
- No standardised communication format for articles. For several decades now, the safety data sheet has been made mandatory as a communication tool for substances and mixtures classified as hazardous (see above). Hence, safety data sheets that have been prepared with care contain the relevant information about SVHC for communication along the supply chain, meaning that the flow of information along the supply chain functions in a well-structured manner until the mixture is incorporated into an article. After that there is the risk that the communication within the supply chain is cut short. There is no standardised communication format for SVHC in articles. A major difference between a standardised size of communication for articles and the safety data sheet for substances and mixtures would be that the required information for articles as set out in Art. 33 REACH is much more limited in

401 *Fischer* 2012, *Gottschlich* 2012.

402 For an overview see *Bunke/Jepsen/Reihlen* 2012.

403 Under REACH, the safety data sheet for substances and mixtures has been expanded in terms of content. The structure of the safety data sheet is set out in Annex II of REACH. In section 2, it must be indicated whether the substance or the mixture as such has the characteristics of a SVHC. Section 3 shall include information on the components of the ingredients, their concentrations or concentration ranges, and their hazard classification. If there are substances that meet the criteria for inclusion in the candidate list (i.e. concentrations exceeding the values indicated in Annex II of REACH, Art. 3(2)), they need to be listed here. Other sections of the safety data sheet include information about the handling of the relevant substances or mixtures.

scope than the information that must be supplied in the safety data sheet for substances and mixtures.

- Unsufficient communication as regards articles. If communication as to SVHC in articles takes place in the supply chain, it is usually a minimal communication. It is merely indicated that either there are no SVHCs or which SVHCs of the candidate list are contained in quantities greater than 0.1 % (name, sometimes CAS number). Only in exceptional cases, this information is supplemented by the level of the SVHC concentration, an indication of the specific part of the article which contains the SVHC and by information as to whether consequences thereof are to be expected in terms of allowing safe use (including safe disposal) of the article. As for complex products consisting of several individual components, it is usually not specified whether the information provided refers to the entire or to the individual component parts. For this reason, the requirement to pass on "sufficient information on the safe use" is usually not met.
  With regard to complex articles, it would furthermore be necessary to indicate whether the existence / non-existence of a SVHC in quantities above 0.1 % refer to the overall article or to individual components (in detail see section 6.4).

6.2.1.2.2 Consumer communication according to Art. 33(2)

Art. 33(2) REACH requires that certain information has to be communicated by the supplier of an article to the consumer on his request. Various surveys show that there have been – at least in the initial phase of REACH – considerable shortcomings as regards the quality of the replies.[404] A part of the replies was wrong, other replies contained meaningless phrases. Often suppliers did not respond at all.

But even if suppliers respond properly and fully to queries, the consumers' right of access in its current form is not practical. This is in particular due to the long period of 45 days that is granted to reply to requests. It is also problematic that a duty to reply to requests does not exist for articles which do not contain any SVHC. As a result, the consumer may not know whether he has not received any response because SVHC were not contained in the respective article, or because the request has not been treated.

For private consumers, standard letters (also electronically-supported) are now available to request this information.[405] They make it easier for him to submit a request to the supplier on candidate list SVHC contained in his articles. The information must be provided regardless of whether the consumer purchases the article. The BUND (German League of the Environment and the Protection of Nature) is also planning to set up a database in which companies may deposit relevant information about their articles. The request is done via a specific smartphone application that allows a direct barcode scanning of an article.[406] In Denmark such a consumer-app[407] started in April 2014. Behind the app there is a database, which is organised by the consumer council Tænk. Companies can feed information into the database and the database also collects the answers given to consumers.

The request tool and the smartphone application are isolated attempts to render the request procedure more operational. They are not available everywhere in the EU. They simplify and – in some cases - accelerate communication between private consumer and supplier. A reliable

404 *BUND* 2010.

405 See: http://www.reach-info.de/auskunftsrecht.htm.

406 *BUND* 2012.

407 See 'Tjek kemien – i dine produkter' (http://tjekkemien.dek/).

response, however, requires that the supplier himself has received reliable information relating to the occurrence of candidate list SHVC in his raw materials from his suppliers, and that the producers / importers keep their SVHC information in the database up to date. However, it may be assumed that, due to the implementation situation described in the previous section, this, in fact, is often not the case.

6.2.1.3 Regulatory options

Against the background of the just examined implementation situation, three very different approaches could be pursued to deal with the communication obligations for articles under Art. 33 REACH:

- Introduction of a standardised communication format for articles (regulatory option 1),
- Labelling requirements for SVHC (and possibly other substances) (regulatory option 2) and
- Extension of the communication requirements to other substances (regulatory option 3).

Another option that will not be further discussed in the scope of this study is the introduction of the obligation to respond to all requests on SVHC forwarded by consumers - even if the relevant articles do not contain any SVHC (see section 6.2.1.2.2). This commitment is important with respect to the functioning of the consumer's right to request information about SVHC in its present form. Currently, a consumer who has not received any reply to a corresponding query does not know whether the supplier has dealt with his request. He therefore cannot conclude that no reply means that the article does not contain any SVHC above a concentration of 0.1 %.

6.2.1.3.1 Regulatory option 1: Introduction of a standardised communication format for articles

A standardised communication format may ensure that sufficient information about SVHC will actually be provided. Depending on the addressee, "sufficient" means:

- Information about the presence of SVHC in the article or component in concentrations above 0.1 %.
- The information which the processing recipient of the component or article needs in order to identify and specify the information to be provided by him. This means: quantitative data to be able to calculate whether he exceeds the 0.1 % threshold in his articles. It is not sufficient for the producer of a piece of furniture, for example, to know that the upholstery he has processed does in fact contain SVHC. He also needs to know its concentration in order to be able to extrapolate it to the total article he produces.
- The information which is necessary to allow safe use of the article itself or safe use of the new article produced therefrom.

Information as to the second of the above mentioned points is needed by the recipient of an article downstream the supply chain. Information as to the third point is needed by both the customer in the supply chain and the private consumer. Releases of candidate list SVHC from articles may take place without intention, e.g. due to evaporation, during subsequent processing as a result of the release of dust, during repair and maintenance work. In order to achieve the protection objectives, especially in the case of such unintentional releases, it is necessary to provide information to the processors, users, or disposers. In most cases there will be ways to standardise the information to safe use (e.g. the note "Disposal in waste incineration plants,

which correspond to the State of the art."). A voluntarily usable range of such standard phrases would probably be a valuable help for many article producers and could be provided.[408]

Such a communication format for articles differs from the information content of the safety data sheet because of its extensive lower range. The function of the safety data sheet as specified by Art. 31 in conjunction with Annex II of REACH is to pass on information about the safe use of substances and mixtures. This information transmission is mandatory for industrial and commercial users. The safety data sheet includes a variety of regulations affecting various aspects such as the rules of behavior in case of fire, storage, and transport provisions. Hence, it goes far beyond the bounds of communication which "only" refers to the presence of certain substances as well as on handling and disposal measures. In order to avoid confusion, and to increase acceptance, we recommend not calling the standardised communication format "Safety data sheet for articles".

A standardised communication format can simplify and enhance the transmission of information throughout the supply chain as well as the informing of consumers. It ensures that not only the name of a SVHC included in the candidate list will be conveyed. There is no need to prescribe that the information structured in this way has to be indicated on an individual document. It could also be integrated into existing means of communication.

Recipients on the one hand are industrial and commercial producers or processors of articles to which this information must be made available by the supplier of the article pursuant to Art. 33(1). The standardised communication format, however, also supports a high quality communication with private consumers making requests in accordance with Art. 33(2) REACH.

The standardised communication format would usefully be mandatory for all articles containing SVHC that are included in the candidate list (on the possibility of an extension to other substances see section 6.2.1.3.3 below) - with regard to the threshold concentration referred to in Art. 33 REACH. In this context, it should be made clear that the threshold value for the concentration of SVHC applies to the component (in case of complex articles consisting of two or more components) (see also section 6.4).[409]

Another possible reference point, which is not being discussed at this place, would be the homogeneous material, as it is used as a basis in the RoHS directive (see also section 6.4).

The standardised communication format for articles should contain the following information[410]:

- First of all the information that the article or its components do not contain any SVHC in quantities above 0.1 %

Or, if SVHC are present:

- Name and CAS number of the substances;
- SVHC-property and classification (H statements);
- Concentration of substances and indication of where (in which part/component) they are to be found; total quantity in article;

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408 For safety data sheets standard phrases on national and European level are available.

409 The number of technical mixtures placed on the market is expected to reach several millions. It can be assumed that the number of marketed articles will exceed the quantities of existing substances and mixtures by several orders of magnitude. However, reliable estimates of the total number of articles which may contain SVHC are currently not available.

410 Regarding the communication to the private consumer particular information can be omitted in the individual case, for example the categorisation of substances.

- Consequences of presence for safe use (processing, usage, maintenance, repair, disposal, recycling);
- Reference to the function of the substances in the article (to understand, why the substance is contained in the article).

In addition, it should be clearly stated who is responsible for the information given and to which product they refer (name and address of the producer, contact person, name of the product).

A standardised communication format helps to ensure that more than just inadequate minimum information will be passed on. Accordingly, information about the exact concentration as well as the necessary protection measures would have to be communicated. Overall it is to be expected that this measure can contribute significantly to achieving the goals associated with Art. 33.

In addition, a standardised communication format supports enforcement authoritites in their controlling tasks. At present, the term "available information" – without a definition – leads to the situation, that authorities have problems to demand more than the name of the substance.

According to an initial assessment, the effort seems to be adequate, taking into account that suppliers, in several cases, have already provided technical data sheets for several articles. However, this applies first and foremost to components that are further processed. These documents might be extended to include a standard text module on candidate SVHC. The German Federal Environment Agency has developed a data entry template as a recommendation for a harmonised communication format for construction products (see Annex, Table 2). [411] Furthermore, the Federal Environment Agency has developed guidelines and an electronic support tool for communication on SVHC in articles, namely the SVHC communicator.[412]

It is expected that it will be easier to implement a standardised communication format if it can be integrated into existing information systems easily. Standardisation can also help to enable suppliers to provide responses more quickly within the 45-day period prescribed.

6.2.1.3.2 Regulatory option 2: Labelling requirements for SVHC (and, in some cases, further substances)

For the time being, there is no general duty as regards the labelling of SVHC in articles in the REACH regulation. The general labelling provisions of the CLP Regulation under Art. 4(8) only refer to articles containing explosive substances.

Two possibilities are conceivable in respect to the labelling obligation:

- Mandatory labelling requirement for all articles containing SVHC included in the candidate list above the specified threshold concentration;
- Mandatory labelling requirement for articles containing SVHC included in the candidate list above the specified threshold concentration, and for which a release (during processing, use or disposal) can be assumed.

Since, in many cases, it will be difficult to assess whether releases are to be expected throughout the entire life cycle of the article, only option 1 shall be closer considered in the following.

The labelling obligation should apply to both articles intended for private consumers as well as to (parts/components of) articles intended for industrial and commercial users.

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411 See http://www.umweltbundesamt.de/en/topics/economics-consumption/products/building-products/eu-law-for-construction-products/format-for-the-mandatory-designation-of.

412 See http://svhc-in-articles-communication.de/.

First and foremost, the labelling should specify the information that one or more SVHC included in the candidate list are contained in the article, supplemented by the names of the substance(s). Moreover, it would be useful to offer users the possibility of retrieving more information via an identification number or a barcode.

If articles are already governed by other directives as regards mandatory labelling, the already existing labelling could be supplemented by a text module on SVHC on the candidate list. Suggestions on product labelling in the context of REACH, GHS and nanotechnology have been developed elsewhere.[413]

The direct labelling on the article allows the industrial and commercial users and consumers alike to directly identify whether an article contains SVHC included in the candidate list or not. Such a labelling requirement could replace the current information scheme for consumers, which grants a period of 45 days for replies, and can therefore be considered to be not sufficiently practical. This would facilitate the choice in favor of articles that are free of these substances, which also increases the pressure to offer articles without SVHC.

6.2.1.3.3 Regulatory option 3: Extension of communication requirements to other substances

The communication duties as set out in Art. 33 relate exclusively to substances meeting the criteria of Art. 57 (a) to (f) REACH and which are included in the candidate list. Here, compliance with the criteria mentioned is not enough. The substance must be on the candidate list as well. Other obligations under REACH, however, are triggered by the sole compliance with substance-related criteria. A safety data sheet for substances is required, for example, as soon as they fulfil the criteria for PBT substances or vPvB substances (Art. 31(1)(b) REACH).

The communication duties could be extended

- by the requirement that compliance with substance-related criteria of Art. 57 REACH would be sufficient to cause communication duties - without the additional step of the substances' inclusion in the candidate list (e.g. substances meeting the criteria for harmonised classification as carcinogenic, without actually being on the candidate list);
- by including additional substances that are not covered by the criteria of Art. 57. This option is described further below in this subsection.

Communication requirements for substances with SVHC properties, which are not listed in the REACH candidate list. The first option above would support the protection objective, but only applies conveniently to those substances which allow direct identification on the basis of their classification (CMR substances Cat. 1A and 1B according to Art. 57(a) to (c) REACH). For substances listed in Art. 57(d) to (e), practical implementation is difficult since the classification system for substances does not reflect PBT and vPvB properties. It is not possible at all for those substances listed in Art. 57(f), for which the existence of an equivalent level of concern has to be identified on a case-by-case basis.

Over the next six years, all relevant SVHC shall be identified within the framework of the SVHC roadmap of the EU Commission.[414] On the basis of the established criteria, the total number of these substances is expected to be in a magnitude of about 500. At this stage there is vigorous debate on which endpoints have to be taken into account as regards Art. 57(f). As regards in particular the substances covered by Art. 57 (d) to (f) REACH, however, the roadmap 2020 will

413 *Steffensen* et al. 2009.

414 ECHA 2014.

not lead to the desired goal, since substances may only be identified after expiration of the registration period in 2018.

If it appears that the inclusion of substances with a harmonised CMR classification is quite lengthy, possibilities can be examined that communication requirements are set on the basis of such a harmonised classification – even before the substance is listed in the candidate list.

Extension of communication requirements on Non-SVHC substances. With regard to the inclusion of additional substances, a number of arguments can be put forward, such as the development of a more consistent substance law (consistency between Framework Directive on Water Policy, the Biocides Directive, and REACH) or the provision of a robust foundation of information for individuals or institutions that want to avoid certain substances.

In this respect, Art. 138 (8) REACH already foresees a review to be carried out by the Commission: "By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Art. 33 to cover other dangerous substances, taking into account the practical experience in implementing that article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation." This involves the communication about problematic substances, which, however – unlike SVHC - are not to be made subject of authorisation.

The communications requirements that are to be reviewed as foreseen in Art. 138(8) should not exclusively focus on the SVHC criteria, but also have regard to other hazardous characteristics. This is expedient, since there is a large number of substances which are classified as hazardous pursuant to the CLP Regulation (and that may chronically affect health or the environment), but which do not meet the SVHC criteria. These include for example substances which are cancerogenic, mutagenic or reprotoxic, classified as CMR-substances Category 2, and substances with H statement 410 ("very toxic to aquatic organisms, may cause long-term adverse effects").

This equally applies to substances with a sensitising effect in respiratory passages (H334) that in particular, but not in standard cases, are identified as SVHC on the basis of Art. 57 (f) REACH, or to skin sensitising substances (H317). In the long term, mandatory communication might make sense for substances possessing acutely toxic properties (e.g. substances marked H300, H310, H330 or H370), even though their presence is rather uncommon in articles. A proposal about hazard classes in accordance with CLP Regulation, classifying problematic substances, has been drawn up in the framework of a research project for the German Federal Environment Agency.[415] Information on these substances - that are no SVHC – should be passed on regardless of a possible inclusion in the candidate list or an authorisation obligation.

If the communication on substances in articles is extended on further hazardous characteristics, it has to be clarified whether a harmonised classification is required regarding these characteristics. In addition, the legal requirements for such a harmonised classification have to be assessed. At the moment, for most of the characteristics listed above only a self-classification is required.

Substances covered by other legislation, such as the priority substances under the Water Framework Directive (see directive 2008/105/EC on environmental quality standards in the field of water policy) should be communicated and identified as such as well. This would enhance the information basis about possible environmental discharges as a result of articles used, and support the achievement of the environmental objectives that have been formulated.

415 *Kalberlah* et al. 2011.

Furthermore, retailers, businesses and consumers should be informed when biocidal substances are present in articles - regardless of the product type to which these biocides belong (the communication obligations currently existing under the Biocides Regulation are only applicable if the biocidal property of the processed article was explicitly emphasised by the producer, see Art. 58(3) Regulation (EU) No. 528/2012). An extension of the communication requirements to cover all biocidal substances seems to be beneficial in the sense that these are active substances with a major impact on the environment deliberately brought about.

Since SVHC measures are the focus of this study, the extension of the communication obligations to "non-SVHC substances" will not be covered in more detail below. At the core, this will be a matter of weighting up the expense of communication on these additional substances and the benefit of the additional information that would be provided by such communication.

6.2.2 Legal analysis of the options

In this section the regulatory options described in the previous section 6.2.1.3 will be examined with regard to whether they are covered by the scope of the current European chemicals regulations and to whether they are compatible with WTO law and European fundamental rights. This refers to the following options:

- Introduction of a standardised communication format for articles (regulatory option 1),
- Labelling requirements for SVHC (regulatory option 2) and
- Extension of communication requirements to other substances (regulatory option 3).

6.2.2.1 Regulatory option 1: Introduction of a standardised communication format for articles

The regulatory option 1 (a standardised communication format for articles) should be regulated in REACH due to its systematic relationship with the existing rules for suppliers to communicate on substances in articles along the supply chain.

The following interpretation will analyse whether a standardised communication format is covered by the current legal framework or needs changes in the legal text. According to Art. 33(1) and (2) REACH any supplier of an article has to provide the recipient or the consumer "…with sufficient information, available to the supplier, to allow safe use of the article including…". This duty includes "…, as a minimum, the name of that substance". As described in section 6.2.1.2.1 in practice suppliers only inform their recipients about the name of the SVHC without any further information about the safe use of the article. Suppliers of articles may argue that in practice they only have knowledge of the name of the substance contained in their article. However, such an understanding and practice of the duties under Art. 33(1) REACH erodes the intention of the provision and runs counter to it. It is the intention of Art. 33 REACH to pass on information on the safe use of articles containing SVHC down the supply chain.[416] A systematic and teleological interpretation of Art. 33(1) REACH leads to the conclusion that suppliers have to inform their recipients about the name of the SVHC and further information that allows the recipient to use the article safely. The legal test for the extent of information to be passed down the supply chain is the "safe use of the article". The name of the substance is only a possible minimal level.[417] As a general rule the substance name is not sufficient to enable the recipient to safely use the article and therefore needs to be supplemented with further information to satisfy the content and rationale of the provision (see section 6.2.1.3.1). Rather,

[416] *ECHA* 2011, p. 21.

[417] Along the same line *ECHA* 2011, p. 21.

it follows from the principle in Art. 1(3) REACH which holds manufacturers, importers and downstream users responsible for their substances that they have to pass down the supply chain all information that is necessary to handle the article safely.[418] With that in mind suppliers of articles cannot argue that they only possess knowledge of the name of a SVHC. Suppliers themselves have to check whether they fall under the notification duty under Art. 7(2). To conduct this assessment suppliers need to know for example the total amount or concentration of SVHC in their article in order to calculate whether the amount of SVHC in their articles is more than one tonne per year.

Moreover, unintentional or intentional violations against the notification duty according to Art. 7(2) REACH are a public offence that is prosecuted according to the law of the Member states (for example in Germany according to § 6 Nr. 1 ChemSanktsV[419]). Element of an offence according to § 6 Nr. 1 ChemSanktsV is that one misses to notify articles containing SVHC or the notification is not correct, not complete or not in due time.

Against the background of the legal interpretation given above regulatory option 1 is covered by the current legal content of Art. 33(1) REACH. A way to clarify the duties is to implement a new Annex XVIII "Standardised communication format for articles". This new Annex XVIII should include a list of all information that a recipient needs for the safe use of articles containing SVHC, i.e.:

- First of all the information that the article or its components do not contain any SVHC in quantities above 0.1 %

Or, if SVHC are present:

- Name and CAS number of the substances;
- Concentration of substances and indication of where (in which part/component) they are to be found;
- Consequences of presence for safe use (processing, usage, maintenance, repair, disposal, recycling);
- Reference to the function of the substances in the article (to understand, why the substance is contained in the article).

Because regulatory option1 can be implemented in the current legal framework, we conclude that it is compatible with International and European trade law.

6.2.2.2 Regulatory option 2: Labelling requirements for SVHC

Starting point for the legal assessment of regulatory option 2 (labelling requirements) is an obligatory labelling of articles containing SVHC. Environment or health-healh related product labels can be found in various product groups and have the purpose to inform about product characteristics.[420] To this aspect the labelling is intended to inform about the presence of SVHC in an article in the following way: "Contains SVHC: [name of the substance], [link to further

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418 *Führ* 2011, chapter 1, para. 47 et seq.

419 Chemikalien-Sanktionsverordnung from 24.4.2013 (Federal Gazette I, p. 944), last amended by Art. 6 of the law from 23.07.2013 (Federal Gazette I, p. 2565).

420 Obligatorylabelling of products can be found frequently with respect to chemical substances and mixtures. Moreover, for certain product groups like household appliances and batteries obligatory labelling exists. Further labelling categories cover „conformity marking" which marks the conformity of a product with legally defined product requirements (for example the CE-Conformity marking) as well as „Content declarations" that inform about the composition of foodstuffs or cosmetics.

information]". However, it is still open where the labelling should be placed, for example on the article itself, on the packaging or in the instruction leaflet.[421]

Regulatory option 2 can be implemented by introducing a labelling duty in product-related regulations. Based on the assumption that there are plenty of product groups containing SVHC, a labelling duty would require that the legislator gains knowledge of the relevant product groups. Subsequently, labelling provision must be introduced into existing product regulations and if no product regulation exists a new regulation covering the labelling duty must be set up. The legislative effort to introduce product specific labelling provisions seems to be remarkable and runs the risk to miss products containing SVHC.

Consequently, the implementation of a labelling duty focuses on the REACH and the CLP Regulation. REACH does already contain provisions regarding the registration and notification of articles containing SVHC as well as obligations to inform the supply chain and the consumer. CLP Regulation covers specific rules for labelling and packaging of substances, mixtures and articles.

The purpose of both regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances, mixtures and articles (see Art. 1(1) CLP Regulation and Art. 1(1) und (2) REACH). Moreover, both regulations contain an identical definition of articles (cf. Art. 2 No 9 CLP Regulation and Art. 3 No 3 REACH). The extension to which articles are regulated under REACH does not encounter substantial limitations besides minimum criteria for the registration and notification of substances in articles (for example the substance must be present in the articles in quantities totalling over 1 tonne per producer or importer per year). In contrast to REACH so far the CLP Regulation does only cover some product groups, i.e. "explosive articles", "articles which are manufactured with a view to producing a practical, explosive or pyrotechnic effect" (cf. Art. 4(8) in connection with Annex I section 2.1 CLP Regulation). However, the purpose of the CLP Regulation in Art. 1(1) allows to extend the labelling requirements to further products groups as long as they are not excluded from the scope of the regulation according to Art. 1(2) CLP Regulation, like medicinal, veterinary or cosmetic products. To achieve this aim articles containing SVHC have to be included in Annex I Section 2.1 of the CLP Regulation.

Furthermore, it has to be examined whether the current CLP Regulation can transport the information requirements listed in regulatory option 2. According to regulatory option 2 the labelling shall inform recipients of articles and consumers about the fact that a SVHC on the candidate list is present in an article and the name of that SVHC. Additionally recipients and consumers shall have the opportunity to get further information on SVHC present in the article with the help of an identification number or barcode on the article.

It must be noted, that at present the CLP Regulation does not contain means to label an article in a rather general way as "Containing SVHC" (cf. Art. 17 ff. in Title III of the CLP Regulation). But the CLP Regulation does cover the classification and labelling of CMR-substances which are germ cell mutagenic, category 1A and 1B (Annex I, Section 3.5), carcinogenic, category 1A and 1B (Annex I, Section 3.6) or reproductive toxic substances, category 1A and 1B (Annex I, Section 3.7). So far the CLP Regulation provides no classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, but attention should be drawn on the fact that it was the intention of the historical legislator to regulate classification and labelling of those substances depending on the development of harmonised criteria at UN level (cf. Art. 53(2) CLP Regulation and Recital 75 of

[421] In this context reference should be made to a hazard labelling for products with carcinogenic substances or with substances toxic for reproduction according to the Californian Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986), see: http://www.oehha.ca.gov/prop65.html (as from 18.11.2014).

the CLP Regulation). Due to the fact that only a selection of identified SVHC is on the candidate list and not all substances which fulfil the SVHC criteria and furthermore an equivalent concern according to Art. 57(f) cannot be systematically integrated into the CLP Regulation, a direct reference to the candidate list would be helpful to determine the substances to which the labelling requirement applies.

Because REACH does already contain criteria for the identification of PBT and vPvB (cf. Art. 57(d) and (e) in connection with Annex XIII REACH) it appears obvious to implement an obligatory labelling for articles containing SVHC in REACH. However, from a systematic point of view that would be misleading. Intrinsic properties of substances are determined according to REACH whereas the classification and labelling follows the harmonised rules of the CLP Regulation. As a consequence REACH does not have any classification and labelling provisions but refers to the CLP Regulation. [422] To introduce a regulation regarding the labelling duty subsequently to Art. 33 would have the advantage to directly refer to substances on the candidate list.

It remains to be assessed whether recipients or consumers can get access to further information on SVHC present in the article with the help of identification numbers or barcodes. Labelling categories of the CLP Regulation are "hazard pictograms", "signal words", "hazard statements" as well as "precautionary statements" addressing for example the storage and disposal of the substance. This information may be especially important for the recipients of articles. For consumers it will be helpful if the product packaging contains a link to further information. In this respect the CLP Regulation itself mentions the link between packaging information in Recital 41: "To ensure proper and comprehensive information provision to consumers on the hazards and safe use of chemicals and mixtures, the use and dissemination of Internet sites and free phone numbers should be promoted, particularly in connection with information provision on specific types of packaging."

As a result, the first variant would be to implement an obligatory labelling for articles containing SVHC in the CLP Regulation. However, as a precondition for the option is that criteria for the classification and labelling of substances as PBT and vPvB are introduced to the CLP Regulation which should be preferably harmonised on the international level. Moreover, the scope of articles covered by Art. 4(8) CLP Regulation needs to be extended. An alternative option is to introduce the labelling obligation for articles containing SVHC in REACH, for example in Art. 33 REACH. The close linking of the labelling issue to the substances on the candidate list speaks in favour of this option. Another regulatory option is to enact a separate regulation with a cross-product obligatory labelling for all articles containing SVHC.

6.2.2.2.1 Compatibility with WTO law

An obligatory labelling is to be classified as a "technical regulation" according to Art. 1.2 in connection with Annex 1 No 1 TBT Agreement[423] (for further details see the remarks in section 2.2.2.1.2). It must be pointed out that the controversial issue whether the TBT Agreement applies not only to product-related labelling rules but to production-related labelling issues, too, is not relevant for this study. Since the TBT Agreement applies to labelling if there are traces of

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422 Cf. the meanwhile deleted referene to the CLP Regulation in Art. 115 REACH in the version from 18.12.2006, OJ. L 396, 30.12.2006, p. 1.

423 "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

a substance in the final product resulting from the use of this substance in the production.[424] As the duty to label SVHC is linked to the presence of a SVHC in the final product it cannot be classified as as sole production-related labelling.

Consequently, the implementation of the regulatory option 2 must be compatible with the TBT Agreement. More precisely, an obligatory labelling for articles containing SVHC introduced on EU-level shall not violate the national treatment and most-favoured nation treatment obligations of Art. 2.1 TBT or in case of a violation it must be justified by legitimate objectives like common interests to protect human health and the environment. For the examination of this question reference is made to the result of the legal examination of an extended authorisation requirement in section 2.2.3 et seq. This is due to the fact that the obligatory labelling addresses the same legal matter like an extended authorisation requirement but at the same time is less trade ristrictive. For the obligatory labelling, too, doubts remain whether imported articles and domestic article containing SVHC are like products with the consequence that the national treatment and most-favoured nation treatment obligations are not violated. But even if they are like products an obligatory labelling does not constitute a legal or de facto discrimination against imported products (see section 3.2 et seq.). As a matter of fact the labelling duty applies to imported and domestic articles containing SVHC equally.

Furthermore an obligatory labelling does not constitute an unnecessary obstacle to international trade under Art. 2.2 TBT Agreement. Technical regulations that are more trade-restrictive than necessary to fulfil a legitimate objective are prohibited according to Art. 2.2. TBT Agreement. The labelling of imported and domestic articles containing SVHC alike has the purpose to improve existing, but deficient, information requirements of producers and importers to their recipients and consumers. Recipients and consumers shall receive information on SVHC present in articles without delay.

Finally, an obligatory labelling has to be necessary to fulfil the legitimate objective. In that regard it must be noted that a scientific risk assessment is not an essential prerequisite to state the necessity of a labelling duty.[425]

The trade restrictive effect of an obligatory labelling can be classified as between an extended authorisation requirement and the existing information duties according to Art. 33 REACH. On the one hand a labelling duty will affect the trade with articles containing SVHC more severely than existing information duties. This is amongst others due to the fact that manufacturers of those articles will have to bear the costs for the labelling. On the other hand the existing obligation to provide information according to Art. 33 REACH is not equally suitable to inform recipients of articles and consumers about SVHC contained in articles as an obligatory labelling. So far suppliers of articles containing SVHC only had to respond to information requests of consumers (Art. 33(2)) on demand. If no consumer is demanding information on the presence of SVHC in an article recipients and suppliers have less incentives to inform themselves about SVHC in their articles. A labelling duty will increase the pressure for all actors to receive information about the presence of SVHC in their articles. With a view to consumers the labelling instrument will enable them to get information on SVHC in articles on the point of sale. Compared with an extended authorisation requirement or a restriction of articles containing SVHC the labelling duty does not examine or ban the trade with those articles and therefore is less trade restrictive than those instruments.

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424 *Lell* 2003, p. 190.

425 Cf. *Lell* 2003, p. 304; With an opposite legal position the United States of America, see: *Streinz* 1998, p. 265, 286 (FN 110a).

As a result a labelling duty does not constitute an unnecessary obstacle to international trade and is compatible with the TBT Agreement.

6.2.2.2.2 Compatibility with the freedom to conduct a business

Regulatory option 2 is based on the assumption that the obligatory labelling of SVHC in articles is introduced on the EU level. It has to be assessed whether an obligatory labelling is compatible with the freedom to conduct a business protected according to Art. 16 of the Charter of Fundamental Rights of the European Union (CFR). This basic freedom is violated if the obligatory labelling of SVHC in articles interferes with the protected sphere of that freedom without justification.

6.2.2.2.2.1 Protected sphere

The freedom to conduct a business protects the exercise of an economic or commercial activity intended to have a certain duration and remuneration.[426] The protected sphere covers not only the freedom to exercise an economic or commercial activity but also the freedom of contract and free competition.[427] Companies who produce articles containing SVHC and put them on the market fall within the material scope of that fundamental right, because aim of their economic activity is to earn money with their products.

The personal scope of Art. 16 CFR covers business activities of legal and natural persons.[428] Similar to the definition of „undertaking" according to Art. 101 TFEU that covers all entities engaged in commercial activity for the provision of goods and services.[429]

As a general rule, producers, distributors or importers of articles containing SVHC are natural persons or legal persons governed by private law. As such they fall within the protected sphere of Art. 16 CFR and can rely on that fundamental right.

6.2.2.2.2.2 Violation of the fundamental right

The duty to label articles containing SVHC does violate the freedom of producers and importers of those articles to conduct their business, if the labelling aims at a disadvantage on their business activities (e.g. an import ban) or has a direct effect on them.[430] Therefore all measures must be classified as interventions which have "sufficient direct and significant impact on the freedom to conduct a business".[431] The ECJ has already ruled that the description and presentation of products constitutes an intervention to Art. 16 CFR.[432] The duty to label the content of SVHC in articles either in the ingredient list or on the product (e.g. "contains SVHC") regulates the description and presentation of products. Thus regulatory option 2 interferes with the freedom to conduct a business protected in Art. 16 CFR.

6.2.2.2.2.3 Justification of the violation

The violation is justified if it complies with the principle of proportionality. Any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law.

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426 *Jarass* 2013, Charta der Grundrechte der EU, Art. 16 Rn. 7.

427 ECJ, C-283/11 – Sky Österreich, 22.1.2013 Rn. 42.

428 *Ruffert* 2011 in: Calliess/Ruffert, EUV/AEUV, Art. 16 Rn 16.

429 *Callies* 2011 in: Calliess/Ruffert, EUV/AEUV, Rn 27.

430 ECJ, C-200/96 – Metronome, Reports of Cases 1998, I-1953 Rn. 28; *Jarass* 2013, Charta der Grundrechte der EU, Art. 16 Rn 13 ff.

431 ECJ, C-435/02 – Springer, Reports of Cases 2004, I-8663 Rn. 49.

432 ECJ, C-306/93 – Winzersekt, Reports of Cases 1994, I-5555 Rn. 24; C-234/85 – Keller, Reports of Cases 1986, 2897 Rn. 9.

The European Court of Justice has explicitly recognised "protection of the environment"[433] and "health protection" as legitimate objectives. The high level of protection of human health is protected according to Art. 35 CFR and has been recognised as a legitimate objective.[434] It is the purpose of an obligatory labelling for articles containing SVHC to give consumers the possibility to avoid buying those articles and thus avoid the exposition to SVHC. In this way the labelling contributes to the legitimate objective to achieve a high level of health within the population.

According to Art. 52(1) CFR each restriction to right stipulated in Art. 16 CFR must be appropriate to ensure the attainment of the objective pursued;[435] for this purpose it is enough if the measure contributes to reach the objective pursued.[436] The labelling duty for articles containing SVHC is suitable to contribute to a high level of protection of human health and the protection of the environment. Due to the labelling it is transparent for consumers which articles do contain SVHC and which do not, thus consumers can avoid buying articles containing SVHC and consequently avoid being exposed to SVHC contained in those articles. Additionally, a lower demand for articles containing SVHC will have an impact on the use of SVHC which benefits the environment.

Moreover, violations are only justified if they are necessary to achieve the legitimate objective. In this context the following ruling of the ECJ is worthwhile to notice: An obligation to provide customers with the exact indication of the ingredients of a feeding stuff impacts seriously the economic interests of producers as it obliges them to disclose the formulas for the composition of their products.[437] However, this ruling would be only applicable to the labelling of articles containing SVHC if the labelling required to disclose the whole composition of such an article. On the contrary regulatory option 2 does only require labelling an article if and as long as it contains SVHC. Therefore the labelling is not more restrictive in substance and time than necessary.

When there is a choice between several appropriate measures recourse must be made to the least onerous with regard to substance and time.[438] It shall not be possible to replace the measure with others, less restrictive measures which attain the same result and do not place a heavier burden on third parties or the general public.[439] It is apparent that less restrictive measures would not achieve the objective to inform consumers about products containing SVHC as effectively as an obligatory labelling of those products. In fact, the current consumers´ right to information according to Art. 33(2) REACH would be less burdensome for the manufacturers and importers of those articles, because it does not cause labelling costs and is expected to have less adverse impact on the sale of products containing SVHC. But the current legislation does not achieve the same result regarding the legitimate objective (see the arguments in section 6.2.1.2.2 and 6.2.1.3.3) and therefore does not constitute the necessary measure.

The same appears to be true for a public register for articles containing SVHC (for details on that regulatory option see section 6.5) which will cause administrative costs for manufacturers and importers to notify their products and will have adverse impact on the sale of products if the information on products containing SVHC is publically available.

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433 ECJ, C-240/83 – ADBHU, Reports of Cases 1985, 531 Rn. 13.

434 *Jarass* 2013, Charta der Grundrechte der EU, Art. 16 Rn 20.

435 ECJ, C-283/11 – Sky Österreich, 22.1.2013 Rn. 50.

436 ECJ, C-280/93 – Deutschland/R, Reports of Cases 1994, I-4973 Rn. 86.

437 ECJ, C-453/03 – Fratelli, Reports of Cases 2005, I-10423 Rn. 83.

438 ECJ, C-184/02 – Spanien/P, Reports of Cases 2004, I-7789 Rn. 57.

439 ECJ, C-283/11 – Sky Österreich, 22.1.2013 Rn. 50.

Furthermore the labelling duty does create less economic burden for the producers and importers than a complete ban of those products.

Finally, the labelling duty must be proportionate, which is the case if the disadvantages caused is not disproportionate to the aims pursued.[440] To this aim the more important the legitimate objective to be followed by a measure is, the more an interference with the freedom to conduct a business can be justified.[441] This means in our case that the disadvantages from labelling which an entrepreneur has to bear have to be balanced with the pursued aim to achieve a high level of protection of human health and protection of the environment. The labelling duty for articles containing SVHC does not restrict the production and distribution of those products, but demands information on the product content. Thus it does not violate the very substance of the freedom to conduct a business. However, an obligatory labelling pursues the important objectives to achieve a high level of protection of human health stated in Art. 35 Sentence 2 CFR and the protection of the environment. As a result the disadvantages for producers of articles containing SVHC are not disproportionate to the aim of environmental and human health protection.

6.2.2.2.2.4 Result

As a result of the legal assessment a labelling duty for producers and importers of articles containing SVHC is compatible with the freedom to conduct a business. In fact the labelling duty interferes with the protected sphere of the freedom to conduct a business, but is justified with preventive health protection and the protection of the environment. With respect to the validity of that result it should be pointed out that the European Court of Justice leaves the legislator with wide discretion regarding interventions with the freedom to conduct a business. Only then an intervention is not justified if the measure is obviously not suitable or not necessary.[442]

6.2.2.3 Regulatory option 3: Extension of communication requirements to other substances

Regulatory option 3 - extending the communication duties in Art. 33 REACH to other substances - will exceed the level of protection envisaged with the REACH regulation. Because according to Art. 33 REACH the communication duty covers only SVHC on the candidate List. This legal assessment is in line with the opinion of the EU Commission stated in in Art. 138(8) REACH, according to which the Commission is obliged to review whether or not the scope of Art. 33 REACH shall be extended by 1 June 2019. If appropriate the Commission will then present a legislative proposal to extend that obligation.

It needs to be noted that an extension of the communication duties of Art. 33 REACH to other substances than mentioned in that Article is not covered by the current legal framework of REACH and requires a change in the legal text of REACH.

6.3 Obligations for substances in articles pursuant Art. 7 REACH and regarding registration of substances on their own

Art. 7 REACH stipulates the requirements for the registration and notification of substances in articles for producers and importers of articles. These obligations only become effective, when several conditions are met. The issue here is not only tonnage and concentration thresholds, but

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440 ECJ, C-283/11 – Sky Österreich, 22.1.2013 Rn. 50.

441 ECJ, C-84/95 – Bosphorus, Reports of Cases 1996, I-3953 Rn. 23; C-183/95 – Affish, Reports of Cases1997, I-4315 Rn. 42; C-317/00 – Invest, Reports of Cases2000, I-9541 Rn. 60.

442 ECJ, C-280/93 – Deutschland/R, Reports of Cases1994, I-4973 Rn. 90; C-306/93 – Winzersekt, Reports of Cases1994, I-5555 Rn. 21, 27; C-44/94 – Fishermen's Organisations, Reports of Cases1995, I-3115 Rn. 58.

also the question of whether releases are intended, foreseeable, or critical, and whether the use in the article(s) has already been considered during the registration by the manufacturer (respectively importer) of the substance. In this respect, very different starting points for strengthening the requirements on substances in articles are to be found in Art. 7 REACH.

When assessing the importance of this article, it has to be noted that Art. 7 REACH expressly addresses producers or importers of articles. In addition to the producers and importers of articles, there are two more groups of actors who can also be obliged under REACH to evaluate the conditions of use of substances used in articles: manufacturers and importers of the substances themselves, and downstream users of these substances.

First and foremost, manufacturers and/or importers of substances are responsible for the registration of substances used in articles. Furthermore, downstream users using substances in articles differently from the conditions of use described in the exposure scenarios communicated by the substance manufacturer or importer, are obliged to evaluate these uses in their own chemical safety report (Art. 37(4) REACH). In addition, they have to inform the European Chemicals Agency on these conditions of use.

Which information in detail has to be submitted by the different actors is specified in the context of the REACH legislation and appended guidance documents at various places. Specific information requirements are dependent of the production or import volume of the examined substance.

- Substance manufacturers and importers: Manufacturers and importers of a substance that is subject to registration must submit a registration dossier. The corresponding data requirements are quantity-dependentdependend and described in the articles 6, 10, 11 and 12. Above a production / import quantity of 10 t/a, a chemical safety report has to be prepared (Art. 14). This is crucial for the issue investigated in this study, since in the chemical safety report the safe use of substances has to be described in exposure scenarios. The structure and content of the exposure scenarios are set out in Annex I (Section 0.7, 0.8 and 5) under REACH and the associated ECHA guidance documents on information requirements and chemical safety assessment.[443] The chemical safety report covers the entire life cycle of the substance. If the substance is used in an article, the actual use (including conditions of use, processing, and disposal of the article) must be considered by the manufacturer/importer of the substance (not of the article!) within the framework of the registration.
- Downstream users: it may occur that a downstream user uses a substance differently from the use described by the registrant of the substance in his exposure scenarios. In these cases, the downstream user under Art. 37(4) of REACH will usually be required to submit his own chemical safety report. This also applies to the case that the downstream user uses the substance in an article. The information requirements for the preparation of a chemical safety report by downstream users are set out in Annex XII. Here, reference is also made to exposure scenarios according to Annex I.
- Producers and importers of articles: They have to submit a registration dossier for substances that are present in their articles under the conditions stipulated by Art. 7(1) (intended release from an article). The requirements to be met by the registration dossier have been set out in the Art. 6, 10, 11, 12 and 14 and in the Annexes I and VI.

[443] These guidelines are available at http://echa.europa.eu/de/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

The following text is concerned with the obligations of producers and importers of articles under REACH in accordance with Art. 7.

6.3.1 Background and description of regulatory options

6.3.1.1 Requirements in REACH

With regard to the key issue under investigation, the Paragraphs 1, 2, 5 and 6 of Art. 7 are of particular relevance.

- Art. 7(1), registration of substances in articles to be submitted by producers or importers of the article, states that the registration for any substance contained in an article only has to be submitted by the producer or the importer of the article if certain conditions are met:
    - If the substance is present in those articles in quantities totaling over 1 t / a / producer or importer;
    - If the substance is *intended* to be released under normal and reasonably foreseeable conditions of use;
    - If the substance has not already been registered for that specific use (Art. 7(6) REACH).
- Art. 7(2), notification to the Agency on the part of the producer or importer of the article. An obligation of notification applies to SVHC substances included in the candidate list,
    - If the substance is present in those articles in quantities totaling over 1 t / a / producer or importer;
    - If the substance is present in those articles above a concentration of 0.1 % weight per weight (w/w)
    - If the substance has not already been registered for that specific use (Art. 7(6) REACH);
    - If an exposition during the application and disposal cannot be excluded (Art. 7(3) REACH).
- Art. 7(5): This article enables the European Chemicals Agency to request, in justified individual cases, a separate registration for an included substance from the producer or importer of the article. Here, too, a set of conditions have to be met:
    - If the substance is present in the article(s) in quantities totaling over 1 t / a / producer or importer;
    - If there are grounds for suspecting that the substance is released from the article(s);
    - If there are grounds for suspecting that the release presents a risk to human health or the environment;
    - If no registration is required pursuant to Article 7(1)
    - If the substance has not already been registered for that specific use (Art. 7(6) REACH);
- Art.7(6): This article stipulates that the obligations set out in article 7(1) to (5) do not apply, if the corresponding use of the substance in an article has already been taken into account

by the producer or importer of the substance in his registration. Registration by the producer of the substance is regulated by Art. 6, 10, 11, 12 and 14 of REACH and Annexes I and VI.[444]

Art. 7(6) shall release the producer or importer of an article from the registration obligations described in Art. 7(1) and from the notification requirements described in Art. 7(2) – provided that he is able to demonstrate that his use has already been registered by the substance manufacturer. This proof requires that the uses that were considered in the framework of the registration by the substance manufacturer shall be described in adequate detail. In the following, we will therefore briefly describe where such information has to be indicated in the registration dossier of the substance manufacturer.

In addition, we will explain the "use descriptor system" which is used for such indications.

Information on the use submitted in the registration dossier: information on the use is to be provided in three different sections of the registration dossiers by the producer of the substance.

- In the technical dossier in accordance with Art. 10(a)(iii) REACH in conjunction with Annex VI, Section 3.5 (for all registered substances, regardless of the production or import volume). In this context, only a brief general description on the use(s) is required. In addition, the production process of the article should be shortly described (Annex VI, Section 3.2). Furthermore, the quantity in which the substance is present in the article and which the producer communicates to the downstream user is to be indicated (Annex VI, Section 3.4).
- In Part B, Section 2 of the chemical safety report according to Annex I REACH. This report is required for registered substances with a production / import volume of above 10 t/a. Here, too, only a brief general description of all identified uses is required.
- In the exposure scenarios (Part B, Section 9 of the chemical safety report according to Annex I REACH) - they are mandatory as part of the chemical safety report for registered substances with a production / import quantity of above 10 t/a per producer / importer. As for the exposure scenario, very precise information is required to prove that the use of the substance is safe.

The respective information on the use provided in this three sections should be mutually consistent.

The use descriptor system: a system which is made up of 5 parts has been developed for the description of the safe use(s) in the framework of exposure scenarios ("use descriptor system")[445]. The five elements characterise the sector where the use takes place ("sector of use"), the process in which it is used ("process category") and the mixture, in which the substance is used ("product category"), or the article, in which the substance is used ("article category"). Moreover, it has to be indicated in what amount releases into the environment could occur ("environmental release categories").

This system should only enable to outline an initial characterisation of a use. It shall, however, be applicable to all uses in all industries - with a limited number of categories. To this aim, the scope of the categories need to be sufficiently broad. Accordingly, all plastic articles and all electronics applications, for example, are covered by only one article category in each case.

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444 These exemptions and the related conditions are well described in the Guidance on substances in articles (*ECHA* 2011).

445 *ECHA* 2010.

The use descriptor system was originally developed for the exposure scenarios, which are part of the chemical safety assessment. There is a first indication at the beginning of the exposure scenarios, as to which use will be described more accurately in the following sections of the exposure scenarios. If possible, the use descriptor system should, however, also be used for the brief general description of the uses in the technical dossier and in Section 2 of the chemical safety report.

The information from the use descriptor system alone is not sufficient to describe a safe use in the exposure scenario. For this purpose, further information is required. With regard to substances in articles, this may be information on a possible release from the article, for example. These data are collected and evaluated (for substances classified as hazardous) in the course of substance registration for the chemical safety assessment. The so-called exposure scenario thus contains the information required for a description of the safe use of the substance. These exposure scenarios are the basis for the risk characterisation. In the context of the use(s) of substances, it is necessary to assess the possibilities of contact with the substance through the skin and the potential release of the substance from the article. [446]

The exposure scenarios are also passed on to the supply chains in the form of annexes to the extended safety data sheet of the substance.

6.3.1.2 State of implementation

There are no data on registration dossiers transmitted by producers or importers of articles pursuant Art. 7(1). It may, however, reasonably be assumed that for substances which are intended to be released from articles, the use in the article has generally already been registered by the manufacturer or importer and that therefore no registrations are required under Art. 7(1).

Notifications pursuant to Art. 7(2) are evaluated by the ECHA and regularly published (usually twice per year). In February 2014, there were 318 notifications, many of which referred to a few widely used plasticizers and flame retardants.

So far, the agency has not use the possibility to request a registration dossier on substances in articles according to Art. 7 (5).

Art. 7(6) refers to cases where the specific use of a substance in an article has already been registered by the manufacturer of this substance.

Here two aspects are relevant. How can the producer of an article assess whether the use of a substance in an article has already been registered by the manufacturer of the substance? Does a registration dossier generally g contain enough information in this respect?

According to the ECHA Guidance on substances in articles, there are two conditions which have to be fulfilled:[447]

- the substance is the same as the substance which has been registered;
- the use under consideration is the same as one of the uses, which are described in an already existing registration of this substance.

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446 The methodological approach concerning the chemical safety assessment on substances in articles is described in the guidance documents on information requirements. The procedure of estimating the consumer exposure to substances in articles is specified in part R15 of these guidelines (*ECHA* 2012b).

447 *ECHA* 2011.

The first point concerns the issue of substance identity, for which conformity of both substances in terms of name and the EINECS or CAS numbers is not always sufficient, but where reference is made to the additional requirements set out in the ECHA guidance documents on the substance identity.[448]

As regards the comparable use, ECHA in its guidance documents outlines the following determination criteria:[449]

- the function of the substance in the article (such as pigment, flame retardant),
- the process, by means of which the substance is incorporated into the article, and
- the type of article into which it is incorporated.

The registrant is required to provide the aforementioned information in accordance with the ECHA guideline on the above-described use descriptor system. As a matter of precaution, however, ECHA states explicitly (highlighted in bold type) that the producer of an article must describe its use more accurately than it can be done by means of the elements of the use descriptor system, if he wants to take advantage of the exception provided for under Art. 7(6) REACH.[450] Furthermore, ECHA recommends to the producer of the article to consult - as sources of information about the substance - the safety data sheets, the company Web page of substance suppliers or the ECHA database for registered substances[451] in order to determine whether a specific use of the substance has already been registered.[452] At this point of the guideline, it is again stressed that the descriptor system alone is not sufficient to prove that the use has been considered by the manufacturer of the substance in his registration.

The fact that a specific use of a substance in an article has been taken into account upon registration by the manufacturer of the substance, pursuant to Art. 7(6) releases the producer of the article from his registration and notification obligations under Art. 7(1) and 7(2). For many substances, the use in the article has been registered by the substance manufacturer from a purely formal point of view. The results from the analyses of exposure scenarios outlined in registration dossiers[453] show, however, that exposure scenarios relating to releases of substances during the use phase of articles usually not exist. Accordingly, such information is also missing in the safety data sheets available on these substances in the supply chains (it has to be noted that it is obligatory to include informative exposure scenarios in the chemical safety assessments according to Annex I of REACH (see section 6.3.2.2)). In consequence, this means that the producer of an article is generally not able to verify whether his use of the substance in his article has already been registered by the producer of the substance.

6.3.2 Regulatory options

Given the existing legal obligations and state of implementation practices, in the following section we will depict two regulatory options relating to the registration requirements for substances in articles pursuant to Art. 7(1) REACH as well as the notification obligations pursuant to Art. 7(2) REACH in connection with Art. 7(6) REACH:

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448 *ECHA* 2011, p. 34.

449 *ECHA* 2011, p. 34.

450 *ECHA* 2011, p. 35.

451 The following link can be used to identify registered substances in the ECHA database: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances (as from 20.7.2014).

452 *ECHA* 2011, p. 36.

453 See *Eurostat* 2012, for example.

- The registration requirement for substances in articles as defined in Art. 7(1) is currently limited to substances intended to be released. Therefore, one way of strengthening the rules for substances in articles is to extend the registration requirement on substances, the release of which on the article's path of life is not intended, but foreseeable due to its material properties and its presence in the article (option 4).
- In view of Art. 7(6), but referring to Annex VI and Annex I (and in this case especially to the preparation of exposure scenarios), another option could be the clarification of the data / information requirements that have to be met if a substance shall be deemed to be registered for use in an article (option 5).

The possibility to propose an amendment of Art. 7 (2) REACH in order to lower the tonnage threshold (> 1 tonne / year) or the concentration limit (0.1 %) laid down in this paragraph will not be investigated in greater detail, since it might be reasonably assumed that such a change presupposes an extensive discussion process on the European level.

In addition, it will not be further investigated to delete exemptions which are currently possible due to Art. 7(6) REACH. As described above, the obligation of the producer or the importer of an article to register or to notify - in accordance with Art. 7(1) and 7(2) - substances that are present in this article, is waived, if this use has already been taken into account by the producer of the substance in the registration of the substance. It can be assumed that this is the reason that currently only few registrations or notifications of substances in articles are submitted by the producer or the importer of an article in practice.

If the derogations according to Art. 7(6) would not exist, producers and importers of articles would be required to submit more registrations and notifications of substances in articles to the European Chemicals Agency. However, it is not necessary to indicate the name of the article, neither for registration under Art. 7(1) nor for notification under Art. 7(2). (Art. 7(4) identifies the information that is required for notification in accordance with Art. 7(2). The information required under Art. 7(4) do not allow identification of individual SVHC-containing articles). Presumably, only already known substance-related information would be reproduced as a result of the above-mentioned amendments in Art. 7(6). However, the focus should be on the objective of improving the quality of the existing information flow in order to achieve the protection goals set out by the REACH regulation.

6.3.2.1 Regulatory option 4: Extension of the registration requirements to unintended release

According to Art. 7(1) REACH, a producer or importer of articles only has to submit a registration dossier for a substance contained in an article, if this substance is intended to be released under normal or reasonably foreseeable conditions of use. By virtue of being limited to intentional releases (such as with fragrances in articles), the registration obligation does not apply to substances which are unintentionally released. Such substances may be plasticizers or solvents, for example. Another example is plastic additives, the release of which to the environment occurs as a result of foreseeable abrasion.

In order to strengthen the requirements for substances in articles, the registration obligations set out in Art. 7(1) could be extended to such substances that may reasonably be expected to be released, even though such a release is not intended.

Two factors should be considered in the assessment of this option, i.e.:

- the option of ECHA to request additional registrations for substances in articles;
- the possibility of waiving registration of the use of the substance in the article, if the substance manufacturer has already registered the specific use.

As regards the opportunities for action that can be selected by ECHA, Art. 7(5) REACH empowers ECHA to request additional registrations by the producer or the importer of an article,

- if the substance is released from the article(s), and if this release presents a risk to human health or the environment.

Thus, Art. 7(5) refers to unintended but predictable releases. It only suggests that ECHA considers this option, however, which presupposes that the authority has grounds for suspecting that the substance will be released and that it will present a risk.

Regarding the waiver of the obligation to register according to Art. 7(6) REACH, in case that the use has already been covered by the registration of the substance: in the above examples, it is to be expected that the use of the substance in the article (including the unintended, but foreseeable release) has already been covered by the registration dossier submitted by the substance manufacturer (albeit often in unduly broad terms, see section 6.3.2.2). As regards plasticizers, for example, their use in articles is a typical field of application arising directly from their function. Manufacturer take account of this use in the course of substance registration. With regard to solvents, their use (e.g. surface treatment) with reference to the relevant articles in some areas of application (such as paints and varnishes) will also be covered by registration on the part of the substance manufacturer. The same applies to plastic additives that are used for the production of tires, for example, and that may be released into the environment as a result of abrasion.

It can be assumed that the use of the substance in the respective article is covered by the registration on the part of the substance manufacturer whenever the latter promotes this usage. This often seems to be the case. In his registration, the manufacturer must take into account the entire life-cycle of the substance, including its use in articles, usage of the respective articles (with any unintended or intended releases of the substance) and reuse, recycling and disposal of the articles containing the substance. However, the information on the use of substances in articles provided in the registration dossiers is often of a very general nature (see section 6.3.2.2).

In the remaining cases, it should be noted that the substance manufacturer in the EEA, if he uses substances, is regarded to be a downstream user. If he uses a substance outside the conditions described in the exposure scenario of the substance, he shall – irrespective of the requirements set out in Art. 7 REACH – pursuant to Art. 37(4) REACH already now develop an own chemical safety report (whose content for downstream users are described in REACH Annex XII).

Therefore, the following rules apply to articles manufactured in the EU: In case 1, the manufacturer of the substance has already registered the use of the substance in an article (in this case, however, a chemical safety report is only required for substances manufactured / imported in quantities of at least 10 t/a). Then, the producer of the article himself does not need to supply a registration dossier or notify the authority.

In case 2, the producer of the substance has not registered the use of the substance in an article. In this case, the user of the substance, who uses the substance for the first time in the context of production of an article, in accordance with Art. 37, must – as a downstream user – carry out an own assessment on this usage which has hitherto not been covered. In other words: regarding producers of articles within the EEA, no cases are seen in which additional registrations of substances in articles will become necessary due to an extension of the obligations under Art. 7(1) to unintended releases. These extensions would only take effect on importers of articles. The obligations under Art. 37 REACH do not apply to them.

Assessment of the importance of the option: It has to be assumed that an amendment of Art. 7(1) (extension to inadvertent release and to cases where a release cannot be precluded) will have little practical effect – due to the interaction with Art. 7(6).

6.3.2.2 Regulatory option 5: Clarification of the information requirements for registered use in an article

Art. 7(6) of REACH waives the obligation for producers and importers of articles to register or notify substances in their articles, on condition that the respective use in the article has already been registered. Under REACH, however, it is only possible to register uses including the related conditions of use that are safe.

Currently, the question of whether such registration actually took place is subject to diverging interpretation. In this respect, it is arguable how much detail should be provided in the registration of the manufacturer of the substance as regards the specific use of the substance in the article. The information given should be sufficient for another actor – the producer of an article – to decide whether his use of the substance in his article is already covered by the registration of the manufacturer of the substance.

As regards the registration dossier, it is common practice that indications about the fact that the substance ultimately enters articles are only given in aggregate form in the technical dossier and in Section 2 of the chemical safety report via the use descriptor system. There is a lack of reliable information in the exposure scenarios in Section 9 of the chemical safety report demonstrating the safe use of the substance in an article. Statements pertaining to the quantities present in the article and to the migration and release potentials and their development over time are required in this regard. This information is dependent on the specific material in which the substance is incorporated, and is usually not indicated in the exposure scenarios provided by the producers of the substances. Hence, it is not communicated in the framework of the safety data sheets. To give an example: in case of packagings for cosmetics, without such data it cannot be assessed whether problematic migration takes place from softeners into the cosmetic product.

The ECHA guidance on exposure assessment for substances in articles clearly specifies that these data necessarily have to be provided. [454] They are, however, neither mentioned in Annex VI, Section 3.5 (to which reference is made in Art. 10(a) (iii) REACH), nor is any relevant information to be found in Annex I which describes exposure scenarios and their contents (Annex I, Section 0.7, 0.8 and 5).

The requirements on the registration of the use of a substance in an article already existing under REACH should be much more clearly described in Annex VI and Annex I. If so, compliance with these requirements could become an integral part of the evaluation of the registration dossiers by the European Chemicals Agency. Furthermore, national authorities could check whether safety data sheets on substances that are known to be used in articles contain sufficient information about this use;

Two consequences are to be expected, if the amendments are made:

- First of all, manufacturers of substances would provide better exposure scenarios on the uses of substances in articles. This applies not only to SVHC included in the candidate list, but also to other substances. As a result, this would increase the informative value of exposure scenarios for the protection of consumers and the environment, but also for occupational

454 *ECHA* 2011.

safety in industrial and professional settings in which articles are used, since these scenarios have hitherto been of little relevance.

- It will be easier for the producer or importer of an article to identify whether its use has already been registered by the producer of the article. Moreover, this is a crucial factor facilitating the decision whether he must become active himself in accordance with Art.7(1) or 7(2). Or whether – pursuant to Art. 7(6) - he is not required to submit his own registration or notification. The number of mandatory registrations / notifications to be submitted by producers of articles will increase. Unnecessary double registrations / notifications are avoided.

In ordert o improve the quality of the communication in the supply chains, ECHA and industry associations developed a specific roadmap (The CSR/ ES roadmap“).[455] It includes specific proposals to improve the quality of exposure scenarios regarding exposure of consumers.

6.3.3 Legal analysis of the regulatory options

This section analyses if regulatory options 4 and 5 can be implemented in the existing legal framework of REACH.

6.3.3.1 Regulatory option 4: Extension of the registration requirements to unintended release

According to regulatory option 4 the registration duty in Art. 7(1) REACH will be extended to articles containing substances which may reasonably be expected to be released, even though such a release is not intended.

The amendment by regulatory option 4 is not in line with the literal interpretation of Art. 7(1)(b) REACH which states: “the substance is intended to be released under normal or reasonably foreseeable conditions of use”. According to the wording a registration is only triggered if the release is “intended”. An example for an intended release is the release of a substance that equips an article with an additional function.[456] However, even in the case a substance is released unitentionally, it is in the discretion of ECHA to require producers or importers of articles to submit a registration according to Art. 7(5) REACH. A precondition is, that ECHA has grounds for suspecting that the release of the substance from the articles presents a risk to human health or the environment.

Looking at the before mentioned cases with a systematic interpretation of REACH provisions other than Art. 7 shows that the manufacturer of a substance and the down-stream user (of a mixture or article containing that substance) are obliged to ensure a high level of protection of human health and the environment. Registrants of substances in quantities of 10 t/a or more are obliged to complete a chemical safety report according ot Art. 14 REACH which adresses the unintended release of substance along their life-cycle if the use of the substances is covered by the registration. If the substance is not covered by the registration the manufacturer of an articles for example has to prepare his own chemical safety report as a downstream user (cf. Art. 37(4) REACH). In the latter case amending Art 7 (1) REACH in a way to cover unintended release of substances would be a redundant provision because of existing duties in Art. 6, 14 and 37 REACH.

However, that is not true for substances that are released unintentionally from imported articles becauses in this case Art. 37(4) REACH does not apply. With a purposive interpretation one could argue that imported articles with unintended release of substances have to be registered

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455 Siehe hierzu http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf.

456 Siehe das Beispiel von *Führ* in: Führ 2011, Kap. 8, Rn. 126.

according to Art 7(1) REACH, because it does not matter from which kind of article the substance is released if a high level of protection of human health and the environment has to be ensured. Such an interpretation, however, is not permissible as it contradicts the clear wording of Art. 7(1) REACH.

6.3.3.2 Regulatory option 5: Clarification of the information requirements of registered uses in articles

Whether regulatory option 5 is covered by the current scope of REACH or needs an amendment of the legal text is assessed hereafter.

Regulatory option 5 has the intention to clarify the information requirements for the registered use of a substance in an article with respect to exposure scenarios of Section 9 of the chemical safety report and the technical dossier. As a consequence in Sections 0.7, 0.8 and 5 of Annex I and Section 3.5 of Annex VI it should be explicitly stated that the registrant has to specify the concentration of the substance in the article, its migration and release potential, and the course of the exposition.

According to Art. 10(a)(iii) REACH the registration of substances requires that manufacturers or importers of substances under Art. 6 REACH or producers or importers of articles under Art. 7(1) and (5) REACH include in their technical dossier "information on the manufacture and use(s) of the substance as specified in Section 3 of Annex VI; this information shall represent all the registrant's identified use(s)." A closer analysis of Section 3 Annex VI shows that so far the registrant is not explicitly required to inform about the data listed in the regulatory option 5. Indeed, the registration requires only a "brief description of the technological process used in manufacture or production of articles" (cf. Section 3.2), "quantities of the substance in articles made available to downstream users" (cf. Section 3.4) and a "brief general description of the identified use(s)" (cf. Section 3.5). Neither Art. 10 nor Annex VI REACH define what a "brief description" of the technological process covers or in which way the "quantities of the substance in the article" should be laid open. Therefore regulatory option 5 is not in contrast to a literal interpretation of Art. 10(a)(iii) in connection with Annex VI REACH. The same is true for Sections 0.7, 0.8 and 5 of Annex I which broadly define the main elements of the exposure part of the chemical safety report.

Furthermore, a teleological and systematic interpretation of Art. 7(6) REACH in connection with Art. 6 and Art. 7(1) and (5) REACH reveals that regulatory option 5 is already covered by the current legal framework as detailed information on the registered use of an article is necessary to achieve a high level of protection of human health and the environment stated in Art. 1(1) REACH. The reason for this is that Art. 7 (6) REACH provides an exemption from the registration and notification according to Art. 7(1) and (2) REACH if the substance has been already registered for that use. Producers or importers who want to make use of the exemption have to compare their use of the substance with a registered use. According to the ECHA-Guideline "Substances in Articles" two conditions have to be fulfilled for this comparison:[457]

- "The substance in question is the same as a substance that has already been registered.
- The use in question is the same as one of the uses described in a registration of this substance that was already made."

Whereas the first condition refers to substance identity the second criteria is to check the identical use. According to the ECHA Guideline the producer or importer has "to describe the function of the substance in the article (e.g. pigment, flame retardant), the process by which the substance is included in the articles and into which type of article" to testify an identical

457 *ECHA* 2011, p. 31.

use.[458] Even though ECHA requires that for this purpose the use descriptor system shall be used it highlights in the same context that "the use in question has to be described more in detail than just by using elements of the use descriptor system."[459] However, the crucial point to make us of the exemption in Art. 7(6) REACH is to receive enough information on registered uses of a substance in order to compare it to one´s own use. To this respect the ECHA Guideline recommends several data sources, inter alia the safety data sheet – and attached exposure scenarios if the substance is registered in quantities of 10 t/a or more.[460] As elaborated in section 6.3.2.2 the level of detail of the information in the safety data sheet is not sufficient to make a proper comparison of the use. In order to compare the use in question with the registered use a reliable estimate of exposure specifications is necessary which includes information on the concentration of the substance in the article, it´s migration and release potential, and the course of the exposition in the safety data sheet. Without such specific information it is very likely that producers and importers will make use of the exemption in Art. 7(6) REACH on the ground of very vague information. This stands in contradiction to the purpose of registration and notification.

As a result it should be made legally binding to give specific information on the use of a substance in an article by including information on the concentration of the substance in the article, it´s migration and release potential, and the course of the exposition in Section 3 of Annex VI and in Section 0.7, 0.8. and 5 of Annex I REACH. These amendments are covered by the current legal framework.

6.4 Clarification of the reference point of the 0.1 % threshold stipulated by Art. 7 and Art. 33 REACH

6.4.1 Background and description of the regulatory option

6.4.1.1 Requirements under REACH

Art. 7(2)(b) and Art. 33(1) and (2) of REACH stipulate notification and information obligations for SVHC in articles, if the respective "substance is present in the article above a concentration of 0.1 % weight by weight (w/w)". In cases where articles are made of several components, the question of the reference point that is appropriate for the defined threshold arises. REACH does not clarify this issue, which is why two different views on how to interpret the standard came into being:

In the view of the Commission, ECHA and a majority of the member states, the 0.1 % threshold refers to the entire article in the form, in which it is passed on in the respective stage of the supply chain. This view is also represented in the preface of an ECHA guidance document on articles in the version updated in April 2011.[461]

A minority of Member States, the so-called "dissenting Member States" (Austria, Belgium, France, Germany, Norway, Sweden), however, follow the approach that the 0.1 % threshold

458 *ECHA* 2011, p. 31.

459 *ECHA* 2011, p. 31.

460 *ECHA* 2011, p. 32.

461 *ECHA* 2011.

refers to the "initial" articles in a manufacturing and supply chain, i.e. de facto the individual components of a (more complex) article.[462]

6.4.1.2 Overview of state of implementation

Companies usually refer to the entire article in their communication. Only in exceptional cases, reference is made to the individual components.[463]

6.4.1.3 Regulatory option 6: Clarification of the reference point of the 0.1 % threshold stipulated by Art. 7 and Art. 33 REACH

Beyond the entire article,

- the individual component or
- the homogeneous material

may be taken as a reference for the 0.1 % threshold.

In the ROHS directive (2001/65/EU) on "the restriction of the use of certain hazardous substances in electrical and electronic equipment", the homogeneous material is taken as reference. According to the definition therein, a homogeneous material cannot be disjointed into different materials by mechanical actions ("'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes").

In the current discussion about the reference point in REACH, the first article which is produced in a process/supply chain is usually chosen as the smallest unit. At this point, the transition from the substance or mixture level (with information on hazardous substances in the safety data sheets) to the level of the article (without a safety data sheet) is taking place. This first article can be used as it is or it can - in the next step - become a component of a complex article (which consists of several components).

If using the homogeneous material as a reference point, the 0.1 % threshold will probably be exceeded in many cases. Components, too, as the complex article, may consist of several materials. Thus demands are growing in respect of analytical procedures for control if the homogeneous material is taken as a reference point. It would require the dismantling of a component into the homogeneous materials which it contains before analysis can take place. Each of the homogeneous materials would have to be analysed separately in this case. The homogeneous materials would be analysed separately – namely with regard to all SVHC of the candidate list, i.e. that can be realistically expected to be included. Nevertheless, it is reasonable to choose the "homogeneous material" as a reference point since this is the step in the production at which it is determined whether critical chemicals will be used (or omitted). In the case of reliable and exhaustive communication throughout the supply chain, it is possible to come to a conclusion concerning the individual homogeneous materials as regards the presence/absence of SVHC. (Since the decision about the use of a substance is made at the level of the homogeneous material, it is definitely advisable to choose it as a reference point for specific material restrictions in articles such as in Annex XVII REACH.)

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462 Principle "once an article, always an article" (see http://www.reach-clp-biozid-helpdesk.de/de/Downloads/Kurzinfo/Kurzinfo%20Einmal%20ein%20Erzeugnis%20-%20immer%20ein%20Erzeugnis%20engl.%20Fassung.pdf?__blob=publicationFile&v=5).

463 *Bunke/Reihlen/Jepsen* 2012.

When the reference "component" is used with complex articles – equally like the reference "homogeneous material" – more precise data can be obtained as when using the reference point "entire article". Examples of components and entire article are the plastic handle with a pair of pliers and the capacitor on an assembled circuit board respectively. Using "component" as a reference for complex articles prevents increases in the absolute quantities that may be contained in the articles until the 0.1 % threshold is reached. The study of KEMI[464], the Swedish chemical authority, provided evidence for this conclusion using several examples. There are examples from various sectors, inter alia from the automobile industry.

- Example automotive industry: With regard to the threshold of 0.1 %, the complete vehicle can be taken as reference. At an average weight of 1,500 kg, up to 1,500 g of an SVHC can be contained in a vehicle, before the 0.1 % threshold is exceeded. However, a single component can also be taken as reference. An electronic component in the car may have a weight of only 0.1 g. In this case, only 0.001 g of an SVHC is allowed. Higher quantities would lead to an excess of the of 0.1 % threshold and trigger obligations according to Art. 7 and Art. 33. [465.]

The approach of using the reference "component" is easier to implement than the approach which takes the "homogeneous material" as a reference.". The reference "component" is moreover supported by the fact that information on the presence or absence of SVHC in this (partial) article must be generated and communicated within the supply chain in any case. Therefore, there is no need to lose this already available information during the assembly of the article as a whole.

According to the above-mentioned dissenting opinion of some Member States relating to the reference of the 0.1 % threshold, the component is considered to be appropriate point of reference. In order to increase the practicability of the reference point and its chances of being implemented, we recommend to use the component as reference point.

The choice of the reference point can be decisive for the achievement of the protection objectives addressed by Art. 33 REACH. Hence, clarification of this issue is of high importance.

6.4.2 Legal analysis of the regulatory option

In the opinion of the authors the current legal framework of REACH requires that the component is considered to be the appropriate reference of the 0.1 % threshold; thus REACH does not need to be amended. However, no detailed reasoning for this opinion will be given, because the question of the correct reference point for the threshold is to be decided by a case in front of the European Court of Justice. Should the court rule that the component is the correct reference point for the 0.1 % threshold and not the entire article it is recommended to clarify this by amending Art. 7 and Art. 33 REACH.

6.5 Introduction of a register for articles containing SVHC

Another legal instrument to enhance transparency for consumers, producers and competent authorities on SVHC in articles available on the European market is a register for articles containing SVHC.

464 *IS* 2010.

465 *Stein-Schaller* 2014.

6.5.1 Background and description of the regulatory option

6.5.1.1 Requirements under REACH and state of implementation

Regarding the background of that regulatory option reference is made to sections 6.2.1, 6.3.1 and 6.4.1. As a result of the background analysis consumers, competent authorities and producers have only insufficient access to information on SVHC in concrete articles.

So far REACH does not contain provisions regarding a register for articles containing SVHC. Even though Art. 7(2) REACH provides a notification duty for articles containing SVHC the duty applies only to uses that have not been registered (cf. Art. 7(6) REACH). Due to the exemption clause identical uses of a substance in the same type of article must not be registered and consequently ECHA is not informed about those specific articles being on the market. Regarding the registration of substances in articles according to Art. 7(1) REACH as well as the notification of articles containing SVHC according to Art. 7(2) REACH no information is publicly available on the concrete article or the concrete producer/importer of a specific article. Only the product types that contain SVHC are published on the ECHA webpage.[466]

However, the private sector, partially in cooperation with environmental NGOs and public authorities, has created its own databases for articles containing SVHC in order to comply with their communication duties according to Art. 33 REACH (for example in Denmark[467]).

6.5.1.2 Regulatory option 7: Register for articles containing SVHC

The purpose and essential elements of a register for articles containing SVHC are described in the following sections.

6.5.1.2.1 Purpose of a register for articles containing SVHC

It is the purpose of the register to create an information basis to help European competent authorities, consumers and actors in the value-chain to identify articles containing SVHC. The information to be submitted to the register (see section 6.5.1.2.3) enables the before mentioned stakeholders to reduce the risk for the health of consumers and employees from articles containing SVHC as wells as to protect the environment from SVHC. Furthermore competent authorities can identify with the help of the register concrete articles containing SVHC which are on the EU market and their uses and thus authorities can take provisions, like (de-)prioritise SVHC for action. Consumers is given the freedom to choose between articles containing SVHC and those without SVHC which gives consumers the possibility to avoid exposure to SVHC. The register will help the actors in the value-chain to comply with their communication obligations to recipients of articles and to consumers. Additionally it will support them in improving the protection of worker´s health and the environment during the production of the articles.

6.5.1.2.2 Precondition for the notification duty

The notification duty should apply for articles containing SVHC produced in the EU or imported to the EU. Taking into account the preconditions for the notification duty according to Art. 7(2) REACH the notification duty for the register shall apply if articles are produced or imported

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466 *ECHA* 2014: Data on Candidate List substances in articles (download at: http://echa.europa.eu/documents/10162/13642/data_candidate_list_substances_in_articles_en.pdf (as from 25.8.2014)).

467 Cf. information on the database so far only available in Danish at: Forbrugerrådet Tænk, Miljøstyrelsen (2014): Tjek kemien - i dine produkter (download at: http://tjekkemien.dk (as from 25.8.2014)).

which contain SVHC in the quantity of 1 t/a[468] per producer or importer and if the SVHC is present in those articles above a concentration of 0,1 % weight by weight (w/w). The notification for the register does not cover the production or import of the SVHC itself or mixtures containing SVHC. An additional duty to notify an article is triggered if a notified article is repackaged or relabelled for other uses than notified.

With respect to the different regulatory options given in sections 6.2 to 6.4 various specifications and extensions to the subject of notification can be discussed. For example the duty to notify an article could apply in case the SVHC is included in the candidate list or only if the SVHC is included in Annex XIV. Based on the intent and purpose of the register for articles containing SVHC the notification duty shall apply if the SVHC contained in the article is stated in the candidate list. This precondition would be coherent with Art. 33 REACH according to which the information duty is triggered by the presence of a SVHC.

Furthermore, one might consider that the notification duty to the register applies besides articles containing SVHC to substances that are not covered by the criteria of Art. 57 REACH (cf. the discussion in section 6.2.1.3.3). If the review according to Art. 138(8) REACH results in an extension of the communication duties of 33 REACH to other substances, a corresponding extension of the notification duty to the register should be considered.

Another important question regarding the determination of the subject to notification is whether only the final product has to be notified or components, too. This question is significant for the total amount of articles to be notified to the register (and thus is crucial for the effort and expense of the potential notifiers as well as for the operation of the database). But it is significant for the enforcement of the notification duty for articles, too, because the notification of components containing SVHC would give the enforcement authorities an indication of further articles in the production chain that fall within the scope of the register.

6.5.1.2.3 Information to be notified

With respect to the scope of information which notifiers should be obliged to submit to the register reference is made to the regulatory option "introduction of a standardised communication format for articles", see section 6.2.1.3.1. It is proposed that notifiers have to submit the following information to the register before they put an article on the market:

- name and address of the notifier;
- product and trade name (including variations of a product), barcode as wells as product category; to this aim it should be referred to existing product categories and product types;
- name and CAS number of the substances;
- SVHC-property and classification (H statements);
- concentration of substances and indication of where (in which part/component) they are to be found; total quantity in article;
- indication of the total amount of SVHC contained in the article per year;
- consequences of presence for safe use (processing, usage, maintenance, repair, disposal, recycling);
- reference to the function of the substances in the article (to understand, why the substance is contained in the article);

[468] When implementing a register it should be considered to lower the thresholds for the notification duty, e.g. to „100 kg" per producer or importer and year (Cf. section 6.3.2).

– in the case of an imported article the country of origin.

6.5.1.2.4 Avoiding duplication of reporting obligations

In this section we will analyse if a notification obligation for articles containing SVHC will lead to avoidable duplicate reporting for producers and importers, because they are already obliged to submit data on SVHC in articles due to informational obligations in national product registries or in sector-specific regulations.

Initially, a duplication of informational obligations for producers and importers could result from so called „product registers“ existing in various European countries[469], for example in Germany[470], Sweden[471], Norway[472], Denmark[473] or Switzerland[474]. Those registers constitute notification duties for producers and importers in the respective countries regarding the placing on the market of dangerous substances and mixtures, PBT- and vPvB-substances as well as certain new substances. Information which must be notified covers name and address of the producer, name and CAS number of the substances, EC-No., classification and labelling, if applicable the identification as PBT or vPvB. The purpose of those national registers is to enable competent national authorities to take preventive measures if they consider that substances or mixtures pose an unacceptable risk for human health and the environment. Furthermore, the register information shall help the treating doctor in case of poisoning. However, the national product registers do not cause a duplication of information obligations for producers and importers, because the so called “products” covered by the national registers are “substances” and “mixtures” but not “articles” in the meaning of the “register for articles containing SVHC”. The information of those national registers does neither help competent national authorities nor consumers to identify articles containing SVHC.

Various European product-specific regulations, like the RoHS-Directive[475], the WEEE- Directive[476], the ELV-Directive[477], the Packaging-Directive[478], the Toy-Directive[479], the Biocidal Products Regulation[480] or Construction Products Regulation[481] impose restrictions on the use of hazardous

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469 Cf. the overview given in *Ahrens* et al. 2001, p. 16.

470 Cf. http://www.bfr.bund.de/de/meldung_von_rezepturen-9375.html (as from 10.6.2014).

471 See the website of the Swedish Chemicals Agency (KEMI): http://www.kemi.se/en/Start/The-Products-Register/ (as from 26.5.2014).

472 See the website: http://www.miljodirektoratet.no/no/Tema/Kjemikalier/Produktregisteret/The_Product_Register/ (as from 10.6.2014).

473 See the website: http://engelsk.arbejdstilsynet.dk/en/Produktregistret.aspx (as from 10.6.2014).

474 See the website: https://www.rpc.admin.ch/rpc/public/index.xhtml?winid=213631 (as from 10.6.2014).

475 Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88.

476 Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), OJ L 197, 24.07.2012, p. 38.

477 Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, OJ L 269, 21.10.2000, p. 34.

478 European Parliament and of the Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10.

479 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p. 1.

480 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.

481 Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 088, 4.4.2011, p. 5.

substances in products as well as communication obligations concerning product characteristics. However, as these regulations don´t stipulate from producers and importers to notify SVHC contained in articles the regulations don´t cause duplicate reporting duties for producers or importers.

To sum it up, neither current national product registries nor product-specific regulations would lead to a duplication of the reporting obligations if a register for articles containing SVHC is implemented.

6.5.1.2.5 Assessment of the impacts of the regulatory option

The register will foster transparency on articles which contain SVHC and are available on the EEA market. Thus it is a means for ECHA and the national competent authorities to comply with their obligation to achieve a high level of protection for human health and the environment regarding the production, placing on the market and uses of substances contained in articles (cf. Art. 1(1) and (2) REACH). With the information on the amount and type of SVHC present in concrete articles the authorities can (de-)prioritise SVHC to be included in Annex XIV. An analysis of the register information may reveal that certain SVHC are not or only in small amounts present in articles available on the EEA Market. Respectively, against the background of approximately 500 potential SVHC it can be questioned whether those SVHC should be treated with less priority regarding their inclusion in Annex XIV REACH or their authorisation. With a view to the authority responsible for the register there are presumably not insubstantial personnel and material costs to build up and run the register, taking into account approx. 150 SVHC on the candidate list ist multiplied with a larger number of articles that contain these SVHC.

Access to publically available information in the register for articles containing SVHC in the internet will offer consumers an easy and up-to-date overview on articles containing SVHC. Thus consumers can inform themselves already before the purchase of an article if it contains SVHC or they can get that information even during the purchase with the help of electronic devices like “Apps” for smart-phones. The same holds true for consumer- and environmental-NGOs.

Producers of complex articles or distributors who are not willing to use or distribute articles containing SVHC can inform themselves on the presence of SVHC in the articles they receive. Furthermore suppliers of articles can use the register to support their communication obligations according to Art. 33 REACH.

The implementation of the register and the corresponding notification obligation imposes costs on the producers and importers of articles. However, the register does not cause additional costs for industry to analyse if and how much SVHC is contained in their articles, because this is part of their existing obligations according to Art. 7 and Art. 33 REACH. Further costs regards personnel costs to notify the data to the competent authority and maintain the information. Important criteria for the amount of costs are the number of articles to be notified and the scope of the information to be delivered. In this respect it is worthwhile to notice that currently 150 candidate substances are known, whereby it remains to be seen to which extent they are used in articles. In essence within this first assessment it is not possible to estimate the costs for industry. In general, sectors which already have established information exchange on sensitive substance in the value-chain[482] will only have additional costs for the submitting of information to the competent authority.

[482] For example the „International Material Data System (IMDS)“ of the automobile industry, used by almost all globally acting Original Equipment Manufacturer (OEMs). The purpose of the IMDS is to collect, analyse and archive information on all components used in the production auf automobiles (Cf. the website of the IMDS-System at: https://www.mdsystem.com/imdsnt/startpage/index.jsp, as from 26.05.2014).

Attention should be paid to the research results regarding efforts and benefits of a European database for ingredients in household products. The results of the interviews conducted with industry associations, retailers, competent authorities and consumer-NGOs in the course of the project show that each stakeholder group expects a high benefit of the database for their own use compared to a lower benefit for all other stakeholders. The considerable effort to keep the entries in the database up-to-date (mainly caused by the enormous variety of products, change of suppliers and the degree of purity and nature of impurities), was the most frequently quoted difficulty.[483]

6.5.2 Legal analysis of the regulatory option

In this section we will analyse if a register for articles containing SVHC is covered by the current REACH and CLP provisions.

Because the register interferes with the rights of the producers and importers of articles containing SVHC its implementation requires a legal basis. Such a legal basis does not exist in the provisions of the current REACH or CLP Regulation, especially it cannot be derived from the interpretation of the provisions regarding the notification of substances in articles according to Art. 7(2) and the communication obligations in Art. 33(1) and (2) REACH. In fact, one can argue that producers and importers are obliged due to current legislation to submit information on SVHC contained in articles to recipients of the article and consumers (see the legal opinion in section 6.2.2.1). However, the before mentioned information duties exist only between individual actors and in the case of consumers only on their request. Moreover, the register in the regulatory option 7 requires an amount of information and enables the combination of substance-related information with product-specific information in a way that is not covered by existing communication duties in REACH.

As the outcome of the legal analysis the implementation of a register for articles containing SVHC is not covered by the current REACH- and CLP Regulation and requires a specific legal basis.

483 *Giegrich* 2011, p. 41, 45.

6.6 Comparison and interrelation of the regulatory options under investigation

In the previous sections, we have explored seven different regulatory options and closely examined the legal implementation of the various approaches with the aim of strengthening the requirements of the REACH Regulation concerning SVHC in articles. At the end of each subsection, initial assessments on the importance of these options for achieving the protection objectives stipulated under REACH were drawn up. Here, we provide a short summary of these assessments:

The communication obligations pursuant to Art. 33 REACH include three regulatory options.

- *Standardised communication format for articles (regulatory option 1):* The implementation of a standardised communication format for (substances in) articles helps to ensure that the information that is necessary to achieve the protections goals will actually be communicated. A major weakness with the current practice - the limitation of the communication regarding Art. 33 REACH to the mere indication of the names of the SVHC - can be overcome by this. Beyond the name of the substances further information should be communicated, e.g. details regarding its concentration, total amount in the article, hazardous properties, location in the article, information on safe use including waste phase.

  It is expected that it will be easier to implement a standardised communication format when it willbe integrated into existing information system. Standardisation can help to enable suppliers to provide responses about SVHC substances in articles more quickly within the 45-day period prescribed. In addition, some of theinformation is required to calculate for a complex article the resulting concentration of SVHC. This is not possible without knowledge of the amount and concentration of SVHC in the components of the complex article (see regulatory option 3). A standardised communication format would also facilitate the enforcement of Art.33 REACH.

  A legal option to implement the standardised communication format for articles in REACH is to implement a new Annex XVIII "Standardised communication format for articles". Such an amendment is covered by the current legal content of Art. 33 (1) REACH. A further step could be the requirement for suppliers to answer information request according to Art. 33(2) REACH even in the case, that the article does not contain an SVHC. This clarification would support the existing information requirements under REACH. A standardised communication format is necessary to fulfill the existing REACH requirements. In addition, such a format can be recommended for the labelling requirements for SVHC (regulatory option 2), for the extension of the communication requirements to other substances (regulatory option 3)and for the product register for articles containing SVHC (regulatory option 7).

- *Labelling requirements for SVHC (regulatory option 2):* Currently, the supplier is granted a period of 45 days to reply to requests about SVHC in his articles. This is considered to be not sufficiently practical. Mandatory labelling for SVHC in articles would ensure that professional users and consumers are directly informed. This would facilitate the choice in favour of articles that are free of these substances, which increases the pressure to offer articles without SVHC. This approach, too, could make a significant contribution to achieving the protection objectives of REACH for substances in articles.

  As on the packaging of the article itself rarely more than the name of a SVHC can be stated it is recommendable that additional information should be given in the internet. It is reasonable to use also in this case the standardised communication format to ensure completeness of information (see regulatory option 1).

  There are several options to implement an obligatory labelling for articles containing SVHC. One is to implement it in the CLP Regulation. However, a precondition for the option is that

criteria for the classification and labelling of PBT and vPvB are introduced to the CLP Regulation which should be preferably harmonised on the international level. Moreover, the scope of articles covered by Art. 4(8) CLP Regulation needs to be extended. An alternative option is to introduce the labelling obligation for articles containing SVHC in Art. 33 REACH. There it would directly amend the existing communication requirements for the substances of the candidate list. Another regulatory option is to enact a separate regulation with a cross-product obligatory labelling for all articles containing SVHC.

The implementation of an obligatory labelling for articles containing SVHC does not contradict WTO rules. The option is compatible with the principle of national treatment and most-favoured nation treatment according to Art. 2.1 TBT Agreement. It is not an unjustified obstacle according to Art. 2.2 TBT Agreement. In addition, it is compatible with the freedom to conduct a business, as protected in the Charter of Fundamental Rights of the European Union. Even though the labelling violates the fundamental freedom of enterprises to conduct a business this can be justified on the ground of the protection of human health and the environment.

- *Extension of the communication requirements to include other substances (regulatory option 3):* The extension of the communication requirements of Art. 33 REACH to include other substances will be examined by the European Commission until June 2019, as stipulated in Art. 138(8) REACH. The communication requirements could not exclusively focus on the SVHC criteria, but also on other hazardous characteristics (e.g. CMR substances Category 2, sensitisers, long-term effects on aquatic organisms). In addition, substances should be included for which reduction objectives exist in other legislations (e.g. Water Framework Directive, Biocide Regulation). Such an amendment would provide professional and private users of the articles with a higher degree of information and also allow a better coordination of the different areas of substance regulation. This extension of the communication requirements is not covered by the present legal text of REACH. It requires a change of the legal text.

  If it appears that the inclusion of substances with a harmonised CMR classification Cat. 1A or 1B is quite lengthy, the possible scenarios to automatically include these substances in the candidate list on the basis of such a harmonised classification should be examined. The fast inclusion of all substances with SVHC properties in the candidate list would increase the effectivity of the existing regulation.

With regard to the registration and notification requirements for producers and importers of articles stipulated in Art. 7 REACH, two options for action have been explored: The extension of the registration duty to inadvertent release, and the clarification of the necessary information of a registered use in accordance with Art. 7(6) REACH.

- *Registration obligation for unintended releases (regulatory option 4).* An extension of the registration obligations on producers and importers of articles in Art. 7(1) to inadvertent release and to cases where a release cannot be precluded will most likely have little practical effect. It can be assumed that the substance producer in the vast majority of cases will already, at least formally, have complied with the requirements regarding the use of the substance in an article in his registration. In these cases, Art. 7(6) REACH waives all obligations for producers/ importers of articles pursuant to Art. 7(1) – and thus also possible extensions of these obligations. It is important that for the registration of the use of a substance in an article information with enough details are given in the registration – this is at present not the case (see regulatory option 5).

- *Information requirements for a registered use (regulatory option 5).* A closer definition of the registration requirements as to information on the use of a substance in an article would probably significantly enhance the exposure scenarios in the registration dossiers. This applies not only to SVHC included in the candidate list, but also to other substances. Registration of the use of a substance in an article requires information regarding the concentration of the substance in the article, data on migration and release rates (which often are material specific) and data on the time dependence of releases. Furthermore, the registered uses should not be too broad and unspecific. As a result, this would increase the informative value of exposure scenarios for the protection of consumers and the environment, but also for occupational safety in industrial and professional settings in which articles are used, since these scenarios have hitherto been of little relevance. Furthermore, the possibility of waiving the registration or notification of SVHC in articles because their use is already registered (Art. 7(6)) would decrease.

A further regulatory option refers to the clarification of the reference point of the 0.1 % threshold.

- *Component as reference point for the 0.1 threshold (regulatory option 6).* If the concentration of SVHC in articles is above 0.1 %, this information has to be communicated in the supply chain according to Art. 33 and notified to ECHA according to Art. 7(2). The interpretation according to which the 0.1 % threshold does not relate to the entire article, but to the component, and that this opinion derives from the legal wording of REACH – drawing the conclusion that no amendments of the legal wording would be required - is currently on the table of the European Court of Justice for decision. The clarification of this reference point is of great importance for ensuring - also for complex articles - that the protection objectives addressed by Art. 33 REACH and Art. 7(2) will be achieved. This can be illustrated with an example. If a SVHC is present in the knobs of end-cutting pliers, the concentration of this SVHC in the whole tool can be below the concentration threshold of 0.1 % - although the user of the tool has direct skin contact with the SVHC. If the reference point is the component (in this example the knob), the danger of such an loss of information does not occur. A further argument in favor of the component as reference point is, that the information for the component should already be available – due to the placing on the market of the component. Therefore it is possible to make use of existing information (as long as the component has been produced in the EU).

  In the opinion of the authors the current legal framework of REACH requires that the component is considered to be the appropriate reference of the 0.1 % threshold; thus REACH does not need to be amended. However, no detailed reasoning for this opinion will be given, because the question of the correct reference point for the threshold is to be decided by a case in front of the European Court of Justice. Should the court rule that the component is the correct reference point for the 0.1 % threshold and not the entire article it is recommended to clarify this by amending Art. 7 and Art. 33 REACH.

The last regulatory option refers to the possibility of implementing a register for articles containing SVHC.

- *Product register for SVHC containing articles (regulatory option 7).* Such a register would promote greater transparency with regard to the presence of SVHC in concrete articlesand thus support ECHA and national authorities. This information could be used to (de-)prioritise follow-up measures on SVHC substances. European consumers as well as industrial and professional users of articles might use the register to have a faster overview of the current situation of SVHC in articles.

It might make sense to discuss the possibility of either to implement the labelling obligation for articles containing SVHC(see regulatory option 2) or to implement a register for such articles. Labelling obligations make it possible that the consumer can see immediately at the point of sale whether an article contains SVHC. On the other hand, the overview on SVHC in all articles of different producers is an important advantage of a register. Nevertheless it requires to build up and maintain an appropriate infrastructure. The requirement to develop a standardised communication format could be linked to the notification obligation for a product register. Irrespective of the register, this option has already been recommended further above (see regulatory option 1). However, the importance of this regulatory option also depends on whether articles containing SVHC will remain on the market in significant amounts in the future or if their market share will decrease due to other measures. For example the rapid inclusion of all relevant SVHC in Annex XIV REACH in combination with an extended authorisation requirement.

As described above, such a register is connected with an detailed notification requirement. It includes and combines information on substances, articles names and commercial names (including all variations of an article). This is not covered by the existing legal text of REACH.

In summary, it can be said that a standardised communication format for articles (regulatory option 1) would to a large extend support the correct implementation of the REACH communication requirements regarding SVHC. It could ensure that not only the name of the SVHC (as an insufficient minimal information) will be communicated. It can be implemented without change of the existing legal framework.

In addition, the clarification of the information requirements for the registered use (regulatory option 5) is a second specification within REACH that can be implemented within the existing legal framework and which might contribute significantly to the achievement of the aims of REACH.

Furthermore, clarification that the 0.1 % threshold (above which articles containing SVHC have to be notified and communicated) refers to the component (regulatory option 6), and not to the overall article, would help to obtain additional information, which would facilitate the replacement of SVHC in articles.

Major changes are also expected from the extension of communication requirements to other substances (regulatory option 3). It supports industrial and professional actors as well as consumers, who want be informed about problematic substances in articles or who want to use articles with less problematic substances. The examination of this option is foreseen by REACH in a review clause.

Finally substantial additional information for the actors in the supply chain and consumers can also be expected from the labelling obligation for SVHC contained in articles (regulatory option 2) and a register for articles containing SVHC (regulatory option 7). A register involves, however, considerable additional efforts for producers and importers of articles and the operator of the register. It has to be clarified whether both options should be implemented in parallel or just one of them. A standardised communication format (regulatory option 1) should be part of both options.

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8 Annex: Example standardised communication format for SVHC in articles

The German Federal Environment Agency published a proposal for a standardised communication format for SVHC in articles.[484] It is based on the results of a research project in which guidance and an electronic tool to support the communication on SVHC were developed (the "SVHC communicator").[485] The communication format is shown in the following table. The flame retardant hexabromocyclododecane has been used as an example.

[484] See http://www.umweltbundesamt.de/en/topics/economics-consumption/products/building-products/eu-law-for-construction-products/format-for-the-mandatory-designation-of (24.9.2014)

[485] See http://svhc-in-articles-communication.de/

Table 2: Standard communication format for SVHC in articles - Example for an insulation foam flame retarded with hexabromocyclododecane (Source: Umweltbundesamt 2014, amended).

Template	Data to be filled in by the manufacturer (here exemplary)
Information on article and manufacturer	
Article	Durex 4 insulation board
Manufacturer	Rock Dur, Merzhauser Str. 173, D-79100 Freiburg
Contact	Peter Hummel, Tel. 0049 (0)761 / 45295-246, p.hummel@rockdur.de
Substance information	
Substance name [a)]	Hexabromocyclododecane (HBCDD)
EC Number	247-148-4, 221-695-9
CAS Number	25637-99-4, 3194-55-6
SVHC property or properties in accordance with REACH regulation [b)]	PBT (article 57d of REACH)
Classification in accordance with CLP regulation [c)]	Repr. 2 (H361); Lact. (H362); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)
Concentration [d)] in product or its part [e)]	0.7 % w/w in whole product
Amount in product [f)]	210 g/m3
Function of the substance	Flame retardant
Instructions for safe use (here exemplary; information to be added when needed)	
Avoid direct contact with water through encased mounting.	
When cutting and processing the product at the construction site, avoid temperatures over 200°C and release of particles from the product.	
Instructions for safe disposal (here exemplary)	
Construction waste that is produced as cutting scrap on the building site to be collected separately and disposed of professionally.	
Incinineration in waste incineration plants according to the state-of-the-art	

a) The substance name shall be provided with the same spelling as on the Candidate List of Substances of Very High Concern for Authorisation.

b) Regulation (EC) No 1907/2006

c) Regulation (EC) No 1272/2008

d) This information is intended for the professional user possibly processing the product further in order to enable the calculation in the next step.

e) If the SVHC is only contained in a concentration above 0.1 % weight by weight (w/w) in a distinct part of the article, this part should be identified here.

f) The amount can be provided as additional or as alternative information for the calculation step (see above). For importers of articles the amount is a compulsory information in order to fulfill the obligations of Article 7(2) of the REACH Regulation.