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Opinion of the German Federal Environment Agency (UBA)

concerning the proposal by the European Commission of 3 December 2008

for the revision of Directive 2002/95/EC

on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)

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Press Relations Officer: Martin Ittershagen
PR-staff: Anke Döpke, Dieter Leutert,
Fotini Mavromati, Theresa Pfeifer, Martin Stallmann
Adress: Postfach 1406, 06813 Dessau-Roßlau
Telephon: 0340/21 03-2122, -2827, -2250, -2318, -3927, -2507
E-Mail: pressestelle@uba.de
Internet: www.umweltbundesamt.de

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A) Summary

It is the purpose of Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) to regulate the exclusion of certain harmful substances from being used in electrical and electronic equipment (EEE). This will result in a reduction of hazardous substances in waste electrical and electronic equipment, facilitate the processing and recycling of such wastes and benefit resource conservation. Simultaneously, the exclusion of certain hazardous substances from being used in EEE will decrease the release of such substances into the environment over the entire product life cycle, and thus, reduce the contamination of the environment as well as occupational exposure and that of consumers. Currently, the RoHS Directive has imposed restrictions on the use of the heavy metals, lead, cadmium, mercury and hexavalent chromium as well as of the flame retardants, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).

On 3 December 2008, the European Commission presented a proposal for the revision of the RoHS Directive[1] [2] and initiated the regulatory procedure. The proposal for a revision of the RoHS Directive contains extensive changes to the Directive. These refer to scope, definitions, mechanisms for including new substances and mechanisms for defining exemptions, as well as conformity assessment.

In the present opinion, UBA has evaluated the essential modifications proposed by the Commission and performed an analysis of the links to the REACH chemicals regulation (Regulation (EC) No 1907/2006).[3]

The motivations for a revision of the RoHS Directive stated by the Commission include the achievement of high standards of environmental and health protection and the simplification and development of a higher consistency of legal regulations. However, the Commission's proposal does only in part meet these objectives. Altogether, the proposal for a further development of the RoHS Directive is insufficient both with regard to its form and substance and therefore, is in need of improvement.

Modifications supported by UBA are those aiming at a simplification and improved preciseness of the Directive, such as modifications regarding scope and definitions. The same applies to the new articles on conformity assessment and market surveillance as far as they serve a better enforcement of the Directive.

In particular, the proposal is insufficient with regard to the articles dealing with the inclusion of new substances in the Directive and with the definition of exemptions from the existing substance restrictions. Firstly, this concerns the fact that the Commission has failed to include new substances to be restricted under the RoHS Directive. Secondly, a number of essential procedural items have

[1] English wording of the proposal together with all additional documents: http://ec.europa.eu/environment/waste/weee/index_en.htm.

[2] Articles and annexes mentioned in the following without additional references will refer to this proposal.

[3] 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).
The text of the Regulation as well as detailed explanations regarding the instruments of "authorisation" and "restriction" under REACH (in German) is available under: www.reach-info.de.

not been resolved by the proposal. They are supposed to be clarified at a later date, without stating any deadline, in the comitology procedure[4].

The Commission has failed to convincingly explain why they did not immediately propose a restriction of use in EEE for the long-disputed and particularly critical plasticisers, DEHP (bis(2-ethylhexyl) phthalate), BBP (butyl benzyl phthalate) and DBP (dibutyl phthalate) as well as the flame retardant, HBCD (hexabromocyclododecane). In EEE, these substances can be replaced by more environmentally compatible alternatives, on principle, without causing any problems[5]. UBA recommends to immediately restrict the use of DEHP, BBP, DBP and HBCD. These substances should be directly added to Annex IV to the RoHS Directive (Annex listing restricted substances).

In EEE, the phthalates, DEHP, BBP and DBP are primarily added to soften PVC cables or rubber parts. In addition, they may be contained in paints and adhesives. All three phthalates have been classified as toxic to reproduction (i.e. as CMR substances – carcinogenic, mutagenic or toxic to reproduction) and have been suspected of causing hormone-like effects in the human body. Because they are not firmly bound in the products, they will evaporate over time. Phthalates being ubiquitous contaminants can be detected in the environment, both in soils and waters as well as in house dust. They may also find their way into foods via the food chain and processing operations. As a result, the level of total exposure from the variety of sources has become so high that in a number of children in Germany, the tolerable daily intake of DEHP has been exceeded[6]. The flame retardant, HBCD, is used mainly in the plastic materials of EEE casings. Also this substance is not firmly bound in the product. HBCD is referred to as a PBT (persistent, bioaccumulative, toxic) substance: It is not readily degradable (persistent) in the environment, accumulates in organisms (bioaccumulative) and is highly toxic to aquatic organisms. As a result of the stability of the substance and its high level of accumulation in organisms and in the food chain, HBCD can be detected also in animals of remote regions such as the polar region, e.g. in polar bears or in seals. Because of the properties mentioned above, the European Chemicals Agency (ECHA) has identified these four substances, i.e. the plasticisers, DEHP, BBP and DBP, as well as the flame retardant, HBCD, as substances of very high concern according to the REACH criteria[7] and has proposed them to become subject to authorisation (see below).

In the proposal for the revision of the RoHS Directive, the four substances, DEHP, BBP, DBP and HBCD, have been listed in the new Annex III. This Annex specifies substances for which restrictions are to be considered. However, neither a deadline has been fixed for a review of these entries nor a methodology for their transfer to Annex IV (Annex listing restricted substances). In the opinion of UBA,

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[4] By means of comitology procedures, the European Commission - in collaboration with supporting committees – is given scope of action for the implementation of European legislation. They have been described in Decision 1999/468/EC (as amended by Decision 2006/512/EC). A short introduction into comitology is found under:http://europa.eu/scadplus/glossary/comitology_en.htm

[5] An overview of the problematic properties of the four substances and possible substitutes is given for example in the study by Öko-Institut e.V. (Institute for Applied Ecology) commissioned by the European Commission proper (2008): http://ec.europa.eu/environment/waste/weee/pdf/hazardous_substances_report.pdf.
Alternative plastic materials for plasticiser-free cable insulation are also described in: Federal Environment Agency (1999): Action Areas and Criteria for a precautionary, sustainable Substance Policy using the example of PVC.

[6] The pilot study for the German Environmental Survey in Children 2001 and further information on plasticisers are available (in German) under: http://www.umweltbundesamt.de/gesundheit/stoffe/weichmacher.htm.

[7] According to REACH, substances of very high concern refer to substances that are carcinogenic, mutagenic or toxic to reproduction of categories 1 and 2 (CMR substances), substances that are persistent, bioaccumulative and toxic (PBT substances), and substances that are very persistent and very bioaccumulative (vPvB substances). On an intermediate-term basis, substances having these properties may be used in the EU only under strict conditions. DEHP, BBP and DBP are toxic to reproduction, category 2, HBCD has been identified as a PBT substance.

orders to evaluate new substances on the basis of Annex III must be backed by clearly defined measures and deadlines. Furthermore, the European Commission should, irrespective of the substances currently listed there, include in the Directive a precise description of the general function of Annex III and establish a procedure for its updating, if required.

In addition to the substances mentioned above, UBA continues to advocate the restriction of the use of medium-chain chlorinated paraffins (MCCP) and the additive use of tetrabromobisphenol A (TBBPA), by means of their inclusion in Annex IV to the RoHS Directive. Both substances are flame retardants being harmful to the environment. These properties have also been sufficiently documented[8].

UBA supports the Commission's approach to maintain the RoHS Directive as an independent instrument instead of phasing it out in favour of the REACH Regulation.

There will be no duplication of regulatory activity if in the future, a substance will be subject to authorisation under the European chemicals regulation REACH, and subject to restriction under the RoHS Directive. The authorisation requirement under REACH (inclusion of a substance in Annex XIV to the REACH Regulation) differs essentially from a restriction under the RoHS Directive. An authorisation requirement under REACH will only refer to the use of a substance within the EU. The European Chemicals Agency has proposed the four substances mentioned above, i.e. DEHP, BBP, DBP and HBDC, to become subject to authorisation under REACH. Because of the existing procedural design, such authorisation requirement would become effective not earlier than within two to five years. As a result, the use of these substances in the EU would then be possible only in exceptional cases. If contained in imported articles, however, these substances are not subject to authorisation. In contrast, a restriction under the RoHS Directive constitutes a regulatory provision referring to specific products (EEE) and therefore, also applies to imported articles.

In addition, also the REACH Regulation has provided for the instrument of restriction besides that of authorisation, which is imposed by means of inclusion of a substance in Annex XVII to REACH. To achieve a comprehensive environmental and health protection, it is decisive whether articles imported from non-European regions, which also include a major share of electrical and electronic equipment, are covered by such legislation or not. The exclusion of hazardous substances from all EEE including imported products can only be ensured by restrictions on the placing on the market under the RoHS Directive or the REACH Regulation, but not by an authorisation requirement under REACH.

This means that a restriction which is to be also applicable to imported articles could as well be achieved by a restriction of substances used in EEE under the REACH Regulation instead of the RoHS Directive. However, this would no longer allow to apply for exemptions for single applications at a later date, as provided for under the RoHS Directive. In addition, the REACH Regulation does not include any provisions regarding product conformity assessment. Last but not least, the RoHS Directive – in connection with the Waste Electrical and Electronic Equipment (WEEE) Directive[9] – provides for substance restrictions also from the aspect of resource conservation while REACH is only aimed at a safe use of substances.

[8] An overview of the properties of these two substances and possible substitutes is also given in the study by the Öko-Institut (2008), see endnote 5.
[9] Directive 2002/96/EC.

UBA welcomes the European Commission's objective to achieve a better alignment of the instruments of the REACH Regulation and the RoHS Directive. However, the proposal for the revision of the RoHS Directive is lacking a concrete specification of the interface with REACH because it has failed to put in concrete terms in particular the methodology for including new substances in Annex IV (Annex listing restricted substances), as well as the responsible bodies and actors, deadlines for decisions, etc. UBA considers it necessary to establish such procedural items already at the level of the Directive.

Therefore, UBA advocates that the methodology for updating Annex IV – and if required, Annex III (Annex listing substances for which restrictions are to be considered) – is stipulated in the Directive proper. The same applies to the methodology for updating Annexes V and VI listing applications exempted from the bans. Clarification at a later date in the comitology procedure appears to be uncertain, postponed to an unknown time and therefore, disadvantageous.

Diverging from the approach for substance restrictions and authorisations under REACH, UBA advocates not to apply the instrument of socio-economic analysis for the RoHS Directive until experience has been gained with regard to this instrument and in particular, a generally accepted methodology has become available.

A detailed presentation and substantiation of the modifications considered necessary is given below in Section B while the links between the RoHS Directive and the REACH Regulation are explained in Section C.

B) Detailed evaluation and proposals for modifications

Preliminary remark

The European Commission has placed the present proposal for the revision of the RoHS Directive in the context of a "better regulation", which is aimed at understandable, effective and enforceable legal provisions. Although a number of measures to restructure the RoHS Directive are considered as meaningful, the present proposal does not yet meet the respective claim in full. Thus, single parts of the proposal appear to be ambiguous. The postponement of new basic regulations to the comitology procedure is considered as disadvantageous by UBA.

Scope

Current state

The scope of the RoHS Directive (Article 2 para 1) was uncoupled from the Waste Electrical and Electronic Equipment Directive (2002/96/EC). The categories of equipment and single products covered by the Directive are now listed separately in Annexes I and II to the RoHS Directive. In the future, also medical devices and monitoring and control instruments will gradually be included in the scope of the Directive.

Article 2 para 3 defines exceptions for equipment to which the RoHS Directive shall not apply.

Evaluation by the Federal Environment Agency (UBA):

- Article 2 para 1: The new provision is based on the claim of an improved legislation and harmonisation and in this regard, it is welcomed by UBA. However, experience gained with regard to enforcement suggests the necessity to improve the list of products specified in Annex II for enforcement purposes. A great number of EEE products are not listed in this Annex. As a consequence, each of such products would require a decision as to whether they come within the respective scope and if so, within which category of equipment. For reasons of legal certainty in enforcement, UBA therefore advocates the establishment of a detailed product list that is uniform on the EU level, centrally maintained and updated and published as part of the comitology procedure at regular intervals, e.g. once or twice a year. As an alternative to this product list, a new Annex to the RoHS Directive could stipulate binding decision criteria (a decision matrix) enabling a fast and transparent decision in cases of unclear product classification.
- Article 2 para 3: On principle, UBA recommends that a legal definition of the term “equipment” used in this paragraph is included in Article 3 in order to provide for legal certainty at an early stage of the procedure. In Article 2 para 3 point b, the term “type of equipment” is used. This term has not been defined and should be replaced by “equipment”.

Substances whose use in electrical and electronic equipment is restricted

Current state

The presently existing bans on the use of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE shall remain unchanged. However, they are no longer included directly in Article 4 para 1 of the Directive but instead, reference is made to the newly created Annex IV listing the restricted substances together with the tolerated maximum concentration values. The Commission's proposal does not contain any suggestions for restrictions of new substances not regulated so far by the RoHS Directive.

Evaluation by UBA

- The shift of the list of restricted substances from the Article part to the new Annex IV (Annex listing restricted substances) is considered as reasonable. It has resulted in a more conspicuous arrangement because it can now clearly be distinguished between substance restrictions and the procedure for the inclusion of new substances.
- The fact that the ban on the use of the flame retardant, decabromodiphenyl ether (DecaBDE), in EEE has been maintained is also rated as positive by UBA. The Commission has explicitly pointed out that the European risk assessment procedure for DecaBDE has not yet been terminated[10] and that there are serious indications of existing environmental and health risks from illegal disposal of discarded equipment containing DecaBDE outside of Europe.
- The fact that the Commission has not included new substances in Annex IV although there had been a number of substantiated proposals in the preliminary stages of the revision has been rated as negative by UBA. In the opinion of UBA, in particular the flame retardant, hexabromocyclododecane (HBCD) and the plasticisers, bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP) and dibutyl phthalate (DBP), should be directly restricted by inclusion in Annex IV to the Directive. All four substances are of ubiquitous distribution, being present in the human population and the environment and have been identified as substances of very high concern under REACH (cf. Section C).
  In addition, UBA recommends a restriction of the additive use of tetrabromobisphenol A (TBBPA) and of medium-chain chlorinated paraffins (MCCP).

Methodology for the inclusion of new substances in the RoHS Directive

Current state

The inclusion of new substances is dealt with in Article 4 para 7 of the Commission's proposal, which is cited below:

"Where there is an unacceptable risk to human health or the environment, arising from the use of substances, and in particular the substances listed in Annex III, which needs to be addressed on a Community-wide basis, the list of prohibited substances in Annex IV shall be reviewed using a meth-

[10] The ultimate results of the required monitoring studies will become available in 2014.

odology based on the process set out in Articles 69 to 72 of Regulation (EC) No 1907/2006[11]. Those measures designed to amend non-essential elements of this Directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2)."

Evaluation by UBA

This Article contains a number of imprecise and insufficient formulations:

- The inclusion of new substances in Annex IV (Annex listing restricted substances) is supposed to be carried out on the basis of the restriction procedure under REACH[12], which is plausible, on principle, against the background of a harmonisation of legislation. Since a reference to REACH Articles 69 to 72 only is incomplete, UBA recommends to add references to Article 68 (shortened restriction procedure for CMR substances[13]) as well as to Article 73 (obligations of the Commission in the decision) of the REACH Regulation.
- Furthermore, UBA advocates that in Article 4 para 7, not only unacceptable risks to human health or the environment should be mentioned as reasons for including a new substance in Annex IV, but also waste management aspects should be explicitly stated as a possible reason. This would correspond to the objective of the RoHS Directive to contribute to the environmentally sound recovery and disposal of waste electrical and electronic equipment, as stated in Article 1.
- UBA criticizes that in the Commission's proposal for the Directive, the methodology to include new substances has not been put in concrete terms but is supposed to be designed later on in the comitology procedure (regulatory procedure with scrutiny) by the regulatory committee of the RoHS Directive. This is not acceptable from the perspective of UBA since the matter concerned is not a technical problem but an essential part of the RoHS Directive. UBA recommends a concrete ruling on the procedure of including new substances in the Directive proper.
- If a restriction procedure is to be established on the basis of the methodology described in REACH, it has to be clarified, for example, whether the services of the corresponding ECHA expert committees[14] can and should be used, as favoured by the Commission in its argument to substantiate the modifications proposed. A consultation of the ECHA committees would offer the advantage that their expertise with regard to chemical assessment could be used and a duplicate consideration of the substances concerned could be prevented. This will, however, require integration of the specific angle of waste management concerning the disposal phase of hazardous substances in products and their objectives with regard to resource conservation, as shown by the experience with recycled plastic materials gained in the past. As an alternative to this linking with REACH panels, one could also consider the establishment of a separate expert panel making close reference to the assessments and procedures under the REACH Regulation.

[11] 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).

[12] REACH Title VIII "Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles", encompassing REACH Articles 68 to 73.

[13] CMR substances = substances identified as carcinogenic, mutagenic or toxic to reproduction.

[14] Committee for Risk Assessment and Committee for Socio-Economic Analysis.

- Due to the analogy with the REACH Regulation, it follows that both the European Commission and the EU Member States may propose restrictions on new substances. UBA proposes that this should be explicitly stipulated by the RoHS Directive.
- UBA supports that the final decision on the inclusion of a new substance in the RoHS Directive should be made, as envisaged, again according to the regulatory procedure with scrutiny by the responsible regulatory committee of the RoHS Directive. However, the Commission's proposal is lacking an explicit mandate to update Annex IV in the regulatory procedure with scrutiny. For reasons of a good legal regulation, UBA advocates to include such a basis for a mandate in Article 4 or 5. The basis for a mandate currently included in sentence 2 fails to clearly distinguish between a mandate to design the methodology to include new substances, on the one hand, and the inclusion of new substances proper, on the other, and is therefore unsuitable with regard to its wording.
- Finally, Article 4 para 7 implies an order to evaluate a restriction of the use of substances listed in Annex III – which currently includes HBCD, DEHP, BBP and DBP. UBA recommends to directly restrict the use of these substances and to include them in Annex IV (see above). Irrespective of the substances specified in Annex III, it is, in the view of UBA, indispensable for evaluation orders to be assigned a fixed deadline by which a decision has to be made. Currently, Annex III does not include any specific data as to measures or deadlines. Furthermore, it is important to clarify the basic function of Annex III and, if necessary, to add the mandate and the procedure for its updating.

Procedure for exemptions from existing substance restrictions

Current state

Articles 5 and 6 of the Commission's proposal provide information as to the procedure for the establishment of exemptions from existing substance bans. A remarkable new feature in this regard consists in the inclusion of socio-economic considerations as a possible argument for an exemption (Article 5 para 1 point b, third indent) while before, requirements were only made with regard to technical properties and aspects of environmental and health compatibility of alternatives. The latter are also contained in the new proposal, where the technical suitability has been specified more explicitly than before by adding a new indent (availability and reliability).

Furthermore, the proposal contains a number of clarifications with regard to exemptions from substance bans, for example concerning their validity period (Article 5 para 2), or envisages such clarifications in the comitology procedure, for example the type of information to be provided (Article 6). It is envisaged for exemptions granted under the RoHS Directive to automatically result in exemptions from the requirement of authorisation under REACH (Article 5 para 4).

Evaluation by UBA

- UBA welcomes the clarifications in matters of procedures and methodologies. However, UBA recommends to describe these in the Directive proper instead of postponing them to the comitology procedure (Article 6). Therefore, implementation measures should be specified already in Article 6 of the Directive proper.

— UBA holds a sceptical view with regard to the inclusion of socio-economic reasons as an additional possibility to substantiate exemptions from substance bans (Article 5 para 5 point b, third indent). In the future, the socio-economic analysis will be a requirement for the application for an authorisation under the REACH Regulation. In addition, socio-economic considerations have implicitly always played a role in the weighing of bans on the manufacture, use or placing on the market of substances. They are, however, extremely problematic to handle from the methodological angle because economic framework conditions may vary extremely and are difficult to predict. As a result, the socio-economic advantages and disadvantages are much more difficult to assess than the technical suitability and availability. Therefore, clear procedures are required for the consideration and discussion of the socio-economic pros and cons of an exemption. The obligation to present the arguments would have to be imposed on industry, other stakeholders would have to be able to provide input, for example non-governmental organisations or companies offering alternatives. Due to the lack of experience gained under the REACH Regulation, UBA recommends to refrain from envisaging exemptions based on the socio-economic route for the time being and to fix a deadline for a review of this fundamental decision. A corresponding review clause for 2012 could be included in the Directive.
— It is unnecessary to repeatedly point out the requirement of the technical suitability of possible alternatives (Article 5 para 1, point b, second indent) because the latter is already implied in the first indent as a subset of "scientifically or technically practicable". It is therefore recommended to delete the second indent.
— The comments by stakeholders on amendments proposed by the Commission should continue to be forwarded to the responsible Committee and therefore, the second sentence in Article 5 para 3 should not be deleted.
— UBA holds the opinion that exemptions granted under the RoHS Directive should not automatically imply an exemption from the authorisation requirements set out in the REACH Regulation (Article 5 para 4). This would be considered as acceptable by UBA only on condition that the standards of the REACH Regulation regarding the production process etc. are also taken into account in the decision on the exemption under the RoHS Directive. Since this is not the case, UBA does not support the envisaged automatism.

Conformity assessment and market surveillance

Current state

With the completely new Articles 7 to 17, the Commission's proposal contains detailed provisions on conformity assessment and market surveillance that have been non-existent so far in the RoHS Directive. Also in this case, the changes are based on the motivation to harmonise this Directive with the provisions of other Directives, particularly with the new internal market package[15].

[15] The internal market package serves to reduce technical trade barriers in the European internal market. It follows the New Approach of 1985 (Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01) and comprises the legal instruments, Decision No 768/2008/EC, Regulation (EC) No 765/2008 and Regulation (EC) No 764/2008, which were adopted in July 2008.

Evaluation by UBA

On principle, UBA supports the proposal by the Commission to stipulate concrete requirements for conformity assessment and market surveillance directly in the Directive in order to provide for a better enforcement of bans on the use of hazardous substances in EEE. There has been no detailed evaluation of the proposal by UBA.

C) Interaction between the RoHS Directive and the REACH Regulation

The European Commission has envisaged to intensify harmonisation of the different legal domains in order to promote comparable standards and better comprehensibility and to avoid a duplication of regulatory efforts. While a comprehensible, unbureaucratic legislation is a meaningful objective, the efforts to integrate different regulation domains may also result in an agreement on the lowest level of protection for environment and health or promote a policy of wait-and-see and constant reference to the other legal domain. The sections below explain different aspects of the interaction between the RoHS Directive and the REACH Regulation.

The substances, HBCD, DEHP, BBP and DBP under REACH

In its Annex III, the Commission's proposal has listed four substances which are to be subjected to priority review with regard to their inclusion in restrictions under the RoHS Directive: the flame retardant, hexabromocyclododecane (HBCD) as well as the plasticisers, bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP) and dibutyl phthalate (DBP).

Apart from the revision of the RoHS Directive, the substances mentioned above were identified as substances of very high concern under REACH in the autumn of 2008 and included in the candidate list (list according to Article 59 para 1 of the REACH Regulation).[16] HBCD has been identified as a PBT substance, DEHP, BBP and DBP are toxic to reproduction, category 2, and thus, classified as CMR substances. Hence, these substances fulfil the conditions to become subject to authorisation requirement. By 1 June 2009, ECHA will produce a draft recommendation for the inclusion of substances in Annex XIV (list of substances subject to authorisation) of the REACH Regulation. This draft recommendation will in all probability include DEHP, BBP, DBP and HBCD and will subsequently be considered by the REACH regulatory committee.

An authorisation requirement under REACH means that a substance may not be used in the EU without an authorisation granted upon application. Substances subject to authorisation are listed in Annex XIV to the REACH Regulation. Conditions for being granted an authorisation include a safe use, lack of alternatives and predominant socio-economic advantages. The authorisation requirement refers only to the placing on the market and the use of substances, respectively, but not to that of articles. Hence, articles produced outside of Europe are not subject to authorisation.

The restriction of the use or placing on the market of a substance in articles under REACH does not provide for exemption applications by industry and applies both to articles produced in the EU and imported articles. Restrictions are listed in Annex XVII to the REACH Regulation. Applications to which the restrictions apply, as well as possible exemptions, will be laid down in a binding way by the Members States in advance. At present, there are no recommendations to restrict the use of DEHP, BBP, DBP and HBCD in articles under REACH.

The substances, HBCD, DEHP, BBP and DBP represent relevant hazardous substances in EEE, which have been identified as substances of very high concern under REACH. At present, these substances are only considered by Annex III to the RoHS proposal. UBA advocates the direct inclusion in An-

[16] For the current state of the candidate list see: http://echa.europa.eu/chem_data/candidate_list_table_en.asp.

nex IV to the RoHS Directive to restrict these substances. In contrast to the authorisation procedure under REACH, this is the only way to definitely ban their use also in imported goods.

Differences between the RoHS Directive and the REACH Regulation

Although both legal instruments refer to the regulation of substances, there are essential differences between the two. This is why they will continue to remain valid in parallel, as explicitly confirmed in Article 2 para 2 of the RoHS proposal as follows: "This Directive shall apply without prejudice to requirements of Community legislation on safety and health, on chemicals, in particular Regulation (EC) 1907/2006 as well as of specific Community waste management legislation."

Below, comments are made on the differences and common features as well as on the existing needs for clarification.

The importance of the disposal phase

In particular the life cycle phase of waste treatment is dealt with only very superficially by REACH. In this legal instrument, the subject of the waste phase is largely left to waste legislation. It has only to be taken into account in the context of considerations on exposure. Yet even these provisions of the REACH Regulation will become effective with delay because the corresponding technical guidance document has remained insufficient so far. However, a revision has been envisaged by ECHA. Only after such a revision has been carried out, it will be possible to evaluate the effectiveness of the REACH instruments regarding the waste phase. It has been the objective of REACH to achieve a safe use of substances over their entire life cycle, i.e. also during waste disposal. A reduction of levels of harmful substances in articles in order to enable a recycling economy and as a result, protect resources, is not mentioned among the objectives of the REACH Regulation. In contrast, the RoHS Directive, in connection with the WEEE Directive, also supports resource conservation measures.

Evaluation of emissions from manufacturing and processing

These phases of the product life cycle are assessed by REACH in detail, while in contrast, no systematic assessment is conducted under the RoHS Directive. The use phase of single EEE is not assessed in a differentiated way by neither of them.

Definition of placing on the market

The concept of "placing on the market" in the RoHS Directive refers to the first making available of an EEE on the European Community market. In contrast, the concept has been assigned a broader meaning under REACH by including each instance of making available, i.e. for example also the transfer of (a substance in) used products to a third party.

Validity for imported articles

Substance restrictions under the RoHS Directive apply directly also to imported articles from non-EU regions. This is the case under REACH only if a restriction has been imposed in Annex XVII, but not in case a substance has been included as being subject to authorisation under Annex XIV.

Measures for conformity assessment

The Commission's proposal for the revision of the RoHS Directive has envisaged measures for conformity assessment defining obligations for manufacturers, importers and distributors and resulting in the labelling of EEE with the CE marking. This serves the purpose of a better enforcement of the RoHS Directive and its harmonisation with existing legal regulations for other product groups, for example for toys or construction products. In contrast, no comparable measures for conformity assessment would be envisaged for EEE under the REACH Regulation because the latter is a regulation referring to substances instead of products (articles). In addition, in the RoHS proposal, the Member States are obliged to perform market surveillance.

Reference levels for concentration limits of restricted substances

In the two legal instruments, different reference levels are used for the concentration limits in articles. The maximum concentration values stated in the RoHS Directive refer to a homogeneous material. The REACH Regulation, based on the interpretation by the European Commission and a majority of the Member States, assumes that the concentration limits are to be applied to the entire article. However, this interpretation has been a subject of controversy and is not shared by Germany, together with other countries, which, especially for reasons of consumer protection, have demanded that the limit should relate to a smaller unit (article component).[17] As a consequence of the objections, ECHA is currently reviewing its interpretation.

Granting of exemptions

The two options under the REACH Regulation of 1) authorisation requirement, i.e. the option of a ban on the use with the possibility to apply for exemptions, and of 2) restriction – without the possibility to apply for exemptions later – are not compatible with the procedure under the RoHS Directive. The RoHS Directive combines two procedures whose combination is not envisaged under REACH, namely a general restriction of substances contained in products - applying to all new products on the European market irrespective of their place of manufacture - with a procedure for granting temporary exemptions. On principle, (temporary) exemptions also exist for restriction under the REACH Regulation. However, there is no established mechanism to apply for such exemptions after entry into force of the restriction ruling. The exemptions are already defined when imposing the restriction.

Consistency of procedures under the RoHS Directive and the REACH Regulation

Methodology for inclusion of new substances

The Commission has proposed that the inclusion of new substances in the RoHS Directive should be in line with the REACH methodology.

However, such proposal fails to take into account essential articles of the REACH Regulation: Neither the simplified procedure for restrictions of CMR substances of Article 68 para 2 nor the deadline for the Commission decision according to Article 73 of the REACH Regulation have been mentioned.

[17] Cf. http://guidance.echa.europa.eu/docs/guidance_document/dissenting_en.pdf.

In its argument to substantiate the RoHS proposal, the Commission furthermore approves of taking advantage of the activities of the ECHA committees (Committee for Socio-Economic Analysis and Committee for Risk Assessment) as far as possible also under the RoHS Directive. This is reasonable insofar as the same substances will not be considered by two different committees and problems affecting both the REACH Regulation and the RoHS Directive can be clarified more easily. In this case, however, the ECHA committees will also have to ensure a consultation of waste management expertise.

A harmonisation with the procedure under REACH would – as envisaged in the Commission's proposal – also mean the introduction of socio-economic considerations under the RoHS Directive. This applies both to the inclusion of new substances in Annex IV and to the establishment of the exemptions in Annexes V and VI, respectively. In this respect, however, the question arises as to what extent consistency between the two legal provisions can be achieved in a convincing way as long as there is no sufficiently tested and generally accepted methodology available for socio-economic analyses.

Approach in cases of simultaneous regulation of a substance under the REACH Regulation and the RoHS Directive

In cases where a substance is considered under both legal instruments - for example if a substance is subject to authorisation under the REACH Regulation and banned in electrical and electronic equipment under the RoHS Directive - the ban under the RoHS Directive will have priority and apply only to EEE. An authorisation under the REACH Regulation will apply to all other fields of application. It can not overrule a restriction under the RoHS Directive.

Therefore, exemption from a restriction under the RoHS Directive can only be obtained by means of the procedure stipulated in the RoHS Directive.

On the other hand, the Commission has proposed that in the future, an exemption granted under the RoHS Directive shall imply an exemption from the authorisation requirement laid down in the REACH Regulation (Article 5 para 4 of the RoHS proposal). As a consequence, a substance subject to authorisation under REACH could then be used again for the production of EEE in the EU, in the field of application to which the exemption refers, without imposing any further requirements. In the view of UBA, the European Commission should abandon the automatism implied in Article 5 para 4. Exemptions from the authorisation requirement are to be regulated by the means available under the REACH Regulation. In particular, it has to be taken into account that the question of exposure during manufacturing and processing is not comprehensively considered by the RoHS Directive, and the REACH Regulation provides for strict requirements for the handling of a substance, which then would perhaps not exist under the RoHS Directive.

Outlook

There are interfaces between the instruments of the RoHS Directive and the REACH Regulation which have to be dealt with by means of clear rules of procedure. The envisaged use of ECHA expertise in the decision on restrictions under the RoHS Directive would ensure that the consequences for regulation under the REACH Regulation are sufficiently taken into account. At the same time, however, it

has to be ensured that also the waste management perspective is taken sufficiently into account by ECHA.

Altogether, UBA holds the opinion that although basic elements of the envisaged clear reference and consistency regarding procedures and methodology between the two legal instruments, REACH Regulation and RoHS Directive, are contained in the Commission's proposal, a satisfactory design of these features is still missing.