TEXTE
08/2012

# Reach and the recycling of plastics

## Reference manual for an appropriate implementation of the REACH requirements for the operators of recycling plants

Umwelt Bundes Amt
Für Mensch und Umwelt

| TEXTE | 08/2012

ENVIRONMENTAL RESEARCH OF THE
FEDERAL MINISTRY OF THE ENVIRONMENT,
NATURE CONSERVATION AND NUCLEAR SAFETY

Project No. (FKZ) 3708 31 305 1
Report No. (UBA-FB) 001522/E

# Reach and the recycling of plastics

## Reference manual for an appropriate implementation of the REACH requirements for the operators of recycling plants

by

**Dirk Jepsen, Antonia Reihlen, Olaf Wirth, Knut Sander**
Ökopol Institut für Ökologie und Politik GmbH, Hamburg

**In cooperation with**
PlasticsEurope Germany
GKV, The German Association of the Plastics Processing Industry
tecpol Technology Development GmbH for Eco-efficient Polymer Recycling
Working group PVC and environment
Poly Beek GmbH
Rampf Ecosystems GmbH & Co. KG
Daimler AG
Volkswagen AG

On behalf of the Federal Environment Agency (Germany)

UMWELTBUNDESAMT

This publication is only available online. It can be downloaded from
http://www.uba.de/uba-info-medien-e/4263.html along with a
German version.



ISSN 1862-4804

Study performed by: Ökopol - Institut für Ökologie und Politik GmbH
Nernstweg 32–34
22765 Hamburg

Study completed in: January 2012

Publisher: Federal Environment Agency (Umweltbundesamt)
Wörlitzer Platz 1
06844 Dessau-Roßlau
Germany
Phone: +49-340-2103-0
Fax: +49-340-2103 2285
Email: info@umweltbundesamt.de
Internet: http://www.umweltbundesamt.de
http://fuer-mensch-und-umwelt.de/

Edited by: Section III 1.2 Implementation of the Electrical and Electronic Equipment Act and the Batteries Act
Wolfgang Beier

Dessau-Roßlau, March 2012

# Table of Contents

## Abbreviations

| | |
|---|---|
| BAuA | German Federal Institute for Occupational Safety and Health |
| BDI | Federal Association of German Industry |
| CLP | Classification, labelling and packaging of chemical substances and mixtures |
| DEHP | Di (2-ethylhexyl) phthalate |
| DSC | Differential Scanning Calorimetry |
| DSD | German Dual System |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EuPR | European Plastic Recyclers |
| GADSL | Global Automotive Declarable Substance List |
| IMDS | International Material Data System |
| LFGB | German Foodstuffs, Consumer Goods and Animal Feed Code |
| MFI Melt | Flow Index |
| MVR | Melt Volume Rate |
| PA | Polyamide |
| PBT | Persistent bioaccumulative and toxic |
| PE-HD | Polyethylene high density |
| PET | Polyethylene terephthalate |
| PMMA | Polymethyl methacrylate |
| PP | Polypropylene |
| PPK | Paper, card and cardboard packaging |
| PVC | Polyvinylchloride |
| REACH | Registration, Evaluation and Authorisation of Chemicals |
| XFA | x-ray fluorescence analysis |
| RoHS | Restriction of the use of certain hazardous substances |
| SDS | Safety data sheet |
| SH | Safety note (under Article 32, REACH) |
| SVHC | Substances of very high concern |
| UBA | German Federal Environment Agency |
| VCI | German Chemical Industry Association |
| vPvB | Very persistent and very bioaccumulative |
| WFD | Waste Framework Directive |

# 1. REACH and plastic recyclers

The European Regulation 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)[1] came into effect on 1 June 2007. This reference manual is intended to describe the most important aspects and regulations for plastic recyclers, and provide the reader with guidance on how successful REACH implementation can be carried out in one's own organisation.

The REACH regulation interfaces with waste legislation at various points, but forms a free-standing, demarcated legislative domain:

- ☐ In principle, REACH does not apply to waste; however,
- ☐ substance manufacturers must consider the disposal of their substances in their risk assessment under REACH.

A recycler becomes the manufacturer of substances when the latter leave the waste regime, thus once again become a product. At that point, other than some special exemptions, recyclers are subject to all the REACH duties that apply to substance manufacturers.

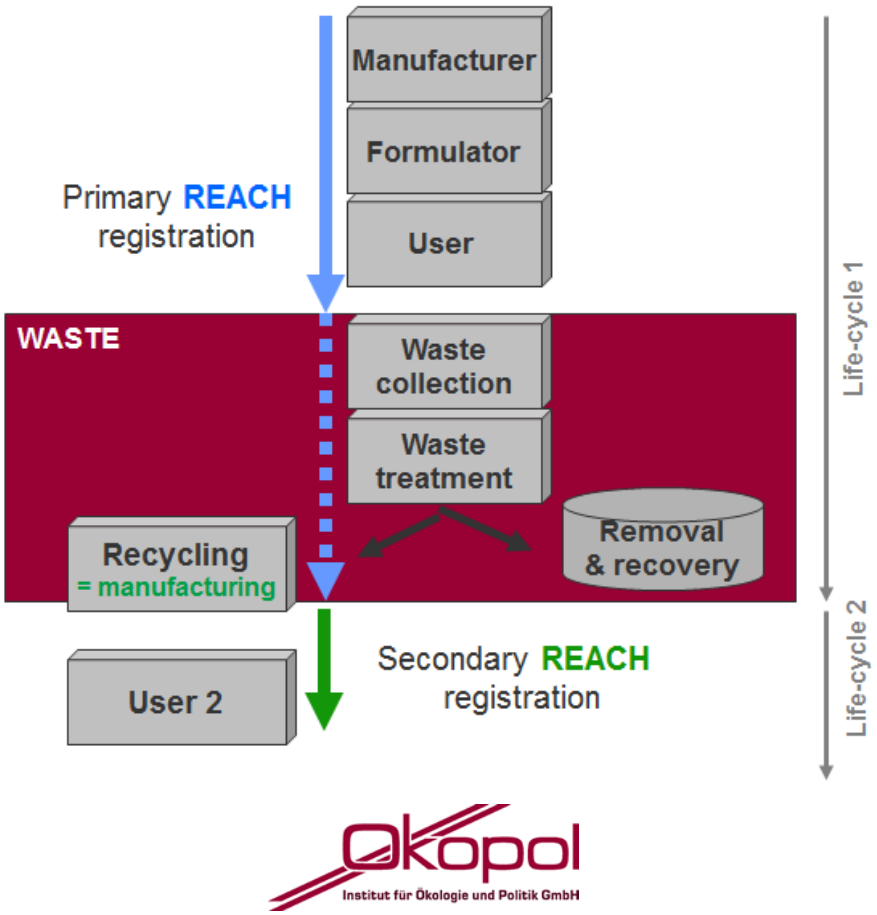


**Fig. 1:** Life-cycle of a substance: interfaces between REACH and waste legislation (blue: primary manufacturer's responsibility, green: secondary manufacturer's/recycler's responsibility)

[1] Regulation (EC) No. 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals

Generally speaking, REACH imposes both on manufacturers and importers and also on downstream users of (chemical) substances, the duties of safety assessment and information disclosure in the supply chain. This applies in particular to hazardous substances. Substances are hazardous if they meet at least one of the criteria specified in Article 3 of the CLP Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006. Even more extensive requirements apply to hazardous substances identified under Article 57, REACH as 'substances of very high concern'[2], and to substances, mixtures[3] and articles that contain them as (impurity) constituents.

The concrete implementation and practical solution approaches to recyclers' duties under REACH are described in the following chapters. Below is an overview of the contents of individual chapters:

**Chapter 2: REACH and waste legislation (beginning and end of waste property)**

Since as a matter of principle, REACH applies to all chemical substances but not to waste, the beginning and end of a material's status as waste are of special significance for recyclers. Chapter 2 provides an overview of the prevailing regulations governing the waste property and its possible future definition under the revised waste framework directive.

**Chapter 3: Registration duties under REACH**

REACH requires manufacturers and importers of substances, to have them registered with the European Chemicals Agency (ECHA) in Helsinki.

As already discussed, recyclers are 'manufacturers' under the REACH definition[4], since they manufacture either a chemical substance, a mixture or an article in which chemical substances are contained. Recyclers are subject to the same rules under REACH as any other substance manufacturer. In the recitals[5] to REACH, however, the legislator made clear that the intention is to accord the recycling of waste a special status. Therefore, Article 2(7d) introduced a 'recycling privilege' that creates special exemptions from registration. The prerequisites for asserting these exemptions are described in Chapter 3.

**Chapter 4: Providing information about recycled substances**

REACH and the CLP Regulation require the distributors of (chemical) substances to determine the hazard profile of these substances (or in the case of recycling, also of the mixtures), and then to carry out appropriate classification and labelling.

In order to support the safe use of their recycled products, recyclers must collect information about the ingredients and provide the classification and labelling to their customers. Chapter 4 describes various methods for correctly providing information about substances, in particular about options for pragmatic and responsible handling of waste stream-specific impurities, and for adequate documentation in order to meet the requirements under REACH.

[2] SVHC = substances of very high concern

[3] With the introduction of the CLP Regulation, the term 'mixture' replaces the former term 'preparation'.

[4] Cf. the relevant legal interpretation of the EU Commission in: Waste and recovered substances, CA/24/2008 rev. 3, Follow-up to 5th Meeting of the Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH), (English version) http://ec.europa.eu/enterprise/reach/docs/reach/waste_paper_ca_090403_en.pdf , (German unofficial translation via REACH Hamburg http://reach.hamburg.de/62.html )

[5] cf. Regulation 1907/2006/EC, recital 11

**Chapter 5: Providing REACH-compliant information to customers**

A central element of REACH is communication between the players regarding the hazardous properties of the chemical substances being used. These duties apply also to recyclers. In the case of hazardous substances and mixtures, safety data sheets should be prepared pursuant to REACH Article 31. Under REACH Article 32, information has also to be provided for certain non-classified substances or mixtures. Manufacturers of articles are required under Article 33 to provide information to their customers about substances of very high concern. For the procedure to be followed and aids for the preparation of these various types of information, see Chapter 5.

# 2. REACH and waste

## 2.1. Interfaces between substance legislation and waste legislation

Part of the life cycle of most industrially manufactured substances is that they are incorporated into products that sooner or later become waste.

REACH Article 2 (2) states: "*Waste as defined in Directive 2006/12/EC*[6]*of the European Parliament and of the Council is not a substance, preparation or article within the meaning of Article 3 of this Regulation".* The above means that waste is not subject to the rules of the REACH regulation, thus establishing a far-reaching exemption from the requirements imposed by REACH.

[6] Directive 2008/98/EC replaced the old Waste Framework directive

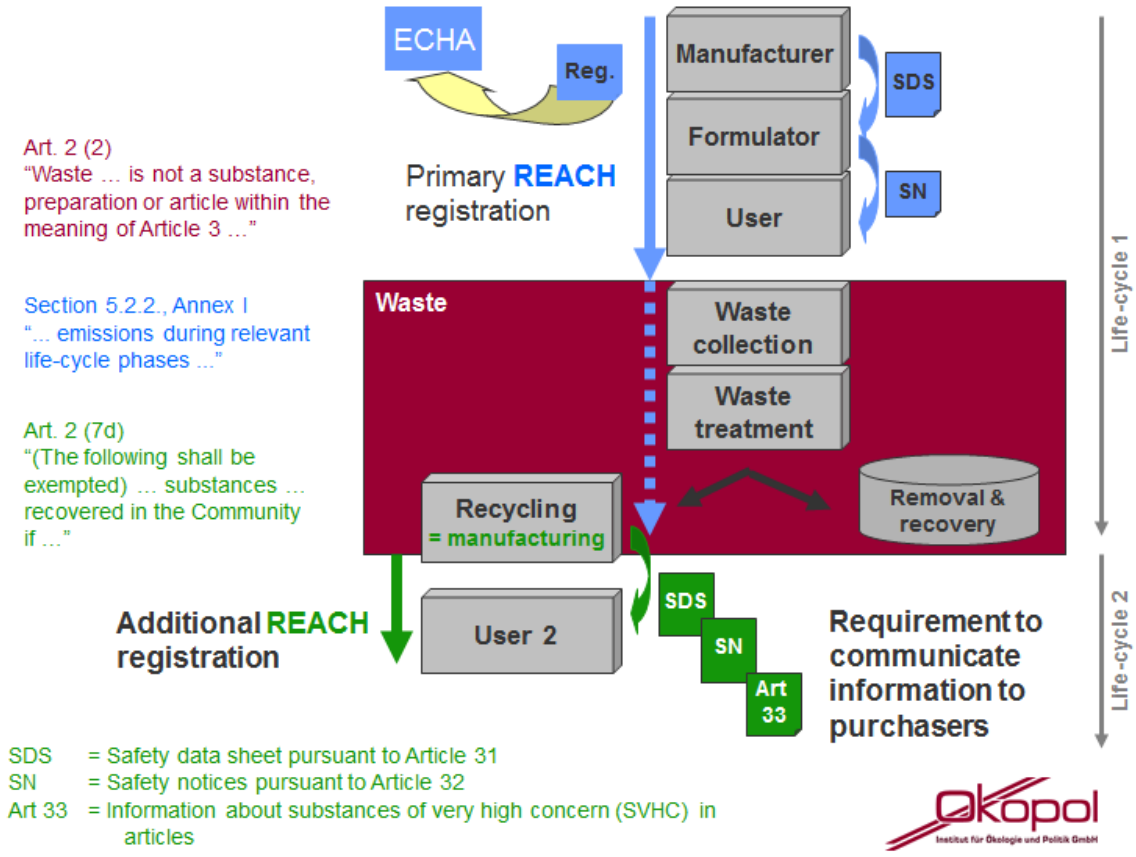


**Fig. 2:** Interfaces between REACH and waste legislation (blue :REACH duties arising from the primary life cycle of the substance, responsibility lies with the primary manufacturer; red: waste phase of the substance, no direct REACH duties; green: REACH duties arising from the secondary life cycle of the substance, responsibility lies with the secondary manufacturer = recycler)

The exclusion of waste from the scope of REACH does not, however, mean that REACH is irrelevant to the waste phase of a substance as such (Fig. 2). For all substances covered by REACH for which a safety assessment has to be carried out as part of the registration process, it is also required explicitly to assess the possible exposure during the waste phase. Specifications relating to use, disposal and risk management procedures that are necessary for safe handling in all life-cycle stages of the substance, should be identified and communicated along the value-added chains[7].

For recyclers of plastics, it is important to demarcate exactly when they have to deal with waste and when not. In purely practical terms, they need to establish whether their 'raw materials' are waste within the meaning of the Waste Framework Directive, or possibly remain substances, mixtures or articles within the meaning of REACH. In the latter case, the recycler is a downstream user with the corresponding duties.

In working practice, the two domains may well overlap. If, for example, polyamide waste from the electrical industry that contains red phosphorus flame retardant is recycled and post-additivated with fresh phosphorus, then in respect of the added phosphorus mixture the recycler is a downstream user and subject to the REACH regulations. Recyclers receive from the flame

[7] This results inter alia from the relevant explanations in sections 5.1.1 and 5.2.2 of Annex I of the REACH Regulation. According to them, as part of REACH registration, the primary manufacturer of a substance should consider all the relevant phases of the life cycle, including the waste phase. In addition, as part of risk management procedures, the primary manufacturer should define procedures "*for waste handling so as to minimise or prevent the exposure of humans and the environment to the substance during waste disposal and/or recycling*".

retardant's supplier an augmented SDS for the phosphorus mixture, and are required to check whether their conditions of use agree with the specifications listed there and whether they implement the recommended risk management procedures[8].

For the polyamide and the fraction of red phosphorus originating in the waste, however, on completion of recycling the recyclers are substance manufacturers under REACH and must fulfil the corresponding obligations including registration, unless they can rely on recycling privilege exemptions under Article 2 (7d). The following diagram shows this situation again.

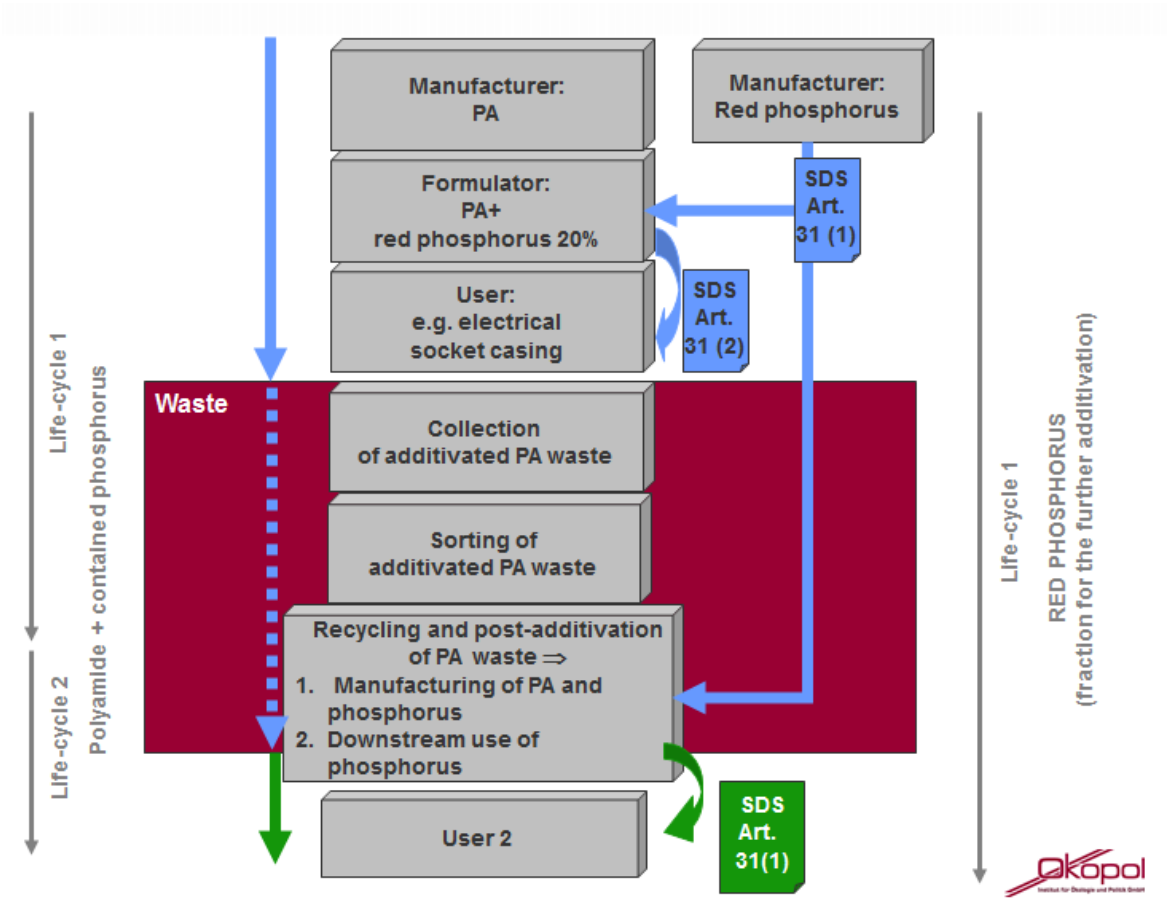


Fig. 3: Recycling of phosphorus-containing polyamide waste from the electrical industry. For substances that originate in the waste, the recycler is a substance manufacturer (polyamide, phosphorus). Post-additivation with 'primary' red phosphorus is a downstream use under REACH. During use by the recycler, this part of the phosphorus is not deemed to be waste. The recycler has, therefore, the simultaneous REACH roles of a recycled material's manufacturer and of a downstream user.

[8] Article 37, REACH describes the procedure carried out by downstream users on receipt of a safety data sheet, and the further options for producing their own chemical safety assessments. Article 39 requires the downstream user to implement the requirements under Article 37 within 12 months of receiving the registration number (i.e. an SDS with registration number). A REACH guideline issued ECHA on the requirements to be met by downstream users is available at http://echa.europa.eu/documents/10162/17226/du_en.pdf

### 2.2. Beginning of the waste property

As regards the beginning of the waste property, is Article 3 (1) – Definitions – of the new Waste Framework Directive 2008/98/EC[9] (WFD) relevant. Here, waste is defined as follows: '*Waste' means any substance or object which the holder discards or intends or is required to discard.* This addresses both the subjective concept of waste – i.e. the intention to discard - and the objective one, i.e. the need to handle materials within the waste regime for reasons of environmental or health protection.

The transition of a material into the waste regime on the basis of the 'objective' waste concept can take place, for example, when car batteries containing heavy metals stand in a public space and leaking of the battery fluid may be feared.

However, the subjective concept of waste plays a significantly greater role. In the normal case, it can be assumed that the holder of a material expresses his intention to discard it by transferring the material into a domain regulated by waste management systems (e.g. a colour-coded statutory recycling bag) or handing it over to a waste management operator (e.g. a waste collector).

For the operators of recycling plants, this means in practice that they can assume with a high degree of certainty that the delivered materials are indeed waste, when they are accompanied by statutory documents for waste. In the future, therefore, clarity should be urged even more emphatically, i.e. the actual delivery of appropriate documentation – even where this has not been made compulsory under statutory waste regulations.

### 2.3. End of the waste property – start of REACH

As regards the end of the waste property of a material, e.g. within a recycling process, Article 6 (1), WFD is pertinent:

*"Certain specified waste shall cease to be waste within the meaning of point (1) of Article 3 when it has undergone a recovery, including recycling, operation and complies with specific criteria to be developed in accordance with the following conditions:*

*a) the substance or object is commonly used for specific purposes;*

*b) a market or demand exists for such a substance or object;*

*c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and*

*d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.*

[9] The new Waste Framework Directives (2008/98/EC) replaced the 'old' Waste Framework Directive.. In this document, the references are always to the new version. Analogous definitions can be found in the 'old' Directive, in Art. 1 subs. 1 (Directive 2006/12/EC).

*The criteria shall include limit values for pollutants where necessary and shall take into account any possible adverse environmental effects of the substance or object."*

Following intensive discussions and legal disputes in recent years around the question "When does waste cease to be waste", the legislator has anticipated that this statutory definition will be inadequate for resolving unambiguously the large number of practical applications.

For this reason, Article 6 (2) of WFD describes a method for further clarifications based on specific substance streams. Accordingly, over the coming years, expert committees will develop concrete definitions and demarcation criteria for various substance streams in delegated legislation processes[10]. For plastics, the process is currently in the pipeline; relevant EU regulations are not expected before 2012.

The decisive question is, at which step during the recycling process (of the recovered materials) the change from waste to (chemical) product takes place. The EU Commission addresses this point by way of interpreting the term 'final recovery'. Accordingly, the relevant process step is the one resulting in a product that is no longer waste.

The form in which the recycled product re-enters the ambit of REACH may vary from case to case. It can be a substance, a mixture or an article.

A potential registration requirement applies to the player who performs the 'final recovery'. All the preceding process steps come under the waste regime; and all subsequent ones are either downstream uses under REACH (the product is a substance or a mixture), or an article is created for which, substantially, only information requirements[11] need to be fulfilled.

Until the implementation of EU-wide regulations concerning the end of waste property for plastic recycling, the present statutory waste provisions apply 'on site'. However, in many cases these have not been broken down at the level of individual process steps. If a plastics recycler wants to achieve clarity about the appropriate implementation of the new statutory requirements that relate to chemicals, it may be useful to find out directly from the competent waste authority where exactly the waste property ends; e.g. as early as the mill material (a substance or mixture under REACH), or only at the downstream manufacturing of profile materials and the like (an article under REACH).

[10] The competent body under WFD is a Technical Adaptation Committee.

[11] Notification (Article 7) and communicating information to customers (Article 33), if the article contains SVHC from the Candidate List. Registration is compulsory only for deliberately released substances, which virtually does not occur in the case of products from recycled materials.

# 3. Exemptions from the registration requirement for substances resulting from recovery processes

Under certain prerequisites, REACH offers recyclers an exemption from the requirement to register substances originating from recycling. This exemption is established in Article 2 (7d), REACH (recycling privilege):

*"The following shall be exempted from Titles II, V and VI[12]:*

*… substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if*

*i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and*

*ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery."*

Thus, several conditions need to be met before the recycling privilege can be asserted. To begin with, the recycler itself must be domiciled in the EU or perform the recycling (the production) in the EU. For plastics recycled outside the EU and then imported as granulate, the importer cannot make use of the recycling privilege. Like all other imported chemicals, the contained substances must be registered.

The further key prerequisites of the recycling privilege,

- Conformity of the identity of the recovered substance with an (already) registered substance, and
- availability of the prescribed information about the registered substance,

are discussed below.

### 3.1. Ensuring substance identity

The requirements of Article 2 (7d) state that the manufactured (or recycled) substance must be identical with an already registered substance. The question then arises as to when substances are identical. Since substances are not 100% pure and may, for example, contain impurities resulting from the manufacturing process, there exists a fundamental rule for determining substance identity under REACH:

*Substances are identical where the main constituent[13] makes up 80% or more of the recyclate and has the same name as another (already registered) substance[14].*

[12] Title II: Registration of Substances, Title V: Downstream users, Title VI: Evaluation.

[13] Main constituent: a constituent, not an additive and not an impurity, present in a substance and making up a significant fraction of it and consequently used for the designation and detailed identification of the substance. (Guidelines for the identification and naming of substances under REACH, http://echa.europa.eu/documents/10162/17235/substance_id_en.pdf ,)

[14] Cf. relevant ECHA guidelines, Guidance for identification and naming of substances in REACH (http://echa.europa.eu/documents/10162/17235/substance_id_en.pdf and Guidance on wasteand recovered substances chapter 2.2.3. Distinction between substance, mixture and article http://echa.europa.eu/documents/10162/17224/waste_recovered_en.pdf ).

If a recyclate, for example, is more than 80% PP polymer, then under REACH it has the substance name polypropylene (PP). Thus, within the meaning of Article 2(7d), it is identical with the corresponding polymer manufactured by means of polymerisation. The remaining 20% can be regarded as impurities in the PP, regardless of their origin (e.g. impurities from the prior use) or purpose (e.g. residual contents of additives) in the original polymer.

This general rule has an exception in recycling, namely where one of the ingredients is recovered deliberately due to a particular property. In this case, it is not a single substance that is manufactured but a mixture.

One example is the recovery of impact-modified PVC (with a physical admixture of polymethyl methacrylate (PMMA, <20%)). Where such waste is recycled in order to obtain again an impact-modified PVC granulate, it is assumed that the PMMA is being recovered deliberately. That is to say, 2 substances are manufactured in the form of a mixture, the plastic PVC and the additive PMMA.

If the recyclate contains several substances (additives, impurities etc) above the 20% impurities limit, then in any event this is a mixture with several substances. For example, a soft PVC compound consisting of 40% plasticiser (e.g. DEHP) and 60% PVC is deemed a mixture under REACH. The recycler has manufactured two substances, the PVC and the DEHP, and must meet the corresponding REACH requirements.

Fig. 4 is an overview of the options usually encountered in plastic recycling for describing substance identity.[15]

[15] There exist further options for substance identification. Normally, however, they do not result in the recycling privilege coming into effect, since recycled plastics are mostly only 'already registered' where the individual components are identified as mono-constituent substances. Cf. also Guideline for the Identification and Naming of Substances under REACH, Chapter 4.2.2 (Multi-constituent substances) and Chapter 4.3.1 (UVCB substances, substances of unknown or variable composition).

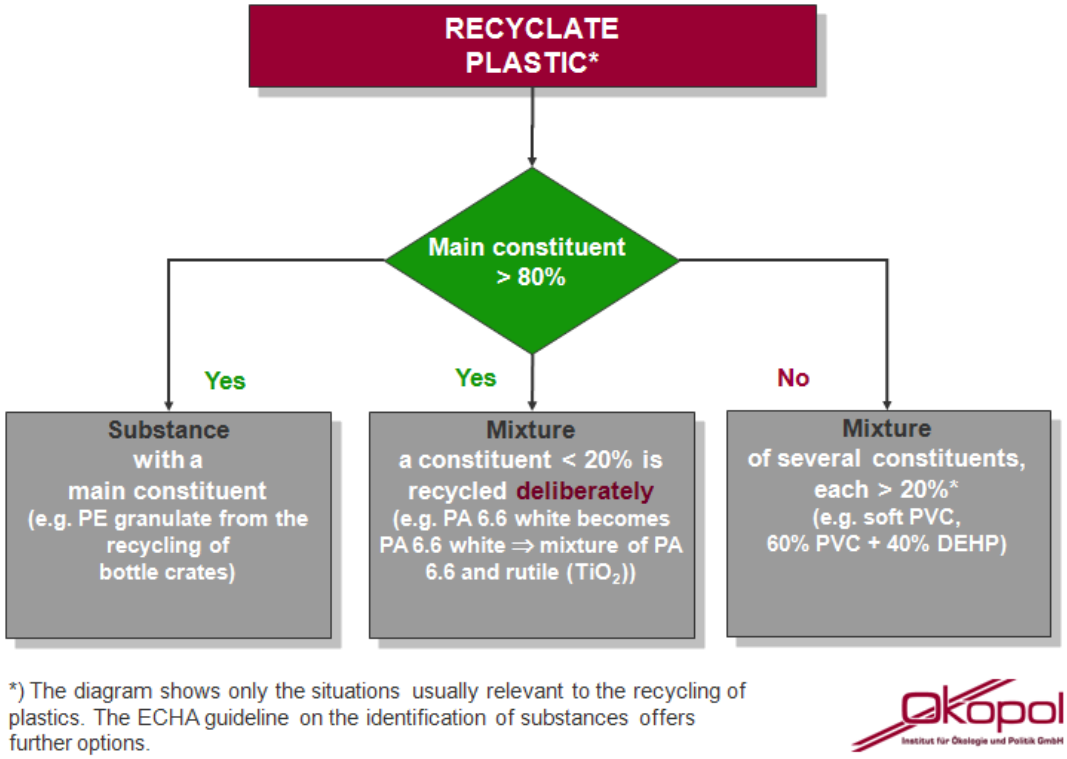


Fig. 4: Flowchart describing the identification of substances in recycled plastics (after CA/24/2008 rev. 3, Chapter 3.1.2.)

In order to make use of the recycling privilege under Article 2 (7d), recyclers need to check whether REACH registration already exists for the substances identified in the recycled material as above. The question in the soft PVC example, then, is this: does a registration exist for the PVC's precursors and does a registration exist for DEHP?

Since September 2009, information on whether registration for a particular substance exists can be looked up on one of the lists published by ECHA[16].

At this point, however, plastics recyclers need to consider another special feature of REACH. Under REACH, polymers have to be registered not as such but rather their chemically bound constituents, i.e. the monomers[17], and other reactants.

The question to be resolved, then, becomes more complicated since on the one hand it is necessary to determine which monomers are contained in the recycled plastic waste, and on the other, to check for the existence of registrations for these monomers. In particular, often the recycler cannot afford to identify the monomers.

[16] http://echa.europa.eu/chem_data/registered_substances_en.asp

[17] Explanations on the polymer concept under REACH and the requirements consequent on this, can be found in the Guidance on polymers http://echa.europa.eu/documents/10162/17224/polymers_en.pdf or http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Therefore, a pragmatic approach was agreed between the industrial associations and the authorities. The appropriate trade associations[18] assist in determining the monomers and additives normally used in various types of plastic. This information can be used as a reference when implementing the REACH registration requirements applicable to recycling.

### 3.2. Availability of information about the recycled substance

According to the wording of REACH Article 2 (7d), plastics recyclers must have information available **about the registered substance**. In the case of polymers, however, this would refer to their monomers, and if relevant to any additives and/or other reactants contained in them. It is, therefore, indispensable for recyclers to have at their disposal the safety data sheets for the monomers and additives contained in the recycled polymer.

In practice, recyclers can request these from the primary manufacturers in paper form and keep them on file. Alternatively, it is legally sufficient if they have access to an appropriate database on the Internet. Currently, the European associations are working under the aegis of EuPR[19] on providing to their members on the Internet a database of safety data sheets for monomers and additives[20].

Since manufacturers of recycled polymers neither handle monomers nor manufacture and market them, however, information about monomers is of little practical benefit for them. Similarly, they are only useful to a very limited degree in the preparation of their own safety data sheets for the recycled polymers.

# 4. Determining the hazard profile

Asserting the recycling privilege under Article 2 (7d) as described in chapter 3, does not exempt recyclers from the other information requirements under REACH and other statutory substance-relevant regulations.

The basis for all further information requirements (classification, labelling, providing information to customers etc) is knowledge about the hazard profile of the substances manufactured/marketed. This chapter discusses which fundamental legal requirements exist in this context and how recyclers can meet these requirements in practice.

[18] See contact details in Chapter 6

[19] European Plastic Recyclers

[20] At the time of preparing this reference manual, it was as yet unclear whether it would also be accessible to non-members and under what terms.

### 4.1. Investigation requirements

In order to be able to meet further requirements with regard to classification, labelling and customer information, recyclers must know the hazard profile of the substances manufactured by them.

This means that recyclers have to determine whether the substances manufactured by them (including any impurities) have hazardous properties (e.g. corrosive, acutely toxic, chronically toxic, carcinogenic etc). As distributors, they are required to search for relevant existing information and evaluate it. This, however, is not an innovation under REACH and had to be done in the past also[21]. The principle applies that all relevant information relating to a substance should be utilised[22].

Recyclers of plastics must bear in mind that the monomers have reacted to create a polymer, and therefore are present as such only as traces. Consequently, no conclusions about the polymer can be drawn from the monomers' safety data sheets (cf. section 3.2). The hazard profile of a plastic, moreover, is determined to a large extent by the type and quantity of any additives.[23]

Furthermore, impurities are of special significance for recyclers. When exercising the recycling privilege, these are allowed to constitute 20% of the product of the recycling process without being specified in more detail. As regards the potentially hazardous properties of the recycled polymer, however, they can be highly relevant such that they have to be identified.

A pragmatic approach to determining the hazardous properties of the recycled plastic, is to regard it as a mixture of substances and evaluate it in accordance with the applicable rules for classification and labelling. The procedure followed in the classification of (recycled) plastics is explained in the following section on the basis of an example.

### 4.2. Classification of plastics

The recycler, as the manufacturer and distributor of a (chemical) substance or a mixture, is required to classify them. The classification of recycled plastics does not differ from the

[21] This requirement is established by Directive 67/548/EEC Article 6. In Germany, it is established by section 5 of the Hazardous Substances Ordinance. The requirement to identify information continues to exist under the CLP Regulation (Article 5 and 6). Like REACH, it is deemed to be a direct European regulation without implementation in national regulations.

[22] Article 6 of Directive 67/548/EEC states: "*Obligation to carry out investigations: Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in Articles 22 to 25 and the criteria in Annex VI.*"

CLP Regulation, Article 5: "*Identification and examination of available information on substances:*

*(1) Manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:*

*a) data generated in accordance with any of the methods referred to in Article 8(3);*

*b) epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases;*

*c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006;*

*d) any new scientific information;*

*e) any other information generated under internationally recognised chemical programmes.*

*The information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used.*

*(2) Manufacturers, importers and downstream users shall examine the information referred to in paragraph 1 to ascertain whether it is adequate, reliable and scientifically valid for the purpose of the evaluation pursuant to Chapter 2 of this Title".*

[23] The hazard profile of an additive in a polymer can differ from the profile it has as a separate substance.

classification of other substances and mixtures. The classification and labelling regulations are laid down in Directives 67/548/EEC and 1999/45/EC, and in the new CLP Regulation[24].

Classification with regard to physical risks (explosivity, flammability etc) relies on test methods listed in Annex VI, No. 2 of Directive 67/548/EEC and Annex I, part 2 of the CLP Regulation. Here, the classification cannot be based on the individual constituents, but must be determined experimentally.

In order to determine the risks to humans and to the environment, the classification can be based on the individual constituents of a substance or a mixture. For example, under Directive 1999/45/EC or the CLP Regulation, a mixture is regarded as carcinogenic if the content of a carcinogenic constituent exceeds 0.1%[25].

Some hazardous properties are deemed to be additive, i.e. the contributions of various components of a mixture (or in the recycler's case, of a substance) to a hazardous property are added up. One example of such a property is human toxicity or environmental hazard. The classification of a plastic granulate that contains both lead and cadmium as stabilisers, should accordingly be based not on the individual contents but on the sum of the constituents[26] as regards human toxicity and environmental hazard.

We may use as an example for the classification of a recycled plastic, the lead-containing PVC from the recycling of window profiles.

A lead content of e.g. > 0.3% means that a PVC granulate has to be classified as hazardous (cf. Fig. 5). Here, it is irrelevant whether the lead content is a deliberately added constituent or an impurity.

[24] The CLP Regulation envisages gradual transition from classification in accordance with Directives 67/548/EEC and 1999/45/EC to the CLP Regulation. Additional information on classification and labelling under CLP is contained in a brochure published by the Federal Environment Agency, with the title The New Classification and Labelling system for Chemicals under GHS (available only in German).

[25] Category 1 and 2 under Directive 67/548/EEC and 1A & 1B under the CLP Regulation

[26] The concentration thresholds for the classification of substances or mixtures as hazardous are defined in Directives 67/548/EEC and 1999/45/EC. The Substances Directive applies until 01 December 2010. After that date, substances are to be classified according to the rules of the CLP Regulation. Mixtures can be classified until 01 June 2015 according to the rules of Directive 1999/45/EC or the CLP Regulation.

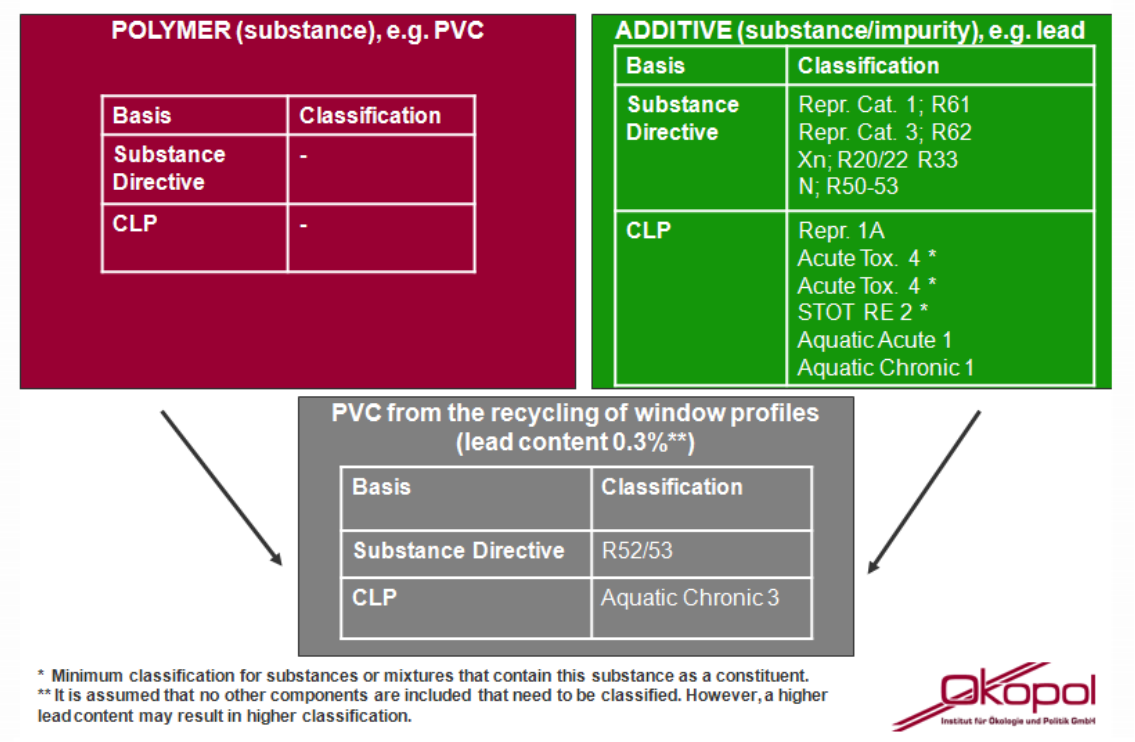


Fig. 5: Classification of PVC granulates according to CLP and Directive 67/548/EEC rules

If the values known to the recycler for the contents of a constituent lie in a typical range, the classification should follow the highest value found for this constituent (i.e. if analyses of different waste batches show fluctuating values, e.g. lead contents of 0.05% - 2%, the highest value is the one to be used in the classification). This ensures the safety of the entire range of a product. If, for example, new analyses suggest that the classification may change, this should be reviewed.

The thresholds starting from which a substance is to be regarded as hazardous, differ significantly from those used to determine the substance's identity. The threshold of 20% explained in chapter 3, at which a substance may still be present without triggering its own registration requirement, is significantly higher than the limits to be used for classification. For many substances, depending on the type of hazardous property, the classification-relevant concentrations ('cut off limits') lie at 0.1 or 1.0%.

The prerequisites for the classification of recycled plastics, require that recyclers investigate the compositions of substances and determine the constituents of their products that are relevant for classification. The procedure depends on the information available to the recycler, and can vary for different waste streams. Possible procedures for identifying hazardous constituents are described in the next section.

### 4.3. Practical options for obtaining the required information

The classification and labelling requirements described in outline above, expect recyclers to characterise 'their' recycled materials completely and appropriately. Naturally, however, it is more difficult for a recycler than for a primary manufacturer to compile the necessary information about the composition of a substance. Against this background, we describe below how such information can be accessed in practice:

In principle, recyclers have two options for obtaining information about the constituents of substances:

a) Complete (laboratory) analysis of the constituents,

b) Accessing available knowledge about the composition.

Option a) (analytics) has the advantage that it can be carried out largely independently of any previously available information about the waste streams and processes. The question remains open, however, for which ingredients the analysis should be performed. In particular, full analysis of the material can generate high costs.

Therefore, this option is not discussed in further detail below.

Option b), accessing available knowledge about the composition, offers a pragmatic concept that permits an equivalent implementation of the investigation requirements imposed on the recycler.

The starting point is the fact that normally at the end of the recycling process, nothing can be contained in a recycled plastic that was not contained previously in the waste input or was added deliberately during recycling[27]. In principle, knowledge can be available in two different respects:

i. There exists 'positive' knowledge about the fact that a substance (or group of substances) is not contained.

ii. There exists 'positive' knowledge about the fact that a substance (or group of substances) is contained.

In the context discussed here, both refer to substances/substance groups that possess hazardous properties and thus may trigger relevant classification/labelling ('problem substances'). Such 'positive' knowledge should be distinguished clearly from 'negative' or non-knowledge, manifested in such statements as e.g.: "Nobody has told me that my input material contains hazardous substances, therefore I will assume that they are not contained in my recyclates".

If it known 'positively' that substances (groups) are not present in the input material (case i), in quality-assured processes their absence in the output, in the secondary plastic, can be assumed also.

If, in contrast, the presence of substances (groups) is known in principle (case ii), the recycler should be clear about of the order of magnitude of such content. Moreover, it is necessary to

[27] e.g. post-additivation → downstream use.

know whether the content changes during the recycling process. One simple example of quantitative enrichment is a mechanical sorting stage of two plastics (e.g. by colour), of which only one colour contains the (problem) substance (e.g. the pigment).

Whilst knowledge about such enrichment effects belongs to the usual operator expertise, the question arising in practice is this: “How do I obtain reliable information about the substances contained in my waste input?”

The composition of the received plastic waste is determined during the preceding life cycle, from manufacturing through processing and use to waste collection. Fig. 6 shows schematically the stages in the life cycle during which potentially problematic substances (i.e. substances that may trigger classification and labelling requirements) may be added or otherwise introduced.

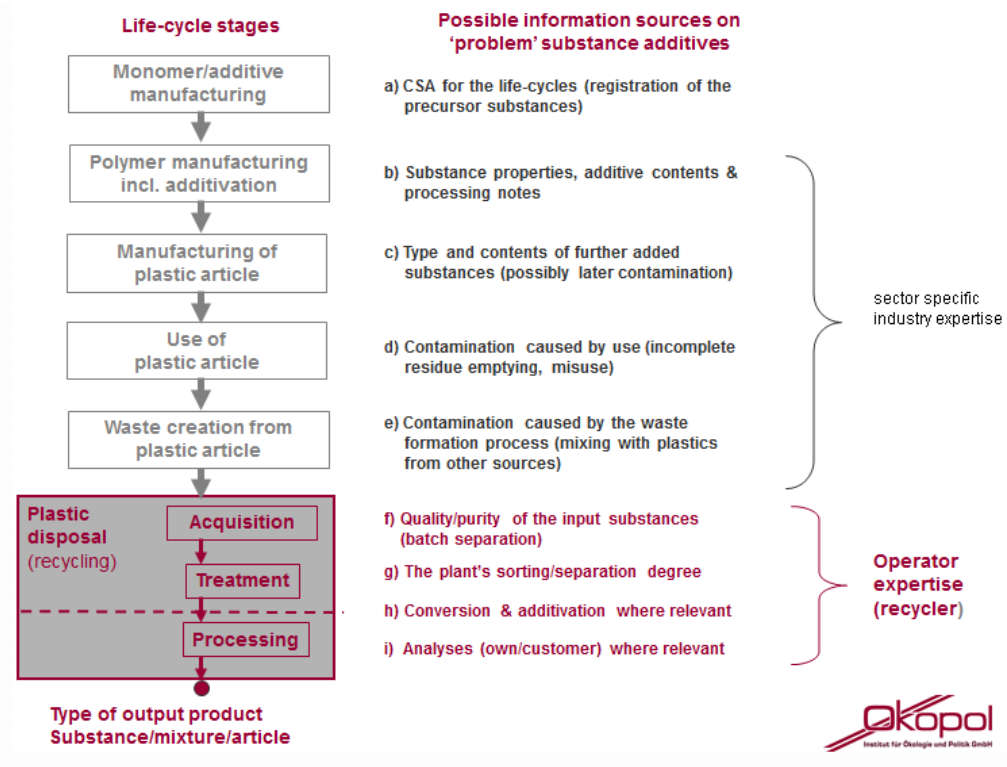


Fig. 6: Stages in the life cycle of a plastic, information sources about potentially problematic additives and types of relevant knowledge

As practical examples show, knowledge about the composition changes outlined above can be referred to as ‘sector specific industry expertise’, in the possession of the various parties taking part in the manufacturing and use chain.

Depending on the type of plastic waste received, operators of recycling plants have a variety of options for utilising this industry expertise. Three cases (Fig. 7) can be distinguished here in principle:

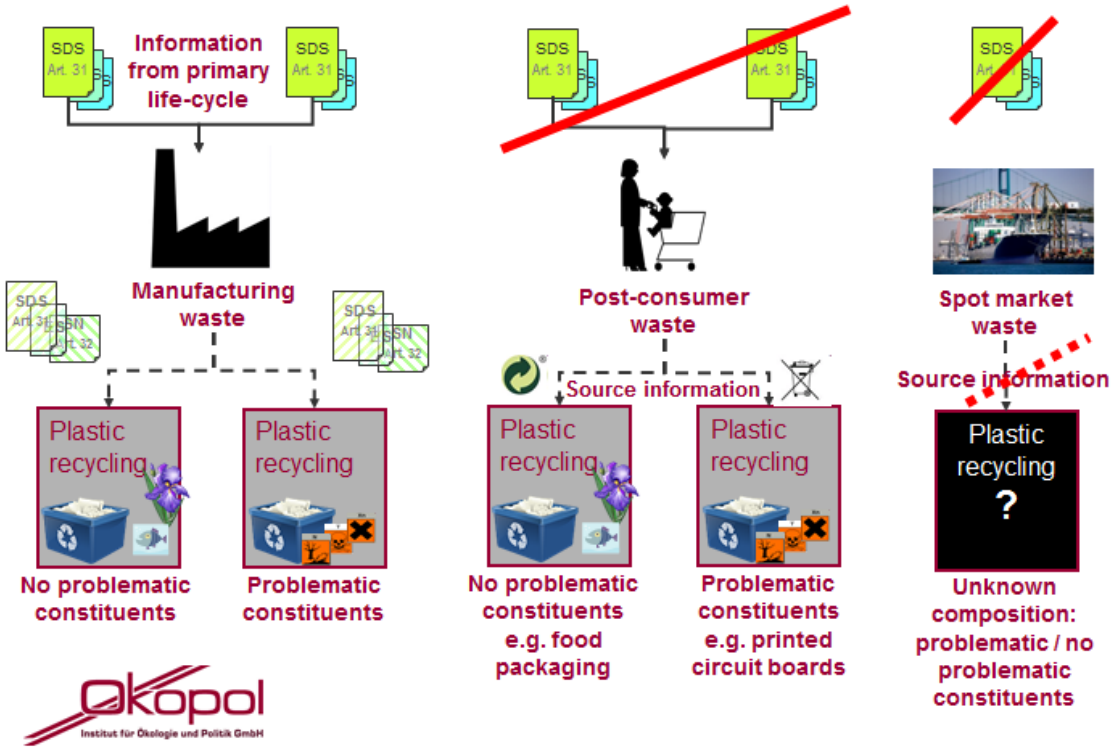


Fig. 7: Various plastic waste streams, defined in terms of the knowledge available about the preceding life cycle stages. Problematic constituents are understood here to be those that may lead to a classification as hazardous under the rules for classification and labelling of substances and mixtures.

☐ **Production waste:** It is (mostly) possible to access directly information about the preceding manufacturing and processing. Useful documents that may be requested from the waste producer include, inter alia:

- The safety data sheets relating to the polymers, additives and other supplements used in the plastic's manufacturing,
- product specifications (incl. any 'black lists', 'positive lists' or product-specific regulations) for the plastic articles that (in part) became waste,
- information on auxiliary materials used in the processing of the plastic articles (e.g. release and cutting agents etc) and which may be contained in the waste as adhered residues.

On the basis of such information, 'positive' knowledge about the presence or absence of 'problematic' substances in the waste stream can be produced with a high degree of reliability. It should be noted, however, that the waste producer is under no legal obligation to make these documents directly available.

- **Post-consumer waste:** In this case, naturally the information flows are interrupted since the waste producer (the end consumer) has no knowledge about the composition nor is 'reachable' by the recycler. These problems notwithstanding, and given separated collection of used plastics from different areas of application, it is still possible in many situations to produce adequate positive knowledge.

  With waste from mixed food packaging, due to statutory food regulations it can be assumed that no substances are (may be) contained that trigger classification.
  In contrast, when receiving plastic fractions from the recycling of used electrical equipment it can be assumed with a high degree of certainty, that flame retardants and possibly other additives are contained that exhibit hazardous properties.

  These assumptions can be verified by contacting the relevant manufacturers (or manufacturing associations) and/or analysing published studies on these particular product and waste streams.

- **Spot market waste:** For waste fractions bought without extensive knowledge about their origins and exact composition, e.g. on the spot market, normally the outlined approach of obtaining sufficient information about the constituents via 'positive industry expertise' must be ruled out.

  In such cases, laboratory analyses of the composition of the waste and/or of the manufactured recycled materials become essential if acceptable legal compliance is to be achieved.

  One of the important aspects in this connection is industrial safety, whose statutory regulations apply independently of REACH: since the employer is required to ascertain whether the use of certain substances may pose risks for employees, it is important, to perform analyses for the input substances. In order to target these laboratory analyses properly, an evaluation of the existing literature covering the use of certain 'problematic' ingredients in plastic applications[28] and making contact with the relevant trade associations[29] may be helpful. Determining potential problematic substances in the output material is a prerequisite if appropriate customer information is to be prepared and the classification and labelling requirements complied with.

### 4.4. Necessary operational quality assurance routines

In order to achieve acceptable legal compliance in terms of the information requirements that apply to the recycled materials manufactured, the methods described above for obtaining 'positive' information need to be supplemented by the implementation and documentation of appropriate quality assurance routines (QA systems).

[28] including historical data in the case of materials for which it is unknown how long they have been on the market.
[29] see contact addresses in Chapter 6 of this manual.

Since the statutory chemicals regulations do not contain concrete provisions governing the investigation requirements, there is no need to implement a QA system set up in accordance with standardised specifications.[30] A quality management system should, however, always comprise the following elements:

1. **Incoming checks:** The recycler should use incoming checks continuously, in order to ensure that the received waste conforms to the assumptions underlying the determination of the hazard profile. These checks can vary from case to case (visual inspection, sampling, supplier verification), but should be proportionate to the probability of fluctuating and potentially problematic substance compositions. This means that where the production waste always arrives from the same waste producer with uniform production, this requirement is easier to comply with than in cases involving changing suppliers.

2. **Separation**: Waste streams with known ingredients should either be processed separately or brought together, in a planned manner, with other streams of known contents. This is the only way of avoiding loss of knowledge about the substance composition.

3. **Process control**: Separation is closely linked to controlling the processes being carried out. The purpose of quality-assured control of the recycling processes is to prevent undesirable mixing and/or substance conversions (e.g. in the event of localised overheating etc).

4. **Outgoing checks**: In analogy with incoming checks, these checks are also designed to ensure that the product conforms to the defined assumptions and to the corresponding requirements in respect of classification, labelling and providing information to customers.

5. **Documentation:** Both the processes carried out and the information/documents generated in order to obtain the relevant 'positive' knowledge relating to the hazard profile, and the type and results of the ongoing checks conducted as part of the QA system, should be documented systematically. Any customer complaints etc arising from abnormal material compositions (e.g. deviations from the specification of the recycled materials that may be identified during the customer's incoming analyses), should be recorded together with the relevant corrective steps taken.

### 4.5. Practical examples

The following section describes, by reference to concrete practical examples, how the above conceptual approaches are or can be implemented in practice:

[30] even though this would, presumably, be regarded favourably in any (liability) legal disputes that may arise e.g. from defective substance classification.

### 4.5.1 Examples for the recycling of production waste

**CASE STUDY: Polyamide fibres from carpet manufacturing (production waste, no hazardous constituents)**

**Waste:** Polyamide 6 and polyamide 6.6 fibres from carpet manufacturing

**Product of the recycling process:** Polyamide granulate (dyed – not dyed)

**QA element 1: Incoming checks:**

On receiving a waste delivery, the waste is inspected visually. A random sample of the material is taken and the batch labelled with a barcode. One part of the sample undergoes standard analysis as outlined below, the remaining part is kept as a retained sample. The barcode is attached to all the documents and containers, also to the sample and its accompanying documents. In preparation, the waste supplier had been asked to provide the safety data sheets for the primary materials. Experience shows that where polyamide fibres arrive from certain countries (e.g. USA), they are likely to include flame retardants in the form of antimony or halogen compounds.

The standard analytics consist of the following steps, which can also be used for statutory purposes:

- ☐ Melting point determination: contamination by other plastics can be ascertained. DSC[31] melting analysis can provide evidence of residual monomer contents.
- ☐ Determination of the fibres' moisture content: a high residual monomer content leads to deposits in the drying oven and correspondingly high moistures.
- ☐ Viscosity test: this may provide evidence about the residual monomer content. Viscometer measurement of the plastic sample dissolved in sulphuric acid, or of the melt flow index (MFI/MVR).
- ☐ Ash content: evidence of inorganic constituents, e.g. antimony, heavy metals – further analyses performed if necessary.
- ☐ Examination of the granulate for magnetic impurities, using a bar magnet.
- ☐ Flame test under an extractor hood: flammability limited – evidence of flame retardant; coloured flame – evidence of chlorine compounds etc.
- ☐ Colour of the fibre: natural white – dyed through – surface-dyed (maximum dye content 1-2%, hazardous dyes listed in SDS).

**QA element 2: Separation**

Only suitable materials are merged, based on the information obtained. Technical acceptability is associated with substance acceptability. Hazardous waste is not processed further.

**QA element 3: Process control**

Permanent process control is ensured.

[31] Differential scanning calorimetry, a method for determining the purity of a substance from its melting behaviour.

**QA element 4: Outgoing checks**

The standard analytics, as described in QA element 1, are performed for the recycled product also (PA6 granulate and PA6.6 granulate). Periodic sampling followed by further analyses of the outgoing material, can be used to verify and document the absence of hazardous properties.

The supplied granulates meet the customer's requirements (e.g. the sector specific Global Automotive Declarable Substance List (GADSL), using the IMDS system).

**Step 5: Documentation**

The barcodes allocated when the goods arrived, are attached to the waste containers, the test reports, the incoming documents (SDS), the retained samples and the end-product (the granulate). This permits electronic tracking of the waste batch, and comprehensive documentation for the authorities or the customer.

**Case study: PA waste, additivated, from the EU's electrical industry (production waste, contains hazardous substances)**

**Waste:** Polyamide waste from the EU's electrical industry (with flame retardant)

**Product:** Plastic granulate, with red phosphorus as flame retardant for use in the electrical industry

Often, additivated polyamide waste from electrical equipment has flame retardant properties. The flame retardant systems are based on various substances, whose varying hazardous properties trigger corresponding REACH requirements. For example, the flame retardant hexabromocyclododecane is a candidate substance, which at a concentration of 0.1% and above in a plastic gives rise to an information requirement. The manufacturer of such a plastic compound would have to prepare a safety data sheet (SDS) in every case. The manufacturer of a plastic article would be required to communicate information under Article 33. If the waste comes from production processes within the EU, positive industry expertise about the substance is available from the plastic's primary life cycle.

The waste streams described in this example contain red phosphorus (~ 20%) as flame retardant. This is certainly desirable, since the end-product of the recycling process is meant to be a plastic compound containing red phosphorus (~ 20-25%). The procedure followed when determining the der REACH requirements must, therefore, ensure that no other flame retardants are present in the input streams. To this end, the recycler carries out the following steps:

In addition to the polyamide's monomers, the recycler has also pre-registered red phosphorus, having expected that the future quantities in the input waste streams processed by him would trigger his own registration requirement (constituent of a mixture, not an impurity).

**QA element 1: Incoming checks**

The waste suppliers (a waste producer or mill material dealer) enclose safety data sheets for the primary materials, thus documenting the plastic's type and source. The safety data sheets are evaluated and then archived (documentation).

**QA element 2: Separation**

Only batches verified by the safety data sheet as free from unwanted ingredients are used.

**QA element 3: Process control**

Permanent process control is ensured.

**QA element 4: Outgoing checks**

Periodically, specific analyses are performed for substances less relevant to the electrical industry (heavy metals in accordance with RoHS, e.g. the presence of bromine is also recorded).

**QA element 5: Documentation**

The product is classified on the basis of the available information, and safety data sheets are prepared.

This example demonstrates that the extent of the required analyses can be minimised by utilising industry expertise and/or the waste producer's expertise. At the same time, the customer-specific standard analytics provide additional verification of the assumptions in the accompanying safety data sheets, for the plastic granulate manufactured. Performing the analyses is not triggered by the statutory chemicals-related regulations. They are requested by the customer on a regular basis.

**Special case: Chemical recycling of polyurethane**

**Waste:** Polyurethane production waste from the EU (hazardous constituents contained/not contained)

**Product:** Liquid mixture of the constituents, whose polyol fraction can react again to make polyurethane plastics.

During the chemical recycling of plastics, individual constituents of the input polymer are recovered and not, as in the 'normal' case, polymers largely identical to the waste input. Such a recycling process must be performed by operators with special expertise under very particular conditions, in order to prevent potential chemical side-reactions. An elevated polymer moisture content can lead to the formation of the carcinogenic substance methylenedianiline (MDA). The formation of such compounds must be monitored and documented, and taken into account during classification and labelling.

The recovered polymer constituents need to be identified, in order to determine and implement the REACH requirements. This is made possible by the available knowledge about the waste materials used and the reactions taking place during recycling.

**QA element 1: Incoming checks**

The waste is delivered, properly sorted, by a waste producer. It is accompanied by the safety data sheets for the isocyanate and polyol components, as agreed contractually.[32]

**QA element 2: Separation**

The individual batches undergo separate chemical conversion in batch mode. Only one polyurethane type at a time is converted. Since safety data sheets are available for the polyurethane's precursors, the recycler has all the information needed about the relevant product's hazardous constituents. They can, therefore, be identified and the end-products' hazardous constituents determined.

[32] Without this information, recycling cannot take place if Article 2 (7d) is to be complied with, since a large number of polyol constituents are in use for this group of plastics.

**QA element 3: Process control**

Recyclers must ensure that the process is carried out by appropriately qualified personnel under very particular conditions. Based on knowledge about the chemical processes taking place under such conditions during recycling, the recycler can largely rule out the presence of unknown chemical compounds, since only the chemical bond between the isocyanate and polyol components is modified. A side-reaction of this process can, however, lead to the formation of amines (< 2%) even under controlled conditions; as regards the hazardous, aromatic diamines, contents of under 0.1% in the recyclate mixture are achieved. It is important to take these impurities into account during classification and labelling, although as monomers these are re-incorporated into the polymer's structure and no longer present in the later (recycled) polyurethane.

The outcome of the recycling process can be described schematically as follows:

Polyurethane → isocyanate fraction with new polyol + polyol

This can lead to the following situations:

☐ Both constituents are remain polymers → the monomers must be registered, or else Article 2 (7d) can be applied to them.

☐ One constituent does not meet the polymer definition under REACH → it is necessary to check whether Article 2 (7d) is applicable (existing registration) to this compound (own substance).

The operator's expertise, therefore, can be utilised during waste treatment in order to ensure that only previously added substances are present unchanged, or those added to the reaction, which however undergo only an exchange at the isocyanate components.

The above considerations result in the following situation:

☐ The construct resulting from the substitute polyol and the isocyanate fraction is a polymer. Article 2 (7d) applies, since it is to be expected that the relevant monomers are registered in the first registration phase; the recycler has pre-registered the monomers, in order to have a transition period until then.

☐ The construct resulting from the substitute polyol and the isocyanate fraction is not a polymer. In this case, the recycler is subject to the full registration requirement under REACH without a transition period, since this is not a phase-in substance and there is no existing registration.

☐ The free polyol is a polymer. Article 2 (7d) applies, since it is to be expected that the relevant monomers are registered in the first registration phase; the recycler has pre-registered the monomers, in order to have a transition period until then.

☐ The free polyol is not a polymer. Again, two cases should be distinguished: if the polyol is a hazardous substance, it should be listed in the SDS and can be identified in this way. If the polyol does not require labelling, it is not listed in the SDS. This substance plays no part in classification and labelling, since it had been characterised in the existing registration as not requiring labelling.

**QA element 4: Outgoing checks**

The recycler can identify all the hazardous constituents in the outgoing products, and comply with the classification and labelling requirements. Recyclers' own safety data sheets and further customer information are prepared on this basis.

**QA element 5: Documentation**

The individual steps are documented for each separate batch, and the constituents listed in the recycler's own safety data sheets.

In this recycling process, it is vital to obtain the previous information from the plastic's first life cycle, since otherwise REACH-compliant recycling is not possible.

### 4.5.2. Post-consumer waste

**Case study: HARD PVC window profile recycling (post-consumer, hazardous)**

**Waste:** Plastic window waste from the demolition of buildings, and plastic profile off-cuts from new windows. Expected hazardous Ingredients: heavy metal stabilisers based on cadmium and lead.

**Product:** Hard PVC plastic granulate for the manufacturing of window profiles

**QA element 1: Incoming checks**

The PVC window waste reaches the recycler via two routes:

1. Window installers have profile off-cuts from window fabrication, which can be collected by recyclers as necessary. At the same time, recyclers can collect window waste dismantled by the installer from the customer's old windows.

2. In the case of major refurbishment or demolition projects, window waste is collected on the customer's building site and delivered to the recycler.

In either case, no separation by ingredients takes place. The following conditions are met by the waste producers during disposal.

Items accepted:

- ☐ Windows with frames made of hollow section profiles in impact-resistant hard PVC
- ☐ External doors (house and balcony doors, French windows), with frames made of hard PVC profiles
- ☐ Shutters (shutter boxes and reinforced roller shutters).

Separation from other materials (e.g. glass, metal, silicone) is not absolutely necessary, since these will be separated off later at the recycling plant in a multistage process.

**QA element 2: Separation**

The PVC material's type purity is an important factor in the processing of window waste (including in relation to other PVC qualities). Therefore, items added to the recycled waste bins incorrectly, including unsuitable plastics (e.g. PVC pipes), are separated manually (visual inspection).

Basically, there are two different PVC qualities where utilisation in window profiles is concerned:

1. PVC, copolymerised with butyl acrylate (tight incorporation of further non-vinyl chloride monomers),
2. PVC, additivated with impact-modified polymethyl methacrylate (PMMA, production of a mixture of two substances in the primary life cycle; PMMA can be regarded as an impurity during the recycling process, since the PVC fraction exceeds 80%)

If these two qualities are processed together over the further course of recycling, the outcome of substance identification is a mixture of the first and second polymers. For the registration exception rule, therefore, the monomers of the first one are to have been pre-registered (vinyl chloride and butyl acrylate) and those of the second (vinyl chloride).

All other additives can be regarded as impurities when identifying the substance, since the polymer content exceeds 80%.

**QA element 3: Process control**

During subsequent separation steps, the PVC is shredded and cleaned (e.g. removal of glass and metal). Finally, melt filtration is carried out in order to remove small particles from the material (the result is 99.9% pure PVC). Part of the recycled material, however, would not reach this degree of purity at a sustainable cost. This fraction is not used in new window profiles, but instead in other construction products (e.g. as the middle layer in three-layer wastewater pipes). A smaller percentage of the PVC recyclate is contaminated with glass even more heavily, such that this fraction needs to be incinerated. These batches need to be analysed for their ingredients before being sent for incineration. Here, lead contents of 3400-11,000 mg/kg (0.34-1.1%) and cadmium contents of 110-190 mg/kg (~ 0.01-0.02%) are found. Comparisons have shown that the heavy metals content of these fractions does not differ significantly from that of the fractions used in window profiles[33].

**QA element 4: Outgoing checks**

Individual investigations of the product and analyses of the material sent for thermal recycling, provided comparable lead and cadmium contents. The concentration of lead means that classification is definitely required; therefore, safety data sheets were prepared. The cadmium level is below the threshold of the CLP Regulation and Directive 67/548 by a factor of five, and consequently is not relevant to the classification. A note about its possible presence was, nonetheless, included in the SDS.

**QA element 5: Documentation**

Analytical reports are documented and used systematically to control the recycling process. Potential impurities are recorded in the safety data sheets.

[33] The differences arise mainly from contamination with glass, rubber and similar constituents. The constituents of the PVC matrix are identical, such that to a small extent lower heavy metal values are to be expected.

In this example, expertise from the preceding chain is combined with the operator's expertise concerning the waste treatment processes. This assists in minimising the cost of analyses.

**Case study: Recycling of starter batteries (post-consumer, hazardous)**

**Waste:** Starter batteries and other Industrial batteries

**Product:** Polypropylene granulate for the production of automotive mouldings

**QA element 1: Incoming checks**

The waste is delivered via a collection system, in part using own resources, in part by external collection operators. The batteries are still in the form of the original product.

**QA element 2: Separation**

Mixing the waste stream with other plastic waste takes place only once the battery material has undergone the first treatment steps. Then it is mixed with material from e.g. bottle tops. Any possible traces of lead impurities, which as a result of process control are already below the classification threshold, are depleted once again in this way since bottle tops do not contain lead due to the statutory regulations in the food industry.

**QA element 3: Process control**

The batteries are crushed mechanically by the recycler. The plastic fractions undergo wet separation. During this step, contamination with lead-containing liquids from the battery's inside is already removed to some extent. Further mechanical crushing or shredding steps are also carried out in contact with water, such that during the course of the process, the PP material is cleaned and possible residual adhering materials are removed.

**QA element 4: Outgoing checks**

To begin with, when initiating the process, daily samples of the battery PP materials were taken in the output[34] and examined for heavy metals by means of XFA analysis (other substances such as e.g. bromine were also checked for with this method).

The customer's specified benchmark values from the automotive industry were maintained regularly and reliably. These figures are identical with the thresholds under the CLP Regulation (e.g. 0.1% for lead). The outcome of the investigations did not lead to the product having to be classified as hazardous.

Based on the positive QA experience with a stable process and uniform quality of the delivered waste, the sampling and analysis interval was extended to once or twice a year.

[34] before blending with additional PP materials from the food industry.

**QA element 4: Documentation**

The entire procedure is integrated and documented in an ISO 9001 quality management system.

In this case study, by utilising knowledge about the ingredients (lead) and a special, established waste treatment system, a hazardous waste (car batteries) is converted to a substance that does not require classification. At this point, analyses are required only for process assurance purposes.

**Case study: Polypropylene packaging waste (post-consumer, no problematic substances contained)[35]**

**Waste:** Pre-sorted polypropylene packaging waste from the German dual recycling system (DSD)

**Product:** Polypropylene granulate for use in technical processes

**QA element 1: Incoming checks**

The pre-sorted waste is delivered by an DSD sorting plant operator.

This is the defined waste fraction 324[36], which is characterised as follows: *"Used, completely emptied, dimensionally stable, system-compliant plastic articles made of polypropylene, 5-litre volume such as e.g. bottles, cups and beakers, including ancillary constituents such as caps, labels etc".*

In accordance with DSD, the substance specification for the delivered waste fraction must fulfil the following conditions:

- ☐ Polypropylene purity at least 94% (w/w) as per specification/description.
- ☐ Contaminants
    - o Maximum total contaminant fraction 6% (w/w)
    - o Metal and mineral contaminants with a unit weight exceeding 100 g and sealing compound cartridges must not be included
    - o Other metal articles < 0.5% (w/w)
    - o Dimensionally stable PE articles < 1% (w/w)
    - o Foamed plastic incl. EPS items < 0.5% (w/w)
    - o Plastic films < 2% (w/w)
    - o Other residual materials < 3 (w/w)

Examples of contaminants:

[35] This example discusses polypropylene recycling from DSD waste. Under the same process conditions, the conclusions also apply by analogously to PET bottle recycling.

[36] DSD GmbH assigns minimum standards to plastic waste. The document covering polypropylene waste can be accessed at:
http://www.gruener-punkt.de/fileadmin/user_upload/Seiteninhalt/Dateien/DKR_Plasticverwertung/pdf_dt/324_Polypropylen.pdf

- ☐ Glass
- ☐ Paper, pasteboard, cardboard
- ☐ Bonded cardboard (e.g. beverage cartons)
- ☐ Aluminium-metallised plastics
- ☐ Foreign matter (e.g. rubber, stones, wood, textiles, nappies)
- ☐ Compostable waste (e.g. food, garden waste)

The recycler carries out an incoming check of the delivered waste bales, in the form of a visual inspection relating to the specification described above.

**QA element 2: Separation**

No material other than the pre-sorted DSD waste is used in the recycling process. Statistical investigations have shown that the delivered PP waste consists of 80% food packaging and 20% other packaging materials[37]. Adhering matter (food residues, contamination from pre-sorting) adds up to ca. 10% of the total delivered weight.

**QA element 3: Process control**

Reprocessing the waste starts with various crushing and shredding steps, all of which are carried out in a wet process using water.

In order to ensure product quality, the recycler has already performed in the past a variety of investigations focusing on the elimination of unwanted constituents (non-PP constituents). These have shown that ca. 90% of the adhering materials are removed by the wet treatment process.

Around 5% of the plastic at the input consists of polyethylene (PE). This has been demonstrated over a period of 2 years, with the help of DSC analyses. This impurity is also present in the recycled granulates at a 5% level, since PE cannot be removed with the methods being used. In contrast, other plastics are removed effectively.

In a subsequent step, the plastic material is placed in an extruder and extruded at 260 °C. Investigations have shown that the original material already consists of 99.7% polyolefins (95% PP and 5% PE). The extrusion has two effects:

1. Volatile constituents (e.g. printing inks) are eliminated,
2. the residual moisture content is decreased.

The material then undergoes melt filtration, in order to remove the residual large-particle materials (metal, wood). This results on average in less than 0.06% impurities in the recycled material.

[37] Food packaging is governed by EU Framework Regulation (EC)1935/2004. Plastics are governed by Directive 2002/72/EC. Other packaging materials are governed by the provisions of the German Foodstuffs, Consumer Goods and Animal Feed Code (LFGB). Certain monomers, additives and other substances are prohibited in this sector.

**QA element 4: Outgoing checks**

This involves a quarterly comprehensive full analysis of a composite sample of the product, i.e. the organic and heavy metals contents are determined. The basis for the substances to be investigated is provided by the customers' substance lists (e.g. the automotive industry's GADSL list). The analyses serve to review and verify the available information about the process and the product.

The granulates do not contain hazardous constituents that would result in classification and labelling.

**QA element 5: Documentation**

Analytical reports are documented and used to control the recycling process. The process and the associated statistical investigations plus the outgoing checks are documented and quality-assured in an ISO 9001:08 quality management system. In addition, there exists an RAL certification mark for auditing the quality-assured process.

There is no requirement to prepare and supply safety data sheets for the granulates manufactured, since they do not have a classification. It is, however, established practice to prepare appropriate documents and provide them to customers.

In the current example, the combination of information about the primary life cycle (packaging material) and the recycler's operator expertise about the processes in use and supplementary analyses, demonstrates that no hazardous constituents above the thresholds established under Directives 67/548/EEC and 1999/45/EC or the CLP Regulation are contained in the product. The substances in the recycled granulate do not trigger information requirements under REACH.

# 5. Recyclers' information requirements for substances from recycling processes

In the previous chapters, the end of the waste properties and the associated start of the REACH requirements were explained, and the prerequisites for exemption from the registration requirement discussed. These exemptions from the registration requirement notwithstanding, recyclers have to meet further requirements vis-à-vis the authorities and their customers. These requirements relate to the communicating of information about any hazardous properties of the manufactured products. The procedure and the statutory regulations for such recycled plastics do not differ from those that apply to plastics from new production, and existed even before REACH came into force.

## 5.1. Labelling of plastics

Additivated plastics are deemed under chemicals legislation to be mixtures of substances that contain a high proportion of polymers. For such mixtures, there exist both under the old substance legislation[38] and under the new CLP Regulation[39] special rules for classification, labelling and the production of safety data sheets.

If, after examination of the mixture's hazardous properties. classification as hazardous is necessary, the recycler must prepare a safety data sheet and provide it to the customer. The safety data sheet should also state the labelling of the mixture resulting from the classification (Chapter 15).

If the hazardous properties are not manifested in the concrete use of the polymer mixture, labelling the container can be dispensed with. The recycler should, however, be able to demonstrate and substantiate why exposure is not to be expected.

It follows, therefore: a plastic compound must necessarily be classified, an SDS must be prepared when determining the classification, whilst the packaging may not need to carry labelling in some circumstances (cf. Fig. 8).

[38] Directive 67/548/EC, Annex VI, 9.3. Alloys, preparations containing polymers, preparations containing elastomers: These preparations shall be classified according to the requirements of Articles 5, 6 and 7 and labelled according to the requirements of Article 10 of Directive 1999/45/EC. However some of these preparations although classified in accordance with Articles 6 and 7 do not present a danger to human health by inhalation, ingestion or contact with the skin or to the aquatic environment in the form in which they are placed on the market. Such preparations do not require a label according to Article 10 or according to Annex V B. 9. However, all the information which would have appeared on the label shall be transmitted to the professional user by means of an information system in a format foreseen in Article 14 of the above-mentioned Directive.

[39] CLP Annex I, 1.3.4. Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers
1.3.4.1. Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of this Annex.
1.3.4.2. Instead, the supplier shall provide the information to downstream users or distributors by means of the SDS.

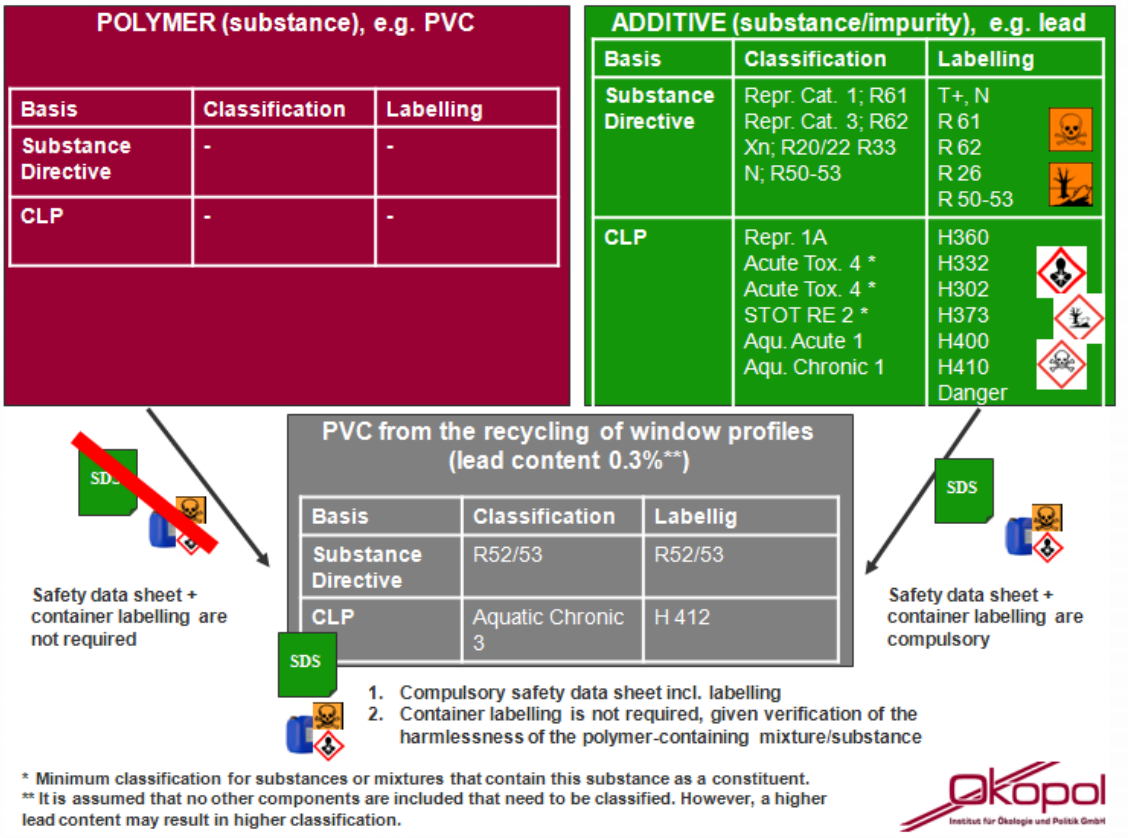


Fig. 8: Classification and labelling of a PVC compound under Directive 1999/45/EC (Dangerous Preparation Directive) and the CLP Regulation (EC) 1272/2008

### 5.2. Classification and labelling inventory – notification

The CLP Regulation[40] requires every importer or manufacturer of a substance to notify the Agency **by 1 December 2010** for the purpose of inclusion in the EU classification and labelling inventory, if the following conditions are met:

- ☐ The substance requires registration under REACH, or
- ☐ The substance is hazardous according to the CLP Regulation and
  - o is manufactured/imported as a pure substance, or
  - o is contained in an imported/manufactured mixture above the classification thresholds specified in the Regulation or the Dangerous Preparations Directive (Directive 1999/45/EC) and results in its classification.

Unlike the REACH requirements, notification under the CLP Regulation is not associated with quantitative thresholds. Plastics recyclers are normally exempted from REACH registration, such that here it is mainly the second point that needs to be taken into account.

If a PE-HD material manufactured in the EU (substance under REACH) derived from bottle crate recycling contains more than 1000 ppm (0.1%) cadmium[41], then under the CLP Regulation it is deemed to be a hazardous substance (cf. Fig. 9) and should therefore be notified to the classification and labelling inventory. The notification duty applies only to the material's manufacturers and importers, not to its users.

[40] CLP Regulation, Article 39

[41] According to a current study by the European Commission (DG ENV: Study to analyse the derogation request on the use of heavy metals in plastic crates and plastic pallets, September 2008), cadmium values between 200 and 1300 ppm are currently being found.

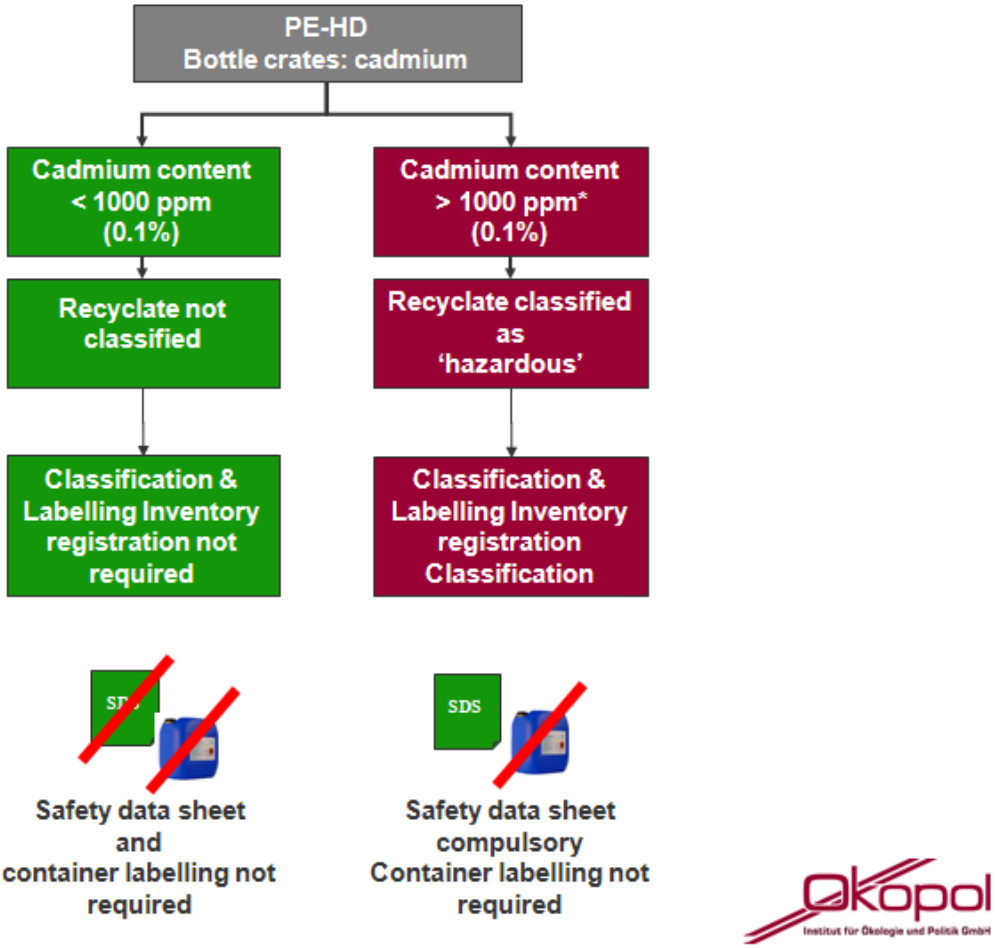


Fig. 9: Differences in classification and labelling as a function of the hazardous ingredient content (in this case, an impurity)

Pursuant to REACH, recyclers manufacture not only substances but also mixtures of several substances (cf. Chapter 3.1.). Where a mixture is manufactured, each hazardous substance has to be notified to the Agency separately.

In practice, this is done by notification via the ECHA's Internet portal, REACH-IT: https://reach-it.echa.europa.eu/reach/public/welcome.faces.

### 5.3. Producing customer documentation

Once recyclers have identified the substances manufactured by them, determined their hazardous constituents and carried out the classification and labelling of their products, they have to communicate this information to their customers. A variety of tools are used to communicate the information, depending on whether a substance, a mixture or an article is involved and what hazardous properties the constituents have.

Recyclers are responsible for ensuring that all the information they produce and communicate in relation to their substances is complete and accurate. They should be aware that to a significant

degree, their customers plan and implement their risk management procedures for handling the product on the basis of this information. When preparing it, they should take into account any information they have received from their suppliers about their raw materials (e.g. additives), i.e. they must also communicate the exposure scenarios they have received, even if they themselves do not have to provide any for the substances manufactured by them.

### 5.3.1. Safety data sheet

REACH defines three conditions that make the provision of a safety data sheet obligatory (Article 31 (1)):

- ☐ The substance or the preparation is classified as dangerous.
- ☐ The substance meets the conditions of a PBT or vPvB[42] substance (e.g. hexabromocyclododecane, at the same time on the Candidate List).
- ☐ A substance on the Candidate List[43] is a constituent of the substance or of the mixture and makes up more than 0.1% of it.

Moreover, if requested by a trade customer, an SDS has to be provided (Article 31 (3)) where:

- ☐ Although the substance or the preparation itself is not hazardous, one of the constituents (> 1% (w/w) in non-gaseous preparations) is a hazardous substance.
- ☐ The substance or the preparation itself is not hazardous, but it contains a PBT/vPvB or some other substance from the Candidate List (> 0.1% (w/w) in non-gaseous preparations).
- ☐ There exists an EU workplace limit for one of the constituents of the substance or mixture.

The SDS serves not only to communicate the hazardous properties of a substance or a mixture, but also to provide information about safe use, including appropriate risk management procedures and conditions of use. These are explained both in the main part of the safety data sheet and in appended exposure scenarios.

It is established practice in the plastics industry to produce safety data sheets for all substances, regardless of their risk. Since no substance safety evaluations have to be performed for plastics derived from recycling processes when asserting the recycling privilege under Article 2 (7d), the recycler also does not produce exposure scenarios that would have to be appended to the SDS.

Several European plastics associations offer initiatives for producing what is referred to as general (generic) exposure scenarios under REACH[44], in order to support registrants[45]. These

[42] PBT = persistent, bioaccumulative, toxic; vPvB = very persistent, very bioaccumulative; the criteria are described in REACH Annex XIII. Normally, recyclers do not register substances and therefore normally do not possess relevant primary data. Substances identified as PBT/vPvB before REACH are listed at http://esis.jrc.ec.europa.eu/index.php?PGM=pbt

[43] The Candidate List is a list of substances for which SVHC (substances of very high concern) properties have been identified and which are candidates for the authorisation procedure.

[44] Exposure scenarios describe under which process conditions and through which risk management procedures the specification is met that the use of a substance or mixture poses no risks to humans or to the environment. Generic exposure scenarios do not cover a particular substance, but only the process. Various EU guidelines have been developed for the production and use of exposure scenarios; these can be downloaded from the ECHA website.

[45] PEST Project, Plastics Exposure Scenario Team, http://pestpublic.plastics.net/public/?id=13

could also be used by recyclers to provide more extensive information about their recyclates. This involves the most detailed assessment possible of typical processes in the plastics industry, and establishing the conditions for safe use of the recycled polymers. The generic exposure scenarios may have to be adapted to the special requirements associated with a particular plastic, and can then be communicated in the appendix to the SDS. In this way, a recycled plastics customer receives information equivalent to the information received when purchasing a primary plastic.

The safety data sheet should be provided in the/an official language of the customer's country. The Federal Association of German Industry (BDI) and BAuA offer templates for the preparation of safety data sheets[46]. These are available as editable documents, with numerous comments and tips[47]. In addition, BDI has prepared a collection of standard phrases that can be used for producing safety data sheets. The German Chemical Industry Association (VCI) publishes an extensive guideline[48].

The production of safety data sheets always requires in-depth familiarity with the rules governing the classification of substances and mixtures. This can never be done by laypersons, and those in charge of producing the data sheets must be given appropriate technical instruction and advanced training. If this cannot be done in-house, production of the data sheets can also be outsourced to external suppliers The WRIC (Waste Recovery Industry Chain) project on the production of SDS-R (safety data sheets – recycling) was established by the European plastics industry associations in order to support recyclers. It is aimed at producing general safety data sheets for various plastics, which can then form the basis for recyclers on which to provide information about their recyclates[49].

### 5.3.2. Safety notices (Article 32, Communicating information)

For substances that do not require statutory safety data sheets, Article 32 of the REACH Regulation specifies that notices about safe use must be made available in other ways. The practice of voluntary safety data sheets (cf. 5.3.1.) meets the requirements of this provision, and offers the customer the advantage of always being able to deal with the same document structure.

The content of these safety notices may cover information about how a substance should be processed (e.g. temperature limits for a thermoplastic, so as to prevent the formation of hazardous substances in the extruder) or which further risks are posed by the substance (e.g. explosion risk due to high levels of dust).

### 5.3.3. Information about substances in articles

If the recycler manufactures not substances or mixtures but articles, under Article 33 of the REACH Regulation there also exist information requirements relating to the ingredients as soon as the product is sent to customers:

---

[46] BAuA: http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/SDS/Muster/Muster.html?__nnn=true&__nnn=true
BDI: http://reach.bdi.info/GHS_SDS_Leerformular_SDS_Stoff_and_Preparation_DE_editierbar_09062009.doc

[47] ECHA; Guidance on the compilation of safety data sheets
http://echa.europa.eu/documents/10162/17235/sds_en.pdf

[48] http://www.vci.de/default~cmd~shd~docnr~115596~lastDokNr~-1.htm

[49] : http://www.beate-kummer.de/fileadmin/user_upload/PDF/120110_Beitrag_REACh_GHS_Recycling.pdf

- ☐ Trade customers receive the information ‘automatically’
- ☐ Private customers receive the information on request within 45 days.

SDSs need not be produced for articles.

REACH requires the communication of information concerning the presence of substances that appear on the Candidate List, as soon as their concentrations in the article exceeds 0.1%. For example, if a PA socket casing with hexabromocyclododecane as flame retardant (> 0.1%) is manufactured, the customer should be notified at least[50] that hexabromocyclododecane is present in the product. The form in which the information is communicated is not regulated in further detail.

[50] ‘At least’ means that further information may be communicated, e.g. with regard to safe disposal, but this is not a statutory requirement.

# 6. Further information

## REACH and Plastic Recycling, contact details of associations & organisations (as of 09.09.2009)

| | | |
|---|---|---|
| PlasticsEurope Germany<br>Dr. Rüdiger Baunemann<br>Mainzer Landstrasse 55<br>60329 Frankfurt am Main<br>Germany | Tel.: +49 69 / 2556-1317<br><br>Fax: +49 69 / 23 59 94 | Email:<br><br>ruediger.baunemann@plasticseurope.org |
| GKV, The German Association of the Plastics Processing Industry<br>Christoph Bornhorn<br>Kaiser-Friedrich-Promenade 43<br>61348 Bad Homburg<br>Germany | Tel.: +49 6172 / 92 66-61<br><br>Fax: +49 6172 / 92 66-74 | Email:<br><br>c.bornhorn@gkv.de |
| EuPC, European Plastics Converters<br>Walter Claes<br>66, Avenue de Cortenbergh<br>1000 Brussels<br>Belgium | Tel.: +32 2 739 6383<br><br>Fax: +32 2 732 4218 | Email:<br><br>walter.claes@eupc.org |
| TecPart, Technical Plastic Products Association<br>Hans-Georg Hock<br>Städelstrasse 10<br>60596 Frankfurt am Main<br>Germany | Tel.: +49 6239 / 40 98 64<br><br>Fax: +49 6239 / 40 98 64 | Email:<br><br>hock@kunststoffmanagement.de |
| pro-K, Industrial Association of Plastic Semi-Finished Products & Consumer Goods<br>Ralf Olsen<br>Städelstrasse 10<br>60596 Frankfurt am Main<br>Germany | Tel.: +49 69 / 27 105-30<br><br>Fax: +49 69 / 23 98 37 | Email:<br><br>ralf.olsen@pro-kunststoff.de |
| PVC and Environment Working Group<br>Werner Preusker<br>Am Hofgarten 1 - 2<br>53113 Bonn<br>Germany | Tel.: +49 228 / 91783-14<br><br>Fax: +49 228 / 538 95 94 | Email:<br><br>preusker@agpu.com |
| WIP Plastics Development Association<br>Knowledge and Innovation Network<br>Polymer Technology<br>Ms Berit Bartram<br>Güntherstrasse 1<br>30519 Hannover<br>Germany | Tel.: +49 511 98490-27<br><br>Fax: +49 511 833574 | Email:<br><br>foerderverein@wip-kunststoffe.de<br><br>www.wip-kunststoffe.de/cms/index.php/Home.wip |

## Contact details of REACH helpdesks and governmental Internet-based information sources

| | | |
|---|---|---|
| REACH<br>ECHA helpdesk<br>Correspondence:<br>P O Box 400<br>00121 Helsinki<br>Finland | | Website:<br><br>http://echa.europa.eu/help/echahelp_en.asp |
| REACH-CLP<br>helpdesk of the Federal Agencies<br>German Federal Institute for Occupational Safety and Health<br>Dept. 5, Federal Agency for Chemicals / Biocide Authorisation<br>Friedrich-Henkel-Weg 1-25<br>44149 Dortmund<br>Germany | REACH-CLP helpdesk of the Federal Agencies:<br>+49 231 / 9071-2971 | Email:<br><br>reach-clp@baua.bund.de<br><br>Website:<br><br>http://www.reach-clp-helpdesk.de |
| REACH<br>Information portal of the German Federal Environment Agency<br>Dept. IV 2.3<br>P O Box 1406<br>06813 Dessau-Rosslau<br>Germany | | email:<br><br>mail@reach-info.de<br><br>website:<br><br>http://www.reach-info.de/ |
| REACH e-learning<br>German Federal Environment Agency website for introduction to and guidance on REACH topics | | website:<br><br>http://ereach.dhigroup.com/MAIN_German/index_German.htm |

## Glossary

| Term | Meaning |
|---|---|
| Article | A product manufactured from one or various materials (fibres, polymer matrix, metal lattice, glass), whose functional properties are determined predominantly by the material's structure, surface structure, form or design and less by its chemical composition. The term 'article' is defined legally in Article 3 of the REACH Regulation. |
| Bioaccumulation | Enrichment of a substance in an organism over and above the concentration in the surrounding medium. It comprises the intake of the substance from the surrounding medium (bioconcentration) and from food (biomagnification). |
| Chemical Safety Assessment (CSA) | For all substances that require registration, a chemical safety assessment has to be performed and a chemical safety report produced if the registrant manufactures or imports these substances in quantities of 10 tonnes or more per year. The chemical safety assessment is a risk assessment, in which the registrant takes into account the risk management measures that he either puts into effect for his own use or proposes to downstream users for their uses. The chemical safety assessment should be performed either for each substance as such or in a preparation or for a substance group. If the substance is classified as hazardous, the chemical safety assessment must include exposure scenarios, exposure estimates and risk descriptions for the stipulated uses. |
| Chemical Safety Report (CSR) | The chemical safety report envisaged by REACH contains the chemical safety assessment that has to be performed for all registered substances which the registrant manufactures or imports in quantities of 10 tonnes or more per year. The chemical safety report contains a detailed chemical safety assessment. |
| Classification | Classification is a process in which given substances or mixtures are assigned to one of the 15 hazard categories, depending on their inherent properties and in accordance with the criteria laid down in Directive 67/548/EEC. If a substance proves to be non-hazardous, it is not classified. CLP (GHS) classifies substances and mixtures in hazard classes. |
| CMR substances | Substances whose effect is carcinogenic (causing cancer), mutagenic (causing genetic mutations) or toxic to reproduction. They are classified in three categories (Directive 67/548/EEC):<br>Category 1A : A human effect has been demonstrated<br>Category B: Unambiguous findings in animal experiments<br>Category 2: There exist grounds for suspicion. |
| Distributor | Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties. |
| Downstream user | Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) is regarded as a downstream user. |
| ECHA | European Chemicals Agency (ECHA)<br>The REACH Regulation establishes a European agency for chemical substances. It is responsible for the technical, scientific and administrative supervision of the REACH system. It carries out the registration process, plays a key role in ensuring uniform assessments, prepares criteria for selecting the substances to be assessed and makes decisions on requiring supplemental data about substances being assessed. It issues opinions and recommendations as part of the authorisation and restriction process. |

| | |
|---|---|
| Exposure | The effect of substances on an organism or on the chemical composition of an environmental medium. |
| Exposure scenario | According to REACH Article 3 (37): “The set of conditions … that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate”. |
| Formulator | An industrial or commercial organisation that manufactures mixtures from individual substances and/or from other mixtures. |
| Import | The physical introduction into the customs territory of the Community. |
| Importer | Any natural or legal person established within the Community who is responsible for the import of substances as such or in mixtures or articles. |
| Information requirements along the supply chain | The party responsible for placing hazardous substances on the market must provide the user with a safety data sheet. For all other substances, basic chemical information that is adequate for risk management procedures should be communicated. In addition, there exists a notification requirement between manufacturers and users in both directions (down- and upstream). This serves to gain new knowledge about chemical hazards and update risk reduction measures. |
| Labelling of substances | Identification of a substance or preparation as hazardous by means of appropriate symbols (e.g. Xn = harmful; N = dangerous for the environment). Not all hazardous properties lead automatically to labelling. |
| Manufacturing | Production or extraction of substances in the natural state. |
| Mixture (formerly ‘preparation’) | Batch, mixture or solution of two or more substances. Pursuant to the CLP Regulation (GHS Regulation), the new term ‘mixture’ replaces that of ‘preparation’. |
| Monomer | A substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. |
| Placing on the market | Supplying or making available, whether in return for payment or free of charge, to a third party. Import into the Community‘s customs area is deemed to be placing on the market. |
| Supply chain | Comprises all the manufacturers and/or importers and/or downstream users whose business activities are linked via a substance, a preparation or a product. |
| Phase-in substances | Chemical substances that either were already on the market in 1981 and are included in the EINECS list, or are included in the ‘no longer polymer’ list.<br>According to REACH Article 3 (20): a “substance that during the ten years before this Regulation came into force, met at least one of the following criteria:<br>1. The substance was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, or imported into them, and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS),<br>2. the substance was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, or imported into them, but not placed on the market by the manufacturer or importer,<br>3. between 18 September 1981 and 31 October 1993, the substance was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, or imported into them, placed on the market by the manufacturer or importer, and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC (EC Official Journal L 259 of 15.10.1979, p. 10) as amended in Directive 79/831/EEC (EC Official Journal L 154 of 5.6.1992, p. 1), but does not meet the definition of a polymer as set out in Directive 67/548/EEC as amended in Directive 92/32/EEC, provided the manufacturer or importer has documentary evidence for this”. |
| PBT substances | Substances that are persistent, bioaccumulable and toxic. These are substances that are not degraded in the environment, accumulate in |

| | |
|---|---|
| | humans and animals and have category 1 and 2 CMR properties or high aquatic toxicity. |
| Polymer | Polymers are not registered under REACH, but the polymer-forming monomers must be registered.<br>A polymer is a substance consisting of molecules characterised by a sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:<br>a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;<br>b) less than a simple weight majority of molecules of the same molecular weight.<br>In the context of this definition, a 'monomer unit' means the reacted form of a monomer substance in a polymer. |
| Product | Substances, preparations, semi-finished products, articles, utility objects assembled in complex fashion or other goods manufactured industrially for the purpose of marketing. |
| REACH | Regulation EC 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| REACH system | A uniform system for chemicals management of new and existing chemicals. It creates a Community-wide framework, under which the holders of substance responsibility must carry out risk management; this includes the assessment of risks posed by substances (risk identification) and the introduction of risk-minimising measures (risk reduction). A registration and if relevant an evaluation process must be implemented. CMR, PBT and vPvB substances undergo an authorisation process ((Registration, Evaluation, Authorisation and Restriction of Chemicals). Furthermore, REACH makes possible Community-wide substance restrictions and labelling specifications. |
| Registrant | The manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance. |
| Registration | All substances manufactured or imported at a quantity exceeding one tonne must be registered. REACH prescribes a timetable for the registration of those substances already on the EU market. The data to be submitted depend primary on the production quantity. If a substance is not registered, it may neither be manufactured nor imported. The provisions governing registration require the manufacturers and importers of chemical substances to acquire knowledge about the substances manufactured and imported by them, and to use this knowledge for the purpose of conducting responsible and sound substance-specific risk management. The manufacturers and importers must deal with the risks of all uses notified to them by their customers. Downstream users are entitled not to state a use, but where relevant may be responsible themselves for carrying out a chemical safety assessment. Conversely, manufacturers are not required to state a substance for a use that they cannot endorse. |
| Registration dossier | A registration dossier must be submitted for every substance manufactured or imported in a quantity exceeding one tonne. Depending on the quantity, it comprises:<br>> 1 t: Technical dossier<br>> 10 t: Technical dossier + chemical safety report<br>> 100 t:Technical dossier + chemical safety report + additional information |
| Risk reduction | The holder of substance responsibility must apply suitable measures for appropriate risk management. |
| Simple weight majority | In polymers, a minimum of 50% by mass of a particular monomer unit. |
| Substance | A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding |

| | |
|---|---|
| | any solvent which may be separated without affecting the stability of the substance or changing its composition.<br>Waste as defined in REACH is not a substance. |
| Substance evaluation | Serves to examine the risks posed by a substance to human health or the environment in the event of suspicion. If the suspicion concerns risk to human health or the environment, the authorities may require supplemental information from the registrant. As a result, authorisation or restriction measures may be decided upon. |
| Substance of very high concern (SVHC) | Substances of very high concern as defined in the REACH Regulation are:<br>1. CMR substances in categories 1 or 2,<br>2. PBT and vPvB substances that meet the criteria in Annex XIII, and<br>3. 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 Annex III – 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 1. and 2. and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. |
| Use | Processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. |
| User | A commercial organisation in which the substances and mixtures are utilised. |
| Value-added chain | Synonym of supply chain. |