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"Effective control"
of substances of very high concern (SVHC)
with properties for which thresholds are not derivable
within the framework
of the REACH authorisation regime

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Short version of the Final Report
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Introduction

1.1
Objective of the project

The objective of this project is the development of minimum demands on "effective control" of substance-related risks that derive from a particular group of industrial chemicals. The project focuses on substances of very high concern (SVHC) for which quantified thresholds are not derivable. Substances of this group could in future be liable to authorisation. Persistent, bioaccumulative and toxic (PBT)-substances and substances that cause equivalent concern are treated within the framework of this project as representative for this group of substances. With the legal framework in mind, the regulation has to be analysed with regard to the specifications it contains on "appropriate" or "effective" control of substances subject to authorisation; since, due to the lack of a quantified effect threshold for this group of substances, the otherwise decisive comparison of PEC and PNEC[1] cannot be made.

In order to illustrate the resulting legal consequences as well as the practical implications for implementation, the research project has investigated exemplary substances and formulated "virtual conditions for their authorisation". The basis for this was provided by the "checklists" documented in Annex B. They list the points that have to be borne in mind by manufacturers and importers of substances in the documentation relating to application for authorisation, and taken into account in the authorisation decision of the authority.

The project approach is designed to thoroughly check that demands on application for authorisation take account of such matters as are of relevance to later monitoring. From the perspective of the "surveillance" that follows authorisation, and taking into consideration the periodic review of the authorisation decision (Article 61 REACh), demands can be defined that have already to be considered in the lodging of an application for authorisation at the beginning of the procedure.[2]

1.2
Relevance of the findings

This scope of work is still relevant. The Guidance published in January 2011 (Guidance on the preparation of an application for authorisation, Version 1) is addressing mostly the controversial[3] question of the substitution plan.[4] The central point of this study –

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1 For a description of REACh-specific definitions and related matters visit: www.hse.gov.uk/reach/definitions.htm and http://echa.cdt.europa.eu/ShowIndex.do?src=en.

2 In a figurative sense one could describe this approach as "taking REACh seriously" or "taking the authorisation procedure seriously".

3 See Führ/Schmolke/Hermann 2010: Legal appraisal: Scope of application of the substitution plan in the authorization procedure under REACh, Darmstadt.

4 Siehe ECHA 2011, part 3 und 4 (pp. 56 – 119).

the adequate control – as formulated in Art. 60(2) suppara1 und Art. 60(4) lit. a,[5] has to be based on concise information on the life cycle of the substance at stake in form of a mass balance for all uses applied for, including point sources as well as diffuse emissions.[6]

The findings derived in this report can be seen as a additional "Guidance" on relevant aspects of the authorization procedure: starting with the application but also including the preparation of the authorization decision as well as the follow up in the light of a review of the authorisation.

1.3
Substance reports on exemplary substances

The working papers on exemplary substances were discussed at a workshop on 24.9.2007 with representatives of the affected industrial sectors. Discussions during the workshop as well as submitted written statements were taken into consideration in the preparation of substance reports. The representatives contributed in each case-study their state of knowledge on substance properties and applications as well as their experience in the management of the respective substance (activities of industry associations, voluntary commitments and possible influence on the part of the industries concerned). This collaborative approach had the target of creating a knowledge base, upon which the requirements in REACh for "substances subject to authorisation without effect-thresholds" can be exemplarily analysed for the purpose of determining whether they take into adequate account the specific problems of this group of substances. For this purpose, the project assumed – for heuristic reasons – that the substances under exemplary examination are subject to authorisation in accordance with Title VII. Two points have to be emphasized for clarification. The selection of exemplary substances in no way implied that the corresponding substances actually meet the criteria for inclusion in Annex XIV, or should as a matter of priority be subject to authorisation. It concerns, on the contrary, a purely hypothetical assumption that serves the purpose of illustrating the "testing" of demands for "effective control".

On the basis of conclusions from the discussion on exemplary substances, demands are formulated in each case on "virtual authorisation".[7]

1.4
Structure of the complete version of the final report

The complete version of the final report describes in chapter 2 which substances may be subject to authorisation in the future. Chapter 3 deals with the substantive demands that are a prerequisite for authorisation from an environmental perspective, and which, at the same time, form the basis for their subsequent control and monitoring.

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5 Siehe section 3.1, p 6.

6 See the checklist for applicants Annex B.I. (p. 11).

7 Referred to as PBT-1 and PBB-2, see Annex D of the complete version of the report (in german). Only anonymized conclusions concerning the two exemplary substances have been adopted in the complete version of the report.

This short version is based, in the main, on Chapter 4 of the complete version, which summarizes the conclusions from the examination of the exemplary substances. In addition, the checklists for parties to the authorisation procedure (Annex B) as well as the draft for a monitoring guide (Annex C) are attached.

Annex A to the complete version contains complementary definitions of terms and documents relevant recitals in the REACh Regulation. Annex D documents (anonymized) reports on the two exemplary substances.

Work on the project was concluded in December 2008 and partially updated in June 2011.

We would like to thank all those who participated in the project and contributed to this report.[8]

Darmstadt, June 2011

Martin Führ

[8] The responsibility for any shortcomings lies, of course, with the authors.

2
Legal framework

Within the scope of this project two existing substances were analysed in debth. The exemplary substances, so the underlying heuristic assumption, fulfill the criteria of Article 60 (3c) (substances with persistent, bioaccumulative and toxic properties, or highly persistent and highly bioaccumulative properties, which are identified according to Article 57 (f), and can therefore be authorized in accordance with the procedure laid down in Article 60 (4)("socio-economic benefits"); that is, when the socio-economic benefits outweigh the risks to human health and the environment. A further precondition for authorisation is that no alternative substances or technologies exist.

The project ignored these issues, however, and concentrated instead on the assessment criterion in Article 60 (4a), according to which, "the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed" has to be considered within the framework of the decision on the granting of authorisation.

In this context, the general minimisation order contained in Article 60 (10) is of relevance, according to which the holder of an authorisation has to ensure that exposure is reduced to as low a level as is technically and practically possible. This, too, has to be documented correspondingly within the scope of "appropriate control" and "effective surveillance".

Undefined legal terms, which have first to be substantiated for realization of appropriate control, are "*appropriateness and effectiveness of the risk management measures proposed*" and "*reduced to as low a level as is technically and practically possible*" *(Art. 60 (10)*.

For the purpose of operationalization, differentiation is suggested (see the complete version, Section 3.6) between

a) the demand for "appropriate control" or "appropriate measures to limit the release of a substance"

b) the requirements for "effective surveillance of exposure" on the other.

2.1
Operationalization of risk characterization

With regard to point a), Annex I No. 6.5 demands for "those human effects and those environmental spheres for which it was not possible to determine a DNEL of PNEC" the performing of a "qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario".

The standards that are to be applied to "qualitative assessment" are not clear yet. The outcome of the REACh Implementation Project 3.2 on the characterization of a dose-effect-ratio for substances, for which effect-concentrations are not determinable, provides methodical support for qualitative assessment of exposure on the basis of DMEL-

values, and thus goes beyond the corresponding REACh provision[9]. However, there is no concretization for industrial practice in particular as effects on the environment are concerned.

Failing operationalization of corresponding demands indicates a fundamental difficulty, which exists with the group of substances under investigation: The whole present practice of risk-assessment of existing and new substances has been based mainly on the assumption that it is possible to "appropriately control" substance-related risks through appropriate risk management measures (and corresponding communications and co-operation along the production chain). This assumption alone ultimately allows the REACh regulative approach based on direct responsibility.

In classic risk characterisation, use specific information on the predicted exposure concentration (PEC) for a certain compartment is to be found in the chemical safety report, which was compared with the predicted no effect concentration(PNEC). The threshold takes uncertainties into account. These factors should as far as possible be substantiated by laboratory results or measurements of the exposure of human beings and the environment.

For substances of very high concern without thresholds the challenge is nevertheless to provide a risk characterization as the basis for the weighting decision. For this purpose, no quantitative limit vales (DNELs and PNECs) are available. Support could be provided by the exposure-related reference values (DMEL in the health area) put forward in the guides on chemical safety assessment. It remains to be seen, however, to what extent these values prove their worth in the health area, and under which circumstances such experiences could be applied to environmental effects.

2.2
Operationalization of effective control

Regarding the requirements for "effective surveillance" (Point b)), REACh provides few points of reference in its Annexes and available guidance documents. A glance at the requirements on surveillance and monitoring mechanisms in other substance-related regulations is more productive.[10] Against this backdrop, an analysis was made of regulations on effective surveillance and on the monitoring of market access and post-marketing control of plant protection agents, genetically modified organisms (GMOs) and GMO products as well as of biocide agents and products in the Act on Plant Protection Agents, the Genetic Engineering Act and the Chemicals Act (see Section 6.7 of the complete version of this report). The results can be summarized as follows:

- control of market placement can be effected with prohibitions (resp. non-authorisation) and use-restrictions for the protection of man and the environment;
- in addition, in all three regulatory areas the applicant is obliged to notify the authority without undue delay of any changes and new information, compared to authori-

[9] ECHA 2008, Part R.8, p.12 ff. (for health effects)

[10] Cf. as a result of analyses in this chapter, the proposal for a new Guidance Document on the REACh Regulation "Monitoring of substances of very high concern" (developed with reference to Annex VII of Directive 2001/18/EC); documented in Annex C, p.19f.

sation, regarding the effects of the authorized substance on man or the environment;

- all three regulatory areas under investigation contain a monitoring programme that has to be submitted by the applicant in the course of the application procedure;
- market placement in all three regulatory areas is initially restricted to 10 years, but can be extended;
- under genetic engineering law, the competent authorities can prohibit, wholly or in part, the operation of manufacturing installations, when secondary provisions or subsequent conditions are violated or existing safety-related facilities and measures are no longer sufficient.

3
Findings from the analysis of exemplary substances

The reports on the two exemplary substances take up the demands developed above and apply them exemplarily, in order to formulate specific demands on documentation and the authorisation decision. This way, the necessity arose to "simulate" the main steps in the authorisation procedure (application and decision) on the basis of information known to experts, and to outline individual demands for each of the exemplary substances.

3.1
General assessment

Each of the existing substances analysed as exemplary substances has been comparatively well investigated. For one substance, for instance, an EU risk assessment exists, whose latest revision is based on more than 1,000 scientific studies. In addition, one can fall back on comparatively broadly-based monitoring data. At the same time, considerable gaps in knowledge and contradictory assessments exist, particularly concerning the quantification of release paths and the fate of the substance in the environment.

As a result, there is a need for research on a number of issues that cannot be adequately resolved with the standard tests of the existing-substance procedure. Agreement was therefore reached, that the industry investigates the following questions within the scope of laboratory and monitoring analyses:

1. How relevant is accumulation in organisms by way of the terrestrial food chain?
2. What is the trend in the exposure of human beings?
3. How should neurotoxic effects in animal testings be assessed?
4. Do toxic, persistent degradation products develop under anaerobic conditions?
5. How should long-distance-transport potential be assessed?

The uncertainties in risk assessment expressed in the above questions are typical for persistent substances that, moreover, are mobile and accumulate in organisms. Their release into the environment and possible effects on human health and ecosystems are

isolated from each other in terms of both time and space. A further aspect could be that adverse environmental effects from a substance subject to authorisation can only be based in part on the release of the substance itself, and that precursor or degradation substances are responsible for exposure. REACh is initially orientated towards individual substances; it demands, however, consideration of the entire life-cycle of substances. This raises the question of how the development of substances from precursor substances can be the subject of chemical safety assessment and, if necessary, the subject of an authorisation decision (for instance, with regard to monitoring), and if precursor substances would then themselves be subject to authorisation. In many cases it could be useful to regulate a "substance group" as a whole and on a graded basis, as is already partly practised in water and installations law.

The authorities are still seeking to improve the scientific basis of decision-making (for example, the EU NORMAN Network[11]) and to implement precautionary measures for the avoidance of substance emissions (for example, ocean protection). These measures are largely implemented independent of the decision criteria of REACh.

The exemplary analysis of "new substances", as defined up to now in the law on new substances, has shown that the information submitted suffices only for the carrying out of risk assessment for industrial use with standard assumptions. This assessment, however, is not in line with REACh, since exposure scenarios pursuant to Annex I of REACh are not available. Furthermore, important parts of the life-cycle, such as manufacture and the waste phase, are not examined. The use of the substances in articles was not assessed in respect of the actual use. The question, under which conditions or risk management measures this use is regarded as safe (degree of polymerization), is not specified. The new substance was therefore not considered in the further course of the project.

3.2 Findings for companies

In view of REACh, and greater direct responsibility on the part of business enterprises, companies should consider most carefully which substances should remain in their portfolio in the long term.

Companies can substantially reduce emissions through proactive risk management. A decisive role falls to industry associations, which can more effectively develop, support and disseminate product stewardship programmes than individual manufacturers. The cooperative approach thus realized anticipates fundamental elements of REACh.

Companies must expect in future that substances of very high concern will be restricted within the scope of sector-specific regulations, or on the basis of Title VIII of the REACh Regulation. Convincing product stewardship programmes could be an important element in emphasizing that participating companies take their product responsibility seriously. This might also play a role in the debate concerning substances to be listed in Annex XIV.

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[11] Network of reference laboratories, research centres and related organisations for the monitoring and biomonitoring of emerging environmental substances; visit http://www.norman-network.com/.

The question, to what extent substitutes or other alternatives are available, is of key importance for the respective companies or industries; and this raises the issue of the properties and effects of substitute substances, which are discussed in the following section.

3.3
Findings for the authorities

Substances with problematic properties, to which PBT and suspected PBT substances belong, do not allow unambiguous risk assessment: Standard tests do not guarantee secure risk characterization, and evidence of persistent substances in the environment give cause for concern until such time as effect mechanisms and fate in the environment are clarified.

A strict risk-based approach by means of the usual concentration-related risk characterisation criteria (for example, PEC/PNEC comparison) is inadequate for this group of substances. The principle of precaution demands an extended perspective and complementary measures. Consideration of emission reduction and the search for substitutes are therefore essential for every substance application. Here, the problem arises that potential substitutes can also expose gaps in knowledge regarding their ecological and toxicological properties, and their use can give rise to similar concern. The problem of gaps in knowledge should at least be eased by REACh, since a basic data set will be available for all substances > 1 to/a production-volume. It appears to be questionable, however, whether this basic data set will allow an adequate clarification of critical issues concerning these substances (see the questions in Section 3.1).

The sectoral programmes show that industry associations can mobilize their members and customers highly efficiently as far as the introduction of precautionary emission reduction measures is concerned.

4
Findings from virtual authorisation procedures

In "simulating" the demands that have to be met in an authorisation procedure, it turned out that clear assignment of the responsibility for providing information is a key element in successful risk management. The text of the Regulation and its Annexes needs to be concretized. In order to fill this gap, appropriate auxiliary guidance documents have been developed (see Annexes B and C)

With regard to this group of substances quantified emission reduction objectives substantiating the minimisation obligation contained in Article 60 (1) REACh are an important element of the authorisation decision. More so than in the registration procedure, it has to be explained how information on corresponding risk reduction measures can be communicated und made obligatory in the production chain. Besides informational elements (examples of "best practice"), contractual commitments and mandatory monitoring measures (for instance, on the operation of installations or the quality structure of articles) play an important role.

Here it is a crucial point that demands on later monitoring have already been considered in the application. Monitoring tasks should be distributed between the applicant

and the authorities in such a way that the substance specific aspects of surveillance should already have been drawn up conceptually and in a implementable manner by the applicant, and made part of the application documentation. Without such preparatory work there is the danger that the authorisation notification either contains specifications that are too stringent, or limits itself to vague demands on content. Both are undesirable on legal and economic reasons.

Assuming that a substance subject to authorisation has previously been properly registered, then much of the documentation on risk management that has to be submitted during the authorisation procedure should already be available. The additional effort involved could be attributed to the greater degree of details required. Apart from that, supplementation might be required with regard to diffuse releases from articles in the hands of consumers, and in connection with disposal.

Data on surveillance and monitoring could hardly have been the subject of registration. Within the chemical safety assessment, however, registrants are obliged to take account of all available data on exposure. Annex I No. 5.2.5 emphasises, in particular, that special consideration has to be given to representative exposure data. Where efforts have already been made at the industry association level concerning sector-related measures on surveillance and monitoring (as in the case of the two existing substances under examination), these can be made use of, and data and practical experience are in any case available for specific areas. If this is not the case, there is a not inconsiderable need for supplementation.

For further details on relevant points and their justification, reference is made to checklists for applicants and the competent authority as documented in Annex B.

[Annexes A and D: See complete version of this report (in german).]

5
Annex B: Checklists for the authorisation procedure

Checklist for effective control of SVHC without exposure thresholds within the framework of authorisation

The purpose of this paper is to provide support for the applicant and the authority, which makes it easier for them to define essential conditions for "effective control" of PBT and similar substances.

Part I contains a check-list that the applicant should bear in mind when he specifies preconditions in accordance with Article 60 (4a) in the documentation.

> Guidelines for drawing up the chemical safety report were developed within the scope of the REACh Implementation Project (RIP) 3.2. In this context, an expert working group (PBT Drafting Group) presented the final report on PBT and vPvB assessment on 26.11.2007. This report forms the agreed basis for chapter R11 of the "Technical Guidance Document for Preparing the Chemical Safety Assessment".[12]
>
> Since the version of the "PBT and vPvB assessment" of 26.11.2007 is less detailed than the preliminary version of 13.03.2007, reference is made below to the earlier version of March 2007 (hereafter quoted as: PBT-p-TGD, March 2007). The demands contained in the chapters of the Technical Guidance Document in RIP 3.2 are more precise than those in RIP 3.7[13]. RIP 3.2 documents therefore form a fundamental basis of the following listing.[14]
>
> It should be added that according to the distribution of responsibility in mandatory consent procedures, the applicant has to show that his application fulfils all statutory preconditions for authorisation.[15] All points that are of relevance to the assessment of authorisation criteria pursuant to Article 60 (4a) and to corresponding requirements pursuant to Article 60 (9) have to be documented in the application.

Part II lists the points that the authority should consider within the scope of the authorisation decision.[16] Part III refers to points that should be considered after the granting of authorisation.

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[12] The Guide to the Conduct of Chemical Safety Assessments comprises two parts: an "Introduction" ("concise guidance", parts A – G of the complete document) and the extensive guide ("reference guidance", part R of the complete document). The task of assessing PBT substances is briefly described in the introductory section of the guide (part C of "concise guidance", about 10 pages) and explained later in more detail (Chapter R11 of the "reference guidance", around 60 pages).

[13] The description in "Appendix 1 DRAFT FORMAT FOR AN APPLICATION FOR AUTHORISATION" under the heading "4 REQUEST FOR AUTHORISATION" in lines 1167 to 1176 does not even attain the level of concretization of the requirements in the regulation, and is therefore not really useful.

[14] In the version of the document in RIP 3.2-2 of 26.11.2007, specific data from the March version is no longer to be found. Within the scope of the consultation, which is presently being conducted (March 2008), the attempt is being made to readopt the original, detailed data. In view of the fact that substances of very high concern (SVHC) are treated within the scope of the authorisation procedure, it would appear to be appropriate to take the specific demands in the version of March 2007 as a basis.

[15] This applies not only for chemical law (pharmaceuticals or plant protection agents), but also, for instance, the law on industrial installations – see Article 6, IPPC Directive and Articles 4 and 4a – 4e of the 9th Federal Immission Control Decree.

[16] A corresponding guidance document is not available from ECHA so far.

I. Points to be considered by the applicant in his application

1. Subject of the application for authorisation

   1.1 Description of the substance and its inherent properties, with particular regard to its hazardous and other properties, which are the reason for the authorisation procedure,[17] as well as specific additional substances and contamination.[18] Corresponding data could already be included in the chemical safety report and in the Annex XV dossier.

   1.2 Information on the use or the uses for which an application for authorisation is made.[19]

   Notes:

   → *Treatment of the following points is limited to the applied for use or uses.*

   → *This is last as well as the lists under II. and III. do not reflect the points to be considered in relation to the "analysis of alternatives" and the "substitution plan" as provided for in Art. 62(4) lit. e) and f) REACh.*

2. Description of the substance life-cycle [20] / mass balance

   2.1 The application describes the entire life-cycle of the substance subject to authorisation (for the manufacturer, for instance, production, formulation and industrial use of the substance, transport[21] to downstream users, use by downstream users, description of the finished article and its intended use, as well as recycling and disposal paths).[22]

   2.2 The application contains a conclusive mass balance for the total quantity of the substance that is manufactured or imported by the applicant and is intended for the applied for use (see No. 8).

3. Data on point sources[23]

   3.1 The application defines the types of point sources (that is, a locally identifiable source whose emission can be quantified, and where emission reduction techniques can be employed) for the entire life-cycle.[24]

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17 Such information is already contained in the Annex XV dossier as well as – if the substance is already registered – in the chemical safety report.

18 See the definition of substance in Article 3 (1) REACh.

19 Corresponding to the regulation on uses in Article 62 (3) REACh.

20 See RIP 3.2-2, PBT Drafting Group, Reference Preliminary - Technical Guidance Document, Chapter PBT and vPvB Assessment, Draft 13 March 2007, No. 1.1.5 (Summary and overall conclusions on PBT and vPvB properties) p. 50 ff.: "appropriate RM measures and OCs [operational conditions should] be developed and indicated in the CSR and SDS to ensure safe handling".

21 The aspect of transport falls within the scope of the law on the transport of dangerous goods. "PBT-p-TGD, March 2007" has already discussed this stage in the life-cycle of a substance, however, under the heading *Rigorous containment of the substance* in Section "1.3.1.1 Options and measures to minimise emissions and exposure"(p. 64).

22 According to RIP 3.7 the manufacturing and formulation steps have also to be described when application is made for authorisation of an end-use by an end-user.

23 See "PBT-p-TGD, March 2007", No. 1.2.3.2., p. 58, where the definition of the term 'point source', as applied here, is to be found.

3.2 The application contains the following data for each identified type of point source:

- Description of the source (life-cycle stage, conditions of substance use).
- Environmental sphere into which release occurs.
- Exposure paths and population groups affected.
- Aggregate phase of the substance; if necessary, characterization of integration into a chemical matrix.
- Constant or interrupted release.
- Description of risk reduction techniques and effectiveness.

3.3 Description of the point source can be dispensed with when this is justified in accordance with Article 62 (5b).

4. Estimate of emission from point sources[25]

In the application, emissions[26] have to be quantified and the predicted environmental exposure for each compartment into which release occurs has to be indicated. For this purpose, the measurement or calculation method has to be selected that is appropriate for the respective source. The method applied has to be described and the degree of data accuracy stated. Emission on a yearly or daily average has also to be stated, as does the share of substance release in total production or total consumption of the substance.

5. Organization or technical measures for emission reduction

Technical or organizational methods (risk management) that are planned for emission minimisation for the respective point source have to be described in the application.[27] The degree of effectiveness of measures regarding emission avoidance at the respective point source has to be stated, as well as the contribution to the reduction in emission of the substance in absolute terms. The overall reduction target for a point source has to be stated, as well as, if applicable, scheduled intermediate steps and targets for attainment of the overall reduction target.

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[24] Points 3 to 8.1 as well as 8.4 are fulfilled by the chemical safety report and the exposure scenarios contained therein; further detail should be provided if necessary.

[25] Cf. Comments in "PBT-p-TGD", No. 1.2.3.3.

[26] The term "Emissions" describes
- not only substance releases as defined in Article 2 No. 10 of PRTR Regulation No. 166/2006, Official Journal L 33/1) and thus "each introduction of pollutants into the environment as a result of human activities, whether intentional or inadvertently, regularly or irregularly, including spillage, emission, introduction, compression, disposal or spoilage, or the introduction by way of the sewage system without final water treatment";
- as well as, if necessary, "transfer beyond the site" pursuant to Article 2 No. 10 of the PRTR Regulation; that is, the "shifting of certain wastes and pollutants present in waste water, which are intended for recycling or disposal, beyond the boundaries of a company facility."

This definition offers the opportunity to link emission-related monitoring of PBT substances with the mechanisms of the PRTR Regulation.

[27] Here, data on the costs of a measure, also regarding socio-economic analysis (SEA) pursuant to Article 60 (4) in connection with Article 62 (5a) and Annex XVI REACh, is of particular relevance; cf. the elements specified in Annex XVI, in particular the first dash. According to Annex XVI, the level and scope of the SEA, or contributions to them, are the responsibility of the applicant for authorisation. The information provided can address the socio-economic impacts at any level.

6. Data on relevant diffuse emission sources[28]

   6.1 The application describes all diffuse emission sources for the entire life-cycle of the substance, and deduces therefrom a set of priorities for risk management.

   6.2 All emissions of the substance during the use of the substance / preparation / article (for example, the processing of a preparation on a building site) have initially to be classified as diffuse sources. As far as final assignment (point or diffuse source) is concerned, in case of doubt the degree of quantifiability and technical avoidability are decisive. This includes the following data:

   - Description of the source (life-cycle step, technical organisational conditions of use).
   - Environmental compartments into which releases occur.
   - Exposure paths and population groups affected.
   - Aggregate phase of the substance; if necessary, characterization of matrix integration.
   - Constant or temporal release.
   - Risk reduction techniques: Description and effectiveness.
   - Service life of the article or material.

7. Characterisation of emissions in the case of diffuse sources[29]

   Emissions in different environmental compartments have to be quantified for the respective diffuse sources in the application. For this purpose, the measurement or calculation method has to be selected that is appropriate for the respective source. The method applied has to be described, the degree of data accuracy stated and the assumptions have to be explained. Emission is stated on yearly average, unless it follows a deviating pattern (for example, seasonal emission). In the case of emissions from an article or material, the emission quantity has to be stated in absolute terms related to an appropriate period (for example, kg/year) and as a share of the total substance quantity contained in the article/material.

8. Mass balance for diffuse sources and point sources

   8.1 On the basis of the results of the above points 3 to 7 the applicant submits a conclusive mass balance in accordance with Point 2.2 for the planned total substance quantity that he intends to manufacture, import or use. He further describes the emission pathways as well as the minimisation measures he recommends.[30]

   8.2 The exposure minimisation target, in accordance with Article 60 (10), is stated in the application together with the required implementation steps.[31] The measures can also be described with which the exposure of workers during the use of the

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[28] Cf. the comments in "PBT-p-TGD", No. 1.2.3.2.

[29] Formulation based on "PBT-p-TGD", No. 1.2.3.3, p. 59f.

[30] See "PBT-p-TGD", No. 1.2.3.1, p. 58: "The information on the life-cycle of each specific use needs to be in sufficient detail to allow a reliable quantification of mass flow and establishment of an emission and loss inventory in the following steps. This includes allocation of emissions and losses to particular life-cycle steps."

[31] This demand has up to now not been adopted in RIP 3.7.

substance, as well as exposure of the environment and exposure on the part of consumers from articles, should be continuously measured or modelled on the basis of measurements or substance concentrations.

8.3 A concept has to be submitted in the application, that proves which minimisation measures for point and diffuse sources are successfully implemented, in accordance with Article 60 (10) REACh, also with downstream actors in the supply chain.[32]

9. Surveillance and monitoring at a local or regional level for the duration of authorisation.[33]

   9.1 The application contains a concept for the surveillance of e*missions* from point sources and the monitoring of release from diffuse sources for the duration of authorisation. This concept includes all relevant life-cycle steps and covers relevant degradation products of the substance.
   The applicant can also carry out this task together with other applicants, downstream users or third parties, or can entrust an association with the task. Responsibility remains with the applicant.

   9.2 The monitoring programme has to be designed in such a way that it supplements existing monitoring programmes at a national or European level.

   9.3 The organization (responsibilities, financing, conduct) as well as agreement with bodies responsible for national and European programmes has to be described in the application.

   9.4 The applicant determines on an annual basis the level of exposure of man and environmental spheres with respect to the substance or its degradation products, and compares this with the status quo before authorisation. He describes the human and environmental subjects of protection considered (for example, exposure bioindicators) as well as the chemical analysis on which the monitoring programme is based.

10. Information on research projects[34]:

    The applicant provides the authority with information on current or planned R & D projects of which he is aware,[35] which relate to the substance and are directed at
    - indistinct effect mechanisms,

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[32] With application for authorisation of the entire production chain this obligation arises from general application obligations.

[33] The duration of obligations is deduced from biocide authorisation pursuant to the German Chemicals Act. According to Article 12b (3) of the Chemicals Act, the competent authority can demand, by way of condition, surveillance and monitoring measures for the duration of the authorisation from the authorisation holder, provided that this is required for the protective purpose laid down in Article 1 of the Chemicals Act.

[34] Since REACh only demands information from the applicant concerning his own research projects, point 10 on information concerning external research tasks goes beyond REACh.

[35] Regarding the completeness of the information provided, and from the point of view of precaution, it appears to be appropriate to demand information on the research activities of third parties, to the extent that these are known to the applicant or can be obtained from general sources accessible to experts.

- impacts in the environment,
- indicators for environmental monitoring and
- [possible substitutes],[36]

and describes, in particular, research objectives, methods, participants and period.

11. Data concerning the communication of substance related information down the supply chain

    The applicant explains whether, and how, he provides information and support arising from authorisation conditions, which go beyond the exposure scenario (for example, monitoring obligations, information on the concentration of SVHC in articles), to downstream users, other users as well as recyclers and disposal companies:

    11.1 To manufacturers and users of preparations that contain the substance subject to authorisation, by means of the safety data sheet or information in accordance with Article 32 REACh as well as, if necessary, additional information on effective control.

    11.2 To disposers of preparations that contain the substance subject to authorisation, by means of the labelling of waste (actively communicate the concentration of substances subject to authorisation).

    11.3 To the users of articles that contain the substance subject to authorisation, also beyond the information required pursuant to Article 33 REACh. This can be achieved through corresponding advice in the directions for use or through labelling of the article itself. Industrial users of articles are requested to pass on information on the substance subject to authorisation to disposal companies.

    11.4 The applicant describes further how he supports downstream users in the supply chain, by means of organizational measures, to meet their own information obligations according to Article 34 REACh.

12. Proposal for the revision period[37]

    The applicant states the circumstances that are relevant for determination of the revision period.[38]

II. Points to be considered by the authority

The following points have to be checked by the authority during the evaluation of the application for authorisation. From these points specifications for notification of authorisation usually emerge.

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[36] This point is made here only for the purpose of completeness, since issues of substitution are not subject to this research project.

[37] CF. Article 60 (9e).

[38] Product cycles play a central role in determination of the revision period; that is, the circumstances that determine how quickly companies can switch production. The statements of the Risk Assessment Committee pursuant to Article 64 (4) as well as the possibility of statements on the basis of Internet publications pursuant to Article 64 (2) serve the purpose of obtaining "contrasting information".

1. Limitation of exposure

   1.1 The authority lays down demands on use conditions of the substance. They include, as a rule, a minimum reduction target that has to be met by the applicant.[39]

   1.2 Beyond that, the authority lays down the overall reduction target for the respective substance as well as the target period.

2. Uses and conditions

   The authority checks whether, on account of information provided by the applicant on risk assessment of the substance, planned uses and risk management measures, authorisation can be granted for the respective use. It specifies limitations on uses or use conditions in the authorisation notification, in accordance with Article 60 (9c-d) REACh, which are necessary for the protection of human health and the environment.

3. Revision period

   The authority checks the circumstances that are decisive for the revision period on the basis of information from I. 12.

   The authorisation notification specifies a "limited revision period".[40]

4. Minimisation obligation pursuant to Article 60 (10) REACh

   4.1 The authority checks whether the technical and practical measures proposed by the applicant as well as their effective implementation are comprehensibly described and, as a result, exposure of the substance liable to authorisation can be kept at the lowest possible level.

   Procedural note: In the authorisation procedure, the ECHA should consult the national authorities responsible for approval under IPPC and water law regarding the planned measures. Co-ordination of national authorities within the scope of such consultation could, for example, occur by way of the Forum established in accordance with Article 76 lit.f and Art. 86 REACh.

   4.2 The authority can require the applicant to submit, within a given period of time, a report concerning progresses in developing risk management measures in accordance with Annex 1 No. 5.1.1 REACh.

5. Conduct of research projects

   The authority examines, within the scope of possible conditions in accordance with Article 60 (9d) REACh, the extent to which the applicant could be obliged – if necessary, together with other applicants - to conduct research on indistinct effect mechanisms, fate in the environment (degradation products), indicators for environmental monitoring, or possible organizational, technical or substance-related alternatives to the substance liable to authorisation.

6. Emissions and immissions (surveillance and monitoring)

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[39] Condition pursuant to Article 60 (9d); arises from the minimisation obligation in Article 60 (10) REACh.

[40] Information in accordance with Article 60 (9f) REACh.

6.1 the auThority examines the applicant's data on surveillance and monitoring of point sources and diffuse sources (annual mass balance, effectiveness of reduction measures) as well as measures for the involvement of downstream users in the supply chain, including the disposal phase, for the purpose of determining whether they are likely to illustrate the success of emission minimisation. If necessary, changes and/or enhancement are proposed.

6.2 The authority examines whether the applicant can substantiate the effectiveness of reduction measures in the applied for uses with local and regional immission based monitoring. The authority examines the notified reference status (SEE P. 18, 9.4) with respect to the substance or its degradation products before authorisation.

6.3 The authority examines the applicant's proposal for report periods concerning activities mentioned in 6.1 and 6.2 and their results. Information on emissions has to be submitted annually, that on local and regional immission monitoring every X years.

7. General environmental monitoring

The competent national authority takes into account substances for which authorisation has been granted in its general environmental monitoring activities. For this purpose it examines the extent to which it includes substances liable to authorisation and their degradation products in existing monitoring programmes or undertakes new monitoring measures.[41]

III. Points for the authorisation holder and the authority after authorisation has been granted

A. Points for the authorisation holder

The authorisation holder is subject to certain obligations concerning substance monitoring as well as documentation and the passing on of information. These relate to all points mentioned under I. Nos. I.8 – I.11 might merit particular attention.

B. Points for the authority

1. Adherence to the overall reduction target in the case of further authorisations of the same substance.

Should the authority intend to grant authorisation for the manufacture or import of the same substance to other applicants, it examines whether measures are necessary for attainment of the total reduction target, and if so, which measures. The authority determines, if necessary, reduction targets for uses that are already authorized, which go beyond II 1.1, within the framework of the review of authorisations pursuant to Article 61 REACh.

[41] Here, the question of responsibilities with regard to general environmental monitoring in accordance with REACh as well as other general and specific monitoring measures (for example, exchange of information between authorities, responsibilities etc.) might have to be regulated.

2. Updating obligation[42]

2.1 The applicant is obliged to inform the authority without undue delay when he acquires new knowledge

- from his own or third-party research activities, or
- from his own or third-party monitoring activities, or
- from other sources to which he has access,

that

- points to relevant ineffectiveness or failure of risk management measures (for example, a measure does not result in emission avoidance), or
- that leads to a change in risk assessment of the substance for authorized uses with regard to human health or the environment (cf. Article 14 (7) and Article 61 (2a) REACh).

2.2 Should new findings arise from 2.1, the holder updates on his own initiative the chemical safety report.[43] At the same time, it has also to be stated whether risk management measures – including control of their efficacy – ought to be adapted, and if so, how.

3. The authority makes monitoring reports available to the public in electronic form without undue delay.[44]

[42] Cf. the updating obligation of registrants in Article 22 (1e) REACh.

[43] See Article 60 (10) in connection with Article 14 (7) REACh.

[44] Based on Article 1 b) in connection with Article 4 (1) of EC Environmental Information Regulation 1367/2006 as well as in analogous application of information obligations pursuant to Article 119 (1e) REACh.

5
Annex C: Proposal for a new Guidance Document to the REACh-Regulation "Monitoring of substances of very high concern"

(developed with reference to Annex VII of the Directive 2001/18/EC)

MONITORING PLAN

This annex describes the objective to be achieved, the general principles and the most basic guidance elements to be followed by an applicant for authorisation (manufacturer, importer and downstream user) in the process of setting up a monitoring plan in accordance with the procedure laid down in Article 60 (9f) REACh, and in respect of the release of substances of very high concern by virtue of Article 55 et seq. REACh.

1. Objective

Monitoring aims to secure a high level of protection for the environment and human health with respect to substances of very high concern - including affected population groups and possibly sensitive population groups with greater need of protection (for example, children or older people). To ensure this objective, monitoring is supposed to guarantee that substances of very high concern will be handled with great caution in line with the precautionary principle.

Monitoring encompasses the realisation of case-by-case specific as well as general observations of the environment and human health, aiming to:

- *verify* the effectiveness of risk management measures taken in accordance with Article 60 (5a)REACh,
- *confirm* that for substances of very high concern the conditions of Annex I No. 6.4 REACh and of Annex I No. 6.5 REACh are observed,
- *ascertain* the occurrence of previously unknown adverse effects on human health or the environment caused by a substance of very high concern or its application, as well as by degradation products.

2. General principles

The monitoring measures set out in the monitoring plan should be commenced at the latest after the *European Chemical Agency* has decided on the authorisation of the substance in compliance with Article 60 (2) and (4) REACh.

Monitoring measures for substances of very high concern should enable the holder of an authorisation to provide objective evidence that exposure of the substances is in accordance with article 60 (10) REACh, reduced to a level as low as technically and practically possible (principle of minimisation).

Evaluation of the data gathered in the process of monitoring should also take into account other environmental conditions not addressed in the chemical safety report (CSR) as well as observation of all relevant emission pathways.

If changes in the environment or effects on human health are observed, further evaluation should follow in order to ascertain whether these changes or effects are caused by a substance of very high concern, its degradation products or by its respective use in articles.

Voluntary monitoring schemes can support and go beyond those risk measurements determined in the monitoring plan, but cannot replace the setting up of a monitoring plan according to Article 60(9f) REACh.

In establishing monitoring measurements, the precautionary principle and especially the principle of proportionality, must be observed.

3. Generation of a monitoring plan (monitoring of emission sources / local and/or regional environmental and health monitoring)

The **monitoring plan** should:

3.1 apply to the single substance of very high concern as well as its authorized uses. Furthermore it should take into account the measurements given in the CSR;

3.2 *take into account* the characteristics of the substances listed in Article 57 REACh, the scope of application of the substance as well as the environmental sphere, into which the substance might be released according to the exposure scenario;

3.3 *regard* the features and effects of the measurements foreseen in the authorisation to limit emissions from point sources and diffuse sources, and consider the opinion of the Risk Assessment Committee in accordance with Article 64 (4a)REACh;

3.4 *provide for* local and/or regional environmental and health monitoring of unexpected adverse effects, as well as for monitoring of emissions from point sources and diffuse sources.

3.4.1 The objective of the **monitoring of emissions** is to check the efficacy of the planned risk management measures and prove the estimated releases as laid down in the authorisation.Thereto the applicant should carry out monitoring of emissions during the period of the authorisation.

The monitoring of emissions should comprise:

- the identification and description of each individual point source and diffuse source (life-cycle stage, operational conditions, etc.),
- the environmental compartments into which the release occurs,
- the exposure route and population (workers, consumers etc.) for direct human exposure,
- the physical state of the released substance,

– In the case where the substance is released associated to a matrix: the nature of the matrix and the nature of the interaction between the matrix and the substance (for example, chemically bound) should be included,

– for point sources, continuous or intermittent release and the description and efficiency of abatement technique(s)

– for diffuse sources, the length of service life of articles or materials

3.4.2 Local and/or regional environmental and health monitoring should be carried out at least during the period of authorisation. The competent authority can define an even longer period if necessary. The monitoring should:

– establish trends in levels of contamination of both the substance and its precursor or degradation products if they are more toxic and bioaccumulative over a suitable period of time;

– ascertain the occurrence of unexpected direct/indirect or accumulative effects, which were designated neither in the authorisation nor in the associated dossiers (including the CSR);

– take into account further existing general routine monitoring measurements; for example, cancer register, blood and breast-milk monitoring, or other bio-monitoring programmes

General monitoring measurements should take into account all substances on the candidate list of REACh by virtue of Annex XIV.

3.5 *facilitate* systematic observation of adverse effects caused by the production and application of authorized substances or the placing on the market of articles containing substances of very high concern;

3.6 *determine* that the applicant should be responsible for the monitoring of emissions and has overall responsibility for the different tasks determined in the monitoring plan, and that he is also responsible for the working-out and due realisation of the monitoring plan should implementation be delegated to other parties;

3.7 *make* the applicant responsible for informing the competent authority about monitoring results (setting up a time frame and schedules for reports on the results of monitoring), and

3.8 *consider* the mechanism for determination and affirmation of all observed adverse effects on human health and the environment, and put applicants and, if necessary, the competent authorities in a position to take appropriate action in order to protect human health and the environment.