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Legal appraisal of the proposed REACh-Annex XIII revision

on behalf of
WWF European Policy Office

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Content

A

Summary

1. The question how PBT/vPvB properties are defined and identified is crucial for many parts of the REACh Regulation. The definition is relevant for other sectoral environmental legislation (e.g. protection of water and soil). The definitions in Annex XIII and the procedural context thus is one of the pivotal parameter within the whole regulatory framework established by REACh; both for the protection goals of the regulation and the legal certainty of registrants and downstream users.
2. The current review process has a clear normative mandate: The revision clause and the recital 76 are providing a definite normative orientation for the amendment of Annex XIII: What is asked for is an improvement ensuring a high level of protection for human health and the environment.
3. The revision of Annex XIII as proposed by the Commission is not deemed adequate for the following reasons:
   - The PBT/vPvB criteria remain the same as in the current Annex XIII and it is unclear how the information mentioned in the other parts relates to section 1.
   - The proposal introduces legal uncertainty because the introduction speaks of a weight of evidence approach which is contradictory to the rigid criteria in section 1.
   - With the still limited PBT definition, many PBT chemicals are likely to stay unidentified. This will undermine the flow of information in the supply chain as well as health and environment protection because companies do not undertake the subsequent consequences for PBT chemicals (i.e. emission characterization, information in supply chain and better controls)
   - Companies may challenge Member State and ECHA PBT identifications using information from section 3 on the basis of the restrictive definition in section 1.
   - If the text as proposed by the European Commission is adopted the "Guidance on PBT Assessment" is confronted with the question to which extent the analysis foreseen in the guidance is covered by legally binding provisions of the regulation.
4. The amendment of Annex XIII as proposed by the European Commission still links the PBT assessment strictly to the results of the tests which are listed in the current version of Annex XIII. No legal consequences are foreseen for substances where monitoring data or other scientific evidence are suggesting that PBT properties are on hand.
5. This could be avoided by introducing an opening clause to the criteria themselves and thus integrating the procedural steps of the "PBT guidance" by ECHA to the wording of Annex XIII. It is recommended to integrate one of the two regulative options discussed in chapter D, page 6.

B
Legal context of the review process

1
Procedural starting point: Art. 138(5) REACh

The current review process is based on Art. 138(5) REACh:

> The Commission shall carry out a review of Annex XIII by 1 December 2008, to assess the adequacy of the criteria for identifying substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, with a view to proposing an amendment to it, if appropriate, in accordance with the procedure referred to in Article 133(4).

2
Normative context: Relations to other parts of REACh

The wording "assess the adequacy" seems to initiate an open review process. However, REACh provides for a clear normative orientation. The revision clause in Art. 138(5) REACh must be read in the light of recital 76:

> Experience at international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case-by-case basis. The criteria in Annex XIII should be reviewed taking into account the current and any new experience in the identification of these substances and if appropriate, be amended with a view to ensuring a high level of protection for human health and the environment.

The recitals of a regulation or a directive form an integrated part of the legal act: They are based on Art. 253 EC Treaty which states that regulations, directives and decisions "shall state the reasons on which they are based". Their legal status is not only that of an "explanatory memorandum"; they are published together with the provisions in the different Articles and Annexes of the legal act. The European Court of Justice uses the considerants for the interpretation of the provisions.

Recital 76 asks for an amendment "with a view to ensuring a high level of protection for human health and the environment." Other aspects may be taken into account, but the core aim of the revision is to guarantee "a high level of protection". This normative mandate is closely linked with the guiding principles of the regulation laid down in Art. 1(3) REACh.

> This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

The burden of proof lies thus with the companies which is also clear from recitals 16, 18, 25 (see Annex, p.10). All provisions of the regulation shall be interpreted in the light of the precautionary principle.[1]

[1] This goes in line with the Community objectives formulated in Art 2 EC Treaty "a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of

These guiding principles are additionally underpinned by the provision of the Annexes, in particular by Annex I. The Annex describes in points 0.5 and 0.6 that manufacturers and importers need to demonstrate why a substance is a PBT or not within their chemical safety assessment (for chemicals >10 tpa, see article 14).

> "The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information". (Annex I points 0.5)

Furthermore from the description in Annex 1, point 4, it is obvious that an expert judgement will be necessary, not only whether the criteria are met but also whether to consider other evidence like monitoring data available for the registrant:

> "If the available information is not sufficient to decide whether the substance fulfils the criteria in Annex XIII, then other evidence like monitoring data available for the registrant and giving rise to an equivalent level of concern shall be considered on a case-by-case basis." (point 4.1 para 2).

In cases when a substance has been identified as PBT/vPvB, an emission characterisation will have to be carried out (for other implications of the provisions in Annex XIII see chapter E, page 9).

3
Conclusion

REACh establishes a regulatory framework for the enactment of self-responsibility aiming at a high level of protection. Due to the factual situation it is impossible to offer for each decision within the process of risk assessment and risk management strictly defined clear cut criteria. This holds true particularly for the question whether a substance has PBT/vPvB properties. The variety of effect mechanisms does not allow to identify these properties with a single test (in the case of bioaccumulation). On the other hand the burden for the registrants would be much higher if they would have to carry out different tests on a regular basis. Thus a combination of defined tests and the consideration of monitoring data and other evidence limits the encumbrance for the registant while at the same time offering a balanced integration of environmental and health aspects.

Even though the guiding principle foresees self-responsibility, there will be a certain control by ECHA and Member States, e.g. within the dossier evaluation and substance evaluation within the registration mechanisms. Furthermore, Annex XIII will be used for identifying PBT/vPvB substances in the context of authorisation. Thus the definitions in Annex XIII are also important for actions taken by public authorities which might interfere with decision taken by industry enacting their obligations under REACh.

In an overall perspective it is not unusual in the field of substance regulation and thus within REACh that the registrant is obliged to take into account scientific evidence and to document the relevant aspects of his decision process. This improves the legal certainty in the context of REACh as well as in cases where the registrant is confronted with an action for damages.

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life". The provisions of the REACh regulation substantiate the Community objectives in a specific manner combining substantial obligations with set of procedural steps.

The revision clause and the recital 76 are providing a definite normative orientation for the amendment of Annex XIII: What is asked for is an improvement ensuring a high level of protection for human health and the environment.

C

Commission Proposal for an amended Annex XIII

The Commission proposal[2] should be measured against the above outlined legal mandate and the aims defined by the Commission itself in the introductory part of the Commission review paper. The analysis presented here will show that the Commission proposal falls short against both yardsticks. Therefore the wording of the proposal should in our opinion be adjusted (see chapter D, page 6).

1

Deficit analysis by the Commission

The above mentioned Commission review document concludes as follows:

"The difference between the number of substances that would be identified using the current criteria of Annex XIII and the number of known PBT/vPvB substances, as identified by the PBT WG is due to a number of inherent characteristics of the current Annex XIII criteria:

1. There is no flexibility built into Annex XIII to work with the criteria in the absence of suitable measured half-life or BCF data.
2. Biomagnification, logKow and bioaccumulation (BAF) are not included in Annex XIII criteria although these are part of the criteria of UNECE and UNEP POP screening criteria.
3. Information on long range transport potential and measured concentration in the environment as an indicator for persistency can hardly be applied under the wording of the current Annex XIII.
4. The wording of Annex XIII does not address persistence, bioaccumulation and toxicity of certain constituents and impurities of substances.
5. The wording of Annex XIII suggests that each of the three (two) criteria needs to be fulfilled in isolation from each other."

From the five items only the fourth is properly addressed by the Commission proposal as the subsequent analysis will show.

2

Structure of the proposed Annex XIII

The proposal has four parts:

0. Introductory remarks (without headline)
1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES
2. INFORMATION RELEVANT FOR THE ASSESSMENT OF P, B, and T PROPERTIES
3. SCREENING AND OTHER INFORMATION

[2] European Commission review, 21.11.08, CA/56/2008.

The introductory remarks are not legally linked with the text of the three following sections. From the perspective of the legal context (see chapter B2, page 2) the fact that the introduction is mentioning "other information" and "screening information" (section 2 und 3) is a step in the right direction. Looking at the legal consequences the important step is still missing as the introductory remarks do not alter the definitions in section 1 and do not clarify what are the legal consequences of section 2.

a)
Section 1: Definition of PBT/vPvB

The definition whether a substance fulfils the PBT criteria is given in Section 1.1:

> "1.1 PBT Substances
> A substance that fulfils all three of the criteria of the sections below is a PBT substance."

They do not differ from the criteria of the current Annex XIII. Due to this systematic location the definition includes only the criteria given in the sections 1.1.1 – 1.1.3. These sections provide precise test criteria. A similar definition is given for vPvB – properties in section 1.2.

The legal consequences are clear-cut: The wording brings no improvement in the sense of recital 76 and Art. 1(3) REACh.

At the same time it remains unclear what might be the legal impact of sections 2 and 3. In combination with the unclear function of the introduction the proposal is leading to legal uncertainty; and it fails short of covering a broader range of de facto PBT oder vPvB substance even when scientists clearly agree that they have these properties.

b)
Section 2: Information relevant for the assessment of P, B, and T properties

Section 2 of the revised Annex proposed by the European Commission describes the role of the PBT assessment in the context of registration (2.1) and authorisation (2.2).

Section 2.1 para 1 of the revised Annex XIII proposed by the European Commission reads as follows:

> For the identification of PBT and vPvB substances in the registration dossier, the registrant shall consider the information which is submitted as part of the technical dossier, as described in Annex I and in Section 3 below.

The text asks the registrant only to "consider", but there is no indication to what end this process will lead and what the legal consequences might be. At this - crucial – point of the application of Annex XIII the registrant is left without normative guidance. The text does not provide any legal link with the definition of a PBT substance in section 1.

In the subsequent paragraphs section 2.1 mainly repeats text from Annex I, but does not provide any specific link between the information from section 3.

c)
Section 3: Secreening and other information

Section 3 describes different types of information which may be used within the screening process outlined in section 2. It provides a list of results from test required under REACH and additional information for the assessment of P, B and T properties.

The section is of descriptive character and does not indicate any specific legal consequences. It merely illustrates the types of information used in the PBT/vPvB assessment.

3
Conclusion

The revision of Annex XIII as proposed by the Commission is not deemed adequate for the following reasons:

1. The PBT/vPvB criteria remain the same as in the current Annex XIII and it is unclear how the information mentioned in the other parts relates to section 1.
2. The proposal introduces legal uncertainty because the introduction speaks of a weight of evidence approach which is contradictory to the rigid criteria in section 1.
3. With the still limited PBT definition, many PBT chemicals are likely to stay un-identified. This will undermine the flow of information in the supply chain as well as health and environment protection because companies do not undertake the subsequent consequences for PBT chemicals (i.e. emission characterization, information in supply chain and better controls)
4. Companies may challenge Member State and ECHA PBT identifications using information from section 3 on the basis of the restrictive definition in section 1.
5. If the text as proposed by the European Commission is adopted the "Guidance on PBT Assessment" is confronted with the question to which extent the analysis foreseen in the guidance is covered by legally binding provisions of the regulation.

The amendment of Annex XIII as proposed by the European Commission still links the PBT assessment strictly to the results of the tests which are listed in the current version of Annex XIII. No legal consequences are foreseen for substances where monitoring data or other scientific evidence are suggesting that PBT properties are on hand. Thus the proposed text does not reflect the reasoning given by the European Commission in the explanatory document. And – more relevant from a legal point of view – the text is not in accordance with the normative requirements set out for the review process (see chapter B3, page 3).

D
Policy options

The revised text needs to reflect the situation that substance do have PBT properties although the specific test criteria from the current Annex XIII are not (fully) met. The fact that the current regulatory criteria are outdated and reflect an old understanding of the science behind is widely acknowledged among scientists today (see SETAC 2008[3]).

A legal text is the societal answer to a real world problem, formulated in the light of the defined regulative objecitives. The text serves the purpose of influencing human behaviour. Thus it should make clear what is expected by the addressee and what are the consequences provided by the law.

[3] Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPS: Summary of o SETAC Pellston Workshop (Klečka/Miur [Eds.], Society of Environmental Toxicologiy and Chemistry, SETAC PRESS, 2008)

In order to solve the definitional problem two options are on-hand:

1. One may add additional definitions to each of the PBT criteria in sections 1.1 and 1.2 of the proposed Annex XIII.
2. The other option is adjusting section 2 and aims at clarifying the potential results of the screening process and linking this result with the PBT definition in section 1.

1
Option 1: Additional qualitative criteria in sections 1.1 and 1.2

In order to integrate "real word evidence" additional qualitative criteria in sections 1.1 and 1.2. This may be exemplified at the criteria "Persistence": To the bullet points in section 1.1.1 another item shall be added as follows

– "there is comparable evidence that the substance is persistent (for example biomonitoring data or indications for long range transport potential)"

In a similar way the other criteria shall be expanded. This is shown in Annex 1 on page 10. This option would allow to include monitoring data and other information.

One question, however, remains open: In a situation where one of the criteria is (just) not met, but others are well met, a balanced approach might come to the conclusion that the substance shall be judged as PBT. This *"in dubio pro PBT"*-approach would integrate the precautonary principle in the PBT Assessment. For this purpose the following sentence should be integrated in section 1.1:[4]

> "A substance is also considered a PBT substance when the data do not allow a direct comparison with all the criteria Sections 1.1 but nevertheless indicate that the substance would have these properties."

This amendment reflects the *"in dubio pro PBT"*-approach formulated in the PBT guidance and referred to in the Commission review document (CA-56-2008, p. 8, 2.4.3 Weight of evidence): It should be noted "even where a criterion is marginally not fulfilled, the overall evidence may be sufficient to justify the conclusion that a substance fulfils the Annex XIII criteria (see the guidance).[5]"

2
Option 2: Assessment conclusions in section 2 and adjusted definition in section 1

In the second option two amendments are crucial: In section 2 three possible conclusions of the screening process are formulated (see chapter b) and the first of those conclusions is integrated in the PBT/vPvB definition in section 1 (chapter a).

a)
Definition of PBT/vPvB

Before section 1.1 the following sentence should be added:

> "A substance where the criteria of the sections below or screening and other information leads to the conclusion i) described in Section 2.1 is a PBT/vPvB substance."

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[4] A similar sentence should be integrated in section 1.2.

[5] See PBT guidance R 11, page 10. Further guidance on this issue is given in chapter R.11.1.5.

Accordingly the definitions at the beginning of the sections 1.1 and 1.2 are dispensable.

b)
Criteria for screening and other information

In order to establish the missing link not only a new sentence 1.3 should be added (see above under D2a)) but also the possible results of the data evaluation for the PBT/vPvB identification should be mentioned and interlinked with the definition in Section 1. Based on the potential conclusions of the PBT/vPvB assessment outlined in the PBT guidance[6] section 2 should continue as follows:

i) The data show that the properties of the substance meet the specific criteria detailed in Sections 1.1 and 1.2 or do not allow a direct comparison with all the criteria Sections 1.1 and 1.2, but nevertheless indicate that the substance would have these properties and the substance is considered a PBT/vPvB.

ii) The data on the properties of the substance do not meet the specific criteria detailed Sections1.1 and 1.2 or do not allow a direct comparison with all the criteria in Sections 1.1 and 1.2 but nevertheless indicate that the substance would not have these properties, and the substance is not considered a PBT/vPvB.

iii) The data on the properties of the substance do not allow a direct comparison with all the criteria in Sections 1.1 and 1.2 and further information is needed.

The second paragraph in Section 2.1 of the proposed Annex XIII paraphrases only parts of Annex I (Section 4.1 para 3). No additional legal clarity is gained since Annex I is already applicable to the registrant. We therefore propose deletion.

3
Comparative discussion

The two options offered in this chapter are to a certain extent functional equivalent. The difference lies within the systematic approach:

– Option 1 offers differentiated additional parameter for the each PBT/vPvB criteria and thus clarifies what are the relevant aspects for the "screening and other information" foreseen in section 3. On the other hand this option would mix (comparatively) clear cut testing criteria with other results where the decision "PBT: yes/no" has to be taken as a result of scientific judgement.

– Option is based on the assumption that two ways may lead to a decision which classifies a substance as PBT/vPvB: The fist path follows the current test criteria while the second one is based on the procedural steps outlined by ECHA in the "PBT guidance" to identify and assess "equivalent evidence" based on other sources.

Both options have in common that a science based judgement is needed, duly documented within the dossier. But this is by no way a regulative innovation or disruption. The whole REACh System is based on the finding that this essential and on the assumption that the different actors within the companies are capable to perform this judgement;

[6] ECHA 2008: Guidance on information requirements and chemical safety assessment - Chapter R.11: PBT Assessment, p. 8 et seqq., 49 et seqq.

supported by the manual provided by the Annexes and the guidance documents. It would be inconsistent to exclude this type of decision just in applying the PBT/vPvB criteria.

E

Recommendation

The question how PBT/vPvB properties are defined and identified is crucial for many parts of the REACh Regulation; namely for the .

- decision whether an exposure assessment and risk characterisation are needed as part of the Chemicals Safety Assessment
- information requirements for substances registered in quantities between 1 and 10 tonnes (Annexes III and VII)
- identification of PBT and vPvB properties in accordance with article 57 (d) and (e).

The definitions in Annex XIII and the procedural context thus is one of the pivotal parameter within the whole regulatory framework established by REACh; both for the protection goals of the regulation and the legal certainty of registrants and downstream users.

REACH PBT criteria will be used as reference in all other EC legislation dealing with substances, e.g. in the field of water protection and the POP Regulation. The acquis communautaire should be designed in a coherent manner aiming at a high consistency of the Community legislation.

Due to the limited criteria in section 1 of the Commission proposal, many chemicals, which de facto have PBT/vPvB properties, will not be picked up, because a company will be legally only required to take the mentioned limited tests as the indicator. Given that the Member States are likely to make more use of the "other information" mentioned in the Annex, legal challenges may be possible over the PBT identification. The proposal by the Commission falls short of both: It does not provide legal certainty and does not bring the improvement for health and environment. The normative mandate for the revision process is not fulfilled.

This could be avoided by introducing an opening clause to the criteria themselves and thus integrating the procedural steps of the "PBT guidance" by ECHA to the wording of Annex XIII. It is recommended to integrate one of the two regulative options discussued in the previous chapter.

F Annexes

1
Relevant recitals to the REACh Regulation

The following recitals are relevant for the interpretation of the normative mandate of the review process:[7]

(16) This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles. This Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.

(18) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, in particular for SMEs.

(25) The responsibility to assess the risks and hazards of substances should be given, in the first place, to the natural or legal persons that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Natural or legal persons handling chemicals should take the necessary risk management measures in accordance with the assessment of the risks of substances and pass on relevant recommendations along the supply chain. This should include describing, documenting and notifying in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance.

2

[7] Recital 76 is quoted in chapter B2, page 2.

Proposed Amendments in Option 1

1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES

1.1 **PBT Substances**

A substance that fulfils all three of the criteria of the sections below is a PBT substance. A substance is also considered a PBT when the data do not allow a direct comparison with all the criteria Sections 1.1 but nevertheless indicate that the substance would have these properties.

1.1.1 Persistence

A substance fulfils the persistence criterion (P) when:

— the degradation half-life in marine water is higher than 60 days;

— the degradation half-life in fresh- or estuarine water is higher than 40 days;

— the degradation half-life in marine sediment is higher than 180 days;

— the degradation half-life in fresh- or estuarine water sediment is higher than 120 days;

— the degradation half-life in soil is higher than 120 days; or

— there is comparable evidence that the substance is persistent (for example biomonitoring data or indications for long range transport potential).

1.1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when:
— the bioconcentration factor is higher than 2 000, or
— there is comparable evidence that the substance is bioaccumulative (for example biomonitoring data, toxicokinetic studies or results of bioaccumulation studies using air-breathing organisms)..

1.1.3. Toxicity

A substance fulfils the toxicity criterion (T) when:
— the long-term no-observed effect concentration (Noec) or EC_{10} for marine or freshwater organisms is less than 0,01 mg/l;
— the substance meets the criteria for classification as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3);
— there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: T, R48, or Xn, R48 according to Directive 67/548/EEC, or
— there is comparable evidence of chronic toxicity.

1.2. **vPvB Substances**

A substance that fulfils the two criteria of the sections below is a vPvB substance. A substance is also considered a vPvB substance when the data do not allow a direct comparison with all the criteria Sections 1.2 but nevertheless indicate that the substance would have these properties.

1.2.1. Persistence

A substance fulfils the very persistence criterion (vP) when:
— the degradation half-life in marine, fresh- or estuarine water is higher than 60 days;
— the degradation half-life in marine, fresh- or estuarine water sediment is higher than 180 days;
— the degradation half-life in soil is higher than 180 days, or
— there is comparable equivalent evidence that the substance is persistent (for example biomonitoring data or long range transport potential).

1.2.2. Bioaccumulation

A substance fulfils the very bioaccumulative criterion (vB) when:
— the bioconcentration factor is higher than 5 000, or

— there is comparable evidence that the substance is bioaccumulative (for example biomonitoring data, toxicokinetic studies or results of bioaccumulation studies using air-breathing organisms).

1