Bundesanstalt für Arbeitsschutz
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Adaptations for substances in nanoform

Regulation (EU) 2018/1881 has already transferred nano-specific information requirements to Annexes VI-X of the REACH Regulation. Today these requirements have been mandatory for more than two years. The experience gained during this time shows that, in addition to anchoring the nano-specific requirements in the Annexes of the REACH Regulation, adjustments are also necessary in the main body of the regulation in order to clarify unclear situations in a legally binding manner and to close remaining regulatory gaps.

Due to this, we propose to introduce a new Article 38a, which describes the obligations of a producer of the nanoform of a substance in a bundled way. This Article has become necessary because an information gap arises for nanoforms, depending on whether they are manufactured in the sense of the REACH definition or produced at the level of a downstream user from another form of the substance. In the first case, the identification and characterisation information on the nanoform is available in a registration dossier. However, if the nanoform is produced by a downstream user, in case of doubt, no information on the structural properties is available. Based on the proposal of this new article, Articles 37 and 38 are left untouched.

It should be stressed here that the proposal is mainly focused on the obligations of the downstream user. If the proposal were to be considered in this or a similar form in a revision of REACH, the effects on other articles would have to be examined more closely.

A new definition for the term "form" is also to be introduced in Article 3:
The aim here is to define the form as generally as possible and to apply it to the description of solid particles. The definition deliberately does not address the fact that other criteria, such as crystallinity, rigidity or surface modification, may be further parameters for distinguishing between two shapes in certain cases. This specification must be made in separate definitions that address special forms, such as the nanoform or also fibres.

At present, the nano definition as given in Annex VI REACH is still used unchanged as a placeholder. However, this will be replaced by a current version as soon as a new Commission recommendation is available.

The proposed amendments are summarised below:
- Introduction of the definition "form of a substance”
- Introduction of the definition "producer of a nanoform of a substance"
- Clarification: modification of the surface leads to a new nanoform
- Impact of the opt-out according to Article 11 on the extent of a dossier

- Introduction of Article 38a by describing the obligations of the downstream user producing a nanoform, e.g.:
  - Characterisation of the nanoform
  - Quantity produced
  - Information on safe use
  - Chemical Safety Report (CSR) of the producer of a substance in nanoform
  - Positive justification for the use of a set of similar nanoforms
  - Transfer of the definition of the terms “nanoform” as well as “set of similar nanoforms” from Annex VI to Article 3

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Current legal status	proposed amendment	Justification
Article 3: Definitions		
	Article 3 42. Form of a substance: three-dimensional shape of a substance, in particular sphere, tube, platelet, fibre.	The term form, which has not been defined so far, is to be introduced in order to take into account the shape of a substance. This also allows for references in other newly introduced definitions.
Annex VI: information required referred to in Article 10 and Article 3: Definitions		
Annex VI […] a nanoform is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm. For this purpose, 'particle' means a minute piece of matter with defined physical boundaries; 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to	**Article 3** 43. Nanoform of a substance: form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm. For this purpose, 'particle' means a minute piece of matter with defined physical boundaries; 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to	The definition of a nanoform and a set of similar nanoforms should be transferred from Annex VI to Article 3, which defines all terms. On the one hand, this corresponds to the general legislative practice of defining terms at the beginning of a set of rules. On the other hand, putting them on an equal footing with other terms mentioned in Article 3 does justice to the importance of these terms. In addition, this is necessary because the proposed amendment also refers to nanoforms in the main body of the regulation. The addition that a substance can be present in different forms is necessary, as it is not yet anchored in the main body of the regulationof the legal text, but only in the notes of Annex VI

the sum of the surface areas of the individual components and 'aggregate' means a particle comprising of strongly bound or fused particles. A nanoform shall be characterised in accordance with section 2.4 below. A substance may have one or more different nanoforms, based on differences in the parameters in points 2.4.2 to 2.4.5.	the sum of the surface areas of the individual components and 'aggregate' means a particle comprising of strongly bound or fused particles. A substance may have one or more different nanoforms, based on differences in the parameters in Annex VI. In particular, the modification of the surface leads to a new nanoform.	and at the level of the Guidance document (Chapter 3.1.3.1)[1]. By way of example, the modification of the surface should be mentioned here for clarification. Points 2.4.2 to 2.4.5 should not be mentioned in the definition in order to avoid adjustments in the main body of the regulation resulting from possible future changes in these points. Possible changes to the wording resulting from the adaptation of the definition recommendation for nanomaterials on the part of the Commission are to be taken into account after its publication.
Annex VI: information required referred to in Article 10 and Article 3: Definitions		
Annex VI A 'set of similar nanoforms' is a group of nanoforms characterised in accordance with section 2.4 where the clearly defined boundaries in the parameters in the points 2.4.2 to 2.4.5 of the individual nanoforms within the set still allow to conclude that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly. A justification shall be provided to demonstrate that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set. A	**Article 3** 44. Set of similar nanoforms: group of nanoforms characterised in accordance with Annex VI for which it can be concluded that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly. A nanoform can only belong to one set of similar nanoforms.	The definition of a set of similar nanoforms should be transferred from Annex VI to Article 3, where all terms are defined. On the one hand, this corresponds to the general legislative practice of defining terms already at the beginning of a set of rules and, on the other hand, does justice to the importance of these terms. Points 2.4 and 2.4.2 to 2.4.5 should not be mentioned in the definition in order to avoid adjustments in the in main body of the regulation resulting from possible future changes in these points. The requirement of justification is not part of the definition and is therefore not adopted here.

[1] Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification, version 2.0, January 2022: https://echa.europa.eu/documents/10162/17250/how_to_register_nano_en.pdf

nanoform can only belong to one set of similar nanoforms.		
Article 3: Definition		
	Article 3 45. Producer of a nanoform of a substance: a downstream user who intentionally produces a nanoform from another form of the same substance. The production of a nanoform of a substance does not constitute the manufacture of a substance within the meaning of this Regulation.	The term producer of a nanoform of a substance is to be newly introduced and defined. This is necessary in order to clearly define in a legally binding way the role of the downstream user, who by definition is not a manufacturer.
Article 6: General obligation to register substances on their own or in mixtures		
1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency.	1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency. The quantity is the sum of the quantities of all forms in which the substance is present as such or in one or more mixtures.	The newly added sentence serves to clarify that in principle all forms of the same substance are part of the joint submission of this substance. This clarification can already be found in the ECHA Guidance[1] in chapter 2.1.2. Thus, the transfer of a regulation from the level of a guidance document to the legal text takes place at this point. Furthermore, the legal basis for the clarification is the OSOR principle[2], which was further developed in Regulation (EU) 2016/9. Accordingly, there is a registration obligation for all manufactured or imported forms of a substance if the sum of these forms reaches or exceeds one tonne per year.

[2] OSOR= **O**ne **S**ubstance **O**ne **R**egistration

Article 7: Registration and notification of substances in articles		
4. The information to be notified shall include the following: (c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;	4. The information to be notified shall include the following: (c) the identity of the substance as specified in sections 2.1 to 2.4.7 of Annex VI;	This is an editorial adjustment to reflect the introduction of point 2.4 in Annex VI. The adjustment also includes the proposed addition of 2.4.7 below.
Article 11: Joint submission of data by multiple registrants		
3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if: (a) it would be disproportionately costly for him to submit this information jointly; or (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or (c) he disagrees with the lead registrant on the selection of this information. If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.	3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if: (a) it would be disproportionately costly for him to submit this information jointly; or (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or (c) he disagrees with the lead registrant on the selection of this information. If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be. Where the registrant of a substance in nanoform which is part of a set of similar nanoforms makes use of this paragraph, he shall submit separately for that nanoform all the information	The newly added second subparagraph of paragraph 3 is intended to clarify that a registrant who registers a nanoform as part of a set of similar nanoforms and makes use of an opt-out cannot refer to the jointly submitted data. The registrant concerned can only refer to these data again by endpoint-specific justifications. This procedure makes sense if the reason for the opt-out is that the data submitted jointly for this endpoint are not representative for the nanoform in question and there are differences in the hazard, exposure and risk assessment. The conditions for inclusion of a nanoform in a set of similar nanoforms are thus no longer fulfilled. This interpretation can currently be found in ECHA's guidance[1] in chapter 5.2.3.2 under point (i).

	referred to in points (iv), (vi), (vii) and (ix) of Article 10(a) and the relevant information referred to in point (viii) of Article 10(a).	
Article 12: Information to be submitted depending on tonnage		
1. The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following: [(a) to (e)]	1. The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following: [(a) to (e)] The quantity is determined via the sum of all forms of the substance of a registrant.	The newly added subparagraph 2 of paragraph 1 is intended to clarify that all forms of a substance are included in the calculation of the total quantity. The extent of the standard data requirements is based on the calculated total quantity. For each form, the standard data requirements corresponding to the total quantity must be fulfilled. This clarification can already be found in the ECHA guidance[1] in chapter 2.1.2, as well as in the examples given there.
Article 38a – new Obligation for producer of a nanoform of a substance to report additional information		
	1. Without prejudice to the provisions of Articles 37 and 38, the downstream user producing one or more nanoforms of a substance in a total quantity of at least 1 tonne per year shall make a notification to the Agency. This shall contain the following information in addition to the requirements referred to in Article 38(2): (a) in addition to the identity of the substance according to sections 2.1 to 2.3.4 of Annex VI, the description of the nanoform(s) according to sections 2.4 to 2.4.7 of Annex VI, (b) the quantity of each nanoform of the substance produced, and the total quantity of all nanoforms produced,	Manufacturer and producer of the same nanoform(s) have different obligations for the characterisation of their nanoform(s) and information required to ensure the safe use of these form(s). This information gap cannot be closed based on the data required in Article 38(2). For this reason, the information listed here is necessary for the protection of humans and the environment. Furthermore, letter (a) is the necessary consequence of the extension of Annex VI by Regulation 2018/1881, which has already taken place, and the proposed extension of 2.4.7 below.

	(c) the information to allow safe use of the substance in nanoform(s); and (d) a chemical safety report prepared in accordance with Article 37(4) by the producer of a substance in nanoform(s). Articles 11, 13, 15, 17, 18, 25, 26, 27, 39 and 46 shall apply *mutatis mutandis*.	The information on quantity in point (b) is a necessary prerequisite for the development of risk management measures. The information gap that currently exists is to be closed additionally with letters (c) and (d). The information serves as a basis for the development of risk measurement measures. To remedy the unequal treatment of producers of nanoforms of a substance and manufacturers/importers of these nanoform(s), the inserted Article is imperative.
Annex VI: Information requirements referred to in Article 10		
2.4. Characterisation of nanoforms of a substance: For each of the characterisation parameters, the information provided may be applicable to either an individual nanoform or a set of similar nanoforms provided that the boundaries of the set are clearly specified. The information in points 2.4.2 – 2.4.5 shall be clearly assigned to the different nanoforms or sets of similar nanoforms identified in point 2.4.1 […]	2.4. Characterisation of nanoforms of a substance: For each of the characterisation parameters, the information provided may be applicable to either an individual nanoform or a set of similar nanoforms provided that the boundaries of the set are clearly specified. The information in points 2.4.2 – 2.4.5 shall be clearly assigned to the different nanoforms or sets of similar nanoforms identified in point 2.4.1 […] 2.4.7. If the concept of the set of similar nanoforms is applied: Justification for the formation of this set(s) demonstrating that a variation within these boundaries set out in 2.4.2. to 2.4.5. does not affect the hazard assessment, exposure assessment and risk assessment of similar nanoforms in the set.	The submission of a justification when applying the concept of set of similar nanoforms should be added as a separate sub-item in Annex VI. So far, this required justification is only mentioned in the notes to Annex VI in the definition of the term set of similar nanoforms. The justification is not part of the definition and is therefore not included in Article 3(44). Since in the case of the application of the concept of a set of similar nanoforms the justification is a standard data requirement that is already checked in the context of the technical

		completeness check (TCC)[3], it should also be explicitly introduced in the corresponding place in Annex VI.

[3] Manual der ECHA „How to prepare registration dossiers covering nanoforms“, October 2021, chapter 2.2.6: https://echa.europa.eu/documents/10162/1804633/howto_prepare_reg_dossiers_nano_en.pdf/5e994573-6bf9-7040-054e-7ab753bd7fd6