II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/1881

of 3 December 2018

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [1], and in particular Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 lays down specific registration duties and obligations on manufacturers, importers and downstream users to generate data on substances they manufacture, import or use to assess the risks related to these substances and to develop and recommend appropriate risk management measures.

(2) The Commission Communication on the Second Regulatory Review on Nanomaterials [2] concluded that Regulation (EC) No 1907/2006 sets the best possible framework for the risk management of nanomaterials when they occur as forms of substances or mixtures but more specific requirements within the framework are necessary.

(3) The Commission performed an impact assessment [3] and further concluded that it is necessary to clarify the registration duties and obligations for nanomaterials. The term nanoform should be defined for the purposes of Regulation (EC) No 1907/2006 on the basis of Commission Recommendation of 18 October 2011 on the definition of nanomaterial.

(4) Nanoforms may have specific toxicological profiles and exposure patterns and may therefore require specific risk assessment and adequate sets of risk management measures.

(5) Without the minimum standard information in the technical dossier and the chemical safety report specifically addressing nanoforms, it is not possible to ascertain whether the potential risks have been adequately assessed. Clarifications to requirements for the registration of substances with nanoforms and related downstream user obligations should be included in the Annexes I, III and VI to XII to Regulation (EC) No 1907/2006. This should ensure a clear and effective implementation with proportionate costs, guaranteeing a high level of protection of human health and the environment without adversely affecting innovation and competitiveness. The adopted changes for nanoforms should be without prejudice to the performance and documentation of risk assessment of other forms of the registered substance, unless it has implicitly included nanoforms in the assessment.

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[1] OJ L 396, 30.12.2006, p. 1.
[2] COM(2012) 572 final.
[3] Impact assessment on Possible amendments of Annexes to REACH for registration of nanomaterials [SWD(2018)474].

(6) Manufacturers and importers should assess and where relevant, generate the necessary information and document in the chemical safety report that the risks, arising from the identified uses of the substance with nanoforms they manufacture or import, are adequately controlled. To ensure clarity, the chemical safety report should describe whether and which different nanoforms are covered by the assessment and how the information is compiled in the report. A use may modify the nanoforms of the substance, potentially changing one nanoform into another form or generating a new nanoform. Downstream users should provide this information up the supply chain to ensure that the use is adequately covered by the registration dossier of the manufacturer or importer, or alternatively cover the specific use in their own chemical safety report.

(7) As the majority of nanomaterials are expected to be nanoforms of phase-in substances, the conditions for the requirements for generation of new toxicological and ecotoxicological information on phase-in low volume substances should be elaborated to ensure that the assessment criteria are based also on the predicted properties of nanoforms. The existing qualitative or quantitative structure-activity relationship (QSAR) and other tools do not yet enable prioritisation; therefore, the insolubility information should be applied as a surrogate for potential toxicological and ecotoxicological aspects for the nanoforms of a substance.

(8) For nanoforms, specific minimum characterisation information should be provided as part of the composition information under the substance identification. Particle size, shape and surface properties of a nanoform may influence its toxicological or ecotoxicological profile, exposure as well as behaviour in the environment.

(9) For reasons of workability and proportionality, it should be possible to group nanoforms with similar characteristics in sets of similar nanoforms. The characterisers of the different nanoforms within sets of similar nanoforms should be provided in ranges of values that clearly define the boundaries of the set of similar nanoforms. When set of similar nanoform is defined, a justification should be provided that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the individual nanoforms within the set of similar nanoforms.

(10) All different nanoforms covered by the registration should be considered by the registrant in the demonstration of safety. Similarly, the information on manufacture, uses of and exposure to the different nanoforms should be provided separately to demonstrate their safe use. Where defined, a set of similar nanoforms may be used to document this information jointly for the nanoforms within the set.

(11) Nanoforms or sets of nanoforms, where defined, should be identified in the joint submission using the same nanoform characterisation principles and should provide the link between the nanoforms identified in the individual registrations and the relevant information in the joint submission.

(12) To allow for adequate assessment of the relevance of any physicochemical, toxicological and ecotoxicological information for the different nanoforms, the test material should be appropriately characterised. For the same reasons, test conditions documented and a scientific justification for the relevance and adequacy of the utilised test material as well as documentation for the relevance and adequacy of the information obtained from means other than testing for the different nanoforms should be provided.

(13) The rate of dissolution in water as well as in relevant biological and environmental media should always be considered for nanoforms as it represents important complementary information to water solubility as a basic physico-chemical property of nanoforms that may determine the approach to their risk assessment and testing.

(14) The partition coefficient in octanol-water is generally used as a proxy for adsorption or accumulation but may often not be applicable to nanoforms. In those cases, the study of dispersion stability in the different relevant test media that significantly influences these endpoints as well as any estimations of exposure to nanoforms, should be considered instead.

(15) Certain physico-chemical properties such as water solubility or partition coefficient in octanol-water serve as input to well established QSARs and other predictive models that can be used for adaptations of some of the information requirements. As the underlying assumptions may not always apply to nanomaterials, such adaptations should be used for nanoforms only with scientific justification. In specific cases, the dissolution rate in the relevant test media may be used instead.

(16) To allow efficient assessment of the potential exposure for inhalable nanoforms, in particular in workplaces, information on dustiness should be provided for the different nanoforms.

(17) The specific properties of the nanoform may sometimes prevent their uptake through the cell wall of bacteria, rendering the in vitro gene mutation study in bacteria (the AMES test B.13-14, OECD TG 471) inappropriate. To ensure that the tiered strategy for mutagenicity can still be implemented also in such cases, one or more other in vitro mutagenicity study(ies) in mammalian cells or other internationally recognised in vitro methods should be provided in such cases also for low-volume substances.

(18) Although acute toxicity testing for the lowest tonnage is required via the oral route, for nanoforms, inhalation is considered as more appropriate route of exposure and should be required instead, unless the exposure to humans is unlikely.

(19) For the generation of information on short term repeated dose and sub-chronic toxicity via inhalation route, testing of a nanoform should always include histopathological determination of brain, lung tissues as well as examination of bronchoalveolar lavage (BAL) fluid, kinetics and an appropriate recovery period, in line with the OECD technical guidance.

(20) Unless the nanoform dissolves fast once entering the organism, the distribution of a nanoform in the body may affect the toxicological profile when compared to other forms of the same substance. Therefore, an assessment of the toxicokinetic behaviour should be available for the chemicals safety assessment of a nanoform, when such assessment is required. This should allow the development of effective testing strategy or its adaptation for the substance with nanoforms with the aim of minimising animal testing. Where relevant, a study complementing the compilation of existing toxicokinetic information should be proposed by the registrant or may be requested by the European Chemicals Agency (the Agency) in accordance with Article 40 or 41 of the Regulation (EC) No 1907/2006.

(21) A number of specific physico-chemical properties in addition to those used to identify the different nanoforms may be considered relevant for scientific understanding of the hazard and exposure of a nanomaterial, with the necessary parameters depending on the individual case. For reasons of workability and proportionality, only registrants for substances (including any nanoforms) that are placed on the market in higher volumes than 10 tonnes/year should be required to explicitly consider such further information in case other particle properties significantly influence hazard or exposure to those nanoforms.

(22) The adaptation of the standard testing requirements in Annexes VII to X to Regulation (EC) No 1907/2006 applying general rules for adaptation under Section 1 of Annex XI should address different nanoforms separately. For grouping of different nanoforms, the molecular structural similarity alone cannot serve as justification for the application of read-across or grouping.

(23) The Agency, in cooperation with Member States and stakeholders, should further develop guidance documents for the application of the test methods and waiving possibilities for the standard information requirements provided by this Regulation for the purposes of Regulation (EC) No 1907/2006.

(24) Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(25) Compliance with the provisions of this Regulation should not be required immediately in order to allow all registrants and downstream users adequate time to adapt to the more specific requirements for substances with nanoforms. However, it should be possible for registrants to comply with those provisions already before the date of application.

(26) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 are amended in accordance with the Annex to this Regulation.

Article 2

By way of derogation from the second paragraph of Article 3, manufacturers and importers registering substances with nanoforms either as non-phase-in or phase-in substances pursuant to Article 5 of Regulation (EC) No 1907/2006 as well as downstream users generating chemical safety reports may comply with this Regulation before 1 January 2020.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 December 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

1. Annex I to Regulation (EC) No 1907/2006 is amended as follows:

(a) Subsection 0.1. is replaced by the following:

'0.1. The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks. The chemical safety report shall also describe whether and which different nanoforms of substances as characterised in Annex VI are manufactured and imported, including an adequate justification for each information requirement describing when and how information on one form is used to demonstrate safety of other forms. The requirements speof the following hazard classes or categories setcific to nanoforms of a substance in this Annex apply to all nanoforms covered by the registration and without prejudice to requirements applicable to other forms of that substance. This Annex shall also apply adapted as necessary to producers and importers of articles required to make a chemical safety assessment as part of a registration.';

(b) Subsection 0.3. is replaced by the following:

'0.3. The chemical safety assessment of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a mixture and in an article, as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The assessment shall address all nanoforms that are covered by the registration. The justifications and conclusions drawn from the assessment shall be relevant to these nanoforms. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.';

(c) Subsection 0.4. is replaced by the following:

'0.4. Substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or "category" of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or "category" of substances. The manufacturer or importer shall provide a justification for this. Where any of the substances exists in one or more nanoforms and data from one form are used in demonstration of the safe use of other forms, in accordance with the general rules set out in Annex XI, a scientific justification shall be given on how, applying the rules for grouping and read-across, the data from a specific test or other information (e.g. methods, results or conclusions) can be used for the other forms of the substance. Similar considerations apply to exposure scenarios and risk management measures.';

(d) The last paragraph in subsection 0.5. is replaced by the following:

'If the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the chemical safety report under the appropriate heading. Where considered necessary, the proposal for a testing strategy may concern several studies addressing respectively different forms of the same substance for the same information requirement. While waiting for results of further testing, he shall record in his chemical safety report, and include in the exposure scenario developed, the interim risk management measures that he has put in place and those he recommends to downstream users intended to manage the risks being explored. The exposure scenarios and interim risk management measures recommended shall address all nanoforms that are covered by the registration.';

(e) Point 0.6.3 is replaced by the following:

'0.6.3. Where as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or, when applicable, nanoforms thereof fulfils the criteria for any of the following hazard classes or categories set

out in Annex I to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB, the chemical safety assessment shall also include steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9, and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.';

(f) After subsection 0.11. the following subsection 0.11.*bis* is added:

'0.11.*bis* When nanoforms are covered by the chemical safety assessment, an appropriate metric for the assessment and presentation of the results in steps 1-6 of the chemical safety assessment under 0.6.1 and 0.6.2 shall be considered, with the justification included in the chemical safety report and summarised in the safety data sheet. A multiple metric presentation, including mass metric information, is preferable. When possible, a method for reciprocal conversion shall be indicated.';

(g) The following sentence is added after the first paragraph of section 1.0.3:

'The assessment shall address all nanoforms that are covered by the registration.';

(h) The second paragraph of point 1.3.1. is replaced by the following:

'The assessment should always include a statement as to whether the substance or, when applicable, nanoforms thereof fulfils or does not fulfil the criteria given in Regulation (EC) No 1272/2008 for classification in the hazard class carcinogenicity category 1A or 1B, in the hazard class germ cell mutagenicity category 1A or 1B or in the hazard class reproductive toxicity category 1A or 1B.';

(i) Point 1.3.2. is replaced by the following:

'1.3.2. If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrants shall indicate and justify the action or decision he has taken as a result.';

(j) The second paragraph of subsection 2.2. is replaced by the following:

'If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.';

(k) The following sentence is added at the end of point 3.0.2.:

'The assessment shall address all nanoforms that are covered by the registration.';

(l) Point 3.2.1. is replaced by the following:

'3.2.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Any M-factor resulting from the application of Article 10 of Regulation (EC) No 1272/2008 shall be presented and, if it is not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008, justified.

The presentation and justification is applied to all nanoforms covered by the registration.';

(m) Point 3.2.2. is replaced by the following:

'3.2.2. If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.';

(n) Point 4.0.2. is replaced by the following:

'4.0.2. The PBT and vPvB assessment shall comprise the following two steps, which shall be clearly identified as such in Part B, Section 8 of the Chemical Safety report. The assessment shall address all nanoforms that are covered by the registration:

Step 1 : Comparison with the Criteria.

Step 2 : Emission Characterisation.

The assessment shall also be summarised in the Safety Data Sheet under heading 12.';

(o) Subsection 4.2. is replaced by the following:

'4.2. Step 2: Emission Characterisation

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance. The estimation shall address all nanoforms that are covered by the registration.';

(p) The first paragraph of subsection 5.0. is replaced by the following:

'The objective of the exposure assessment shall be to make a quantitative and qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4. The assessment shall address all nanoforms that are covered by the registration. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:';

(q) The following sentence is added at the end of point 5.2.2.:

'When nanoforms are covered by the registration, the emission estimation for these shall, where relevant, take account of situations when the conditions outlined in Annex XI section 3.2 point (c) are fulfilled.';

(r) Point 5.2.3. is replaced by the following:

'5.2.3. A characterisation of possible degradation, transformation, or reaction processes, and an estimation of environmental distribution and fate shall be performed.

When nanoforms are covered by the registration, a characterisation of the dissolution rate, the particle aggregation, the agglomeration and of the particle surface chemistry changes shall be included.'

2. Annex III to Regulation (EC) No 1907/2006 is replaced by the following:

'CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES

Criteria for substances and, when applicable, for nanoforms thereof, registered between 1 and 10 tonnes, with reference to Article 12(1)(a) and (b):

(a) substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;

(b) substances:

(i) with dispersive or diffuse use(s) particularly where such substances are used in consumer mixtures or incorporated into consumer articles; and

(ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under Regulation (EC) No 1272/2008 or for substances with nanoforms, unless those nanoforms are soluble in biological and environmental media.'

3. Annex VI to Regulation (EC) No 1907/2006 is amended as follows:

(a) The subtitle and the introductory text under the current subtitle 'Guidance note on fulfilling the requirements of annexes VI to XI' are replaced by the following:

'NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use, and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

A substance is defined in accordance with Article 3(1) and identified in accordance with section 2 in this Annex. A substance is always manufactured or imported in at least one form. A substance can also occur in more than one form.

For all nanoforms covered by the registration certain specific information items shall be provided. Nanoforms shall be characterised as provided for in this Annex. The registrant shall justify why the information provided in the joint registration, covering the information requirements for the registered substances with nanoforms, is adequate for assessing the nanoforms. Information relevant to cover information requirements for such a substance can also be submitted separately by individual registrants, where justified in accordance with Article 11(3).

More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties relevant for the hazard, exposure and risk assessment and management of nanoforms. The information shall be reported in such a manner that it is clear which information in the joint submission pertains to which nanoform of the substance.

Where technically and scientifically justified, the methodologies set out in Annex XI.1.5 shall be used within a registration dossier when two or more forms of a substance are "grouped" for the purposes of one, more or possibly all the information requirements.

The requirements specific to nanoforms apply without prejudice to requirements applicable to other forms of a substance.

Definition of a nanoform and a set of similar nanoforms:

On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial [1], 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 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.

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 nanoform can only belong to one set of similar nanoforms

The term "nanoform", when it is referred to in the other Annexes, shall refer to a nanoform or a set of similar nanoforms, when one has been defined, as defined in this Annex.';

(b) Step 1 is replaced by the following:

'STEP 1 — GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance.

Wherever practicable, registrations should be submitted jointly, in accordance with Articles 11 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance including on all nanoforms of the substance that are covered by the registration, regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, *in vivo* and *in vitro* testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests.

In addition, information on exposure, use and risk management measures in accordance with article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.';

[1] OJ L 275, 20.10.2011, p. 38.

(c) Step 3 is replaced by the following:

'STEP 3 — IDENTIFY INFORMATION GAPS

The registrant shall then compare the information needs for the substance with the information already available and the extent to which currently available information can be applied to all nanoforms covered by the registration and identify where there are gaps.

It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.';

(d) Step 4 is replaced by the following:

'STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes VII and VIII), or a testing strategy shall be proposed (Annexes IX and X), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.

The above approach shall also apply if there is a gap of available information for one or more nanoforms of the substance included in the jointly submitted registration dossier.

In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.';

(e) The introductory text in Section 2 Identification of the substance is replaced by the following:

'For each substance, the information given in this section shall be sufficient to enable each substance to be identified and the different nanoforms to be characterised. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.';

(f) Subsection 2.3. is replaced by the following:

'2.3. Composition of each substance. Where a registration covers one or more nanoforms, these nanoforms shall be characterised pursuant to section 2.4 of this Annex.

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (e.g. ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

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.

2.4.1. Names or other identifiers of the nanoforms or sets of similar nanoforms of the substance

2.4.2. Number based particle size distribution with indication of the number fraction of constituent particles in the size range within 1 nm – 100 nm.

2.4.3. Description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number.

2.4.4. Shape, aspect ratio and other morphological characterisation: crystallinity, information on assembly structure including e.g. shell like structures or hollow structures, if appropriate

2.4.5. Surface area (specific surface area by volume, specific surface area by mass or both)

2.4.6. Description of the analytical methods or the appropriate bibliographical references for the information elements in this sub-section. This information shall be sufficient to allow the methods to be reproduced.';

(g) In section 3, the following introductory text is added after the title 'INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)':

'Where a substance being registered is manufactured or imported in one or several nanoforms, the information on manufacture and use under 3.1-3.7 shall include separate information on the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4.';

(h) In section 5, the introductory text is replaced by the following:

'This information shall be consistent with that in the Safety Data Sheet where such a Safety Data Sheet is required according to Article 31.

Where a substance being registered is also manufactured or imported in one or several nanoforms, the information pursuant to this Section shall address the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4 where relevant.';

(i) In section 6, the following introductory text is added after the title 'INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFACTURER OR IMPORTER':

'Where a substance being registered is manufactured or imported in one or several nanoforms, the information pursuant to this Section shall address the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4 separately.'

4. Annex VII to Regulation (EC) No 1907/2006 is amended as follows:

(a) In the introductory text, the following text is added after the third paragraph:

'Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.';

(b) Subsection 7.7 is replaced by the following:

'7.7. Water solubility For nanoforms, in addition the testing of dissolution rate in water as well as in relevant biological and environmental media shall be considered.	7.7. The study does not need to be conducted if: — the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or — the substance is readily oxidisable in water. If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed. For nanoforms the potential confounding effect of dispersion shall be assessed when conducting the study.';

(c) Subsection 7.8 is replaced by the following:

'7.8. Partition coefficient n-octanol/water	7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided. For nanoforms the potential confounding effect of dispersion in octanol and water shall be assessed when conducting the study. For nanoforms, whether of inorganic or organic substances, for which the partition coefficient n-octanol/water is not applicable the study of dispersion stability shall be considered instead.';

(d) After subsection 7.14., the following is added:

'7.14*bis* Dustiness For nanoforms	7.14*bis*. The study does not need to be conducted if exposure to granular form of the substance during its life-cycle can be excluded.';

(e) Point 8.4.1. is replaced by the following:

'8.4.1. *In vitro* gene mutation study in bacteria	8.4.1. The study does not need to be conducted for nanoforms where it is not appropriate. In this case other studies involving one or more *in vitro* mutagenicity study(ies) in mammalian cells (Annex VIII, sections 8.4.2. and 8.4.3 or other internationally recognised *in vitro* methods) shall be provided.';

(f) Point 8.5.1 is replaced by the following:

'8.5.1. By oral route	8.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available. For nanoforms, a study by the oral route shall be replaced by a study by the inhalation route (8.5.2), unless exposure of humans via inhalation is unlikely, taking into account the possibility of exposure to aerosols, particles or droplets of an inhalable size.';

(g) Point 9.1.1. is replaced by the following:

'9.1.1. Short-term toxicity testing on invertebrates (preferred species *Daphnia*) The registrant may consider long-term toxicity testing instead of short-term.	9.1.1. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, — a long-term aquatic toxicity study on invertebrates is available, or — adequate information for environmental classification and labelling is available. For nanoforms, the study may not be waived on the basis of high insolubility in water alone. The long-term aquatic toxicity study on *Daphnia* (Annex IX, section 9.1.5.) shall be considered if the substance is poorly water soluble, or for nanoforms if they have low dissolution rate in the relevant test media.';

(h) Point 9.1.2. is replaced by the following:

'9.1.2. Growth inhibition study aquatic plants (algae preferred)	9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.';

5. Annex VIII to Regulation (EC) No 1907/2006 is amended as follows:

(a) In the introductory text, the following text is added after the first paragraph:

'Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.';

(b) A new section is inserted:

'7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

7.14ter. Further information on physicochemical properties Only for nanoforms	Further testing for nanoforms covered by the registration shall be considered by the registrant or may be required by the Agency in accordance with Article 41, if there is an indication that specific additional particle properties significantly influence the hazard of or the exposure to those nanoforms.';

(c) Subsection 8.5. is replaced by the following:

'8.5. Acute toxicity	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin. In addition to the oral route (8.5.1.) or to the inhalation route (8.5.2) for nanoforms, for substances other than gases, the information mentioned under 8.5.1. to 8.5.3. shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided.';

(d) Point 8.6.1 is replaced by the following:

'8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.1. The short-term toxicity study (28 days) does not need to be conducted if: — a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used, or — where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products, or — relevant human exposure can be excluded in accordance with Annex XI Section 3. The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if: — inhalation of the substance is unlikely, and

— skin contact in production and/or use is likely, and

— the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.

Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance.

The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant if: the frequency and duration of human exposure indicates that a longer term study is appropriate;

and one of the following conditions is met:

— other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or

— appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.

Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case of:

— failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or

— toxicity of particular concern (e.g. serious/severe effects), or

— indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, and in particular for nanoforms indirect genotoxicity), or

— the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made, or

— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected), or

— effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.';

(e) Subsection 8.8. is replaced by the following:

'8.8. Toxicokinetics	
8.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information.	For nanoforms without high dissolution rate in biological media a toxicokinetics study shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case such an assessment cannot be performed on the basis of relevant available information, including from the study conducted in accordance with 8.6.1. The choice of the study will depend on the remaining information gaps and the results of the chemical safety assessment.';

(f) Point 9.1.3 is replaced by the following:

'9.1.3. Short-term toxicity testing on fish: the registrant may consider long-term toxicity testing instead of short-term.	9.1.3. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on fish is available. For nanoforms, the study may not be waived on the basis of high insolubility in water alone. Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment. The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble, or for nanoforms if they have low dissolution rate in the relevant test media.';

(g) Point 9.1.4. is replaced by the following:

'9.1.4. Activated sludge respiration inhibition testing	9.1.4. The study does not need to be conducted if: — there is no emission to a sewage treatment plant, or — there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or — the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. For nanoforms, the study may not be waived on the basis of high insolubility in water alone. The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.';

(h) Subsection 9.2. is replaced by the following:

'9.2. Degradation	9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance.

	For nanoforms that are not soluble, nor have high dissolution rate, such test(s) shall consider morphological transformation (e.g. irreversible changes in particle size, shape and surface properties, loss of coating), chemical transformation (e.g. oxidation, reduction) and other abiotic degradation (e.g. photolysis). The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.';

(i) Section 9.2.2 is replaced by the following:

'9.2.2. Abiotic 9.2.2.1. Hydrolysis as a function of pH.	9.2.2.1. The study does not need to be conducted if: — the substance is readily biodegradable, or — the substance is highly insoluble in water. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.';

(j) Point 9.3.1. is replaced by the following:

'9.3.1. Adsorption/desorption screening	9.3.1. The study does not need to be conducted if: — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient), or — the substance and its relevant degradation products decompose rapidly. For nanoforms, use of any physicochemical property (e.g. octanol-water partition coefficient) as a reason for waiving the study shall include adequate justification of its relevance to low potential for adsorption.';

6. Annex IX to Regulation (EC) No 1907/2006 is amended as follows:

(a) In the introductory text, the following text is added after the second paragraph:

'Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.';

(b) Point 8.6.2 is replaced by the following:

'8.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or

— the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure.

The appropriate route shall be chosen on the following basis:

Testing by the dermal route is appropriate if:

(1) skin contact in production and/or use is likely; and

(2) the physicochemical properties suggest a significant rate of absorption through the skin; and

(3) one of the following conditions is met:

— toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or

— systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or

— *in vitro* tests indicate significant dermal absorption, or

— significant dermal toxicity or dermal penetration is recognised for structurally-related substances.

Testing by the inhalation route is appropriate if:

— exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance.

Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of:

— failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or

— toxicity of particular concern (e.g. serious/severe effects), or

— indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, and in particular for nanoforms indirect genotoxicity), or

— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).';

(c) Point 9.2.1.2. is replaced by the following:

'9.2.1.2. Simulation testing on ultimate degradation in surface water	9.2.1.2. The study need not be conducted if: the substances is highly insoluble in water, or the substance is readily biodegradable. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.';

(d) Subsection 9.3. is replaced by the following:

'9.3. Fate and behaviour in the environment	
9.3.2. Bioaccumulation in aquatic species, preferably fish	9.3.2. The study need not be conducted if: the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes, or direct and indirect exposure of the aquatic compartment is unlikely. For nanoforms, use of any physicochemical property (e.g. octanol water partition coefficient, dissolution rate, dispersion stability) as a reason for waiving the study shall include adequate justification of its relevance to low potential for bioaccumulation or unlikely direct and indirect exposure of the aquatic compartment.
9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII	9.3.3. The study need not be conducted if: based on the physicochemical properties, the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or the substance and its degradation products decompose rapidly. For nanoforms, use of any physicochemical property (e.g. octanol water partition coefficient, dissolution rate, dispersion stability) as a reason for waiving the study shall include adequate justification of its relevance to low potential for adsorption.';

(e) Subsection 9.4 is replaced by the following:

'9.4. Effects on terrestrial organisms	9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. Where the equilibrium partitioning method is applied to nanoforms, this shall be scientifically justified. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.';

7. Annex X to Regulation (EC) No 1907/2006 is amended as follows:

(a) In the introductory text, the following text is added after the second paragraph:

'Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.';

(b) Point 8.6.3. is replaced by the following:

	'8.6.3. A long-term repeated toxicity study (≥ 12 months) may be proposed by the registrant or required by the Agency in accordance with Articles 40 or 41 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: — serious or severe toxicity effects of particular concern were observed in the 28-day or 90-day study for which the available evidence is inadequate for toxicological evaluation or risk characterisation, or — effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28-day or 90-day study, or — the substance may have a dangerous property that cannot be detected in a 90-day study. If nanoforms are covered by the registration, physicochemical characteristics, in particular particle size, shape and other morphological parameters, surface functionalisation and surface area, as well as molecular structure shall be taken into consideration when determining if one of the conditions above are met.';

8. Annex XI to Regulation (EC) No 1907/2006 is amended as follows:

(a) In the introductory text, the following text is added after the last paragraph:

'The requirements specific to nanoforms in this Annex are without prejudice to requirements applicable to other forms of a substance.';

(b) Point 1.1.3. is replaced by the following:

'1.1.3. *Historical human data*

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data and clinical studies, shall be considered.

The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.';

(c) Subsection 1.2. is replaced by the following:

'1.2. **Weight of evidence**

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

further testing on vertebrate animals for that property shall be omitted,

further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.';

(d) Subsection 1.3. is replaced by the following:

'1.3. **Qualitative or Quantitative structure-activity relationship ((Q)SAR)**

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— results are adequate for the purpose of classification and labelling and/or risk assessment, and

— adequate and reliable documentation of the applied method is provided.

The Agency in collaboration with the Commission, Member States and interested parties shall develop and provide guidance in assessing which (Q)SARs will meet these conditions and provide examples.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.';

(e) The last paragraph in Section 1.4 is replaced by the following:

'Such confirmation may be waived if the following conditions are met:

(1) results are derived from an *in vitro* method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

(2) results are adequate for the purpose of classification and labelling and/or risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

When nanoforms are covered by the registration the above approach in points (1) to (3) shall address the nanoforms separately.';

(f) The first paragraph in Section 1.5 is replaced by the following:

'Substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately. For grouping different nanoforms of the same substance the molecular structural similarities alone cannot serve as a justification.

If nanoforms covered by a registration are grouped or placed in a "category" with other forms, including other nanoforms, of the substance in the same registration the obligations above shall apply in the same manner.'

9. Annex XII to Regulation (EC) No 1907/2006 is amended as follows:

(a) The introductory text is replaced by the following:

'INTRODUCTION

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the Safety Data Sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a mixture or in an article.

The assessment shall address all nanoforms that are covered by the registration. Justifications and conclusions drawn from the assessment shall be relevant to the nanoforms, from their receipt by the downstream user, for his own uses and for his identified uses further down the supply chain.

In carrying out the chemical safety assessment and producing the Chemical Safety Report, the downstream user shall take account of information received from the supplier of the chemical in accordance with Article 31 and 32 of this Regulation.

When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, an appropriate metric for the assessment and presentation of the results in steps 1- 6 of the chemical safety assessment under 0.6.1 and 0.6.2 shall be considered, with the justification included in the chemical safety report and summarised in the safety data sheet. A multiple metric presentation is preferable, ensuring availability of mass metric information.

Where available and appropriate, an assessment carried out under Community legislation, (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified. Assessments carried out under other international and national programmes may also be taken into account.

The process which the downstream user goes through in carrying out the chemical safety assessment and in producing his Chemical Safety Report, involves three steps:';

(b) Under Step 2, the following text is added after the first paragraph:

'When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, the assessment shall cover the hazard, PBT and vPvB assessment of nanoforms(s) as used.';

(c) Under Step 2, the third paragraph is replaced by the following:

'In those cases where the downstream user considers that information, in addition to that provided by the supplier, is necessary for producing his Chemical Safety Report, the downstream user shall gather this information. Where this information can only be obtained by testing on vertebrate animals, he shall submit a proposal for a testing strategy to the Agency in accordance with Article 38. He shall explain why he considers that additional information is necessary. While waiting for results of further testing, he shall record in his chemical safety report the risk management measures intended to manage the risks being explored that he has put in place. The above record taking shall address all nanoforms that are covered by his own uses or his identified uses down the supply chain. Such information shall be relevant to the nanoforms.'