

## NIA Newsletter - Additional Information -

This document summarizes nano-specific amendments, as currently suggested by the [European Parliament's Committee on the Environment, Public Health and Food Safety \(ENVI\)](#) (19<sup>th</sup> March 2010).<sup>1</sup>

Excerpts, [ENVI amendments 77-196](#):

*Amendment 80, Recital 3b (new): (3b) There is scientific uncertainty about the safety of nanomaterials for human health and the environment, no internationally agreed definition of a nanomaterial and no internationally agreed test guidelines; The Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted on 28-29 September 2005 an opinion on nanotechnologies which concluded that there are "major gaps in the knowledge necessary for risk assessment and concludes that "existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles". There is increasing scientific evidence that some carbon nanotubes may behave like asbestos fibres and thus have severe impact on human health. The same holds for nanosilver particles which may end up in the environment and may have severe impact on soil, aquatic and terrestrial organisms. (Justification: A 2009 research project on emerging nanotechnologies found that about 807 products are available on the market containing nanomaterials, some of which are EEE. There is a common agreement amongst nanotoxicologists that risks of severe impacts on health and the environment are real, precautionary measures are therefore warranted in regards to nanomaterials. This amendment is linked to the amendment of Art. 4 (1) b new, suggesting a labelling for nanosilver and carbon nanotubes.)<sup>2</sup>*

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<sup>1</sup> Follow this link for [more information on the amendments proposed by the European Parliament's ENVI Committee](#).

<sup>2</sup> Article 4 [amendments as [suggested by the European Commission](#)]: **Prevention**

- 1. Member States shall ensure that, [electrical and electronic equipment] EEE including spare parts for its repair or its reuse placed on the market does not contain the substances listed in Annex IV.
- 2. For the purposes of this Directive, a maximum concentration value by weight in homogeneous materials as specified in Annex IV shall be tolerated
- 3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 1st January 2014, to in vitro medical devices which are placed on the market from 1st January 2016 and to industrial monitoring and control instruments which are placed on the market from 1st January 2017.
- 4. Paragraph 1 shall not apply to spare parts for the repair or to the reuse of the following:
  - (a) EEE placed on the market before 1 July 2006.
  - (b) Medical devices placed on the market before 1st January 2014.
  - (c) In vitro diagnostic medical devices placed on the market before 1st January 2016.
  - (d) Monitoring and control instruments placed on the market before 1st January 2014.
  - (e) Industrial monitoring and control instruments placed on the market before 1<sup>st</sup> January 2017.
  - (f) EEE which benefited from an exemption and was placed on the market before that exemption expired.
- 5. Paragraph 1 shall not apply to active implantable medical devices. By 2020 the Commission shall review the exclusion of active implantable medical devices with a view to propose inclusion.

*Amendment 97, Recital 14a (new): (14a) The use of nanomaterials in electrical and electronic equipment may increase with the further development of technology. There is sufficient information available to prohibit the use of nanosilver and certain carbon nanotubes in electrical and electronic equipment. There is inadequate information about the use of other nanomaterials in electrical and electronic equipment and the risks associated with such use. In order to enable the Commission to assess the safety of nanomaterials in electrical and electronic equipment, economic operators should notify the use of nanomaterials in electrical and electronic equipment and provide all relevant data with regard to their safety for human health and the environment. The Commission should assess*

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- 6. Paragraph 1 shall not apply to the applications listed in Annexes V and VI.
  - 7. When there is an unacceptable risk to human health or the environment, arising from the use of substances, and in particular the substances listed in Annex III, which needs to be addressed on a Community-wide basis, the list of prohibited substances in Annex IV shall be reviewed using a methodology based on the process set out in Articles 69 to 72 of Regulation (EC) No 1907/2006. Those measures designed to amend non essential elements of this Directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2)

Article 5 [amendments as [suggested by the European Commission](#)]: **Adaptation of the Annexes to scientific and technical progress**

- 1. The Commission shall, for the purposes of adapting the annexes to scientific and technical progress, adopt the following measures:
  - (a) any necessary amendments to Annex II
  - (b) Include materials and components of EEE in Annexes V and VI where either of the following conditions is fulfilled:
    - their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4(1) is scientifically or technically impracticable;
    - the availability and reliability of substitutes is not ensured,
    - the negative environmental health consumer safety or socio-economic impacts caused by substitution are likely to outweigh the environmental, health or consumer safety and/or socio-economic benefits thereof;
  - (c) delete materials and components of EEE from Annexes V and VI where the conditions set out in point (b) are no longer fulfilled. Those measures designed to amend non essential elements of this directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2).
- 2. Measures adopted in accordance with point b of paragraph 1 shall have a maximum validity period of four years and may be renewed. The Commission shall decide in due time on any application for renewal that is submitted no later than 18 months before an exemption expires.
- 3. Before Annexes are amended, the Commission shall *inter alia* consult producers of electrical and electronic equipment, recyclers, treatment operators, environmental organisations and employee and consumer associations.
- 4. As long as materials or components are included in Annexes V and VI to this Directive, on the basis of Article 5(1)(b) of this Directive, those applications shall also be considered exempted from the authorisation requirements set out in Article 58(2) of the regulation (EC) No 1907/2006.

ANNEX III: Substances referred to in Article 4(7)

ANNEX IV: Prohibited substances referred to in Article 4(7) and maximum concentration values tolerated by weight in homogeneous materials adopted

*the information received, and come forward with a legislative proposal for adequate risk management, if necessary.*

*Producers should label electrical and electronic equipment that contains nanomaterials to enable consumers to make an informed choice. (Justification: Nanosilver is already being used as an antimicrobial in EEE, e.g. as a coating for mobile phones, or even released by washing machines. Apart from such uses being superfluous, they endanger human health and the environment. Carbon nanotubes may be used in EEE, yet it has been shown that they can have asbestos-like properties. We need to put an end to the lack of information about the use and the safety of nanomaterials in EEE. Producers should be obliged to report uses and safety data to allow the Commission to prepare for the necessary legislative action, and label their products accordingly.)*

*Amendment 100, Recital 20:(20) In order to allow the provisions of this Directive to be adapted to technical and scientific progress and to adopt other necessary measures, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty in respect of the adaptation of Annexes V, VI, VIa and VIb, the applicability of Annex V for industrial monitoring and control instruments, detailed rules for compliance with maximum concentration values and the application of the labelling of nanomaterials in electrical and electronic equipment, and adaptations to REACH. [...]*

*Amendment 159 (Jill Evans), Article 3 - point p a (new): (pa) "nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale.*

*Properties that are characteristic to the nanoscale include:*

*(i) those related to the large specific surface area of the materials considered and/or*

*(ii) specific physico-chemical properties that are different from those of the nonnanoform of the same material.*

*(Justification: A definition of nanomaterials needs to be introduced. The definition here is the one agreed to by all three institutions in the context of the regulation on novel food.)*

*Amendment 160 (Kathleen Van Brempt, Judith A. Merckies, Åsa Westlund), Article 3 - point p a (new): (pa) 'nanomaterial' means any intentionally produced material that has one or more dimensions of the order up to 300 nm or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions up to the order of 300 nm, including structures, agglomerates or aggregates, and those which may have a size above the order of 300 nm but retain properties that are characteristic to the nanoscale:*

- i. properties related to the large specific surface area of the materials considered;*
- ii. specific physico-chemical properties that are different from those of the nonnanoform of the same material.*

*(Justification: With regards to labelling of specific nano-substances and potential future provisions on nanomaterial, a comprehensive definition of nanomaterial is necessary in order to maximise consumer protection. This should take into account a wide size range (up to 300nm), the specific nano-properties of these particular materials, and encompass the agglomerates and aggregates.)*

Amendment 175 (Åsa Westlund), Article 3 - point p a (new): (pa) "nanomaterial": any intentionally produced material in which the particle size has been altered.

(Justification: A definition of nanomaterials is justified given that they are mentioned in the Directive.)

Excerpts, [amendments 197-339](#):

Amendment 250, Article 5 a (new): Article 5a, Nanomaterials: 1. Economic operators shall notify the Commission of the use of nanomaterials in EEE and provide all relevant data with regard to their safety for human health and the environment over their life cycle. 2. No later than [...\*], having regard to the information provided by economic operators pursuant to paragraph 1, the Commission shall assess the safety of

nanomaterials in EEE for human health and the environment, in particular during use and treatment, and communicate its findings in a report to the European Parliament and the Council. This report shall be accompanied by a legislative proposal for adequate risk management of nanomaterials in EEE, if necessary. 3. Economic operators shall label EEE that contains nanomaterials no later than

[...\*\*]. \* insert date 36 months after entry into force of the Directive. \*\* insert date 24 months after entry into force of the Directive. (Justification: We need to put an end to the lack of information about the use and the safety of nanomaterials in EEE. Producers should be obliged to report uses and safety data to allow the Commission to prepare for the necessary legislative action. Consumers should know whether EEE contains nanomaterials.)

Amendment 261 (Kathleen Van Brempt, Judith A. Markies, Åsa Westlund), Article 6 - paragraph 1 - indent 3 a (new): - labelling requirements for the substances included in Annex IVa (new) in accordance with Article 4(1)b (new),<sup>2</sup> with regard to the improvement of recyclability. These requirements shall take into account provisions under Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of eco-design requirements for energy-using products, avoiding the creation of overlaps with the latter but establishing synergies where possible. A standard for the identification and detection of nanomaterials needs to be developed, to be used for this Directive, but also in view of broader application for other legislation with relevance to nanomaterials. (Justification: For some substances the Öko-Institut's study recommended labelling. Where labelling improves the recyclability and security during treatment of WEEE and consumers' information, it should be taken into account. In this context, further thought should also be given to improving the recyclability of plastics through better ways of distinguishing halogencontaining plastics from other types of plastics. An optimal linkage with the Eco-design Directive has to be ensured. (Linked to Amdt of Article 4 (1) b new and to Amdt on Annex Iva new.)<sup>2</sup>

Amendment 263 (Jill Evans), Article 6 - paragraph 1 - indent 3 a (new): - the application of the labelling requirements for nanomaterials of Article 5a(3).<sup>2</sup> (Linked to the new Article 5a(3).) (Justification: To ensure harmonised labelling of nanomaterials in EEE, the Commission should be conferred the powers to adopt detailed rules for the application of that requirement.)

Amendment 309 (Åsa Westlund), Annex III: Substances referred to in Article 4(7)

1. Arsenic compounds
2. Beryllium and its compounds
3. Antimony trioxide

4. Dinickel trioxide
5. Bisphenol A
6. Brominated organic substances other than brominated flame retardants
7. Chlorinated organic substances other than chlorinated flame retardants or plasticisers
8. Nanomaterial
9. Silver ions used for biocide
10. Substances of very high concern which appear on the candidate list referred to in Article 59(1) of Regulation (EC) No. 1907/2006  
(Justification: A list which is constantly updated in this way may have a positive effect in terms of the substitution of these substances.)

Amendment 310 (Kathleen Van Brempt, Judith A Merkies), Annex III: Substances referred to in Article 6a<sup>3</sup>

1. Polyvinylchloride (PVC)
2. Nano-materials, especially asbestos-like carbon-nanotubes and nanosilver
3. Butyl benzyl phthalate (BBP)
4. Dibutylphthalate (DBP)

(Justification: These substances need further examination before a decision on the need for a ban or labelling requirements can be taken.)

Amendment 313 (Sabine Wils), Annex IV: Prohibited substances referred to in Article 4(7)<sup>2</sup> and maximum concentration values tolerated by weight in homogeneous Materials Prohibited substances referred to in Article 4(7) and maximum concentration values tolerated by weight in homogeneous materials

Part A

- Lead (0.1 %) Lead (0.1 %)  
Mercury (0.1 %) Mercury (0.1 %)  
Cadmium (0.01 %) Cadmium (0.01 %)  
Hexavalent chromium (0.1 %)  
Polybrominated biphenyls (PBB) (0.1 %)  
Polybrominated diphenyl ethers (PBDE) (0.1 %)  
Polybrominated diphenyl ethers (PBDE) (0.1 %)

Part B

- Arsenic compounds (0.1%)  
Beryllium and its compounds (0.1%)  
Antimony trioxide (0.1%)  
Bisphenol A (0.1 %)  
Organobromines other than brominated flame retardants (0.1%)  
Organochlorines other than chlorinated flame retardants or plasticisers (0.1%)  
Carbon nanotubes similar to asbestos (limit of detection)

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<sup>3</sup> Article 6 [amendments as [suggested by the European Commission](#)]: **Implementing measures**

The Commission shall adopt detailed rules for:

- applications for the exemption including a format and types of information to be provided when introducing those applications, including analysis of the alternatives and, if suitable alternatives are available, substitution plans as referred to in Regulation (EC) 1907/2006.
- Complying with the maximum concentration values of Article (4) (2)
- The implementation of Article 5(2), taking into account the need for legal certainty for economic operators pending a Commission Decision on renewal of exemptions.
- Those measures designed to amend non essential elements of this directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(2)

Polyvinylchloride (PVC) (0.1 %)  
Chlorinated plasticisers (0.1 %)  
Bis (2-ethylhexyl) phthalate (DEHP) (0.1%)  
Butyl benzyl phthalate (BBP) (0.1 %)  
Dibutylphthalate (DBP) (0.1 %)  
Nanosilver (limit of detection)

*(Justification: The substances added to the Commission proposal present a major hazard to people and the environment in the phases of production and/or use and recovery.)*

*Amendment 316 (Jill Evans), Annex IV: Prohibited substances referred to in Article 4(7) and maximum concentration values tolerated by weight in homogeneous materials  
Prohibited substances referred to in Article 4(7) and maximum concentration values tolerated by weight in homogeneous materials<sup>2</sup>*

Part A

Lead (0,1%)  
Mercury (0,1%)  
Cadmium (0,01%)  
Hexavalent chromium (0,1%)  
Polybrominated biphenyls (PBB) (0,1%)  
Polybrominated diphenyl ethers (PBDE) (0,1%)

Nanosilver (detection limit)

Long multi-walled carbon nanotubes (detection limit)

*(Justification: Nanosilver is already being used as an antimicrobial in EEE, e.g. as a coating for mobile phones, or even released by washing machines. Apart from such uses being superfluous, they endanger human health and the environment. Carbon nanotubes may be used in EEE, yet it has been shown that they can have asbestos-like properties. Respected authorities such as the UK Royal Commission on Environmental Pollution, the UK Health and Safety Executive or the German Environment Agency have raised concern about these nanomaterials or even recommended against their use.)*

Amendment 317 (Kathleen Van Brempt, Judith A. Merkies, Åsa Westlund), Annex IVa (new):  
(Annex IV a)<sup>4</sup>

1. Nano-silver
2. Asbestos like carbon-nanotubes
3. Beryllium metall
4. Beryllium oxide (BeO)

*(Justification: For some substances labelling has been recommended by the Öko-Institut (item 3 & 4). For items 1 and 2, there is scientific evidence that exposure to long multiwalled carbon nanotubes may result in asbestos-like disease and that the release of nanosilver particles may lead to adverse impacts on human health and the environment. Further research remaining necessary, labelling would be a first step to support careful handling of these substances. An optimal interlinkage with the Eco-design Directive has to be ensured. (Linked to Amdt of Art. 6 (1) indent 3 a new and Amdt on Art. 4 (1) b new))*

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<sup>4</sup> ANNEX IV: Prohibited substances referred to in Article 4(7) and maximum concentration values tolerated by weight in homogeneous materials adopted