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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS 1 - 110

Draft report
Carl Schlyter
(PE418.270v01-00)

on regulatory aspects of nanomaterials
(COM(2008)0366 – 2008/2208(INI))

Amendment 1
Amalia Sartori

Motion for a resolution
Citation 2 a (new)

Motion for a resolution

Amendment

– having regard to the Commission Communication "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007" ("the action plan")¹,

Or. en

Amendment 2
Anne Ferreira

Motion for a resolution
Citation 4 a (new)

Motion for a resolution

Amendment

– having regard to the opinion of the Scientific Committee on New and Emerging Health Risks published on 19 January 2009²,

Or. fr

Amendment 3
Amalia Sartori

Motion for a resolution
Citation 5 a (new)

¹ *Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee - Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007 COM(2007)0505.*

² *Opinion on Risk Assessment of Products of Nanotechnologies; 19 January 2009;*
http://ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o_023.pdf

Motion for a resolution

Amendment

– having regard to the Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research¹,

Or. en

**Amendment 4
Amalia Sartori**

**Motion for a resolution
Citation 5 b (new)**

Motion for a resolution

Amendment

– having regard to the opinion from the European Group on Ethics in Science and New Technologies to the European Commission on the ethical aspects of nanomedicine²,

Or. en

**Amendment 5
Amalia Sartori**

**Motion for a resolution
Citation 8 a (new)**

Motion for a resolution

Amendment

– having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation

¹ Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research C(2008) 424 final.

² EGE Opinion No 21, 17 January 2007.

Amendment 6
Amalia Sartori, Frédérique Ries

Motion for a resolution
Recital A a (new)

Motion for a resolution

Amendment

Aa. Whereas nanomaterials are making a huge contribution to advances across a wide range of sectors; whereas these advances will ultimately be to the benefit of citizens and can make an important contribution to the competitiveness of the European Union's economy; whereas these advances will also allow for improved policy decisions in the fields of public health, employment, occupational safety and health, information society, energy, transport, security and space,

Amendment 7
Frédérique Ries

Motion for a resolution
Recital A a (new)

Motion for a resolution

Amendment

Aa. whereas despite the introduction of a specific European strategy on nanotechnologies and the subsequent allocation of around 3 500 000 000 EUR for research in nanosciences for the 7th Framework Programme for Research and

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Technological Development, the European Union is lagging behind its current main competitors – the USA, Japan and South Korea – who account for over half of the investment and two-thirds of the patents filed worldwide; whereas it is therefore necessary to take this economic reality into account when developing any type of regulatory framework at Community level;

Or. fr

**Amendment 8
Amalia Sartori**

**Motion for a resolution
Recital C**

Motion for a resolution

C. whereas nanomaterials ***are likely to be the next "big thing", especially given that manipulating all matter has been man's ultimate dream for centuries,***

Amendment

C. whereas nanomaterials ***offer the potential to support the Lisbon strategy to turn the EU into "the most competitive and dynamic knowledge-based economy in the world capable of sustainable growth with more and better jobs, and greater social cohesion and respect for the environment" by 2010,***

Or. en

**Amendment 9
Holger Kraemer**

**Motion for a resolution
Recital C**

Motion for a resolution

C. whereas nanomaterials ***are likely to be the next "big thing", especially given that manipulating all matter has been man's ultimate dream for centuries,***

Amendment

C. whereas nanomaterials ***contribute to the resolution of global challenges and help the European Union in its aim to become "the most competitive and dynamic***

*knowledge-based economy in the world'
(Lisbon Strategy),*

Or. de

Amendment 10

Thomas Ulmer, Anja Weisgerber

Motion for a resolution

Recital C

Motion for a resolution

C. whereas nanomaterials *are likely to be the next "big thing", especially given that manipulating all matter has been man's ultimate dream for centuries,*

Amendment

C. whereas nanomaterials *contribute to the resolution of global challenges and help the European Union in its aim to become 'the most competitive and dynamic knowledge-based economy in the world' (Lisbon Strategy),*

Or. de

Amendment 11

Anne Ferreira

Motion for a resolution

Recital C

Motion for a resolution

C. whereas nanomaterials are likely to be the next "big thing", *especially given that manipulating all matter has been man's ultimate dream for centuries,*

Amendment

C. whereas nanomaterials are likely to be the next "big thing",

Or. fr

Amendment 12
Frédérique Ries

Motion for a resolution
Recital D

Motion for a resolution

D. whereas the current discussion about nanomaterials is characterised **by many contradictions or even paradoxes, with disagreement and thus political struggles, starting at as basic a level as the definitions, for instance:**

- **while nanomaterials are generally considered to be materials of a size in the order of 100 nm or less, this is often misrepresented as a range between 1 and 100 nm, even though the term “order” relates to a dimension rather than to a precise size,**
- **while many people believe that different properties due to size effects should be an independent criterion for the definition of nanomaterials, others suggest using this in a cumulative manner, thus limiting the scope of the definition,**
- **while some people suggest that the definition should be further narrowed to insoluble and persistent nanomaterials, thus already applying potential risk considerations at the level of definitions, others argue against such an a priori limitation,**

Amendment

D. whereas the current discussion about nanomaterials **within the European Union** is characterised, **like any conflicting debates on completely new technologies already present in daily life for which there is an element of the unknown as regards properties that may emerge, by the division of the scientific community into those in favour and those against research into nanotechnologies which has its corollary in political doctrine; whereas it would also be more effective to have these new technologies covered by a safe, multi-faceted and evolving body of law that would be based on a precautionary strategy to avoid the two pitfalls of systematic recourse to moratoria in the absence of full information on the product or equivalent treatment for all products containing nanoparticles without taking into account either their real harm or the final use to which they are put,**

Or. fr

Amendment 13
Amalia Sartori

Motion for a resolution
Recital D

Motion for a resolution

D. whereas the current discussion about nanomaterials is characterised by **many contradictions or even paradoxes, with disagreement and thus political struggles, starting at as basic a level as the definitions, for instance:**

- **while nanomaterials are generally considered to be materials of a size in the order of 100 nm or less, this is often misrepresented as a range between 1 and 100 nm, even though the term “order” relates to a dimension rather than to a precise size,**
- **while many people believe that different properties due to size effects should be an independent criterion for the definition of nanomaterials, others suggest using this in a cumulative manner, thus limiting the scope of the definition,**
- **while some people suggest that the definition should be further narrowed to insoluble and persistent nanomaterials, thus already applying potential risk considerations at the level of definitions, others argue against such an a priori limitation,**

Amendment

D. whereas the current discussion about nanomaterials is characterised by **a lack of information and knowledge; whereas a fully developed set of harmonised definitions is not currently available although a number of international standards are either available or in progress, defining “nanoscale” as a “size range from approximately 1 nm to 100 nm”, and often distinguishing between:**

- **Nano-objects, defined as “materials with one, two or three external dimensions at the nanoscale”, i.e. as materials constituted by isolated objects with very small dimensions;**
- **Nano-structured materials, defined as materials “having an internal or surface structure at the nanoscale”, e.g. exhibiting cavities of small dimensions.**

Whereas the European Commission shall promote a harmonized definition for nanomaterial at the level of the United Nations and other competent bodies and shall present to the European Parliament and the Council a revision of all European legislative framework related with this subject,

Or. en

Amendment 14
Anne Ferreira

Motion for a resolution
Recital D indent 1

Motion for a resolution

- while nanomaterials are generally considered to be materials *of a size in the order of 100 nm or less*, this is often misrepresented as a *range* between 1 and 100 nm, even though the term “order” relates to a dimension rather than to a precise size,

Amendment

- while nanomaterials are generally considered to be materials *of a size in the order of 100 nm*, this is often misrepresented as a *range* between 1 and 100 nm, even though the term “order” relates to a dimension rather than to a precise size,

Or. fr

Amendment 15
Frédérique Ries

Motion for a resolution
Recital D b (new)

Motion for a resolution

Amendment

Db. whereas the almost infinite application of nanotechnologies to such diverse sectors as electronics, textiles, biomedical, health and well-being, agri-food or energy makes it impossible to introduce a single regulatory framework at Community level,

Or. fr

Amendment 16
Anne Ferreira

Motion for a resolution
Recital D a (new)

Motion for a resolution

Amendment

Da. whereas the regulatory aspects of nanomaterials should also cover nanoparticles and the different nanotechnologies and nano-objects such as nanotubes, nanofibres, nanofilms, nanoaggregates, nanoagglomerates (or aggregates of nanoparticles or nanomaterials), etc. and their applications, as well as nanostructured materials, and this situation would suggest a need to adopt a methodological approach, test protocols and other specific measures,

Or. fr

Amendment 17

Amalia Sartori, Frédérique Ries

Motion for a resolution

Recital E

Motion for a resolution

Amendment

E. whereas in the context of REACH, it has so far not even been possible to agree on guidance on the identification of nanomaterials, leaving important decisions in the context of registration to economic operators,

E. whereas in the context of REACH, further guidance and advice on nanomaterials, in particular on substance identification, is needed,

Or. en

Amendment 18

Anne Ferreira

Motion for a resolution

Recital E

Motion for a resolution

E. whereas in the context of REACH, it has so far not even been possible to agree on guidance on the identification of nanomaterials, *leaving* important decisions in the context of registration to economic operators,

Amendment

E. whereas in the context of REACH, it has so far not even been possible to agree on guidance on the identification of nanomaterials ***and on the need for specific tests and assessments of nanotechnologies and nanomaterials; whereas this situation leaves*** important decisions in the context of registration to economic operators,

Or. fr

Amendment 19
Holger Krahmer

Motion for a resolution
Recital F

Motion for a resolution

F. whereas ***there is no clear*** information about the ***actual*** use of nanomaterials in consumer products, ***for instance:***

- ***while inventories by renowned institutions list more than 800 manufacturer-identified nanotechnology-based consumer products currently on the market, trade associations of the same manufacturers question these figures, on the basis that they are overestimations, without providing any concrete figures themselves,***
- ***while companies happily use "nano-claims", as the term "nano" seems to have a positive marketing effect, they are strictly opposed to objective labelling requirements,***

Amendment

F. whereas information about the use of nanomaterials in consumer products ***varies from one information source to another and whereas REACH will provide a clear picture of such uses,***

Amendment 20
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Recital F

Motion for a resolution

F. whereas there is ***no clear*** information about the actual use of nanomaterials in consumer products, for instance:

- ***while inventories by renowned institutions list more than 800 manufacturer-identified nanotechnology-based consumer products currently on the market, trade associations of the same manufacturers question these figures, on the basis that they are overestimations, without providing any concrete figures themselves,***
- ***while companies happily use "nano-claims", as the term "nano" seems to have a positive marketing effect, they are strictly opposed to objective labelling requirements,***

Amendment

F. whereas information about the use of nanomaterials in consumer products ***varies from one information source to another and whereas REACH will provide a clear picture of such uses,***

Amendment 21
Carl Schlyter

Motion for a resolution
Recital F a (new)

Motion for a resolution

Amendment

Fa. whereas the lack of clarity about the

actual use of nanomaterials in consumer products is unlikely to change, unless there are clear notification requirements on the use of nanomaterials, as well as full enforcement of Directive 2006/114/EC concerning misleading and comparative advertising,

Or. en

Amendment 22

Amalia Sartori, Frédérique Ries

Motion for a resolution

Recital G

Motion for a resolution

G. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials; *however, the same diversity shrinks to near zero when it comes to a regulatory discussion about nanomaterials,*

Amendment

G. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials *that need to be regulated if they are not already covered by present regulations,*

Or. en

Amendment 23

Anne Ferreira

Motion for a resolution

Recital G

Motion for a resolution

G. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials; however, the same diversity shrinks *to near zero* when it comes to a regulatory discussion about nanomaterials,

Amendment

G. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials; however, the same diversity shrinks *considerably* when it comes to *the reality and use of nanotechnologies and nanomaterials in numerous applications*

and products and a regulatory discussion about nanomaterials,

Or. fr

Amendment 24
Frédérique Ries

Motion for a resolution
Recital G a (new)

Motion for a resolution

Amendment

Ga. whereas it is, at the same time, essential that the scope of existing Community legislation or Community legislation in the course of amendment be extended to cover nanomaterials. This includes 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), Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, Regulation (EC) No 1830/2003 of the European Parliament and of the Council

of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products,

Or. fr

Amendment 25
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Recital H

Motion for a resolution

H. whereas ***there is a major controversy*** about the possibility of assessing the safety of nanomaterials: ***while*** the scientific committees of the Commission ***point to major deficiencies not only in key data, but even in methods of obtaining such data, many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,***

Amendment

H. whereas ***the debate*** about the possibility of assessing the safety of nanomaterials ***is ongoing, and*** the scientific committees of the Commission ***and the OECD have noted that the available testing methods are applicable in principle; whereas this view is shared by most representatives of the industry, who also observe that the necessary data for assessing the safety of commercial products are available in respect of the vast majority of the nanomaterials currently manufactured,***

Or. de

Amendment 26
Holger Krahmer

Motion for a resolution
Recital H

Motion for a resolution

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials: while the scientific committees of the Commission *point to major deficiencies not only in key data, but even in methods of obtaining such data, many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,*

Amendment

H. whereas *the debate* about the possibility of assessing the safety of nanomaterials *is ongoing, and* the scientific committees of the Commission *and the OECD have noted that the available testing methods are applicable in principle; whereas this view is shared by most representatives of the industry, who also observe that the necessary data for assessing the safety of commercial products are available in respect of the vast majority of the nanomaterials currently manufactured,*

Or. de

Amendment 27
Amalia Sartori

Motion for a resolution
Recital H

Motion for a resolution

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials: *while the* scientific committees of the *Commission* point to major deficiencies not only in key data, but even in methods of obtaining such data, *many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,*

Amendment

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials; *whereas the* scientific committees *and Agencies* of the *European Union* point to major deficiencies not only in key data, but even in methods of obtaining such data; *whereas the European Union thus needs to continue to invest in R&D in the field of nanomaterials and to develop, in collaboration with its agencies and international partners, methods of evaluation and an appropriate and harmonised metrology and nomenclature,*

Amendment 28
Anne Ferreira

Motion for a resolution
Recital H

Motion for a resolution

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials: **while** the scientific committees of the Commission point to major deficiencies not only in key data, but even in methods of obtaining such data, many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,

Amendment

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials **even though** the scientific committees of the Commission point to major deficiencies not only in key data, but even in methods of obtaining such data **and closing the knowledge gap regarding nanotechnologies and nanomaterials; whereas** many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,

Or. fr

Amendment 29
Carl Schlyter

Motion for a resolution
Recital H a (new)

Motion for a resolution

Ha. whereas SCENIHR identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials, and considered that these observations indicate potential hazards which should be taken into consideration,

Amendment

Or. en

Amendment 30
Carl Schlyter

Motion for a resolution
Recital H b (new)

Motion for a resolution

Amendment

Hb. whereas SCENIHR furthermore found a general lack of high quality exposure data both for humans and the environment and expects risk assessment procedures to remain under development until there is sufficient scientific information available to characterise the possible harmful effects on humans and the environment, thus concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised,

Or. en

Amendment 31
Carl Schlyter

Motion for a resolution
Recital H c (new)

Motion for a resolution

Amendment

Hc. whereas the combination of evidence of hazards for certain nanomaterials and the overall lack of methods to properly assess the risks of nanomaterials is a reason for concern,

Or. en

Amendment 32
Carl Schlyter

Motion for a resolution
Recital H d (new)

Motion for a resolution

Amendment

Hd. whereas current funding into the environmental, health and safety aspects of nanomaterials in the Seventh Framework Programme for Research (FP7) is far too low; whereas moreover the evaluation criteria for granting research projects to assess the safety of nanomaterials under FP7 are too restrictive (i.e. they have a narrow innovation bias), and thus do not sufficiently promote the urgent development of scientific methods to assess nanomaterials,

Or. en

Amendment 33
Anne Ferreira

Motion for a resolution
Recital H a (new)

Motion for a resolution

Amendment

Ha. whereas a significant proportion of the funds in the 7th Framework Programme for research and technological development earmarked for nanotechnologies are allocated to research and development programmes for nanotechnologies, at the expense of evaluation and the drafting and development of specific methodologies to assess the safety and environmental and health impact of nanotechnologies and nanomaterials,

Or. fr

Amendment 34
Carl Schlyter

Motion for a resolution
Recital H e (new)

Motion for a resolution

Amendment

He, whereas the knowledge about potential health and environmental impacts lags significantly behind the pace of market developments, thus raising fundamental questions about the ability of the current governance model to deal with emerging technologies in "real time",

Or. en

Amendment 35
Anne Ferreira

Motion for a resolution
Recital I

Motion for a resolution

Amendment

I. whereas Parliament had called for investigation of the effects of nanoparticles that are not readily soluble or biodegradable, in accordance with the precautionary principle, before such particles are put into production and placed on the market,

I. whereas, ***in its resolution of 28 September 2006 on nanosciences and nanotechnologies: an action plan for Europe 2005-2009¹***, Parliament had called for investigation of the effects of nanoparticles that are not readily soluble or biodegradable, in accordance with the precautionary principle, before such particles are put into production and placed on the market,

Or. fr

¹ OJ C 306 E, 15.12.2006, p. 426.

Amendment 36
Anne Ferreira

Motion for a resolution
Recital J

Motion for a resolution

J. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" is seriously ***undermined*** by the complete absence of any information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits,

Amendment

J. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" is seriously ***diminished*** by the complete absence of any information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits, ***raising doubts about the interest and specific value added of nanotechnologies and nanomaterials in comparison to conventional technologies, materials and substances,***

Or. fr

Amendment 37
Amalia Sartori

Motion for a resolution
Recital J

Motion for a resolution

J. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" ***is seriously undermined by the complete absence of any*** information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits,

Amendment

J. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" ***would be greater with more*** information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits,

Or. en

Amendment 38
Amalia Sartori

Motion for a resolution
Recital K

Motion for a resolution

K. whereas the Commission presented ***only a legalistic*** overview of relevant Community legislation ***without considering current or likely future use of nanomaterials and without detailing the specific nature of nanomaterials and the resulting challenges,***

Amendment

K. whereas the Commission presented ***an*** overview of ***the*** relevant Community legislation ***focusing on nanomaterials currently in production and/or placed on the market,***

Or. en

Amendment 39
Holger Krahmer

Motion for a resolution
Recital L

Motion for a resolution

L. whereas the Commission's overview shows that ***there are no*** nano-specific provisions in Community legislation ***for the time being,***

Amendment

L. whereas the Commission's overview shows that nano-specific provisions in Community legislation ***are not necessary, since nanomaterials are substances and since substances are sufficiently covered by legislation on chemical substances and by sector-specific legislation,***

Or. de

Amendment 40
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Recital L

Motion for a resolution

L. whereas the Commission's overview shows that there are no nano-specific provisions in Community legislation for the time being,

Amendment

L. whereas the Commission's overview shows that nano-specific provisions in Community legislation ***are not necessary, since nanomaterials are substances and since substances are sufficiently covered by legislation on chemical substances and by sector-specific legislation,***

Or. de

Amendment 41
Carl Schlyter

Motion for a resolution
Recital L a (new)

Motion for a resolution

Amendment

La. whereas a closer look at REACH reveals many deficiencies to deal with nanomaterials, for example:

- the one tonne threshold excludes nanomaterials produced in low quantities, even though such nanomaterials are present in consumer articles,

- an exposure assessment only becomes mandatory for substances produced by a manufacturer above 10 tonnes/year and if they have been found to meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC; however, given the current difficulties with hazard identification, an exposure assessment may well not be provided due to non-identification of hazards on the basis of existing methodology, even though an exposure assessment is crucial for a proper risk assessment of nanomaterials,

- the REACH notification requirements for substances in articles only concern

substances of very high concern that are on the candidate list and when they are present in concentrations above 0.1% by weight in the article and in a total quantity of over one tonne in those articles per producer per year; however, as not a single nanomaterial is currently on the candidate list, such listing will be difficult in light of the problems with hazard identification of nanomaterials, and even if those problems could be overcome, the nanomaterials would most likely not exceed the tonnage and concentration thresholds, so that it is highly unlikely that REACH in its current form will lead to notification of nanomaterials in articles,

Or. en

Amendment 42
Anne Ferreira

Motion for a resolution
Recital L a (new)

Motion for a resolution

Amendment

La. whereas substances that may be used in the form of nanomaterials are excluded from the scope of Regulation (EC) No 1907/2006 (REACH), thus ruling out evaluation of these substances, including their nanometric forms; whereas under Regulation (EC) No 1907/2006 (REACH), nanomaterials are not considered as high-risk substances and, as regards the substances covered by the Articles, notification of substances classified as CMR is only compulsory above a 0,1% threshold; whereas the assessment of exposure to the substances is only required if the substance is assessed as toxic for human health or the environment,

Amendment 43
Carl Schlyter

Motion for a resolution
Recital L b (new)

Motion for a resolution

Amendment

Lb. whereas waste legislation in the absence of nano-specific provisions may not apply correctly, for example:

- adequate waste treatment depends inter alia on the hazardousness of a waste (e.g. acceptance criteria for different wastes in a landfill), but will not apply for nanomaterials as long as there is no agreed method for hazard identification, thus leading to non-specific treatment of nanomaterials depending on the general nature of the waste they end up in (anything from municipal solid waste to hazardous waste),

- emission limit values for waste incineration only apply to certain known pollutants and not for nanomaterials, even though some might have to be classified as pollutants, or might have special requirements (e.g. carbon nanotubes, which can present asbestos-like properties, are stable until very high temperatures),

Or. en

Amendment 44
Carl Schlyter

Motion for a resolution
Recital L c (new)

Motion for a resolution

Amendment

Lc. whereas air and water legislation are blind to nano-specific challenges, as existing limits or quality standards are mass-based, but nanomaterials require different metrics to adequately assess them (e.g. number of particles or total surface area),

Or. en

Amendment 45

Carl Schlyter

Motion for a resolution

Recital L d (new)

Motion for a resolution

Amendment

Ld. whereas legislation on integrated pollution prevention and control (IPPC) will not adequately cover the potential risks of nanomaterials:

- manufacture of certain nanomaterials may not be covered adequately, as they do not fit into any category of traditional chemical nomenclature (e.g. fullerenes - they are not organic substances, and they are very different from inorganic bulk carbon),

- processing after manufacturing may not be covered (e.g. the processing of carbon nanotubes into articles),

- it is difficult to see how best available techniques reference documents (BREFs) can be established for the various nanomaterials, given the need for a case-by-case approach to nanomaterials,

Or. en

Amendment 46
Carl Schlyter

Motion for a resolution
Recital L e (new)

Motion for a resolution

Amendment

Le. whereas there are fundamental problems with regard to the effectiveness of key provisions of worker protection legislation in relation to nanomaterials:

- the obligation on employers to conduct a risk assessment as a basis for risk management measures such as substitution or occupational exposure limits is undermined by the absence of adequate and agreed risk assessment methodologies for nanomaterials and even provisions,

- existing instruments often fail to adequately detect nanomaterials, thus making it difficult to control exposure,

Or. en

Amendment 47
Carl Schlyter

Motion for a resolution
Recital L f (new)

Motion for a resolution

Amendment

Lf. whereas the significant amendments concerning nanomaterials currently negotiated between the Council and the European Parliament in the context of the recast of the cosmetics directive and the review of the regulation on novel food, respectively, highlight the clear need to amend Community legislation to address nanomaterials adequately,

Or. en

Amendment 48
Carl Schlyter

Motion for a resolution
Recital L g (new)

Motion for a resolution

Amendment

Lg. whereas the current debate about regulatory aspects of nanomaterials is largely limited to expert circles, even though nanomaterials have the potential to bring about far-ranging societal change, which requires wide-ranging public consultation and full public participation in decision-making,

Or. en

Amendment 49
Frédérique Ries

Motion for a resolution
Recital M

Motion for a resolution

Amendment

M. whereas a broad application of patents to nanomaterials could stifle further innovation,

M. whereas a broad application of patents to nanomaterials, ***as well as the excessive cost of patenting and the absence of patent access facilities for very small businesses and small and medium-sized enterprises (SMEs)***, could stifle further innovation,

Or. fr

Amendment 50
Anne Ferreira

Motion for a resolution
Recital N

Motion for a resolution

N. whereas the likely convergence of nanotechnology with biotechnology and information technology raises serious **ethical** questions,

Amendment

N. whereas the likely convergence of nanotechnology with biotechnology, **biology, cognitive sciences** and information technology raises serious questions **relating to ethics, safety, security and respect for fundamental rights**,

Or. fr

Amendment 51

Amalia Sartori

Motion for a resolution

Recital N

Motion for a resolution

N. whereas the likely convergence of nanotechnology with biotechnology and information technology raises serious ethical questions,

Amendment

N. whereas the likely convergence of nanotechnology with biotechnology and information technology raises serious ethical questions, **that need to be analysed by a new opinion of the European Group on Ethics in Science and New Technologies**,

Or. en

Amendment 52

Amalia Sartori

Motion for a resolution

Recital N a (new)

Motion for a resolution

Amendment

Na. whereas the European Code of Conduct for responsible nanosciences and nanotechnologies research is an essential instrument for safe, integrated and responsible research in nanomaterials;

whereas the Code must be adopted and respected by all producers intending to manufacture or place goods on the market,

Or. en

Amendment 53
Anne Ferreira

Motion for a resolution
Recital N a (new)

Motion for a resolution

Amendment

Na. whereas the precautionary principle, the polluter-pays principle and sustainability objectives should form the basis of the regulatory and guidance framework for nanotechnologies and nanomaterials, these principles and objectives should help steer the development of nanotechnologies and nanomaterials towards uses that are of greatest benefit to society,

Or. fr

Amendment 54
Frédérique Ries

Motion for a resolution
Paragraph 1

Motion for a resolution

Amendment

1. Is convinced that the benefits of nanomaterials *can only be realised within a clear regulatory framework that fully addresses the very nature of potential safety problems relating to nanomaterials;*

1. Is convinced that the benefits of nanomaterials *will be all the greater if they respond to the real needs of citizens, through the introduction of legislative or other standards that are tailored to the vast range of expected technological and industrial applications and pay heed to health and safety aspects as well as the*

research and development, protection of intellectual property rights and innovation dimensions;

Or. fr

Amendment 55

Anne Ferreira

Motion for a resolution

Paragraph 1

Motion for a resolution

1. Is convinced that the benefits of nanomaterials can only be realised within a clear regulatory framework that fully addresses the very nature of potential safety problems relating to nanomaterials;

Amendment

1. Is convinced that the benefits of ***nanotechnologies and*** nanomaterials can only be realised within a clear regulatory ***and policy*** framework that fully addresses ***nanotechnologies and materials and their current and future applications as well as*** the very nature of potential safety problems relating to nanomaterials;

Or. fr

Amendment 56

Thomas Ulmer, Anja Weisgerber

Motion for a resolution

Paragraph 3

Motion for a resolution

3. ***Considers it highly misleading for the Commission to state, in the absence of any nano-specific provisions in Community law, that current legislation covers in principle the relevant risks relating to nanomaterials, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively blind to its risks;***

Amendment

3. ***Supports the Commission's view that current legislation covers in principle the risks of nanomaterials; agrees that the data and methods to assess the risks are applicable in principle, and that the further adaptation of these methods must be tested by the OECD Working Party on Manufactured Nanomaterials;***

Amendment 57
Holger Krahmer

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Considers it highly misleading for the Commission to state, in the absence of any nano-specific provisions in Community law, that current legislation covers in principle the relevant risks relating to nanomaterials, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively blind to its risks;

Amendment

3. Supports the Commission's view that current legislation covers in principle the risks of nanomaterials; agrees that the data and methods to assess the risks are applicable in principle, and that the further adaptation of these methods must be tested by the OECD Working Party on Manufactured Nanomaterials;

Amendment 58
Amalia Sartori

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Considers it highly misleading for the Commission to state, in the absence of any nano-specific provisions in Community law, that current legislation covers in principle the relevant risks relating to nanomaterials, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively blind to its risks;

Amendment

3. Considers that current legislation, whilst covering in principle the relevant risks relating to nanomaterials, needs to be completed by appropriate data, test methods and methods to assess the risks relating to nanomaterials so as to ensure the necessary level of protection;

Amendment 59
Amalia Sartori

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Considers that as long as current legislation is devoid of any nano-specific provisions, and as long as data and even methods to assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection;

Amendment

deleted

Or. en

Amendment 60
Frédérique Ries

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Considers that as long as current legislation is devoid of any nano-specific provisions, and as long as data and even methods to assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection;

Amendment

4. Considers that it is important to include nanomaterials within the scope of Community legislation concerning everyday consumer products, and not just for legislation in the process of amendment such as Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products and Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, but also 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), Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy;

Or. fr

Amendment 61
Holger Krahmer

Motion for a resolution
Paragraph 4

Motion for a resolution

Amendment

4. Considers that as long as current

4. Considers that *while nanomaterials are*

legislation is devoid of any nano-specific provisions, and as long as data and even methods to assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection;

adequately covered by current law and the OECD has confirmed the applicability of the testing methods, the instruments for the implementation of the current legislation need to be further developed;

Or. de

Amendment 62
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Considers that as long as current legislation is devoid of any nano-specific provisions, and as long as data and even methods to assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection;

Amendment

4. Considers that *while nanomaterials are adequately covered by current law and the OECD has confirmed the applicability of the testing methods, the instruments for the implementation of the current legislation need to be further developed;*

Or. de

Amendment 63
Holger Krahmer

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Considers that the *proposed* implementation *focus does not provide the* "safe and integrated approach" to

Amendment

5. Considers that the *necessary steps are being taken towards the* implementation of a "safe and integrated approach" to

nanotechnologies advocated by the Commission, *given that numerous nanomaterials are already on the market, particularly in sensitive applications such as personal care products or cleaning products, without adequate safety;*

nanotechnologies *as* advocated by the Commission;

Or. de

Amendment 64
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Considers that the *proposed* implementation *focus does not provide the* "safe and integrated approach" to nanotechnologies advocated by the Commission, *given that numerous nanomaterials are already on the market, particularly in sensitive applications such as personal care products or cleaning products, without adequate safety;*

Amendment

5. Considers that the *necessary steps are being taken towards the* implementation of *a* "safe and integrated approach" to nanotechnologies *as* advocated by the Commission;

Or. de

Amendment 65
Amalia Sartori, Frédérique Ries

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Considers that *the proposed implementation focus does not provide the* "safe and integrated approach" to nanotechnologies advocated by the *Commission, given that numerous* nanomaterials are already on the market, particularly in sensitive applications such

Amendment

5. Considers that *the concept of the* "safe, *responsible* and integrated approach" to nanotechnologies advocated by the *European Union, is jeopardized by the lack of information on* nanomaterials *that* are already on the market, particularly in sensitive applications such as personal

as personal *care* products or cleaning products, *without adequate safety assessment, and without adequate consumer information about these uses;*

products. *Asks the Commission to report before June 2011 on the presence and safety of nanomaterials on the European market and the extent of the need to create a Special European Fund, within the 7th Framework Programme, to finance research on the safe development and use of nanomaterials;*

Or. en

Amendment 66

Anne Ferreira

Motion for a resolution

Paragraph 5 a (new)

Motion for a resolution

Amendment

5a. Urges that no market authorisation be given for products containing nanotechnologies or nanomaterials that present a risk linked to the exposure of workers or consumers or to an uncontrolled spread in the environment; considers that such a measure is necessary pending the development of specific assessment methods that make it possible to obtain scientific data showing that the nanotechnologies and nanomaterials used are safe for human health and the environment;

Or. fr

Amendment 67

Anne Ferreira

Motion for a resolution

Paragraph 5 b (new)

Motion for a resolution

Amendment

5b. Urges that products already on the market which contain nanotechnologies

or nanomaterials be re-assessed on the basis of the "no data, no market" principle contained in Regulation (EC) No 1907/2006 (REACH), and be withdrawn from the market if it turns out that no data are available or that the data are not sufficient to determine that they are safe for human health and the environment;

Or. fr

Amendment 68
Anne Ferreira

Motion for a resolution
Paragraph 5 c (new)

Motion for a resolution

Amendment

5c. Calls for packaging and segregation measures to be taken concerning waste from products containing nanotechnologies and nanomaterials, and for air treatment and waste water treatment in the nanotechnologies and nanomaterials industries in order to avoid the uncontrolled spread of nanotechnologies and nanomaterials;

Or. fr

Amendment 69
Carl Schlyter

Motion for a resolution
Paragraph 5 a (new)

Motion for a resolution

Amendment

5a. Calls on the Commission to fundamentally rethink its approach to regulating nanomaterials, and to urgently revise all relevant legislation so as to

establish an adaptive management system with early warnings and risk categories, before the technology is so established that its development can no longer be steered without major disruptions;

Or. en

Amendment 70

Amalia Sartori

Motion for a resolution

Paragraph 6

Motion for a resolution

6. Calls on the Commission to **propose** reviews **of** all relevant legislation by the end of **2009** to **fully implement the principle "no data, no market" for all applications of nanomaterials in consumer products or in products leading to discharges to the environment;**

Amendment

6. Calls on the Commission to review all relevant legislation by the end of **2012** to **ensure that legislative provisions and implementation tools reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed;**

Or. en

Amendment 71

Frédérique Ries

Motion for a resolution

Paragraph 6

Motion for a resolution

6. Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" **for all applications** of nanomaterials **in** consumer products **or in products leading to discharges to the environment;**

Amendment

6. Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" **for applications** of nanomaterials **with a probable or proven health or environmental impact used in the preparation of** consumer products;

Amendment 72
Kartika Tamara Liotard, Jens Holm

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" for all applications of nanomaterials in consumer products or in products leading to discharges to the environment;

Amendment

6. Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" **by *demanding test-based assessment and approval of materials in near-market-use stage*** for all applications of nanomaterials in consumer products or in products leading to discharges to the environment;

Or. en

Amendment 73
Anne Ferreira

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Calls on the Commission to submit, by 30 June 2010, a clear and coherent policy framework on the fundamental aspects of the definition of nanotechnologies and nanomaterials, focussing primarily on the following objectives :

- redefining the size from 0.3nm to 300nm,

- including substances with nanomaterial-like properties in the relevant legislation, even if their size is greater than that defined in the legislation,

- having the relevant legislation cover all nanotechnologies and all nanomaterials, regardless of their specific characteristics, such as accumulative, persistent, etc., as well as aggregates, agglomerates, recombinants and self-assembling materials;

Or. fr

Amendment 74
Carl Schlyter

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Calls for the introduction of a comprehensive science-based definition of nanomaterials in Community legislation as a prerequisite for nano-specific amendments to relevant horizontal and sectoral legislation;

Or. en

Amendment 75
Kartika Tamara Liotard, Jens Holm

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Calls on the Commission to create an inventory of the types and uses of nanomaterials before and after their placing on the EU market and make it publicly available;

Or. en

Amendment 76
Anne Ferreira

Motion for a resolution
Paragraph 7 b (new)

Motion for a resolution

Amendment

7b. Calls for an inventory to be compiled of the different types and uses of nanotechnologies and nanomaterials and of public and private research, and for this inventory to be publicly accessible;

Or. fr

Amendment 77
Carl Schlyter

Motion for a resolution
Paragraph 7 b (new)

Motion for a resolution

Amendment

7b. Calls specifically for amendments to REACH that ensure the following not later than 18 months after entry into force:

- simplified registration for nanomaterials manufactured or imported (with a threshold based on e.g. surface activity instead of tonnage), providing core data on physico-chemical properties as well as toxicological and ecotoxicological effects,***
- a chemical safety report with exposure assessment for all registered nanomaterials irrespective of hazard identification,***
- notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles irrespective of tonnage and concentration thresholds;***

Or. en

Amendment 78
Carl Schlyter

Motion for a resolution
Paragraph 7 c (new)

Motion for a resolution

Amendment

7c. Calls for the application of a "Duty of Care" for manufacturers that wish to place nanomaterials onto the market;

Or. en

Amendment 79
Carl Schlyter

Motion for a resolution
Paragraph 7 d (new)

Motion for a resolution

Amendment

7d. Calls specifically for amendments to waste legislation to adequately address nanomaterials, such as:

- a separate entry for nanomaterials in the list of waste established by Decision 2000/532/EC,

- a revision of the waste acceptance criteria in landfills in Decision 2003/33/EC,

- a revision of relevant emission limit values for waste incineration to supplement the mass-based measurements by metrics based on particle number and/or surface;

Or. en

Amendment 80
Carl Schlyter

Motion for a resolution
Paragraph 7 e (new)

Motion for a resolution

Amendment

7e. Calls specifically for a revision of emission limit values and environmental quality standards in air and water legislation to supplement the mass-based measurements by metrics based on particle number and/or surface to adequately address nanomaterials;

Or. en

Amendment 81
Carl Schlyter

Motion for a resolution
Paragraph 7 f (new)

Motion for a resolution

Amendment

7f. Calls specifically for amendments of the IPPC directive to ensure for all relevant nanomaterials that:

- manufacture and processing are covered,***
- BREFs are newly established or adapted;***

Or. en

Amendment 82
Carl Schlyter

Motion for a resolution
Paragraph 7 g (new)

Motion for a resolution

Amendment

7g. Calls specifically for amendments to worker protection legislation to ensure that nanomaterials are only used in closed systems as long as it is not possible to reliably detect and control exposure;

Or. en

**Amendment 83
Holger Krahmer**

**Motion for a resolution
Paragraph 8**

Motion for a resolution

Amendment

8. Reiterates its call for labelling of consumer products containing nanomaterials;

deleted

Or. de

**Amendment 84
Thomas Ulmer, Anja Weisgerber**

**Motion for a resolution
Paragraph 8**

Motion for a resolution

Amendment

8. Reiterates its call for labelling of consumer products containing nanomaterials;

deleted

Or. de

Amendment 85
Anne Ferreira

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Reiterates its call *for labelling of consumer* products containing nanomaterials;

Amendment

8. Reiterates its call *for mandatory labelling at Community level of products manufactured using nanotechnologies and/or* containing nanomaterials, *intended for intermediate or final use, in order to ensure that workers and consumers have clear, reliable and transparent information; emphasises the need to adopt provisions relating to the protection of workers working with nanotechnologies and/or nanomaterials;*

Or. fr

Amendment 86
Amalia Sartori, Frédérique Ries

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Reiterates its call for *labelling* of consumer products containing nanomaterials;

Amendment

8. Reiterates its call for *the provision of information to consumers. All ingredients present in the form of nanomaterials shall be indicated in the list of ingredients by preceding the name of the ingredient with the word 'nano';*

Or. en

Amendment 87
Carl Schlyter

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

Amendment

;

8a. Calls for full enforcement of Directive 2006/114/EC concerning misleading and comparative advertising to ensure that that there is no misleading advertising with nanomaterials;

Or. en

Amendment 88
Kathy Sinnott

Motion for a resolution
Paragraph 8 b (new)

Motion for a resolution

Amendment

8b. Recommends the establishment of a feedback portal where nanomaterial researchers from industry, academia and citizen users can share experiences, report and share findings and find out the latest information, and which will regularly review these contributions.

Or. en

Amendment 89
Amalia Sartori, Frédérique Ries

Motion for a resolution
Paragraph 9

Motion for a resolution

Amendment

9. Calls for the urgent development of adequate testing protocols to assess the hazard of, and exposure to, nanomaterials over their entire life cycle, using a multi-disciplinary approach;

9. Calls for the urgent development of adequate testing protocols ***and metrology standards*** to assess the hazard of, and exposure to, nanomaterials over their entire life cycle, using a multi-disciplinary approach; ***and calls for the establishment of a Special European Fund, within the***

7th Framework Program, to finance research on this field;

Or. en

Amendment 90
Åsa Westlund

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Asks that when a substance has already been covered by Community legislation and there has been a significant change in the production methods, source materials or particle size through nanotechnology, the substance prepared by those new methods or materials be considered as a different substance, and a new entry in the Community legislation or change in the specifications on how the substance may be used shall be required before it may be placed on the market.

Or. sv

Amendment 91
Kartika Tamara Liotard, Jens Holm

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Calls on the Commission to prioritise funding and research on environmental and human health aspects of nanomaterials;

Or. en

Amendment 92
Carl Schlyter

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Calls for a major stepping up of the funding of research into the environmental, health and safety aspects of nanomaterials over their life cycle; calls specifically on the Commission to revise the evaluation criteria under FP7 so that FP7 attracts and funds significantly more research to improve the scientific methodology to assess nanomaterials;

Or. en

Amendment 93
Carl Schlyter

Motion for a resolution
Paragraph 9 b (new)

Motion for a resolution

Amendment

9b. Calls on the Commission to promote coordination and exchange between Member States on research and development, risk assessment, guidance development and regulation of nanomaterials by using existing mechanisms (e.g. REACH Competent Authorities Subgroup on Nanomaterials) or by creating additional ones, if appropriate;

Or. en

Amendment 94
Carl Schlyter

Motion for a resolution
Paragraph 9 c (new)

Motion for a resolution

Amendment

9c. Calls on the Commission to make an impact assessment on the costs and benefits of creating a European institute on nanomaterials;

Or. en

Amendment 95
Carl Schlyter

Motion for a resolution
Paragraph 9 d (new)

Motion for a resolution

Amendment

9d. Calls on the Commission to promote an EU-wide public debate in the Member States on regulatory aspects of nanomaterials;

Or. en

Amendment 96
Kartika Tamara Liotard, Jens Holm

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Asks the Commission and the Member States to undertake an EU-wide public debate on nanotechnologies and nanomaterials and seek public opinion on which developments are considered acceptable or necessary and under which

conditions;

Or. en

Amendment 97

Anne Ferreira

Motion for a resolution

Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Calls on the Commission and the Member States to launch an EU-wide public debate on nanotechnologies and nanomaterials in order to find out which developments regarding nanotechnologies and nanomaterials are considered desirable or necessary and under which conditions,

Or. fr

Amendment 98

Carl Schlyter

Motion for a resolution

Paragraph 9 e (new)

Motion for a resolution

Amendment

9e. Calls on the Commission to ensure full public participation in all decision-making related to nanomaterials;

Or. en

Amendment 99

Holger Krahmer

Motion for a resolution

Paragraph 10

Motion for a resolution

10. Calls for potential patent rights *to be limited to specific applications or production methods of nanomaterials, and not to be extended to nanomaterials themselves, to avoid stifling innovation and to avoid creating a North-South "nano-divide"*;

Amendment

10. Calls for potential patent rights *to be granted in accordance with existing patent law in order to ensure an appropriate level of protection for patent holders and not to discourage innovations by strict supervision of the patent criteria*;

Or. de

Amendment 100

Thomas Ulmer, Anja Weisgerber

Motion for a resolution

Paragraph 10

Motion for a resolution

10. Calls for potential patent rights *to be limited to specific applications or production methods of nanomaterials, and not to be extended to nanomaterials themselves, to avoid stifling innovation and to avoid creating a North-South "nano-divide"*;

Amendment

10. Calls for potential patent rights *to be granted in accordance with existing patent law in order to ensure an appropriate level of protection for patent holders and not to discourage innovations by strict supervision of the patent criteria*;

Or. de

Amendment 101

Frédérique Ries

Motion for a resolution

Paragraph 10

Motion for a resolution

10. Calls for *potential* patent rights to be

Amendment

10. ***Recognises that it is essential to***

limited to specific applications or production methods of nanomaterials, and **not** to be extended to nanomaterials themselves, to avoid stifling innovation and to avoid creating a North-South "nano-divide";

remove the obstacles preventing very small businesses and SMEs in particular from accessing patents and calls at the same time for patent rights to be limited to specific applications or production methods of nanomaterials, and ***only*** to be extended to nanomaterials themselves ***on an exceptional basis***, to avoid stifling innovation and to avoid creating a North-South "nano-divide";

Or. fr

Amendment 102
Frédérique Ries

Motion for a resolution
Paragraph 11

Motion for a resolution

11. Considers that ethical guidelines need to be developed in due time ***to ensure full respect for ethical values in possible future use of nanotechnology converging with biomedical applications;***

Amendment

11. Considers that ***stringent*** ethical guidelines need to be developed in due time, ***particularly for nanomedicine, such guidelines being the right to privacy, free and informed consent, the limits set on non-therapeutic human enhancement, whilst offering encouragement to this promising interdisciplinary domain with breakthrough technologies such as molecular imaging and diagnostics, which can offer impressive benefits for the early diagnosis and smart and cost-effective treatment of many diseases;***

Or. fr

Amendment 103
Amalia Sartori

Motion for a resolution
Paragraph 11

Motion for a resolution

11. Considers that ethical guidelines need to be developed in due time to ensure full respect for ethical values in possible future use of nanotechnology converging with biomedical applications;

Amendment

11. Considers that ethical guidelines need to be developed in due time to ensure full respect for ethical values in possible future use of nanotechnology converging with biomedical applications *and asks the European Group on Ethics in Science and New Technologies to draw up an opinion on this issue, building on its Opinion No 21 of 17 January 2007 on "Ethical aspects of nanomedicine" and drawing on the ethical opinion issued by EU national ethics bodies as well as the work undertaken by international organisations such as UNESCO;*

Or. en

Amendment 104

Anne Ferreira

Motion for a resolution

Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. Underlines the need for a rapid improvement of the scientific knowledge and thus calls for a Community research policy to be drawn up in the field of nanotechnologies and nanomaterials;

Or. fr

Amendment 105

Anne Ferreira

Motion for a resolution

Paragraph 11 b (new)

Motion for a resolution

Amendment

11b. Calls, therefore, for a substantial proportion of the funding earmarked for nanotechnologies and nanomaterials in the 7th Framework Programme for research and technological development to be allocated to projects for developing specific methods for the assessment of nanotechnologies and nanomaterials, in order to reduce the gaps in knowledge about nanotechnologies and nanomaterials, their safety and their effects on the environment and human health, including at work;

Or. fr

Amendment 106

Anne Ferreira

Motion for a resolution

Paragraph 11 c (new)

Motion for a resolution

Amendment

11c. Calls on the Commission and Member States to propose, as soon as possible, the establishment of a permanent and independent European decision-making platform responsible for monitoring nanotechnologies and nanomaterials, and a basic and applied research programme on the methodology for this monitoring (particularly metrology, detection, toxicity and epidemiology);

Or. fr

Amendment 107
Holger Kraemer

Motion for a resolution
Paragraph 12

Motion for a resolution

Amendment

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given the very high number of air pollution-related deaths every year;

deleted

Or. de

Amendment 108
Amalia Sartori

Motion for a resolution
Paragraph 12

Motion for a resolution

Amendment

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given the very high number of air pollution-related deaths every year;

deleted

Or. en

Amendment 109
Thomas Ulmer, Anja Weisgerber

Motion for a resolution
Paragraph 12

Motion for a resolution

Amendment

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given the very high number of air pollution-related deaths every year;

deleted

Or. de

Amendment 110

Anne Ferreira

Motion for a resolution

Paragraph 12

Motion for a resolution

Amendment

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given the very high number of air pollution-related deaths every year;

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given ***that the legislation on air quality does not cover the emission of very fine particles (of under 2,5µm) into the ambient air and in view of*** the very high number of air pollution-related deaths every year;

Or. fr