

EUROPEAN PARLIAMENT

2004



2009

Committee on the Environment, Public Health and Food Safety

2008/2208(INI)

30.3.2009

COMPROMISE AND CONSOLIDATED AMENDMENTS 1 - 35

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

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

Bloc A: Benefits

Amendment 1

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 6 (first and third parts)

Motion for a resolution

Recital A and Aa

Motion for a resolution

A. whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as "nanomaterials") promises multiple benefits in innumerable applications for consumers, patients and the environment, as nanomaterials can provide different or new properties compared to the same substance or material in normal form;

Amendment

A. whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as "nanomaterials") promises **important advances with** multiple benefits in innumerable applications for consumers, patients and the environment, as nanomaterials can provide different or new properties compared to the same substance or material in normal form;

Aa. whereas the advances in nanomaterials are expected to have significant influence on policy decisions in the fields of public health, employment, occupational safety and health, information society, energy, transport, security and space,

Or. en

Amendment 2

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 6 (second part), 8, 9/10, 11, EMPL 2 (first part)

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 ***the safe development of nanomaterials can make an important contribution to the competitiveness of the European Union's economy and to the achievement of the Lisbon strategy,***

Bloc B: Knowledge gaps and research

Amendment 3

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 7

Motion for a resolution

Recital Ab (new)

Motion for a resolution

Amendment

Ab. 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 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;

Or. en

Amendment 4

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 27 and 28; 25/26 fall

Motion for a resolution

Recital H

Motion for a resolution

Amendment

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,**

H. whereas there is a major **debate** 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 invest more into adequate assessment of nanomaterials to close the knowledge gaps and to develop and implement as fast as possible, and, in collaboration with its agencies and international partners, methods of evaluation and an appropriate and harmonised metrology and nomenclature,**

Or. en

Amendment 5

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 32; 33 falls

Motion for a resolution

Recital Hd (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; whereas it is essential to allocate sufficient resources for research on the safe development and use of nanomaterials,

Amendment 6

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 89 (first part)

Motion for a resolution

Paragraph 9

Motion for a resolution

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;

Amendment

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;

Or. en

Amendment 7

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 65 (third part), 89 (second part), 91, 92, 104, 105

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, e.g. via the establishment of a special European Fund within FP7; furthermore 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;

Bloc C: Definitions

Amendment 8

PPE-DE, PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 13 (first part); 14 falls

Motion for a resolution

Recital D and Da

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 significant lack of knowledge and information, leading to** disagreement and political struggles, starting **at the** level of definitions:

- a) concerning the size: approximate indication of the size (“in the order of 100 nm or less”) versus a specific size range (“between 1 and 100 nm”),**
- b) concerning different/new properties: different/new properties due to size effects as an independent criterion versus using such properties as an additional criterion for the definition of nanomaterials,**
- c) concerning problematic properties: limitation of the definition of nanomaterials to certain properties (e.g. insoluble or persistent), or not making such limitations,**

Da. 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 "having one or more dimensions of the order of 100 nm or less", and often distinguishing between:

*- nano-objects, defined as “discrete pieces of 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,*

Or. en

Amendment 9

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 13 (last part) and 74; first part of 73 (intro plus first two indents) fall

Motion for a resolution

Paragraph 7 a and 7 b (new)

Motion for a resolution

Amendment

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

7b. Calls on the European Commission to promote the adoption of a harmonized definition for nanomaterials at the international level and to adapt the relevant European legislative framework accordingly,

Or. en

Bloc D: General regulatory aspects

Amendment 10

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing partially Amendments 24 and 60

Motion for a resolution

Citation 6 a (new)

Motion for a resolution

Amendment

- having regard to 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,

Or. en

Amendment 11

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing partially Amendments 24 and 60

Motion for a resolution

Citation 8 a (new)

Motion for a resolution

Amendment

- having regard to 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, Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, and 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, to 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, and to to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients,

Or. en

Amendment 12

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment complementing Amendments 21 and 87

Motion for a resolution

Citation 9 a (new)

Motion for a resolution

Amendment

- having regard to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising,

Or. en

Amendment 13

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 12, 16, 22, 53 and EMPL 6; 39/40 fall

Motion for a resolution

Recital L a (new)

Motion for a resolution

Amendment

La. whereas nanomaterials should be covered by a multi-faceted, differentiated and adaptive body of law based on the precautionary principle and on the principle of producer responsibility to ensure the safe production, use and disposal of nanomaterials before the technology is put on the market, while avoiding systematic recourse to general moratoria or undifferentiated treatment of different applications of nanomaterials,

Or. en

Amendment 14

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 15

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, personal care products, cleaning products, food or energy makes it impossible to introduce a single regulatory framework at Community level,

Or. en

Amendment 15

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 36 and 37

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 ***rather limited due to the*** absence of information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits, ***which also makes it difficult to judge their specific added value compared to conventional technologies, materials and substances,***

Or. en

Amendment 16

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 38

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 only a ***general*** overview of ***the*** relevant Community legislation, without considering the specific nature of nanomaterials and the resulting challenges,

Or. en

Amendment 17

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 47

Motion for a resolution

Recital L f (new)

Motion for a resolution

Amendment

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

Or. en

Amendment 18

PPE-DE, PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 54 and 55

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 ***use of nanomaterials should respond to the real needs of citizens and that their*** benefits can only be realised ***in a safe and responsible manner*** within a clear regulatory ***and policy*** framework ***(legislative and other provisions)*** that ***explicitly*** addresses ***existing and expected applications of nanomaterials as well as*** the very nature of potential ***health, environmental and*** safety problems ***over their life cycle***;

Amendment 19

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 58; 56/57 fall

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. **Does not agree**, in the absence of any nano-specific provisions in Community law, **with the Commission's conclusion** 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 **unable to address** their risks;

Amendment 20

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment; 59 and 61/62 fall

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

Amendment 21

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 65 (first part); 63/64 fall

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 assessment, and without adequate consumer information about these uses;***

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 the use and on the safety of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers;***

Or. en

Amendment 22

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 67, 69, 70, 71, 72, 73 (third part), EMPL 5 (first part), EMPL 11; 72 falls

Motion for a resolution

Paragraph 6

Motion for a resolution

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 all applications of nanomaterials in **consumer products or in products leading to discharges to the environment**;

6. Calls on the Commission to **review** all relevant legislation **within two years** to **implement** the principle "no data, no market" for all applications of nanomaterials in products **with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed**;

Or. en

Amendment 23

PSE, ALDE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 60

Motion for a resolution

Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Considers it particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals (REACH, biocides), food (foodstuffs, food additives, food and feed products from genetically modified organisms), relevant legislation on worker protection, as well as legislation on air quality, water quality and waste;

Or. en

Amendment 24

PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 66

Motion for a resolution

Paragraph 7 b (new)

Motion for a resolution

Amendment

7b. Considers that products containing nanomaterials that present a risk to human health due to exposure of workers or consumers or an unacceptable risk for the environment should not be placed on the market;

Or. en

Bloc E: REACH

Amendment 25

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 17 and 18

Motion for a resolution

Recital E and La (new)

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,

deleted

La. whereas in the context of REACH, it has already been agreed that further guidance and advice on nanomaterials, in particular on substance identification, as well as an adaptation of risk assessment methods is needed,

Or. en

Amendment 26

PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 41 and 42

Motion for a resolution

Recital Lb (new)

Motion for a resolution

Amendment

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

- the tonnage thresholds might not be adequate, as the properties and potential risks of nanomaterial are determined to a greater extent by particle number, surface structure and surface activity than by their tonnage,

- 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 27
PSE, Greens/EFA, GUE/NGL
Consolidated amendment replacing Amendments 77

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

Bloc F: Inventories, labelling and certain other regulatory aspects

Amendment 28
PSE, Greens/EFA, GUE/NGL
Consolidated amendment; 19/20 fall

Motion for a resolution
Recital F

Motion for a resolution

Amendment

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,

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 use "nano-claims", as the term "nano" seems to have a positive marketing effect, they are opposed to objective labelling requirements,

Or. en

Amendment 29

PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 21

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 their 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 30

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment; 23 falls

Motion for a resolution

PE423.726v01-00

20/23

AM\778360EN.doc

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, ***but fail to provide reliable information about current uses,***

Or. en

Amendment 31

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 65 (second part), 75, 76

Motion for a resolution

Paragraph 7 d (new)

Motion for a resolution

Amendment

7d. Calls on the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as e.g. recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time;

Or. en

Amendment 32

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 85 (first part) and 86; 83/84 fall

Motion for a resolution

Paragraph 8

Motion for a resolution

Amendment

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

8. Reiterates its call for **the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labelling of the product (e.g. in the list of ingredients, the name of such ingredients should be followed by the word 'nano' in brackets)**;

Or. en

Amendment 33

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 87

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 34

PPE-DE, PSE, ALDE, Greens/EFA, GUE/NGL

Compromise amendment replacing Amendments 85 (last part), EMPL 8, EMPL 9 and EMPL 11

Motion for a resolution

Paragraph 7 i (new)

Motion for a resolution

Amendment

7i. Underlines the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials;

Or. en

Amendment 35

PSE, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendments 110; 107/108/109 fall

Motion for a resolution

Paragraph 12

Motion for a resolution

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;

Amendment

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

Or. en