THE FUTURE EU ACTION PLAN ON NANOTECHNOLOGY:

A NEW CHANCE TO GET THINGS RIGHT

ANEC/BEUC input to the Commission's public consultation
"Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015"

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Summary

Consumer organisations acknowledge that nanotechnology may bring important benefits but are concerned that they may also pose new risks which have never been evaluated. In spite of a drastic lack of knowledge about the safety of nanomaterials and nanotechnologies and early warnings, consumer products containing nanomaterials and nanotechnologies continue to come on to the EU market as illustrated by the ANEC/BEUC inventory of November 2009[1].

The EU 2004-2009 Action Plan on nanosciences and nanotechnologies had unfortunately not been shaped with a view to put environment, safety and health at the center of the technology development. In view of its upcoming revision, we strongly call for the 2010-2015 EU Action Plan to take account of consumer-relevant concerns. In this paper, we make concrete proposals for actions to be included in the future Action Plan. In particular, we urge for the future Action Plan to:

- Carefully and objectively **assess the risks and true benefits** posed by the use of nanotechnologies and nanomaterials to human health, safety and the environment;
- Urgently **address** the main consumers' concerns such as the **lack of knowledge and transparency about products** on the market containing nanomaterials and the lack of proper consumer product information;
- Put in place a pro-active governance approach at EU level by **developing specific nano-regulations** and better implementing existing ones to provide a high level of safety for consumers;
- Increase the pace of **revision of existing regulations** in order to meet the specific characteristics of nanotechnologies and nanomaterials
- Develop new policy actions aimed at establishing a **mandatory reporting scheme** for the notification of the use of nanomaterials and a **public inventory of nanomaterials** which are used in consumer products;
- Increase and support funding for **research regarding health, safety and environmental aspects** of nanotechnologies and nanomaterials;
- Set up **a long-term societal dialogue** in order to increase consumer awareness and knowledge about nanotechnologies and nanomaterials.

[1] ANEC/BEUC inventory of products claiming to contain nanoparticles, Nov 09, available on ANEC and BEUC websites at www.anec.eu and www.beuc.eu

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Introduction

The EU 2005-2009 Action Plan for Nanosciences and Nanotechnologies[2] came to an end in December 2009 and the European Commission is planning to develop a new action plan for the time period 2010-2015. In this context, the Commission has recently launched a public consultation[3] that takes the form of an online questionnaire in order to gather stakeholders' opinions and ideas for the new action plan and the consultation will end on 19th February 2010.

ANEC and BEUC have contributed to the consultation by filling in the Commission's questionnaire online[4] but felt frustrated about the nature of the consultation that did not allow us to develop our views and recommendations further to the Commission. This paper is therefore a complementary contribution of our online contribution aiming at better explaining the views we put forward in our answers and developing on our recommendations for an ambitious and efficient future action plan on nanomaterials and nanotechnologies. In preparation for it, ANEC and BEUC considered not only the questions raised by the Commission in the public consultation's document but more importantly the recent Commission Communication on the second implementation report[5] of the 2005-2009 Action Plan.

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2 COM(2005) 243.
3 Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015.
4 Contribution available on the ANEC and BEUC websites. The Commission may also decide to publish individual contributions on its website after the consultation's closing date (19 Feb. 2010).
5 Commission Communication COM(2009) 607.

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1. Overall comments

We have long deplored the fact that the 2004-2009 Action Plan had not been shaped (and implemented) with a view to put environment, safety and health at the center of the technology development. Although we acknowledge that some actions have been undertaken (e.g. adoption of the recommendation for a Code of Conduct for responsible nanosciences and nanotechnologies research[6]), the previous action plan consisted mainly of developing research aimed at fostering innovation and promoting the interest of industry thereby making the EU competitive in the nanotechnology area. However, not sufficiently ambitious has been done in view to ensure the sustainable and safe development of this technology for our society.

The new action plan is THE opportunity for the Commission to get things right from a consumer point of view. In light of the concerns raised by nanotechnologies and nanomaterials, in particular regarding their safety, environmental and health aspects, much more needs to be done to reassure citizens and consumers that in the future action plan, a right and fair balance is aimed for between economic benefits on the one hand and with societal, social and environmental benefits on the other hand. In particular, efforts with respect to societal dialogue, adaptation of regulations, market transparency and monitoring, and safety assessment must be stepped up as a matter of urgency. Ambitious and forward looking actions in these areas must constitute the core of the next Action Plan and the Commission must ensure that the necessary resources and efforts are foreseen. In this paper, we make recommendations for specific actions that would help deliver tangible results and progress under these four headlines. We also make proposals for other actions to be foreseen in order to ensure the sustainability of the technology. We appeal to the Commission to include these actions in the next Action Plan and to take our concerns into account.

2. Reviewing and adapting legislation

Given the rapid development and use of nanotechnologies and nanomaterials, it is crucial and particularly urgent to adapt nano relevant regulatory measures in order to safeguard consumer health and safety, as well as the environment. As already raised in our policy position of June 2009[7], we are convinced that regulatory measures ought to be urgently taken without further delay to protect health, safety and the environment.

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6 C(2008) 424.

7 Joint ANEC/BEUC position "Nanotechnology: Small is beautiful but is it safe?", June 2009.

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Although we consider it a late decision, we welcome that in the second implementation report of the 2004-2009 nano action plan, the Commission stresses the need to review the adequacy of regulation, adapt implementation instruments and make regulatory change when necessary, and engage where possible with international developments[8].

To this aim, the Commission announced its commitment to present an updated regulatory review in 2011[9], where particular attention to the points raised by the European Parliament[10] and the European Economic and Social Committee[11] will be given. Depending on needs, the Commission commits to propose regulatory changes.

We call on the Commission to:

a) **Undertake a thorough review of all EU legislation that is relevant to nanomaterials and nanotechnologies by 2011** (and not simply evaluate the need to review legislation)

   The review should address consumer protection policies and product safety legislation. It should also encompass chemical legislation such as REACH, and environmental[12] and workers' protection legislation. In particular, the review should address the adequacy of specific legal safety requirements such as limit values for certain chemicals in products. It is important to foresee the adaptation of such specific requirements in legislation while fostering standardisation developments for technical specifications only such as nomenclatures and test methodologies.

   Further to the review, the Commission should publish an extensive report highlighting data gaps and needs for adapting existing relevant legislation (e.g. specific legal requirements) and identifying follow up actions that ought to be undertaken to fill in those gaps. The report should include a clear timeline for the adaptation of legislation or the establishment of new ones if deemed necessary.

b) **Close the regulatory gaps in the field of nanotechnologies and nanomaterials as soon as possible.** This should be done either through adapting existing legislation or developing new legislation

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8 COM(2009) 607, p.10.
9 COM(2009) 607, p.7.
10 European Parliament's Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI)).
11 Opinion of 25 February 2009 on the Communication on Regulatory Aspects of Nanomaterials, INT/456.
12 E.g. WEEE Directive, RoHS Directive.

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In its 2008 Communication on nanomaterials[13], the Commission had concluded that current regulations are suitable with regard to the use of nanotechnologies and the management of related risks. ANEC and BEUC expressed a strong disagreement with this conclusion on several occasions: concerns about regulatory deficits have been raised repeatedly and ought to be addressed as a matter of urgency in order to ensure comprehensive and consistent product life cycle analysis and risk identification and upfront management.

The Commission should close regulatory gaps that have already been clearly identified and demonstrated[14] without waiting for the legislative review to be finished. With regard to specific provision that should be included in European product safety legislation, please refer to section 4.

c) **Improve the implementation of legislation**[15] through e.g. increased market surveillance and control activities, empowered related authorities and improved cooperation between Members States and non-EU countries.

3. Concrete recommendations to adapt legislation related to consumer products that contain nanomaterials

In order to ensure that European legislation is adapted to nanomaterials, we call for the Commission to undertake the following actions:

a) **Make clear reference to nanomaterials in all legislative texts governing sectors concerned by nanosciences and nanotechnology applications**

This should be done by e.g. introducing a legal definition for nanomaterials and adopting nano specific provisions in existing legislation.

b) **Adopt legal definitions to support defined regulatory requirements**

The lack of specific definitions in legislative texts leads to legal uncertainties and hampers the development of regulatory requirements. These definitions should be consistent with those developed by independent scientific bodies, such as the EU Scientific Committees. The EU should work towards the development of legal definitions of nanomaterials and nanotechnologies for all EU legislation. Although these definitions may not necessarily be the same than those used in the fundamental research area, they should be coherent with the latter. They should however remain clear and easily applicable to ensure proper enforcement of the legislation.

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13 Commission Communication "Regulatory aspects of nanomaterials", COM(2008) 366.

14 Such as the inadequacy of volume thresholds that are set for chemicals' registration and safety assessment in the REACH Regulation.

15 This action is identified in the consultation document "Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015", section 8 "Improve the implementation of existing legislation".

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c) **Ensure the application of the precautionary principle**

It is important to ensure that the precautionary principle is applied in the field of nanotechnologies and in particular in product safety and consumer policies that are relevant to nanomaterials. There are major knowledge gaps in all phases of the risk assessment of nanomaterials hence scientific bodies call for the precautionary principle to be applied. This principle should be explicitly identified as a driving principle for all actions foreseen in the action plan and ought to be introduced as a basis for all nano-relevant legislation.

d) **Require a pre-market safety assessment of nanomaterials before they are allowed to be used in products**

It is crucial that nanomaterials and products that contain nanomaterials are fully risk-assessed by independent Scientific Committees before they are allowed on the market. This is particularly important for nanomaterials that are intended to be used in consumer products with which consumers come in direct, close or regular contact (e.g. food products) or in products leading to important impacts on the environment. The risk assessment should be performed taking into account all steps of the life-cycle of the products.

The "no data - no market" principle should apply. Industry should be required to provide data about the identification and specification of the substance, the quantity in which the substance is used, the toxicological profile of the substance and relevant safety data, information about the test methodologies used and finally, reasonably foreseeable exposure conditions.

e) **Introduce labelling requirements**

In the case of products that must indicate a list of ingredients (e.g. food), the name of the ingredient in nano form should be followed by the word 'nano' in brackets. This labelling provision would not constitute a warning as such; it would rather present factual information about the ingredients used herewith allowing consumers to make informed choices and judgements about any potential risks or benefits involved. This approach would also help traceability of products and surveillance of potential effects. We are also convinced that this will also help evaluate the level of consumer and environmental exposure to nanomaterials.

For products that do not contain a list of ingredients, the need for labelling should be evaluated on a case-by-case basis, taking into account the level of exposure and related potential risks.

f) **Ensure specific safety requirements are adapted to the characteristics of nanomaterials** (e.g. content limit value for certain chemicals in products)

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4. Market transparency and monitoring

Today, identifying consumer products that contain nanomaterials is barely possible. Data about what is currently on the market or in the pipeline, and information about use and exposure is urgently needed. The establishment of robust mechanisms for market transparency and monitoring is urgently needed in order to:

- ensure that the public receive the information they need to make informed judgements and decisions about the use of nanomaterials and nanotechnologies in relation to consumer products;
- allow effective regulation as regulators can not make decisions based on speculations. In particular, given the significant gaps in knowledge, market data are particularly crucial to provide information on exposure and exposure pathways that are needed for identifying risk management measures.

In this context, we welcome as a first step the Commission's announced intention to present information on types and uses of nanomaterials, including safety aspects in 2011[16]. We urge the Commission to be proactive and ambitious and to set up mechanisms to comprehensively monitor the market and beyond, adopt measures to create adequate conditions for market transparency.

ANEC and BEUC call on the Commission to:

a) **Establish a mandatory reporting scheme** through which industry would have to notify the use of nanomaterials, the quantity they produce and the products in which nanomaterials are contained.

Considering the UK and US experiences with voluntary reporting schemes that failed to live up to expectations, it is crucial that the EU reporting scheme is made mandatory. Such an approach has already been taken up by Canada and France who are going to institute national mandatory reporting schemes. The Commission may need to consider how best to link this scheme with existing reporting systems of chemicals such as those foreseen under REACH and the new Cosmetics Regulation.

b) **Set up an authoritative / official inventory of all nanomaterials that are used in consumer products**

This inventory should be made publicly available in order to ensure transparency and contribute to building consumers' confidence. It should contain information as to the types, quantities, uses and safety aspects of nanomaterials and must be based on the mandatory reporting scheme mentioned above.

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[16] COM(2009) 607, p9

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c) **Require clear and truthful information on consumer products**

In particular, the Commission should propose measures with regard to the labelling of consumer products (see section 3) but also the substantiation of 'nano' claims[17]*.*

d) **Develop traceability mechanisms and ensure information provision** all along the value chain, from producers to consumers and recyclers, following the entire life-cycle of products ('cradle to cradle')

5. Need for allowing risk assessment and risk management throughout the product life cycle

Significant gaps in knowledge must be addressed for regulators to adequately assess the risk of nanomaterials.

ANEC and BEUC call on the Commission to:

a) **Support the development of specific test methods for nanomaterials**

Traditional risk assessment methodologies have been shown to be inadequate for taking account of all characteristics of nanomaterials. Safety and risk assessment methodologies taking account of all characteristics of nanomaterials ought to be developed and harmonised. Standardisation could be used to establish such methods and other technical specifications. Research allowing classifying nanomaterials would also be complementary.

b) **Commission and support research regarding health, safety and environmental (HSE) aspects** of nanotechnologies and nanomaterials

The Commission should ensure that priority is given to research on HSE issues. This includes for instance research to allow identification of nanomaterials and understanding of their behaviours, but also toxicology and ecotoxicology research. Public funding to research on HSE implications ought to be increased drastically. So far, the majority of research resources in particular under the previous action plan have been allocated to innovation and commercial developments. In the early stages of development, we urge the Commission to restore the balance and significantly increase the proportion of resources devoted to HSE research. Prioritisation of areas for research funding would be an important field with which the public could be engaged.

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[17] This action is identified in the consultation document "Towards a strategic nanotechnology action plan (SNAP) 2010-2015", section 9 "Require adequate information on consumer products (e.g. claims verification, labelling of consumer products".

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c) **Support the generation of data regarding exposure of workers, consumers and the environment**[18] on the basis of adequate measuring tools

So far, research on exposure has focused on workplace exposure[19]*; although these efforts must be pursued, more attention to consumers and environment exposure assessments is urgently needed.*

d) **Assess the relevance and effectiveness of the EC voluntary Code of Conduct for responsible nanosciences and nanotechnologies research**[20]

A revision of the Code of Conduct is planned for 2010 and a public consultation has already been carried out by the Commission[21]*. In case the code of Conduct would be shown to be ineffective or insufficient, as ANEC and BEUC expect, we urge the Commission to take action in order to ensure that research in this area will be made in the best responsible and sustainable manner possible in the future.*

e) **Give mandate to the EU Agencies to review and adapt safety and risk assessment procedures and guidelines**

For instance a mandate could be given to EFSA regarding the guidelines that exist for food additives, supplements, packaging and novel foods. Such mandates to the EU Agencies would ensure that:

i. Nanomaterials are explicitly identified and adequately characterised in the evaluation dossiers;

ii. Risk assessment approaches take account of the specific risks associated with the particular characteristics of nanomaterials.

f) **Develop research on ethical, legal and social implications (ELSI) of nanotechnologies and nanomaterials**

g) **Promote scientists' capacity building to communicate independent and balanced information** on the benefits and risks associated with the use of nanotechnology, in a transparent manner

h) **Pursue and reinforce support to collaboration, networking and knowledge sharing among researchers**, in particular in the area of toxicology, ecotoxicology and risk assessment research[22]

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[18] The accompanying document (SEC(2009)1468) to the second implementation report itself indicates that the activity "Promote safe and cost-effective measures to minimize exposure of workers, consumers and the environment (…)" has shown "(…) relatively little progress".

[19] SEC(2009)1468, p28.

[20] EC Recommendation C(2008) 424.

[21] http://ec.europa.eu/research/consultations/nano-code/consultation_en.htm

[22] In document SEC(2009)1468, this action area is said to be "partially fulfilled". We do not fully agree with this statement and consider that more efforts must urgently be undertaken.

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6. Ensuring responsible industrial innovation and technology development

As highlighted by the Commission, there is a need to strengthen the mechanisms available for industrial innovation, stressing the concept of open innovation and to facilitate technology transfer.

ANEC and BEUC call on the Commission to:

a) **Apply the "no data – no market" principle to drive safe and responsible product developments and technological innovation**

The Commission should establish the adequate regulatory conditions to ensure that product developments and technological innovation are inseparable from the evaluation of health, safety and environmental impacts. The "no data - no market" principle ought to be considered as a basic principle in the area of nanotechnologies and nanomaterials (see section 4).

b) **Foster innovation that is driven by public expectations and societal demands** (e.g. in the areas of environmental protection and medical treatments)

7. Societal dialogue and access to information

We welcome the Commission's conclusion in its second implementation report on the existing action plan that a societal dialogue should be implemented. The Commission also states that public opinion and issues related to consumer, environmental and worker protection ought to be monitored. We agree with this statement and consider that specific actions ought to be foreseen in order to improve the present EU governance related to nanotechnologies, guarantee full transparency and ensure public engagement and effective dialogue with citizens.

Under the future Action Plan, we call on the Commission to undertake the following actions:

a) **Support communication about nanomaterials and nanotechnologies, related benefits and risks as well as uncertainties** through media designed to give the public easy access to balanced and reliable sources of information

Past experience[23] has shown that citizens including consumers are willing to know about nanotechnology and should be given the power and means to make their mind about it and react in case of a damage.

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[23] E.g. Which? Consumer panel in the UK, VZBV Consumer survey in Germany, Publifocus undertaken in Switzerland.

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b) **Develop, encourage and support public engagement activities** with a view to steering the development of nanotechnologies in directions which are socially desirable and publicly negotiated

Public engagement activities, such as effective participatory processes and public dialogues, allow the public to fully engage into decisions which will have an impact on their everyday life. Citizens should not only be given the opportunity to express their views and concerns but should also be reassured that their opinions are fully integrated in the development of such a technology and its applications, research programmes and regulatory advances.

Public engagement is a prerequisite to true communication and citizens' empowerment, and a condition for building public trust. This is also a way to prevent a full rejection of the technology and ensure the sustainable development and use of nanotechnologies and nanomaterials.

We strongly support all public engagement activities (including dialogues, citizens' juries and public debates) that have already been undertaken at various levels including at European level and national level[24]*. However these actions are still very limited in number and geographically (only a few Member States have taken initiatives) and should be improved and multiplied in the future.*

c) **Pursue and reinforce dialogue with stakeholders** and ensure that dialogue leads to identifiable outcomes and follow up actions

Unlike the Commission[25]*, we consider that dialogues that are being held between institutional bodies including the Commission and stakeholders in relation to nanotechnology are neither sufficient nor effective. At European level, our organisations have been taking part in DG SANCO's dialogue on nanotechnologies and nanomaterials. Although we appreciate that this dialogue has already been run for several years, we remain sceptical as to what concrete actions or decisions, such as the introduction of regulatory developments from the side of the Commission, they have lead to. For instance, in the past years, it has mainly been the European Parliament (and stakeholders) proposing the introduction of nano-specific provisions rather than the European Commission (cf. Cosmetics Regulation, Novel Foods Regulation).*

In addition, we are disappointed by the absence of a dialogue that would involve all the Commission's DGs concerned by nanotechnology. The future Action Plan should consider the establishment of dialogues involving a wide range of DGs and stakeholders. However, it is crucial that any dialogue ought to be set with a view

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[24] http://ec.europa.eu/nanotechnology/dialogues_en.html

[25] The accompanying document of the Action Plan 2005-2010 implementation report identifies the action area "Create the conditions for and pursue a true dialogue with the stakeholders concerning N&N (…)" as "partially fulfilled" (SEC(2009) 1468).

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to identifying key actions and policy instruments that ensure the sustainability of technology development.

In the third Nano Safety for Success Dialogue conference[26] *that was held in Brussels in November 2009, DG SANCO announced that four focused dialogues would be organised to ensure progress on some of the key issues that emerged during the conference and called on stakeholders to highlight the issues they considered as priorities. Although ANEC and BEUC already made concrete proposals for issues to be subject to dialogues, we would like to reiterate our call for these dialogues to lead to concrete actions and recommendations*[27]*.*

d) **Develop measures that guarantee public access to information** including safety data and list of nano-products available on the market (see section 4)

e) **Develop research about public perception and understanding of nanotechnologies and nanomaterials**

The Eurobarometer special survey on science and technology[28] *carried out between January and February 2005 is a good example of the types of actions that could contribute to increasing policy-makers' knowledge about citizens' opinions, needs, wills and concerns in relation to nanotechnologies and nanomaterials. We encourage the Commission to consider, among other actions, the launch of a European-wide citizens' survey on nanotechnologies, nanomaterials and related applications in the future Action Plan.*

8. Enhancing coordination and exchange of information

ANEC and BEUC call on the Commission to **pursue development of collaboration between European institutions, Member States, non-European countries, and with international organisations and stakeholders.**

END.

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[26] http://ec.europa.eu/health/ph_risk/ev_20091103_en.htm

[27] LDE/2009277/cma – ANEC Ref.: ANEC-PT-2009-Nano-023, 03/12/2009.

[28] Special Eurobarometer "Social values, Science and Technology", published in June 2005 and available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_225_report_en.pdf

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