

Reply form
for the public consultation on
Proposal for a Commission definition of the term "nanomaterial"
Send to ENV-NANO-CONSULTATION@ec.europa.eu

Name	Azoulay / Duprez
Surname	David / Louise
Title	Managing Attorney / Policy Officer
Name of organisation	<p>Centre for International Environmental Law (CIEL) European Environmental Bureau (EEB)</p> <p>On behalf of:</p> <ol style="list-style-type: none"> 1. Centre for International Environmental Law (CIEL) 2. European Environmental Bureau (EEB) 3. Client Earth 4. European Environmental Citizens' Organisation for Standardisation 5. Food and Water Watch Europe 6. Friends of the Earth Europe 7. Greenpeace Europe 8. Health & Environment Alliance 9. Health Care Without Harm Europe 10. Pesticide Action Network Europe 11. Women in Europe for a Common Future 12. Action For Breast Cancer Foundation 13. Associazione Malattie da Intossicazione Cronica e/o Ambientale 14. Bund für Umwelt und Naturschutz Deutschland e.V. (BUND/ FoE Germany) 15. Deutscher Naturschutzring 16. EU Environmental Bureau Austria / EU-Umweltbüro 17. Federation inter-environnement Wallonie 18. France nature Environnement 19. Initiativ Liewensufank 20. Institute for Sustainable Development 21. International Baby Food Action Network (IBFAN) Luxembourg 22. International Chemical Secretariat – ChemSec (Sweden) 23. Mediterranean Information Office for Environment, Culture and Sustainable Development (MIO –ECSDE) 24. Pestizid Aktions-Netzwerk e.V. / Pesticide Action Network - Germany 25. The Irish Doctors Environmental Association (IDEA) 26. APROMAC (Associação de Proteção ao meio Ambiente de Cianorte) (Brésil) 27. Center for Food Safety (USA) 28. Centro de Análisis y Acción en Tóxicos y sus Alternativas (CAATA) (Mexico) 29. Citizen against chemical pollution (Japan)

	<p>30. Commonweal (USA)</p> <p>31. Confederacion General del Trabajo de la Republica Argentina</p> <p>32. Food and Water Watch US</p> <p>33. Friends of the Earth United States</p> <p>34. Grassroots Alliance PERESVET (Russia)</p> <p>35. Humane Society International (USA)</p> <p>36. Institute for Agriculture and Trade Policy (IATP) (USA)</p> <p>37. International Center for Technology Assessment (ICTA) (USA)</p> <p>38. International PoPs Elimination Network (IPEN)</p> <p>39. Island Sustainability Alliance (C.I.) Inc. (Cook Islands)</p> <p>40. Nanotechnology Citizen Engagement Organization (NanoCEO) (USA)</p> <p>41. National Resources Defense Council (NRDC) (USA)</p> <p>42. National Toxic Network Inc. (Australia)</p> <p>43. Pesticide Action Network Aotearoa (New Zealand)</p> <p>44. Red de Accion sobre Plaguicidas y sus Alternativas para América Latina (RAP-AL)/ Pesticide Action Network Latin America (Mexico)</p> <p>45. SEEPOM (Société d'Education Environnementale et de Protection des Oiseaux au Maroc)</p> <p>46. Toxisphera (Brazil)</p>
Postal address	<p>Centre for International Environmental Law (CIEL) Rue des Savoises, 15 1205 Geneva Switzerland</p> <p>European Environmental Bureau (EEB) 34, Bd. de Waterloo B-1000 Brussels Belgium</p>
Country	Switzerland / Belgium
E-mail address	dazoulay@ciel.org / louise.duprez@eeb.org
Phone number	CIEL: +41 22 321 47 74 EEB: +32 2 289 13 07

*With this consultation we are seeking your reasoned opinion, to be described below. Please note we **do not accept** comments in track changes in the European Commission proposed text. The consultation closes on 19 November 2010.*

European Environmental Bureau (EEB) ID number: 06798511314-27

International and European environmental, health, and animal protection NGOs welcome the publication of a European Commission draft recommendation on the definition of the term "nanomaterial".

The adoption of an overarching, broadly applicable definition of nanomaterials will enable long awaited regulatory activities to start catching up with market development to ensure safe and responsible product development.

In particular, NGOs welcome the specific provisions of:

- **Paragraph 7**, calling for a regular review of the definition;
- **Paragraph 8**, in particular provisions based on SCENIHR's recommendation to base size distribution on particle numbers rather than mass concentration;
- **Paragraph 9**, in that it specifies the inclusion of aggregates and agglomerates,
- **Paragraph 10**, about the provision of additional guidance, but insist that the preparation and implementation of such guidelines should not delay the use and implementation of the recommended definition, nor undermine the objective of high level of protection of humans and the environment;
- **Paragraph 11**, in particular the reference to the possible inclusion of other materials, notably, materials such as fullerenes, smaller than 1nm;
- **Paragraph 12**, as the only way to give coherence to the burgeoning field of nanomaterials regulation in the EU.

On the draft proposed definition itself, environmental, health and animal protection NGOs would like to make the following comments:

The present understanding of nanomaterials properties and potential health and environmental impacts is still very limited and therefore warrants much research and careful evaluation.

Based on early evidence showing that some particles up to several hundred nanometers share many of the novel properties of nanomaterials under 100nm that are critical for risk assessment¹, and on SCENIHR's acknowledgment that science cannot set an upper size limit value for nano-properties, NGOs favour a larger size range (i.e. 0,3 to 300 nm²) to define nanomaterials. This larger size range would allow more research and a better understanding of all nanomaterials, and whether particular nanomaterials may present concerns for human health or not³, and importantly, in what size range.

In this context, and as described in the technical comments provided to the SCENIHR's opinion, we call for the undertaking of a sensitivity analysis, to verify that the adopted size range captures as much material as possible about which there is already concern, while avoiding materials that do not give rise to nano scale-related concerns. This study should start immediately after the adoption and implementation of the proposed definition in order to be considered in the future revision process of the definition mentioned in paragraph 7 of the Commission's proposal.

In the meantime, signatories welcome the adoption of a reasonable and workable 1% threshold of the particle number size distribution as a way to include in the definition, and put under scrutiny, certain materials, which may exhibit nano specific hazardous properties in the larger size range.

Should this 1% threshold be modified pursuant to this consultation, it is our position that the size range chosen in this definition (1-100nm) should also be modified to a higher range

¹ These novel properties include very high reactivity, bioactivity and bioavailability, increased influence of particle surface effects, strong particle surface adhesion and strong ability to bind proteins. Cedervall et al, 2007; Garnett and Kallinteri 2006; Linse et al. 2007.

² See for example Friends of the Earth Australia's Discussion paper on nanotechnology standardisation and nomenclature issues, August 2008, available at http://www.ecostandard.org/downloads_a/2008-10-06_foea_nanotechnology.pdf

³ As stressed by SCENIHR's opinion that "[the] uncertainty (...) warrants the careful evaluation of possible risks associated with nanotechnology products" and that "Although the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanomaterials, they may not be sufficient to address all the hazards (...) it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanomaterials" (SCENHIR-June 2007)

(such as 0,3-300 nm) to allow the definition to capture as much material as possible about which there is already concern (including fullerenes).

We would like to emphasise that any attempt to narrow the scope of a definition for nanomaterials at this stage could lead to potentially harmful substances escaping scrutiny, as well as to the potential exclusion in the future of substances that are presently not engineered to nano-sizes and configurations. Such a narrowed definition would deprive legislators of the necessary flexibility that is critical for the regulation of present issues, as well as for more complex upcoming challenges, including future generations of nanomaterials.

List of signatories:

- ***European NGOs***

Centre for International Environmental Law

Rue des Savoises, 15
1205 Geneva
Switzerland

European Environmental Bureau

Federation of Environmental Citizens Organisations
34, Bd. de Waterloo
B-1000 Brussels
Belgium

Client Earth

36 Avenue de Tervueren,
1040 Brussels
Belgium

European Environmental Citizens' Organisation for Standardisation

Mundo-B
Rue d'Edimbourg, 26
B-1050 Brussels
Belgium

Food and Water Watch Europe

Rue d'Edimbourg 26
Brussels 1050
Belgium

Friends of the Earth Europe

Postal address: Mundo-b building,
Rue d-Edimbourg 26,
1050 Brussels
Belgium

Greenpeace Europe

Belliardstraat 199
1040 Brussels
Belgium

Health & Environment Alliance

28 Boulevard Charlemagne
B-1000 Brussels
Belgium

Health Care Without Harm Europe

Rue de la Pépinière 1
1000 Brussels
Belgium

Pesticide Action Network Europe

Rue de la Pépinière 1
1000 Brussels
Belgium

Women in Europe for a Common Future

Sankt Jakobs Platz 10
80331 München
Germany

- *European national NGOs*

Action For Breast Cancer Foundation

27, Papa Pawlu V Street
Qawra, St. Paul's Bay
SPB 1111
Malta

Associazione Malattie da Intossicazione Cronica e/o Ambientale

A.M.I.C.A.
P.O .Box 3131
00121 Rome
Italy

Bund für Umwelt und Naturschutz Deutschland e.V. (BUND)

Friends of the Earth Germany

Am Köllnischen Park 1
10179 Berlin
Germany

Deutscher Naturschutzring

Koblenzer Straße 65
53173 Bonn
Germany

EU Environmental Bureau Austria

EU-Umweltbüro
Strozzigasse 10/7-9
1080 Vienna
Austria

Federation Inter-Environnement Wallonie

98 rue Nanon
5000 Namur
Belgium

France nature Environnement

81-83 bd Port-Royal
75013 Paris
France

Initiativ Liewensufank

20, rue de Contern
L-5955 Itzig
Luxemburg

Institute for Sustainable Development

Metelkova 6
1000 Ljubljana
Slovenia

International Baby Food Action Network (IBFAN) Luxembourg

GIFA
Avenue de la Paix 11
1202 Geneva
Switzerland

International chemical Secretariat (Chemsec)

P.O.Box 7005,
SE - 402 31 Göteborg
Sweden

MIO –ECSDE

Mediterranean Information Office for Environment, Culture and Sustainable Development
12, Kyrristou str. 105 56
Athens
Greece

Pestizid Aktions-Netzwerk e.V.

Pesticide Action Network - Germany
Nernstweg 32
D - 22765 Hamburg
Germany

The Irish Doctors Environmental Association

IDEA
Millbrook Clinic, Bandon,
Co Cork
Ireland

- *International NGOs*

APROMAC (Associação de Proteção ao meio Ambiente de Cianorte)

Rua Afonso Pena SN - Fundos da Extensão da UEM em Cianorte
CEP: 87200-000
CIANORTE - PARANÁ
Brazil

Centro de Análisis y Acción en Tóxicos y sus Alternativas (CAATA)

Amado Nervo 23, int 2, Col San Juanito, Texcoco. Edo de Mexico
CP 56121

Mexico

Center for Food Safety

660 Pennsylvania Ave., SE,
#302
Washington DC 20003
USA

Citizen against chemical pollution (Japan)

Z Bldg. 4F, 7-10-1 Kameido, Koto-ku,
Tokyo, 136-0071
Japan

Commonweal

PO Box 316
Bolin, CA 94924
USA

Confederation General del Trabajo de la republica Argentina

Secretaría de Relaciones Internacionales de CGTRA
Cevallos 520 4º Piso - Buenos Aires
Argentina

Food and Water Watch US

1616 P Street, NW
Suite 300
Washington, DC 20036
USA

Friends of the Earth United States

1717 Massachusetts Avenue, NW, Suite 600
Washington DC
20036-2002
USA

Grassroots Alliance PERESVET

Olega Koshevogo St., 80 of 12,
241029 Bryansk
RUSSIA

Humane Society International

2100 L St., NW
Washington, D.C. 20037
USA

International Center for Technology Assessment (ICTA)

660 Pennsylvania Ave., SE
Suite 302
Washington, DC 20003
USA

International PoPs Elimination Network (IPEN), secretariat

PO Box 7256
SE-402 35, Göteborg,
Sweden

Institute for Agriculture and Trade Policy (IATP)

2105 First Avenue South
Minneapolis MN 55404
USA

Island Sustainability Alliance (C.I.) Inc.

P.O. Box 492
Rarotonga,
Cook Islands

Nanotechnology Citizen Engagement Organization (NanoCEO)

1311 Lake View Ave.
Madison, WI 53704
USA

National Resources Defense Council (NRDC)

40 West 20th Street
New York, NY 10011
USA

National Toxic Network Inc. (Australia)

PO Box 173
Bangalow NSW 2479
Australia

Pesticide Action Network Aotearoa

PO Box 296
Ostend
Waiheke Island
Auckland 1843
New Zealand

**Red de Accion sobre Plaguicidas y sus Alternativas para América Latina (RAP-AL)/
Pesticide Action Network Latin America**

Centro de Estudios sobre Tecnologías Apropiadas de la Argentina
Rivadavia 4097
P.O. Box 89 (1727), Marcos Paz
Buenos Aires
Argentina

SEEPOM

Société d'Education Environnementale et de Protection des Oiseaux au Maroc

N°3 lot 1
Haj Kaddour
B.P : 48
Région de Meknes
Morocco

Toxisphera

Rua Afonso Pena SN - Fundos da Extensão da UEM em Cianorte
CEP: 87200-000
CIANORTE - PARANÁ
Brazil