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CONTENTS

Editorial

The present issue of *elni Review* (1/2011) covers a variety of recent international environmental law issues alongside two country-specific contributions on EEE-waste regulation in Zanzibar, Tanzania and chemical substances legislation in China respectively. The key focus of the current edition of the journal, is *chemical substances regulation*.

Three articles approach this topic from different points of view:

First off, *Gareth Callegy* provides an overview of the legal impacts of the "Chinese REACH" legislation; an amendment to Chinese law which recently entered into force. By comparing the legal obligations arising from Regulation (EC) No. 1907/2006 (REACH) and the Chinese pendant, he points out inter alia the legal issues which European registrants will face when marketing chemical substances to the "Middle Kingdom."

Subsequently, *Julian Schenten* analyses the state of affairs as regards the regulation of Nanomaterials in the food sector. Focusing on Regulation (EC) No. 258/97 on Novel Food, he identifies the weaknesses in terms of health protection and points out necessary key features which reasonable regulation of such chemical substances should have.

The third article concentrating on chemicals is by *Vito Buonsante*; it creates a bridge between the REACH Regulation and access to documents claims. In this context the author examines the interaction and gaps in the REACH and Aarhus Convention systems as well as the role of the European Chemicals Agency (ECHA).

The other contributions cover a variety of up-to-date legal issues:

Head of Legal at Friends of the Earth England, Wales and Northern Ireland, *Gita Parihar*, shows the legal impacts of the Cancun UN climate negotiations which took place in December 2010. In doing so, she develops a line of reasoning which remains relevant beyond the Bangkok Climate talks in April 2011.

Asking in his title 'A human right to a clean and healthy environment in Europe: Dream or reality?', *Jan Van de Venis* provides an introduction to the development of a human right to a healthy environment on a global scale. He analyses the ways in which this human rights-based approach to environmental issues evolved, what tangible benefits such a right could bring, along with where it currently stands globally and, more specifically, in Europe under the European Convention on Human Rights.

The contribution that follows, *Tania Van Laer* examines whether EU law allows Member States to justify, on the basis of animal welfare, unilateral measures that impose trade restrictions. At the same time she considers the main principles of the free movement of goods as well as the established view of the Court of Justice.

The final article outlines the electronic waste situation in Zanzibar, Tanzania. In the absence of consumer protection provisions and specific environmental guidelines to regulate the import of these products or manage their safe disposal, the small island state is failing to implement the principles of the Basel Convention. Against this background *Aboud S. Jumbe* presents the current activities of the Department of Environment, Zanzibar, which is now in the advanced stages of preparing a legal document which contains a set of regulations on the import, handling, and disposal of used and waste electrical and electronics equipment.

Finally, the issue covers recent developments regarding the situation of access to justice in Ireland – the only EU country in which the parliament has not ratified the 1998 UNECE Aarhus Convention.

Contributions for the next issue of the elni Review are very welcome. Please send them to the editors by September 2011.

Julian Schenten/Gerhard Roller

May 2011

elni Forum 2011

24th May 2011
in Brussels, Belgium

"Access to Documents at European Level – Key issues and practical experiences"

Bondine Kloostra presents key issues on access to documents regarding environmental information, including a recent decision of the ECJ (Stichting Natuur en Milieu). Vito Buonsante and Ludwig Krämer will present their practical experiences in access to documents, including the access to documents held by the European Chemicals Agency (ECHA). Eva Kruzikova will provide the point of view of the EU Commission.

This event will be held at the EU Liaison Office of the German Research Organisations (KoWi), Rue du Trône 98, 1050 Brussels, 8th Floor.

For more information about participation, including registration forms, please visit http://www.elni.org/elni-events.0.html.

Nanomaterials and European Novel Food law: The uncertain path to reasonable regulation

Julian Schenten

1 Introduction

Compared to their basic material, referred to as bulk, nanomaterials are equipped with new properties that are basically connected to their large surface in proportion to the small mass and increased mobility due to their size (a nanometer [nm] equals one billionth of a meter). A priori these properties are associated with economic and ecological opportunities. Possible applications of nanomaterials in nearly all branches of industry range from their use in the context of material efficiency where the substances allow innovations in the automobile industry or environmental technology, to consumer-related applications in pharmacology, cosmetics and medical science as well as the food sector. At the same time, their unique properties are also connected with possible risks to human health and the environment.

Community law has several legislations for managing the potential risks, e.g. the general chemicals Regulation (EC) 1907/2006 (REACh)[1], which as a principle also covers nanomaterials[2], or in the field of product legislation, e.g. Regulation (EC) 1223/2009 on cosmetic products[3] which inter alia sets out a notification procedure covering certain nanomaterials. Explicitly excluded from the scope of REACh are substances in food or feeding stuffs.[4] Such products fall within the scope of special legislation on food and related products.

The objective of the present article is to examine whether current regulations at the European level are capable of adequately controlling the risks associated with engineered nanomaterials of anthropogenic origin[5] (ENM)[6] in food products. In this context it is crucial to examine closely the Novel Food Regulation (EC) 258/97[7] and its attempted revision, which recently failed. A consideration of the legislative procedure and a discussion of the legislative bodies' different positions will also be included. In contrast, the regulatory controls of food contact materials[8] such as food packaging or food additives[9] would go beyond the scope of this article.[10] Prior to the legal analysis some remarks will be made about the state of the art regarding risk assessment and the application of ENM in the food sector.

2 Risk assessment of ENM and their application in food: What we (do not) know

2.1 Nano-related risks and their assessment

A good place to start is the risks arising from ENM that relate to their extremely small size. In several studies it has been observed that substances in the nanoscale may cause increased negative effects compared to their bulk counterparts.[11] Of most interest for the present article are possible impacts on human health that are attributable to the ingestion of ENM via the gastrointestinal tract. There is no consensus between scientists on the uptake of ENM via this exposure route. While some tests on animals found that specific nanoparticulate substances could reach the lymphatic system after absorption through the intestinal wall, others maintain that there is no uptake at all; this tie-game, combined with a lack of data, makes a final evaluation impossible.[12] The same applies with the question of the effects to the intestinal epithelium: While early in-vivo studies on particular fullerenes[13] showed that only a very small portion of the particles administered were absorbed and did not cause acute

1 Regulation (EC) No. 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh), OJ L. 136 of 29 May 2007, pp. 3-280.

2 For comprehensive information on this subject see S. Merenyi, M. Führ, K. Ordnung, *Regulation of Nanomaterials under present and future Chemicals legislation - Analysis and regulative options*, 1 elni 1-8 (2009) (3 et seq.).

3 Regulation (EC) No. 1223/2009 of 30 November 2009 on cosmetic products, OJ L. 342 of 22 December 2009, pp. 59-209.

4 Art. 2(5)(b) Regulation (EC) 1907/2006.

5 Besides there also exist natural nanomaterials. Milk for instance contains natural nanoparticles in the form of casein micelles.

6 For a comprehensive definition see S. Merenyi, M. Führ, K. Ordnung, *supra* note 2, 2; also see section 3.3.4(i).

7 Regulation (EC) No 258/97 of 27 January 1997 concerning novel foods and novel food ingredients, OJ L. 43 of 14 February 1997, pp. 1 – 6.

8 Such materials fall within the scope of Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food, OJ L. 338 of 13 November 2004, pp. 4-17; see also section 4.

9 Which fall within the scope of Regulation (EC) No 1333/2008 of 16 December 2008 on food additives, OJ L. 354 of 31. December 2008, pp. 16-33 and Regulation (EC) No 1331/2008 of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L. 354 of 31 December 2008, pp. 1-6.

10 For more detail, see NanoKommission Working Group 3, *Review of Nanomaterial and Nanoproduct Regulation* (2010), pp. 34 – 39, available at http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf.

11 D. Xiong, et al., *Effects of nano-scale TiO2, ZnO and their bulk counterparts on zebrafish: Acute toxicity, oxidative stress and oxidative damage, Sci Total Environ* (2011), doi:10.1016/j.scitotenv.2011.01.015. For comprehensive information see S. F. Hansen, *Regulation and Risk Assessment of Nanomaterials – Too Little, Too Late?* (2009), p. 29 et seq.

12 With further references H. F. Krug, P. Wick, *Nanotoxicology: An Interdisciplinary Challenge*, 50 Angew. Chem. Int. Ed. (2011), 2–21 (section 3.4).

13 Spherical molecules, which are made up solely of carbon atoms and – as for example in the case of the C-60 – have the structure of a football.

toxic effects, other studies reveal an acute cytotoxicity and genotoxicity for zinc oxide[14], titanium dioxide[15] and silicon dioxide[16] at relatively high concentrations.[17] On the basis of these and additional scientific results, however, consumer and environment protection associations draw a very gloomy picture of nanoscience applications relating to food.[18]

Despite the steady flow of – not infrequently contradictory – new scientific reports and information on nanoscale substances,[19] many problems regarding their risk assessment remain: We are facing a general lack of systematic screening, (long-term) testing and surveillance. Research is hampered as, for example, not only the properties of nanoscale substances differ completely compared to their bulk material counterparts, but also nanoparticulate substances with the same molecular structure and yet differing sizes (e.g. titanium dioxide with 20 nm or 80 nm) may cause significant differences as to their effects, making generalisations on potential impacts impossible. Moreover, in-vitro tests do not generally say much about the risks connected to their in-vivo exposure on human health and the environment.

Against the background of the above-mentioned scientific uncertainty, the European Food Safety Authority (EFSA) published an opinion of its Scientific Committee in March 2009 on the potential risks arising from nanotechnologies on food and feed safety.[20] In its document the Scientific Committee came to the conclusion that established international approaches to risk assessment can also, as a general rule, be applied to ENM. However, the committee furthermore states "*that a case-by-case approach would be necessary and that, in practice, current data limitations and a lack of validated test methodologies could make risk assessment of specific nano products very difficult and subject to a high degree of uncertainty*"[21] since appropriate "*risk assessment processes are still under development*".[22] As a result EFSA has launched a public consultation on its draft guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed.[23] Consideration will need to be given to the extent to which the recently published outcome of that consultation may resolve the difficulties pointed out.[24]

2.2 ENM applications in the food sector

In the quoted opinion EFSA's Scientific Committee also takes a position regarding the application of ENM in the field of food and feed. While a variety of available applications involving active food contact materials[25] has been identified by the authority, including polyethylene (PET) beer bottles with nano-clay gas-barrier or polypropylene food containers with nano-silver for antimicrobial action, the food industry stated to EFSA that apart from R&D *"[…] nanomaterials with new functionalities [ENM], [are] up to now not used in the food field…"*.[26] This evaluation generally applies regardless of sources like the ANAC/BEUC nanoproduct inventory[27] which lists 475 products (including the category 'food & beverage') available to European consumers and which claim to contain nanomaterials as these claims are not verified and there are currently no binding definitions for nanomaterials.[28] Given the economical opportunities associated with ENM – according to a report edited by the Allianz Group in co-operation with the OECD, the economic potential of innovation in the food and agriculture sector in terms of nanotechnologies could even exceed that of farm mechanisation[29]. Nonetheless it is very likely that industry will use such applications for future food production. Against this background there is a particular need for appropriate regulation of ENM in food.

14 Sold as nutritional additives and used as antimicrobial in food packaging.

15 In its small microparticle form widely used as food additive; nanoparticle form used as antimicrobial and U.V. protector in food packaging and storage containers and sold as food additive.

16 Particles a few hundred nm in size used as food additives, nano form touted for use in food packaging.

17 H. F. Krug, P. Wick, *supra* note 12, see section 4.3. for further references.

18 Friends of the Earth, *Out of the Laboratory and onto our Plates - Nanotechnology in Food & Agriculture*, 2008, p. 22 et seq.

19 See, for example, www.chemicalwatch.com with news reports on the issue on a nearly weekly basis.

20 EFSA, *Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety*, The EFSA Journal (2009) 958, 1-39, available at http://www.efsa.europa.eu/en/efsajournal/doc/958.pdf

21 See EFSA press release from 5 March 2009, http://www.efsa.europa.eu/en/press/news/sc090305.htm (28.01.2011). For the full opinion see EFSA, *supra* note 20.

22 EFSA, *supra* note 20, 2; see also the report EMERGNANO, carried by the UK based Institute of Occupational Medicine, giving a detailed review and analysis of research carried out worldwide on environment, health and safety aspects of ENM including issues relating to hazard, exposure and risk assessment. Regarding ENM in food the report concludes that "*very little is known in regard to potential exposure, uptake, toxico- dynamics/ kinetics of NPs through the ingestion route*" see IOM, *EMERGNANO Report* (2009), p. 119.

23 See http://www.efsa.europa.eu/en/consultations/call/scaf110114.pdf. Comments could be committed until 25 February 2011.

24 EFSA, *Scientific Opinion: Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain*, The EFSA Journal (2011) 2140, 1-36, available at http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf.

25 *Supra* note 8.

26 EFSA, *supra* note 20, 9 et seq.

27 The inventory and explanatory leaflet can be found on www.beuc.eu and www.anec.eu.

28 The German government's NanoKommission, *supra* note 10, 45.

29 The Allianz Center for Technology and Allianz Global Risks in co-operation with the OECD International Futures Programme, *Small sizes that matter: Opportunities and risks of Nanotechnologies Report*, p. 17 with further references.

3 Relevant laws in the food sector

First, food containing nanoparticulate ingredients are subject to the basic Food Law Regulation (EC) 178/2002[30] according to which the placing on the market of unsafe food is forbidden. Furthermore, under certain conditions the provisions of the Novel Food Regulation (EC) 258/1997 may become relevant. It is questionable, however, whether these sets of rules provide a reasonable regulation of ENM in foods.

3.1 Regulation (EC) 178/2002

As mentioned above, Art. 14(1) of Regulation (EC) 178/2002 stipulates that only safe food may be placed on the market, whereas food shall be deemed unsafe if it is considered to be injurious to health or unfit for human consumption (see also Art. 14(2)). According to 14(4), in determining whether any food is injurious to health the probable immediate, short-term or long-term effects of that food on the health of a person consuming it as well as its probable cumulative toxic effects should be taken into account, among other things,. Since health impairment needs to be "*probable*", general statements as to whether ENM would fall under this category are not possible; instead the decisions need to be made on a case-by-case basis. In addition, the regulation does not provide for any nano-specific tests. Ultimately the only person responsible for the safety of a food product is the particular business operator, Art. 17.

Then again, in view of the precautionary principle (see section 3.3.4(iii) below), Art. 7 prescribes that in situations where the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional and proportional risk management measures may be adopted. In this case the mere "*possibility*" may suffice for action to be taken. As shown in section 2.1, there are already several scientific sources indicating the potential toxic effects caused by the application of ENM in food. Against this background, it is conceivable that Art. 7(1) would constitute the basis for governmental urgent risk measures such as health warnings, immediate product re-calls, and maybe even total bans if unregulated usage of ENM in the food sector were to spread. However, since these measures would constitute drastic interventions in the economic rights of the producers, it is questionable whether the provision would force the authorities to take the necessary restrictive steps.

In short, Regulation (EC) 178/2002 is not capable of adequately controlling the risks associated with ENM in food products.

3.2 Novel Food Regulation (EC) 258/97

Regulation (EC) 258/97 applies to foods and food ingredients meeting two criteria: they have not been used for human consumption to a significant degree within the European Union before 15 May 1997, the date of the entry into force of the regulation, and they furthermore fall under one of the categories listed in Art. 1(2). Of this article points (c) "*foods and food ingredients with a new or intentionally modified primary molecular structure*" and particularly (f), as it refers "*to foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances*", appear to be relevant to ENM.[31] It may be assumed that the application of the nanotechnologies in order to modify foods or their ingredients – thereby causing "*significant changes […] which affect their nutritional value*" – constitute a "*production process not currently used,*" especially not to a significant degree before 15 May 1997.[32] As a result, ENM represent novel foods or food ingredients and subsequently fall within the scope of application of Regulation (EC) 258/97 according to which they must not present a danger for the consumer or mislead him or her (Art. 3).

The regulation requires mandatory pre-marked approvals of novel foods: Pursuant to Art. 4 et seq, the person intending to place a novel food on the Community market has to undergo an approval procedure executed by the Member State in which the product is to be placed on the market for the first time. In the course of this procedure the applicant must submit all "*necessary information*", including copies of studies being carried out, followed by an initial assessment of the application performed by the competent food assessment body of the respective Member State to consider whether or not the food or food ingredient requires additional assessment. The result of the additional assessment can be supplementary obligations like authorisations (Art. 7) or a specific labelling (Art. 8).

In light of EFSA's findings (section 2.1) and despite Commission Recommendation 97/618[33] outlining the

30 Regulation (EC) No. 178/2002 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, OJ L. 31 of 1 February 2002, pp. 1 – 24.

31 For the applicability of Art. 1(2)(e) to "foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" also comes into consideration whereas it is doubtful whether one might speak of ENM as "having a history of save food use", see A. Meisterernst et al., *Nanopartikel in Lebensmitteln und Kosmetika – wissenschaftliche und rechtliche Aspekte*, StoffR 4 (2006) , pp. 146 – 154 (151).

32 NanoKommission, *supra* note 10, 32; M. C. Bauer et al., *Nanotechnologie – Regulatorische und haftungsrechtliche Herausforderung*, StoffR 1 (2010), pp. 2 – 11, (3).

33 Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support

very comprehensive extent to which these safety assessments need to be performed; it is again uncertain whether this instrument is capable of reliably estimating nano-related risks.

In addition, the protective function of Regulation (EC) 258/97 concerning ENM can easily be levered: Particle size does not belong to the factors when considering the safety of a specific food. As a consequence, if a substance has already been approved in its bulk form, there is no regulatory trigger which would require a new mandatory safety assessment, if the same applicant uses the similar substance – now at the nanoscale – for the application originally applied for.[34] Moreover, if a particular nanoscale substance has already been approved as a food additive[35] irrespective of particle size – as is the case for titanium dioxide – such a substance does not even fall within the scope of Regulation (EC) 258/97.[36] All in all there are protection gaps which raise concern.

3.3 Failed revision of Novel Foods Regulation

In January 2008 the Commission submitted a proposal[37] for a new regulation on novel foods. First of all, in order to resolve the problem of there being specific differences in the assessment of food safety among the Member States, a centralised EU-level procedure was proposed, meaning all applications for the approval of novel foods would have to be submitted to the Commission and then directed to EFSA.[38] Furthermore, clearly aware of the regulatory difficulties in the food sector concerning ENM, the Commission intended to clarify that "*[n]ovel food should […] include foods […] modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food.*"[39] In the following legislative co-decision procedure the Council and the European Parliament appeared to have contrasting perceptions regarding reasonable regulation of ENM in novel foods. However, in the end their dissent regarding the treatment of food from cloned animals and their offspring[40] became an insurmountable obstacle: On 28 March 2011, after six weeks of conciliation – the very last resort of the Community co-decision procedure, Art. 294 of the TFEU – no agreement could be reached[41] and the proposed act was subsequently not adopted. Instead, the current Regulation (EC) 258/97 will remain in force, leaving three years of legislative debate to have been in vain.

To profit from the past three years of negotiations, the following section will nevertheless examine the different positions of the legislative bodies, points out progress made in coping with possible risks arising from ENM and discusses the nano-related key issues of the negotiations in order to define the key features for a reasonable future regulation of such chemical substances in food products.

3.3.1 Stance of the European Parliament

After stating in its legislative resolution of 25 May 2009[42] that "*[t]est methods currently available are not adequate for assessing the risks associated with nanomaterials*" (recital 13)[43], the European Parliament adds a definition of 'engineered nanomaterials'[44] to the draft, which shall include intentionally produced substances in the order of 100 nm and less that have specific physico-chemical properties or those connected to the large surface in relation to the small volume. Additionally the definition shall be adjusted to "*technical and scientific progress and with definitions subsequently agreed at international level.*" The most controversial amendments, however, are certainly Art. 8(6) providing labelling obligations – the word "nano" in brackets – for foods containing ingredients present in the form of nanomaterials, followed by Art. 7(2) stipulating that foods using nanotechnologies may not be authorised until specific safety assessment methods have been developed and approved that permit a reliable assessment of the safety of the respective foods. Moreover, as a safety net Art. 7(4) prescribes that "*[i]n the event of doubt, due, for example, to insufficient scientific certainty or lack of data, the precautionary principle shall be applied*

applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council, OJ L. 253 of 16 September 1997, pp. 1 – 36.

34 Similarly, Friends of the Earth, *supra* note 18, p. 38.

35 See *supra* note 9.

36 M. Meyer, *Aktionismus oder wahrer Fortschritt?*, StoffR 1 (2010) pp. 11 – 18, at 15.

37 Proposal of 14.1.2008 for a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001, COM(2007) 872 final.

38 *Id*., 7.

39 *Id.*, 10.

40 See http://www.eu2011.hu/news/presidency-seeks-compromise-novel-food.

41 European Parliament, *Press release* of 29 March, 20110328IPR16525.

42 Position of the European Parliament adopted at first reading on 25 March 2009, P6_TC1-COD(2008)0002, OJ C 117/E of 6.5.2010, pp. 237 – 254.

43 Taking into account SCENIHR, *Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies* (2005), available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/ scenihr_o_003b.pdf (14.2.2010), which at a very early stadium came to the conclusion that existing (eco-)toxicological methods may not be able to reveal the potential risks of ENM, see recital 6 of the legislative resolution.

44 Art. 3(2)(f), 'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale.
Properties that are characteristic to the nanoscale include:
(i) those related to the large specific surface area of the materials considered and/or
(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

and the food in question shall not be included in the Union list." Finally food additives, food enzymes and certain flavourings not used before 15 May 1997 shall be subject to the Regulation if they contain ENM (Art. 2(3)).[45]

3.3.2 Stance of the Council

In its position at first reading[46] the Council adopts the European Parliament's definition, Art. 3(2)(c). At the same time, while acknowledging that "*[a]t present, there is inadequate information on the risks associated with engineered nanomaterials*" (recital 20), the Council does not intend to generally refuse any approvals until specific reliable safety assessments are available. Instead, in cases where there might be doubt concerning the safety of food containing ENM, they refer to the general applicability of the precautionary principle as well as to an intended postponement of the entry into force of the regulation by 24 months – a period in which the Council appears to be confident that the respective risk assessment methodologies will be developed.[47] Finally, the Council supports specific labelling on a case-by-case basis instead of the general obligations as preferred by the European Parliament.

3.3.3 Further procedural history

In its second reading vote on 7 July 2010[48] the European Parliament insisted on the labelling of food containing ENM as set out in its first position and also on its claim to not authorise food containing ENM until reliable nano-specific risk assessment methods are available, amendments 75 and 120.

Meanwhile, in an opinion[49] of 11 October 2010 the Commission supported the inclusion of a definition of ENM in the draft and basically also considered the general labelling obligations as useful,[50] but did not share the Parliament's view that the available test methods were inappropriate and the subsequent non-inclusion of food containing or consisting of ENM in the Union list of approved novel foods until reliable risk assessment methods have been developed.[51]

In December 2010 the Council rejected the Parliament's second reading amendments, leaving the draft subject to a conciliation procedure in accordance with Art. 294(10) – (12) of the TFEU,[52] which also did not produce a satisfying compromise.

3.3.4 Discussion

In the following sections the differing positions of the European Parliament and the Council on the nano-related key issues *definition*, *labelling* and *pre-marked risk assessment* are to be discussed.

(i) Definition

Regarding the definition[53] of ENM, both legislative organs share the same view. Compared to the wording of Regulation (EC) 258/97, the definition ensures that ENM fall within the scope of the new regulation and are thus subject to pre-marked approval irrespective of any changes that ENM might cause in the properties of foods.

However, in view of a recently published SCENIHR report the decision to narrow the scope down to substances "*of the order of 100 nm or less*" appears very dubious, as there is no scientific basis for the appropriateness of that value and the properties associated with ENM can also be apparent in substances at a particle size way beyond that.[54] Furthermore, it has been criticised that the definition requires the presence of specific properties.[55]

What is still lacking is a clarification that nanoparticulate substances with the same molecular structure but differing sizes constitute dissimilar ENM for the purpose of the Regulation and are therefore each subject to the pre-marked risk assessment on their own.

(ii) Labelling

The positions of the European Parliament and Council differ significantly on the question of labelling. The Parliament – basically supported by the Commission – prefers to include on the list of ingredients the general designation 'nano' in brackets whenever any ingredient is present at the nanoscale, while the Council favours retaining the current procedure under Regulation (EC) 258/97 allowing labelling obligations on a case-by-case basis.

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45 The possible impacts of this inclusion and further proposals concerning food additives, food enzymes and flavourings are not part of the examination at hand as this would exceed its scope.

46 Position (EU) No 6/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001, adopted by the Council on 15 March 2010, OJ C 122/E of 11 May 2010, pp. 38 – 57.

47 *Id.*, 55; see also recital 18 enumerating among other things the precautionary principle as parameter for authorization decisions.

48 European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for adopting a regulation of the European Parliament and of theCouncil on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (11261/3/2009 – C7-0078/2010 – 2008/0002(COD)).

49 Opinion of the Commission pursuant to Ar. 294(7)(c) of the TFEU of 11.10.2010, on the European Parliament's amendments to the Council's position regarding the proposal for a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (COM(2010) 570 final – 2008/0002 (COD).

50 *Id.*, 3.

51 *Id.*, 5.

52 Council of the European Union, *Press Release 17323/10*, p. 28.

53 *Supra* note 44.

54 "*As there is no scientific evidence to qualify the appropriateness of the 100 nm cut-off, it is important to consider the whole nanoscale metric (1-999 nm)*," SCENHIR, Scientific Basis for the Definition of the Term "nanomaterial" (December 2010), p. 29, available at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf (14.2.2011).

55 NanoKommission, *supra* note 10, 8.

A controversy has ensued on the question of labelling.[56] For a start, consumer and environment protection NGOs favour general labelling obligations in accordance with the Parliament. In contrast industry associations prefer a voluntary labelling scheme or render the current labelling requirements according to Regulation (EC) 258/97 as sufficient, while demanding the presence of hazardous properties as a precondition for mandatory labelling. Furthermore, they refer to general product safety obligations which already ensure that only safe products are put on the market. Finally, others discuss whether all such products that are open to the environment (as opposed to materials bound in a stable matrix; e.g. lithium-ion batteries used for computers), including food components, should require labelling, and moreover question whether the information 'nano' alone is not expressive and whether a clearer indication of there being risks associated with the product would be more important.

Product labelling is a means that allows the consumer to make informed decisions. In a representative 2007 survey of 1000 consumers, commissioned by the German Federal Institute for Risk Assessment (BfR), a clear majority of the respondents decided against the use of nanotechnology in food.[57] Surveys from other countries like the U.S.A. show similar results.[58] Assuming that consumers do not want to eat nanofood, labelling is a prerequisite to enable informed decisions to be made – to decide in favour of or against the specific product. Representatives from the industry meanwhile claim that only those ingredients in the nanoscale should require a label that can potentially cause negative effects to human health.[59] However, one has to keep in mind EFSA's statement concerning today's inappropriate test methods, especially in the food sector, in terms of revealing potential health risks associated with ENM (section 2.1). This means that as long as approvals of novel foods containing ENM – i.e. the inclusion of the specific food in the Union list – may not guarantee the safety of the product, the consumer has the right to obtain labelling information indicating any nanoparticulate ingredient, irrespective of its properties. On condition that concerns are not dispelled, this obligation is furthermore evident from the applicability of the precautionary principle (section 3.3.4(iii)).

Then again, this labelling must also ensure that no stigmatisation of the application of ENM as such will take place. Science has shown that the impacts on health of a specific nanoscale substance with a size of 3 nm might be different from the effects of the same substance at 30 nm. As a consequence, the mere information 'nano' is not sufficient, as it could lead to the formation of prejudices. Instead, the designation 'nano' must be followed by the exact size of the relevant particle since hazardous properties are most of the time connected with substances of particular sizes.[60] Coupled with this, of course, the consumer needs to have easily accessible information about the specific properties associated with the different particle sizes. It is conceivable for this information to be made publicly available in a nanoproduct register.[61] Since Regulation (EC) 1223/2009 on cosmetic products already provides for a catalogue of all nanomaterials used in cosmetic products placed on the market,[62] a similar instrument for nanomaterials used in food products would be a means of coherent Community action. The legal feasibility of a nanoproduct register has also been demonstrated.[63]

(iii) Pre-market risk assessment as implication of the precautionary principle

The Parliament's 120 amendment to the Council position, stipulating "*[f]oods to which production processes have been applied that require specific risk assessment methods (for example, foods produced using nanotechnologies) may not be included in the Union list until such specific methods have been approved by the Authority for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective foods is safe*", constitutes the most controversial issue in this context. As the prescribed methods are not available yet, the wording represents a de facto moratorium on the use of ENM in food products, thereby ensuring that consumers will not be test objects on a 'trial and error' basis in terms of potential negative effects.[64]

While acknowledging its restrictiveness, the provision is a logical consequence resulting from the precautionary principle, which is of general applicability in European primary law[65] and is moreover embedded in current European food related legislature, namely Art. 7 of Regulation (EC) 178/2002 (see section 3.1.). It is also not challenged by the Council in its position at first reading that the authorisation of a novel food

56 Presumably representative for the international debate, one can derive the whole range of opinions from the results of the 2nd phase of the German NanoDialog, see NanoKommission, *supra* note 10, 62 et seq.

57 BfR, *The majority of consumers view the development of nanotechnology favourably*, Press Release of 19.12.2007, available at http://www.bfr.bund.de/cd/10563 (09.2.2011).

58 See Friends of the Earth, *supra* note 18, 44 with more references.

59 NanoKommission, *supra* note 10, 62.

60 Referring to Regulation (EC) 1223/2009 on cosmetic products: Meyer, *supra* note 36, 17 et seq.

61 For a detailed discussion of the nanoproduct register see NanoKommission, *supra* note 10, 45 et seq.

62 *Supra* note 3, Art. 16(10)(a).

63 A. Hermann, M. Möller, *Legal feasibility study on the introduction of a nanoproduct register*, 2010, available at http://www.bmu.de/files/pdfs/allgemein/application/pdf/bericht_nanoproduktregister_en_bf.pdf.

64 Meyer, *supra* note 36, 16.

65 Art. 191(2) of the TFEU; Communication of the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1 final.

should take into account that rule.[66] In general, the precautionary principle intervenes when human health is exposed to risks, meaning the occurrence of harm is possible or cannot be ruled out, as opposed to hazards that are present at a sufficient likelihood of harm. Thus cases characterised by uncertainty are also covered[67], which, against the background of the studies referred to in section 2.1, includes uncertainties relating to ENM as well.

In addition one has to consider the objectives of the new regulation. In accordance with Art. 1 of the Council's position at first reading,[68] its purpose is to "*ensur[e] a high level of protection of human health and consumers' interests, whilst ensuring the effective functioning of the internal market […]*". Recital 1 furthermore refers to the harmonisation of differing Member State laws concerning the safety of food.[69] However, the targets of market harmonisation and health protection do not mutually exclude one another, but constitute the need for Community-wide safe products. Since the distribution of *safe* food can subsequently be considered the main objective of the draft regulation – irrespective of the fact that Art. 95 of the TEC (now Art. 114 of the TFEU) seeking for an improvement of the internal market, instead of the environmental norm Art. 175 TEC (Art. 192 of the TFEU) formulates its legal basis[70] – instruments have to be established that are capable of ensuring the achievement of that aim. In this view, the described moratorium is not only justified but necessary.

4 Conclusion and outlook

The discussion in section 3.3.4 shows the features required in a reasonable regulation of ENM in novel food. However, in the foreseeable future the analysed Regulations (EC) 178/2002 and especially 258/97 will constitute the only available legal framework to cope with the nano-related risks. It is to be hoped that in the next attempt to revise novel food law, the Council und European Parliament will not exhaust the complete co-decision procedure, but will rather come to an early compromise, since the legal positions should have become clear. Perhaps in the meantime the proposed EU legislation on food information to consumers will ensure that proper labelling requirements on ENM come into force.[71]

In addition it should be examined whether the regulatory controls of food additives, food enzymes and flavourings at the nanoscale are adequate and secure as these objects will also not benefit from the failed revision now. The new Commission Regulation on plastic materials having contact with food[72], which will enter into force on 1 May 2011, sets a good example by acknowledging in its 23rd recital that *"it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles."* As a consequence, Art. 9(2) stipulates that nanoscale substances shall only be used if explicitly authorised and mentioned in the specifications in Annex I of the Regulation. Moreover, the Member State activities concerning nanoproduct inventories in, for instance, Belgium[73], Germany[74] and the UK[75] are to be observed.

66 Recital 18 Position (EU) No 6/2010 of the Council at first reading, *supra* note 46.

67 NanoKommission, *supra* note 10, 11 et seq.

68 *Supra* note 46.

69 The protection of human health is the objective of recital 2.

70 In the history of the Community there are many examples of directives and regulations aiming foremost at the reduction of risks to human health and the environment that are yet based on Art. 95 TEC, L. Krämer, *E.C. Environmental Law* (4th ed., 2000), pp. 56-59.

71 See the statement of a spokesman from the Greens, http://chemicalwatch.com/7085/nano-food-labelling-falls-foul-of-eu-failure-to-agree-novel-foods-regulation (29.3.2011).

72 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L. 12 of 15 January 2011, pp. 1-89.

73 See http://www.euractiv.com/en/food/reach-register-ensure-traceability-nanomaterials-news-497781 (16.2.2011).

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.
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elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

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Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

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The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

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elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researches, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

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