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Briefing paper

Original citation:

Falkner, R, Breggin, L, Jaspers, N, Pendergrass, J and Porter, R. Oct 2009 *Consumer labelling of nanomaterials in the EU and US: convergence or divergence?* Briefing paper, Chatham House, London, UK.

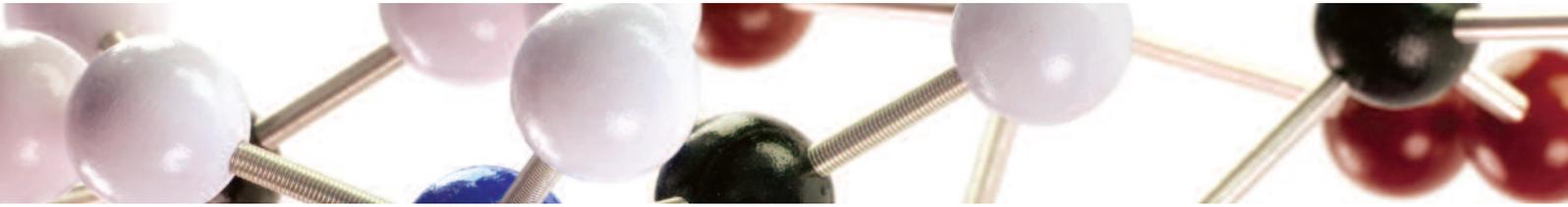
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Originally available from [Chatham House](#)

Available in LSE Research Online: Dec 2009

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Consumer Labelling of Nanomaterials in the EU and US: Convergence or Divergence?

Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter

Energy, Environment and Resource Governance | October 2009 | EERG BP 2009/03

Summary points

- Consumer labelling of nanomaterials is set to become an important and potentially controversial issue on the transatlantic regulatory agenda.
- With an estimated 1,000 nano-enabled products already on the market, calls are rising for mandatory consumer labelling of nanomaterials.
- The US and EU currently do not have a general labelling requirement for nanomaterials, but certain product-specific labelling rules in the food and cosmetics area may apply to nanomaterials.
- While US authorities have to date failed to respond to calls for comprehensive nanomaterials labelling, draft versions of the EU's revised novel foods and cosmetics laws already contain such requirements.
- In the light of the potential divergence between US and EU approaches to consumer labelling of nanomaterials, governments should consider the implications of such a development for international trade and potential means of promoting the development of common approaches.

Introduction

Nanotechnologies have opened the way to a wide range of innovative products in food, cosmetics, healthcare, computing, energy storage and other areas. The result of the deliberate manipulation of matter at the molecular level (typically at a scale of approximately 100 nanometres or less, a nanometre being one-billionth of a metre), nanomaterials have been used in a growing number of products that are available to consumers worldwide. Reliable information about the level of commercialization is as yet missing, but the Project on Emerging Nanotechnologies (PEN) estimates that 1,000 consumer products currently on the market either contain nanomaterials or are nano-enabled.

Our understanding of how nanomaterials interact with the environment and the human body has not kept pace with the development of nanotechnologies. Early results of research suggest that the safety of all nanomaterials cannot be taken for granted. The ongoing expansion of nanotechnologies may produce novel nanostructures that cause currently unknown forms of hazard. While researchers and regulatory agencies are seeking to fill existing scientific knowledge gaps, the commercialization of nano-enabled products continues, primarily in North America, Europe and Asia. EU and US regulators have generally concluded that any risks posed by nanomaterials can be addressed using existing legal and regulatory frameworks, but minor adjustments to specific regulations and their implementation are being made in order to close any potential gaps or eliminate uncertainties.

A growing number of consumer organizations and environmental campaign groups on both sides of the Atlantic are now calling on governments to go one step further. Among other things, some have demanded the introduction of mandatory labelling of nanomaterials in consumer products. The identification of regulated materials through labelling is a widely used instrument of risk management and generally serves two purposes: to inform consumers about the presence of hazardous substances and provide safe use guidelines; and to enable consumers to make an informed choice. At present, no nanotechnology-focused labelling require-

ments exist in the US and EU, but food and cosmetics safety laws in particular include labelling provisions for specific substances that may apply to certain nanomaterials.

While US regulators have indicated no intention to change the status quo, EU institutions are currently revising novel foods and cosmetics laws, which are widely expected to include rules for comprehensive consumer labelling that explicitly target nanomaterials or nanotechnologies. These developments in European law are likely to bring about a significant change in the EU's risk management approach to nanomaterials. They may in fact open up a gap between the regulatory approaches taken in the EU and those in the US, with far-reaching consequences for international trade in nano-enabled products.

“While US regulators have indicated no intention to change the status quo, EU institutions are currently revising novel foods and cosmetics laws, which are widely expected to include rules for comprehensive consumer labelling that explicitly target nanomaterials or nanotechnologies”

In the past, rules on consumer labelling have proved to be a controversial issue on the transatlantic regulatory agenda. In the case of genetically modified (GM) food, for example, the US has repeatedly rejected calls for the introduction of consumer labelling, whereas the EU has introduced such a requirement for all food products containing, or produced with the help of, GM organisms. The transatlantic GM food conflict came to a head in 2003 when the US, together with Canada and Argentina, launched a World Trade Organization

(WTO) case against the EU's regulatory regime. Although the WTO's dispute settlement panel ruling in 2006 found the EU to be in breach of international trade rules, it did not address, or require changes to, the EU's new GM food labelling law of 2004. GM food labelling has thus remained a sensitive issue in transatlantic relations and international trade.¹

This briefing paper, which builds on the findings of a project that investigated transatlantic regulatory cooperation in nanotechnologies, reviews the status quo in nanomaterials labelling in the EU and US and considers the implications of potentially diverging labelling regimes for transatlantic relations and regulatory cooperation. It reviews existing labelling rules in food and cosmetics regulation and considers the changes to labelling requirements that may result from the ongoing revision of European law in this area.

Nanomaterials labelling in the US and EU: the status quo

Both the US and the EU regulate labelling on several types of consumer products, but none of these regulations currently requires product labels to indicate the presence of nanomaterials or the use of nanotechnologies. Although nanomaterial labelling could be required for a variety of products, such requirements have been proposed for only food and cosmetic products to date. In this paper, therefore, we consider only food and cosmetics labelling regulations.²

Food labelling

United States: The Food and Drug Administration (FDA) bears primary responsibility for food safety in the US pursuant to multiple legal authorities governing food, food ingredients and dietary supplements. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the

Fair Packaging and Labeling Act (FPLA) and other statutes, the FDA reviews and approves new food and colour additives before they can be marketed. Similarly, producers must notify the FDA before placing new food contact materials on the market. For other food ingredients and dietary supplements, the agency relies mainly on post-market regulatory tools, including labelling, to ensure product safety. Labels on food products must be truthful and not misleading and must include information required by the FDA (such as ingredients), among other requirements. For products subject to pre-market authorization, the FDA generally reviews labels on a case-by-case basis. However, it does not review labels for products not subject to pre-market review – including food products. As a result, food manufacturers market products without receiving FDA pre-approval for their labels.

The FDA has not issued explicit guidance on the disclosure of nanomaterial use in labelling for any product category. Hypothetically, labelling of nanomaterials in food could result in cases of misbranding by including misleading representations about either the benefits or the risks of nanomaterials. In its Nanotechnology Task Force report, published in 2007, the FDA considered both permissible and mandatory labelling in response to a stakeholder suggestion that it should require all products containing nanomaterials to disclose that use on their label. The Task Force concluded that the FDA could determine that 'a particular use of a particular nanoscale material, or the use of nanoscale materials more generally, was a material fact for a category of products' and require labels to include information on the use of such materials.³ However, the Task Force recommended against such action by the agency, noting that 'the current science does not support a finding that classes of products with

1 See Lieberman, S. and T. Gray (2008). 'The World Trade Organization's Report on the EU's Moratorium on Biotech Products: The Wisdom of the US Challenge to the EU in the WTO', *Global Environmental Politics* 8(1): 33–52; and Falkner, R., ed. (2007). *The International Politics of Genetically Modified Food: Diplomacy, Trade and Law*. Basingstoke, Palgrave Macmillan.

2 A more detailed discussion of food and cosmetics regulation in the EU and US can be found in our main project report, *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, chapters 5 and 6, available at www.chathamhouse.org.uk/nanotechnology.

3 FDA (2007). *Nanotechnology: A Report of the US Food and Drug Administration Nanotechnology Task Force*, p. 35. Available at: <http://www.fda.gov/nanotechnology/taskforce/report2007.pdf>.

nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials'.⁴ Instead, the Task Force recommended that the FDA consider whether labelling must or may include disclosure of nanomaterial use on a case-by-case basis across all product categories.

European Union: Food legislation in the EU has changed significantly over the past decade in the wake of a series of health and safety crises, leading to a strengthening of EU authority and the creation of the European Food Safety Authority (EFSA) as an independent agency. Food regulation is now largely determined at the EU level, and national food laws in EU Member States generally implement decisions taken by EU authorities. The presentation, advertising and labelling of foodstuffs is regulated by Directive 2000/13/EC, which requires labels to include a variety of information, including ingredients, durability, net quantity and storage condition. Other EC Directives and Regulations include additional, more specific labelling requirements that apply to, for example, products making health and nutrition claims, mineral waters, dietetic and weight reduction foods, foods for special medical purposes, vitamins and minerals, food contact materials, food additives and food supplements. While there is no general requirement in EU law to label nanomaterials in food contact materials (e.g. food packaging), some groups of materials, including active and intelligent materials and articles (e.g. self-replicating nanostructures), may be subject to specific labelling requirements.⁵ In addition, the Novel Foods Regulation and the Directive on food supplements are particularly relevant to nanomaterials labelling.

The Novel Foods Regulation (EC 258/97) applies to foods and food ingredients (except food enzymes, additives, flavourings and extraction solvents) not consumed in the EU before 15 May 1997. It establishes a legal requirement for all novel foods to be assessed

for safety and approved before they are introduced to the market. Once a novel food has received regulatory approval, the producer is obliged to inform consumers, through labelling, of any novel food characteristics or properties. The label also must describe the method by which this characteristic or property was obtained. Although the Novel Foods Regulation was originally drafted to address genetically modified foods and feeds, it is considered to be of central importance to the regulation of newly emerging nanomaterials in food products. In its existing formulation, the Regulation does not explicitly mention nanotechnology or particle size as a relevant criterion, but includes two categories in Article 1(2) that are considered as fall-back provisions:

(c) foods and food ingredients with a new or intentionally modified primary molecular structure; [...]

(f) 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.

Debate continues on whether the existing definition of 'novel food' provides comprehensive coverage for nanomaterials.⁶ Many, though arguably not all, nanomaterials in food may thus fall under the general labelling requirement of the EU's Novel Foods Regulation. However, the current revision of the Regulation is intended to address the uncertainty in the definition of novel foods (see below).

The EU Directive (2002/46/EC) on food supplements, such as vitamins and minerals, likewise does not explicitly mention nanotechnologies or nanomaterials. According to the Directive, only those supplements that are listed on so-called positive lists are allowed to be

⁴ Ibid.

⁵ Regulation (EC) No. 1935/2004, Article 5(i).

⁶ Gergely, A. et al. (2009 forthcoming). 'Small Ingredients in a Big Picture: Regulatory Perspectives on Nanotechnologies in Foods and Food Contact Materials', in Q. Chaudhry, ed., *Applications and Implications of Nanotechnologies for Foods and Food Contact Materials*.

marketed in Europe. Listing requires a prior safety assessment by the EFSA, and authorized food supplements need to be labelled so that consumers can make informed choices. Member States' competent authorities are responsible for the monitoring of this Directive, and are entitled temporarily to suspend or restrict authorizations of supplements, in cases where new information or a reassessment of existing information indicates threats to human health. The European Commission points out that the authorization procedures as well as the safeguard provisions of the Directive ensure that 'risks associated with the use of vitamins and minerals in "nano" forms [are] dealt with in an appropriate way'. However, it also acknowledges ambiguity in the existing rules that may need to be addressed in future revisions of the Directive, particularly in the form of an explicit requirement to provide information on the particle form and production process of supplements.⁷

‘The EU Novel Foods Regulation provides a general labelling requirement for food and food ingredients produced with a novel process, which may apply to a wide range of nanomaterials in food’

In sum, both the US and the EU contain extensive mandatory labelling requirements for food products, including disclosure of product ingredients, and specific labelling requirements differ for different categories of food products. While many of these requirements are analogous in both jurisdictions, the EU requires more information disclosure on food product labels in some respects, such as requiring suffi-

cient information to enable traceability of food products, including food contact materials. In addition, the EU Novel Foods Regulation provides a general labelling requirement for food and food ingredients produced with a novel process, which may apply to a wide range of nanomaterials in food.

Cosmetics labelling

US and EU cosmetics laws and regulations neither require nanotechnology-specific labelling of cosmetics nor explicitly refer to nanotechnologies or nanomaterials.

United States: As with food, the FDA regulates cosmetics labelling under the FFDCa and FPLA. With the exception of colour additives (see food), its cosmetics authority does not include pre-market notification or review and is limited to post-market tools, including labelling and monitoring. The FFDCa authorizes the agency to remove adulterated and misbranded products from the market through judicial action. A cosmetic product is misbranded if the label is false or misleading or fails to include required information, among other reasons. Identification of specific material information for inclusion on cosmetic product labels is determined by FDA regulation, but the agency does not review or approve cosmetics labels before marketing.

The FDA's cosmetic labelling requirements focus on both the inclusion of material information and the avoidance of false or misleading information. FDA regulations require cosmetics to bear a list of ingredients and include all relevant warnings. Manufacturers conduct safety substantiation prior to marketing but are not required to submit the resulting safety information to the FDA. Products that have not been 'adequately substantiated for safety prior to marketing' must bear a warning label to that effect. Few cosmetic products bear this warning label, suggesting that cosmetics companies are substantiating the safety of

⁷ European Commission (2008). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials, COM(2008) 366 final, 24.

their ingredients and products. The FDA generally lacks the authority to inspect records, however, and does not systematically gauge compliance with this regulation.

European Union: The EU's 1976 Cosmetics Directive, together with amendments, provides the framework for the regulation of product composition, labelling and packaging of cosmetics. It requires manufacturers to carry out risk assessment and establishes positive and negative lists for certain permitted and prohibited substances. The European Commission's DG Enterprise and Industry is responsible for administering and supervising the implementation of the Cosmetics Directive, and the Directorate-General Health and Consumers (DG SANCO)'s Scientific Committee on Consumer Products (SCCP) provides scientific assessments of the safety of cosmetic products. Partly because of the Directive's perceived uncertainty over borderline products (medicinal versus cosmetic) and lack of precise legal definitions, the European Commission has proposed to recast the Directive in the form of a new Regulation.

Manufacturers must assess the safety of their products before marketing them, but do not normally have to seek pre-market approval for produced or imported cosmetic products (except for certain substances used in colorants, UV filters and preservatives). The Directive establishes a series of lists of prohibited, restricted and permitted substances. Annex III, for example, lists substances whose use may be permitted only for certain types of cosmetics, or which are subject to special labelling requirements, such as hydrogen peroxide, formaldehyde or aluminium fluoride.

The Cosmetics Directive provides post-market tools to supplement its targeted pre-market review of cosmetic ingredients. In its current form, it does not require a general requirement for producers to identify nanomaterials on the list of ingredients. While the Cosmetics Directive does not contain any explicit reference to particle size or nanomaterials, the European

Commission argues that it broadly covers health-related risks of nanomaterials in cosmetic products.⁸ At the same time, however, the Commission acknowledges that a revision of the current framework may be necessary. Such a revision is now in progress in the form of a recast of the Cosmetics Directive to a Regulation. Although nanomaterials were not explicitly mentioned in the Commission's original draft Regulation, amendments by the European Parliament have now introduced such explicit references in the latest version of the proposed Regulation (see below).

In sum, in both the US and the EU, labelling is a primary tool for regulating cosmetics marketing. Each jurisdiction has developed unique rules for labelling, although important elements such as ingredient lists, amount of contents and the name and place of business of responsible entities are common to both. In the US, the FDA Task Force concluded that requiring disclosure of nanomaterials on product labels is unwarranted and that such disclosure may mislead consumers if voluntarily included because the risks and benefits of nanomaterials as a class are uncertain and their presence therefore is not material to product safety. Similarly, in Europe, the Cosmetics Directive does not require producers to identify nanomaterials on product labels. However, the proposed Regulation may significantly alter this situation to require nanomaterial disclosure, marking a significant change in labelling authority under European cosmetics law. The next section considers the implications for transatlantic regulatory cooperation of the changes under way in European food and cosmetics law.

Comprehensive nanomaterials labelling on the horizon in Europe

A growing number of consumer organizations, trade unions and environmental campaign groups have recently called for the introduction of comprehensive labelling of nanomaterials in consumer products, including the Australian Council of Trade Unions

⁸ European Commission (2008). Commission Staff Working Document: Accompanying Document to the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials, p. 17.

(ACTU), the UK's Consumers' Association Which?, the European Environmental Bureau (EEB), the European Consumers' Organisation (BEUC), Natural Resources Defense Council, Friends of the Earth, the International Center for Technology Assessment, and the ETC Group.⁹ A broad coalition of US, European and international civil society groups included mandatory consumer labelling in its 'Principles for the Oversight of Nanotechnologies and Nanomaterials',¹⁰ and as recently as June 2009, a resolution passed by the member organizations of the Trans Atlantic Consumer Dialogue (TACD) reiterated the demand that '[c]onsumer products containing nano-ingredients and with which consumers come in direct, close or regular contact must be labeled'.¹¹

‘The push for mandatory labelling is particularly strong in Europe, where regulatory review and revision processes have already resulted in the first draft legislation to include more extensive consumer labelling of nanomaterials in food and cosmetic products.’

The push for mandatory labelling is particularly strong in Europe, where regulatory review and revision processes have already resulted in the first draft legislation to include more extensive consumer labelling of nanomaterials in food and cosmetic products. If adopted, these legislative proposals would represent a significant shift in the EU's regulatory approach, with potentially far-reaching consequences for transatlantic regulatory cooperation in the field of nanomaterials.

Novel Foods: In January 2008, the European Commission adopted a proposal that would rewrite the scope of the Novel Foods legislation to include new technologies derived from nanosciences. By specifically mentioning nanotechnology in the definition of 'novel food',¹² the proposed reform provides an opportunity to remove any ambiguity from the existing Regulation. In a vote on 25 March 2009, the European Parliament (EP) endorsed the principles behind the European Commission's proposal, but went one step further and urged the Commission to introduce mandatory labelling of nanomaterials in the list of ingredients.¹³ It also approved the inclusion of a new category for defining novel foods that includes an explicit reference to 'food containing or consisting of engineered nanomaterials not used for food production within the Community before 15 May 1997', which would provide a firmer basis for covering nanomaterials under the Novel Foods Regulation. The EP proposal also defines 'engineered nanomaterial' to mean:

9 ACTU, 'Nanotechnology – Why Unions are Concerned' fact sheet, April 2009 (<http://www.actu.asn.au/Media/Mediareleases/Nanotechposespossiblehealthandsafetyrisktoworkersandneedsregulation.aspx>); EEB position paper on nanotechnologies and nanomaterials, February 2008 (<http://www.nanocap.eu/Flex/Site/Download.aspx?ID=3753>); Which? 'Small Wonder? Nanotechnology and Cosmetics' Briefing, November 2008; BfR Consumer Conference on Nanotechnology in Foods, Cosmetics and Textiles, 20 November 2006 (http://www.bfr.bund.de/cm/245/bfr_consumer_conference_on_nanotechnology_in_foods_cosmetics_and_textiles.pdf); 'Nanotechnology's Invisible Threat: Small Science, Big Consequences' NRDC Issue Paper, May 2007 (<http://www.nrdc.org/health/science/nano/nano.pdf>); CTA and Friends of the Earth Challenge FDA to Regulate Nanoparticles at FDA Hearing, 10.10.2006 (http://www.icta.org/press/release.cfm?news_id=21).

10 <http://nanoaction.org/nanoaction/doc/nano-02-18-08.pdf>.

11 Trans Atlantic Consumer Dialogue, Resolution on Consumer Products Containing Nanoparticles, June 2009 (http://www.tacd.org/index2.php?option=com_docman&task=doc_view&gid=215&Itemid=40).

12 'Novel food should include ... foods modified by new production processes, such as nanotechnology and nanoscience ...' European Commission (2008). Proposal for a Regulation of the European Parliament and the Council on Novel Foods: Explanatory Memorandum, COM(2007) 872 final, 2008/0002 (COD), p. 10.

13 See European Parliament, Press Release, Novel foods, MEPs set new rules (2009), available at http://www.europarl.europa.eu/news/expert/infopress_page/067-52498-082-03-13-911-20090324IPR52497-23-03-2009-2009-false/default_en.htm.

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 characteristic to the nanoscale’ include ‘those related to the large specific surface area of the materials considered’; and ‘specific physico-chemical properties that are different from those of the non-nanoform of the same material’.¹⁴ The EP proposal requires the Commission to adjust these definitions in the light of technical and scientific progress and the emergence of agreed definitions at the international level.

Uncertainty remains, of course, about the precise wording of the new Novel Foods Regulation, as European institutions seek a compromise between different legislative proposals put forward so far. The European Council, representing EU Member States, passed its own version in June 2009, in which it acknowledges that ‘there is inadequate information on the risks associated with engineered nanomaterials’ and calls for the development of definitions and appropriate test methods.¹⁵ The European Parliament will consider the Council’s position in a second reading of the revised Regulation, due to take place in the autumn of 2009, and the Council and Parliament will have to work out a compromise before the revised Regulation can be adopted and enters into force.

Cosmetics Regulation: The current proposal to recast the Cosmetics Directive in the form of a Regulation was approved by the European Parliament at its first reading on 24 March 2009.¹⁶ The new Regulation

includes important changes with regard to the regulation of nanomaterials in cosmetic products and strengthens and centralizes regulatory oversight of cosmetics in Europe. It also seeks to create greater legal certainty with regard to the coverage of nanomaterials by explicitly mentioning and defining them in the draft text.

The proposed cosmetics Regulation also contains new provisions that would strengthen market surveillance and consumer labelling of nanomaterials in cosmetics. It stipulates that the European Commission shall make publicly available ‘a catalogue of all nanomaterials used in cosmetic products, including those used as colorants, UV-filters and preservatives in a separate section, placed on the market, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions’ (Article 16, Paragraph 10(a)). Furthermore, Article 19 establishes a general labelling requirement for nanomaterials: ‘All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word “nano” in brackets.’

Although details of the final compromise on the cosmetics Regulation remain to be worked out, observers expect the new text to be agreed by the end of 2009 but not to enter into force before 2012. The new Regulation is likely to continue the principle of case-by-case risk assessment but will provide a firmer legal basis for establishing a system of market surveillance and consumer labelling specifically aimed at nanomaterials.

European Parliament resolution: In a sign of its growing resolve on questions of nanotechnology regulation, the European Parliament passed a non-binding resolution on 24 April 2009 calling for a number of measures to strengthen nanomaterials oversight in

14 European Parliament (2009). Legislative Resolution of 25 March 2009 on the Proposal for a Regulation of the European Parliament and of the Council on Novel Foods and Amending Regulation (EC) No. XXX/XXXX [common procedure]. COM(2007)0872 – C6-0027/2008 – 2008/0002(COD).

15 European Council (2009). Proposal for a Regulation of the European Parliament and of the Council on Novel Foods and Amending Regulation (EC) No. XXX/XXXX [common procedure] (LA) (First reading), 10754/09, recital 16a.

16 European Parliament (2009). Legislative Resolution of 24 March 2009 on the Proposal for a Regulation of the European Parliament and of the Council on Cosmetic Products (Recast). COM(2008)0049 – C6-0053/2008 – 2008/0035(COD).

Europe. The resolution, which was passed by 362 votes to 4, with 5 abstentions, supports the introduction of a general labelling requirement for nanomaterials in consumer products.¹⁷ It thus goes one step beyond the European Commission's position, which, while noting the 'possibility that a need would be identified for specific labelling requirements',¹⁸ had hitherto focused on the strengthening and implementation of existing provisions, including the case-by-case application of labelling requirements as they already exist in European food and cosmetics law.

US position: In contrast to the EU, to date US legislators and regulators have not indicated a need to introduce comprehensive nanomaterials labelling. The FDA considered and rejected labelling of nanomaterials under food and cosmetics law in 2007. This was in part owing to a lack of understanding of the risks presented by nanomaterials in regulated products generally, and in part because labels for cosmetics and other products must include material information to avoid misbranding, thus providing a basis for case-by-case disclosure of nanomaterial risks where appropriate and to avoid misleading claims regarding the benefits of nanomaterials. Since 2007, the agency has evinced no intent to reconsider this conclusion. Similarly, although legislators on Capitol Hill have introduced several bills relating to food safety in the wake of food-borne disease outbreaks, these proposed bills do not address nanomaterials or labelling. The Obama administration is currently reviewing a number of nanotechnology-related policy decisions taken in preceding years in other contexts, but there are no signs of a fundamental shift in policy that would lead to a comprehensive labelling requirement for nanomaterials in food or cosmetic products in the near term.

Implications and recommendations

As a result of the growing trade in nanomaterials and nano-enabled consumer products, differences in risk

management approaches and decisions will have important repercussions for international trade and coordination of risk regulation. Emerging differences in consumer labelling regimes, in particular, pose a challenge to regulatory cooperation between the EU and US; they may complicate and even slow down current moves towards transatlantic regulatory convergence.

‘Differences in risk management approaches and decisions will have important repercussions for international trade and coordination of risk regulation’

So far, neither the US nor the EU has introduced legally binding consumer labelling requirements that are specifically designed for nanomaterials, although current legislative developments in the EU point to a strengthening of labelling requirements in Europe. Regulatory agencies on both sides of the Atlantic are already authorized to introduce nanomaterials labelling requirements in certain circumscribed cases, including through the development of guidance documents for the implementation of existing food and cosmetics labelling requirements. But while current regulatory praxis points to continued case-by-case decision-making, legislative developments in the European Parliament suggest a more fundamental change in the European approach. The precise nature of the legislative changes in the EU is still to be decided, but both US and EU authorities would be well advised to take seriously the prospect of diverging labelling regimes.

Achieving coordination and convergence in risk management is, of course, more difficult to achieve

¹⁷ European Parliament (2009). Non-legislative Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials, 2008/2208(INI).

¹⁸ European Commission (2008). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials, COM(2008) 366 final, p. 10.

than coordination in the scientific building blocks of risk assessment because national differences in societal values and risk preferences permeate risk management decision-making. The debate over whether and how to label nanomaterials remains deeply divided between those who call for comprehensive labelling and those who raise fundamental questions about its appropriateness and necessity.

Some stakeholders interviewed for this project warned that labelling would be a costly way to inform the public about the presence of materials that will most likely be of little consequence to human health or the environment. Meaningful labelling is, as one interviewee put it, 'hard to get right'. Both US and EU industry interviewees, in particular, questioned the usefulness and legitimacy of a general labelling requirement for all products that contain nanomaterials. Some compared this to the labelling of GM food in the EU, which informs the consumer of the use of a certain technology, but not of specific risks involved in the consumption of GM food. Others noted the danger of information overload and were concerned that labels might confuse consumers more than inform them.

On the other hand, some interviewees suggested that the labelling of nanomaterials in food and cosmetics products would be of particular importance in future, not least as a means of building consumer trust through enhanced transparency. Some see this becoming increasingly important as more and more nanomaterials enter the market. Although most producer companies remain sceptical about a general labelling requirement, some retail firms (e.g. supermarkets) are likely to view nano-labelling more favourably, as a way of assuring consumers that no risks, whether actual or potential, are hidden from them. Several civil society and consumer groups have called for better labelling provisions as part of a broader attempt to ensure consumers' 'right to know' and 'informed choice'.¹⁹

The 'informed choice' argument for nanomaterials labelling is seen by proponents as a means of ensuring that consumers are free to express views not only on the safety of nanomaterials but also on ethical dimensions of the use of nanotechnologies, particularly in food and cosmetics. In this perspective, labelling becomes a tool for embedding nanomaterials regulation in a wider social and ethical context without sacrificing the scientific foundations of the core risk assessment process. Opponents have pointed out, however, that any comprehensive labelling of nanomaterials would be misleading, particularly if it failed to notify consumers either of specific health or environmental risks or of specific benefits of the nanomaterials. A question that is at the heart of such disagreements is whether ethical concerns that are unrelated to specific concerns about environmental and health risks are legitimate reasons for introducing a labelling regime.

Such differences in interpretation of labelling schemes are not unique to the debate on nanomaterials. Similar arguments have been used in the context of the use of genetically modified organisms in food production and the creation of biotechnology-based labelling requirements in the EU.²⁰ They have also characterized the debate on whether technology- or process-based labelling regimes violate the international trade rules of the WTO system, and particularly the rules of the Technical Barriers to Trade (TBT) Agreement. This is not the place to rehearse the arguments of this long-running debate,²¹ but we merely wish to point to the possibility that differences in EU and US labelling regimes for nanomaterials will also play into future transatlantic relations within a WTO context. Both sides should therefore consider the implications of different labelling requirements, whether already established or newly created, for the proper functioning of international trade.

If the US and EU were to explore the possibility of developing common approaches or standards for nano-

19 See 'Nanomaterials in Cosmetics: BEUC cautiously welcomes new regulation', available at <http://www.eubusiness.com/Consumer/beuc-press.09-03-25> (accessed on 8 July 2009).

20 For an overview, see Weirich, P. (ed.) (2007). *Labeling Genetically Modified Food. The Philosophical and Legal Debate*. Oxford: Oxford University Press.

21 See Hobbs, J.E. and W.A. Kerr, 'Consumer information, labelling and international trade in agri-food products', *Food Policy*, 31(1), February 2006, 78–89; and Melsner, D. and P.E. Robertson, 'Eco-labelling and the Trade-Environment Debate', *The World Economy*, 28(1), January 2005, 49–62.

materials labelling, such an undertaking should involve a multi-stakeholder forum to engage relevant groups from industry and civil society in order to give full weight to the different commercial and ethical concerns. Current transatlantic dialogues, such as those within the Trans Atlantic Consumers Dialogue (TACD) and the TransAtlantic Business Dialogue (TABD), could provide useful fora for taking this debate forward.

Some coordination efforts in this context are already under way at the international level, but with only limited success. Both the United States and EU are in the process of implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which will standardize the information on hazards and toxicity from internationally traded chemicals and is expected to provide a basis for harmonization of rules and regulations on chemicals.²² In the food area, the Codex of Alimentarius Commission has promoted international harmonization of rules on food safety labelling. While Codex has made progress in a number of areas, an international

agreement on standards for the labelling of biotech food products has so far proved elusive.²³ International agreement on cosmetics labelling has similarly failed to materialize, underlining the complexity of reaching international agreement in the field of labelling.

Labelling of nanomaterials in consumer products is likely to be more widely used as an increasing number of nano-enabled products enter the market. It is noteworthy that amid the controversy on legally binding consumer labelling requirements specifically targeted at nanomaterials, some companies have recently introduced the first voluntary labelling in positive (identifying nanomaterials) and negative (declaring to be free of nanomaterials) forms. The emergence of such private labelling schemes, although not inconsistent with WTO rules *per se*, nevertheless raises the spectre of the growth of an increasingly complex and inconsistent set of labelling rules that complicate the flow of nano-enabled goods across international borders. The time is ripe, therefore, for the EU and US to lead the way in creating internationally coordinated approaches for nanomaterials labelling.

²² See United Nations Economic Commission for Europe, available at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.

²³ Sand, P.H. (2006). 'Labelling Genetically Modified Food: The Right to Know'. *Review of European Community & International Environmental Law* 15(2): 185–92.

About the research project **Regulating Nanotechnologies in the EU and US**

This paper is based on the findings of a research project conducted in 2008–09 by a research team from the London School of Economics, the Environmental Law Institute, Chatham House and the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars. The project was funded by a European Commission grant and involved a comparative analysis of US and EU nanomaterials regulation in the areas of chemicals, food and cosmetics. More information on the research project and team can be found at www.lse.ac.uk/nanoregulation.

Other publications by the project team:

- Linda Breggin, Robert Falkner, Nico Jaspers, John Pendergrass and Read Porter
Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation. Report (London: Chatham House, September 2009), 120 pages.
- Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter
Regulating Nanomaterials: A Transatlantic Agenda. EERG Briefing Paper 2009/02 (London: Chatham House), 8 pages.

Both publications can be downloaded at www.chathamhouse.org.uk/nanotechnology.

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The views expressed in this briefing paper are the sole responsibility of the authors, and do not represent the views of the institutions of the project consortium, the United States or the European Union.

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Registered charity no: 208223

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Designed and typeset by SoapBox, www.soapboxcommunications.co.uk

