Simply Swallow? – The Application of Nanotechnologies in European Food Law

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The application of the existing regulatory framework for the use of nanotechnologies in food, until recently followed the same path as the regulation of nanotechnologies as a whole. In particular, the European Commission adhered to the incremental approach, preferring to trust the generic provisions on consumer and occupational health and safety, and adjusting it for specific nano related concerns which may be shown when appropriate testing methods etc. will have been developed. The European Parliament however has recently followed a different track, demanding in the specific case of novel foods that no foodstuff containing nanoparticles be allowed to be marketed until specific test protocols and risk assessment tools have been agreed. Given the EU’s insistence on the precautionary principle, that is an unsurprising development, if one which perhaps the European Commission and industry alike were trying to avoid.

The background to the use of nanotechnologies in food and feed has been reported in a previous volume of the EFFL, hence shall not be repeated here. While until fairly recently nano boasts were made quite regularly by producers of consumer products, the current mood among manufacturers is more akin to one of nano-stigma, with manufacturers removing nano claims from packaging and marketing, and, for instance, differences emerging in the use of nano language between US and EU websites of cosmetics companies. This development is the result of increasing concerns of the public and part of the regulatory community’s response to the technology, as we describe in this contribution.

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2 In a previous stage indeed, many manufacturers attached “nano” claims to foods and other consumer products, for marketing purposes mainly, without there being any guarantee of nanoparticles actually being present in these products or indeed nanotechnologies having played a part in the production process. See also the suggestion by Haber and Stahle, note 1 above, 401. For instance, the first reported incident where nanotechnologies was thought to have led to immediate health concerns, the “NanoMagic” episode, very soon turned out not to have involved nanoparticles at all, the product concerned having used the prefix “Nano” purely for marketing reasons.


1. Formal regulators’ reviews of the adequacy of current legislation

A number of regulatory bodies worldwide have carried out formal reviews to determine the adequacy of current regulatory frameworks in their jurisdiction. These effectively concluded that at the least where regulatory oversight includes generic obligations (of the “materials put on the market must be safe”-type, or “employees must be protected from reasonably foreseeable health and safety risks”), the existing legal frameworks could be considered “adequate” to deal with potential risks posed by nanotechnologies. This led to a more or less unanimous consensus among regulatory bodies worldwide, that for the regulation of nanotechnologies, one ought to adopt what is dubbed the “incremental approach”: 
as and when risks emerge, they would be dealt with in specific pieces of legislation. One such study was the June 2008 Communication of the European Commission, and the accompanying Staff working document. The latter reviewed general food legislation (Regulation 178/2002), novel foods, food contact materials or FCMs, food additives, food supplements, and feed legislation. The Communication effectively provides for a concise handbook of EU food and feed law. It concluded, for the food sector much as for the other sectors reviewed, that the current legislation, given its generic requirements of consumer health and safety, ought to be able to cover any risks associated with nanotechnologies and, if need be, allow for specific measures to be taken vis-à-vis the technology.

The publication of these reviews – which in the case of the European Union took over a year between draft and final stage, confirmed industry’s view that nanotechnology in all its applications is sufficiently regulated by the current laws and regulations. If and when risks emerge, they would be regulated. This development however bypassed one member of that regulatory community in particular: the European Parliament.

II. Parliament ahoy

The intervention of the European Parliament in the regulation of nanotechnologies to a large degree is the history of a development foretold. There are indeed two parallels in the regulatory history of nanotechnologies which we are all reminded of yet subsequently argue very hard to rule out for the nano scenario.

Firstly: biotech and, in particular, the regulation of genetically modified organisms in the EU. Following the requests for market approvals for food and feed containing GMOs, Member States and Members of the European Parliament alike found the regulatory regime wanting, took a long time to negotiate what they argued was a comprehensive regime, and in the meantime halted the approval of any applications. This in turn famously led to a World Trade Organisation condemnation of the EU’s regulatory system on the basis of an “undue delay” (a standard imposed by the Agreement on Sanitary and Phytosanitary Standards – SPS). It was clear that citizens revolt against the unknowns of the technology, and the subsequent sensitivity of national governments and the European Parliament towards this revolt, fuelled the regulatory response of the EU. This, it was argued at the time of nanotechnologies reaching a slightly larger audience than the laboratories, was a mistake which was not going to be repeated with nano: hence the calls for proactive regulation.

Interestingly, an immediate result of the biotech/GMO debacle, is the emphasis in the nano community on products and processes which carry a promise for the improvement of life and the environment of individual consumers, as opposed to the products which were first being rolled out in biotechnology, which had a direct impact on collective communities such as agriculture.

A second usual suspect which is flagged when one addresses the regulation of nanotechnologies, are the health impact and related litigation of asbestos fibres – not so much for the very question as to whether insoluble nanoparticles may have asbestos-type properties, but rather for the process-related issues of regulating in uncertainty.

It is against the background of the divide between the enormous promise of the technologies, and the considerable uncertainties in employing them, that the European Parliament adopted a Resolution on regulatory aspects of nanomaterials, and employed the scepticism apparent in the resolution as a guideline in its vote on two ongoing regulatory revisions, of the Novel Foods Regulation and Cosmetics Directive respectively. The Resolution shows that Parliament is clearly frustrated with the lack of progress in assessing the risk of nanotechnological process and use of nanomaterials, and it highlights some glaring paradoxes in the regulatory discussion. This includes the rather absurd divide between “nano inventories” of reputable research institutions on the one hand, and rebuttal of such claims by industry on the other (e.g. in the cosmetics industry).

6 See also Geert van Calster, Diana Megan Bowman and Joel U’Silva, “Sufficient or deficient? A review of the adequacy of current EU legislative instruments for regulating nanotechnologies across three industry sectors” forthcoming in Law, Innovation and Technology Journal, 2009, and Geegely, Bowman, Chaudry, note 3 above.
In March 2009, the European Parliament suggested amendments to the recast of the EU Cosmetics Directive.8 Parliament, apparently with support of the Member States Governments (hence with a high likelihood of this going into the final Regulation) has called for a nano-specific safety assessment procedure for all products containing nanomaterials, which could lead to a ban on a substance if there is a risk to human health. This of course requires the introduction of a definition of nanomaterials in the Regulation. According to the definition proposed by Parliament, “nanomaterial” for the purpose of the Cosmetics Directive, means an insoluble or bioreistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. Any ingredients in the product present in the form of nanomaterials will also have to be clearly indicated on the packaging, should Parliament have its way (which it probably will).

Following its review of legislative measures for nanomaterials in cosmetics, the European Parliament also in March 2009 voted in favour of a report dealing with an update of the EU rules on novel foods, which also proposes special treatment of nanoparticles and nanomaterials.9 According to the proposal, nano-specific test methods should be developed as a matter of urgency and nanomaterials present in food should be entered on a list of approved nanomaterials, for food contact materials accompanied by a limit on migration into or onto the food products contained in such packaging.

This means in practice that until such methods have been developed, no such materials will be allowed on the market – in other words, a moratorium.

The European Parliament also proposes to amend the definition of a “novel food” to include food containing or consisting of “engineered nanomaterials”, however MEPs did not support the inclusion of terminology referring to “produced with the aid of nanotechnology”. All ingredients present in the form of nanomaterials will have to be clearly indicated in the list of ingredients. It is not clear at the moment whether Parliament will have enough support from Council for it to push through its proposals.

“Engineered nanomaterials” is defined by Parliament as 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.

Parliament advocates in other words a freeze on market authorisation for products with nanoparticles that are not readily soluble or biodegradable.

It is noteworthy that Parliament did not include nanotechnologies employed in the production process, but not included in the final product, as a regulatory trigger.

III. Handle with caution

The precautionary principle is of course quoted as the one distinguishing feature between the EU (and its Member States) and others. In this author’s experience, the principle is best pondered by contrasting it with the prevention principle.

Principle 2 of the Rio Declaration:10 States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

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8 European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation on cosmetics products, A6-0484/2008. Rather than a Directive, the new text will take the form of a “Regulation”, making it more directly enforceable.
Principle 15 of the Rio Declaration:

*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The prevention principle (principle of preventive action) obliges the authorities to take action at the earliest possible stage, if at all possible prior to any damage occurring, to prevent known risks from being realised. There is no undisputed definition of the precautionary principle. It is generally defined in a negative sense, in that according to the principle, States must not defer regulatory action even if there is no conclusive scientific proof between a given (in)action and damage to human health and/or the environment. The two principles at issue differ as follows.

As for the content of the principles, the classic method of distinguishing between them is by describing them in terms of risk analysis. The principle of preventive action deals with known risks; the link between certain activities or occurrences and environmental damage occurring, is certain, and States are obliged to prevent the damage from occurring. The precautionary principle by contrast deals with uncertain risks. For the activities concerned, there is no watertight proof that a given human activity causes damage; indeed there may in some cases not even be a proof of damage. Evidently, this distinction works as a core introduction to the precautionary principle, but does not carry it much further than that. Indeed fully-known risks are extraordinarily rare.

Importantly, the legal weight of both principles also differs. The prevention principle, in its international context, is part of public international law. It is an application of *sic utere tuo ut alienum non laedas*, which is a natural limit to the sovereignty principle, and explicitly recognised for instance in the *Trail Smelter* arbitrage.11 The legal nature of the precautionary principle, on the other hand, is disputed. A number of Treaties include the principle, and it is certainly a general principle within certain regional context, such as in particular the European Union.12 But it is arguably too early to refer to the principle as being part of public international law.

Early in 2000, the Commission adopted a Communication on the precautionary principle, which was designed in particular to ease tensions with the United States13 and which arguably may be called the highest-profile exercise so far to try and translate the principle into specific guidelines. Importantly, the Communication was initially sponsored in particular by the trade directorate-general at the European Commission. Sir Leo (now Lord) Brittan, the then trade Commissioner, launched the Communication as a handbook for the use of the principle in EU risk analysis, with a view to reassuring the Union’s trade partners that recourse to the principle was not haphazard, unpredictable and therefore, arguably, a violation of international trade agreements, but rather well thought-through, and systematic.

The Commission insists in this document that the precautionary principle in its European context is a justified part of risk management. The latter, the Commission insists, is not a purely scientific exercise but to a considerable degree a policy process. The communication details that any measures taken on the basis of the principle, have to be proportionate *vis-à-vis* the level of environmental protection sought; that they must not be discriminatory in their application (in particular *vis-à-vis* the trading partners of the EC), that they have to be consistent with any measures which have already been taken; (consistency); that they have to be based on technical analysis and, where possible, economic cost and benefit analysis; and that they have to be subject to constant monitoring and evaluation, including potential review (in particular with a view to integrating potential new scientific developments).

While the precautionary principle may usefully be quoted as a focal point for the divide between in particular the United States and the European Union, in reality the dichotomy between the United States and the EU in terms of risk analysis, goes further than that, and certainly deeper than the belief as to whether the precautionary principle is a bind-

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11 US v Canada, 3 RIAA (1941) 1907.
ing principle of international law. In particular the EU and its Member States view risk analysis as a linear process, in which the various steps of a risk analysis process (see above: risk identification, risk assessment, risk management, and risk communication), are neatly divided. Importantly, the EU assigns the responsibility and the main lead in each of these steps to different professional groupings. Whilst the steps of risk identification and certainly that of risk assessment are a responsibility of scientists, the step of risk management is very firmly seen as a political step, in which elected politicians on both the national scene and the European scene, take the lead. This preponderant role of politicians in risk management makes the process prone, so its critics say, to being susceptible to scaremongering, and to recourse to the precautionary principle.

Whether it is this view on risk analysis which makes institutions like the European Parliament take a more active note of citizens panels’ early warning signals with respect to nanotechnologies, or, conversely, European citizens’ concerns over a variety of technologies which has given rise to this specific view on risk analysis, the fact is that in a precautionary context, the European Parliament intervention is not surprising. If and when written in the statute books, in the author’s view this will lead to consolidation in industry and the scientific community, whereby industry no longer ponders simultaneous roll-out of nanotechnologies across a wide variety of products and applications, but rather focuses on those where the technology has the most promise, preferably from a consumer welfare point of view. It is in these focused areas that risk assessment will also need to be concentrated.

IV. Conclusion

Parliament’s intervention and the argued need for priority which goes with it, undoubtedly is a wake-up call for the European Commission and industry alike. Successive food scandals in the EU have led to a lack of confidence among the European public in its regulators’ capacity to manage the health, safety and environmental aspects of technologies, and the European Parliament undoubtedly is picking up that mood. This development has also altered the state of regulatory affairs for nanotechnologies oversight: while until now one could talk of “proactive” action to regulate the technologies, one now arguably has to revert to reactive action, if not to actually proven health or environmental risks, then at least reactive to the European Parliament initiative.