



Response to House of Lords Science and
Technology Select Committee on
Nanotechnologies and Food

Response from the ESRC Centre of Business Relationships,
Accountability, Sustainability & Society, Cardiff University

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Respondent Profile

The ESRC funded Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) at Cardiff University is a major research centre dedicated to providing a critical view on all aspects of business relationships that affect issues surrounding sustainability, accountability and their interaction with different components of society. The comments provided in the response are based on the report 'An Overview of the Framework of Current Regulation Affecting the Development and Marketing of Nanomaterials', written by the respondents for the Office of Science and Innovation in December 2006. The report is located at: <http://www.berr.gov.uk/files/file36167.pdf>.

Currently, BRASS is conducting research for the Department for the Environment, Food and Rural Affairs on the application of corporate social responsibility by the nanotechnologies industries in the context of safeguarding the environment and human health.

Introduction

BRASS welcomes this opportunity to contribute to the invitation to submit written evidence on the use of nanotechnologies in the food sector. In view of our previous work, and given our role as social science researchers, we have restricted our responses to the questions relating to the regulatory framework and to public engagement.

Regulatory Framework

Q. 1. Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

In principle, current uses of nanotechnologies and nanomaterials will fall within the scope of a range of existing regulatory provisions. There is no nano-specific legislation, either in the UK or EU. The regulation of nanomaterials is therefore question of whether, and to what extent, legislative provisions designed to manage risks from *bulk*-scale materials also cover potential risks from materials at nano-scale. Given that current uses of nanotechnologies tend to involve the nano-scale versions of materials already subject to regulatory control, there are usually obvious regulatory regimes into which nanomaterials will fall. Nanomaterials may be caught within the remit of a wide range of existing legislative provisions, in areas such as consumer protection, occupational health and safety, and environmental protection.

There are instances, however, in which regulatory gaps can arise (see BRASS, 2006). First, nanomaterials may fall outside the remit of existing provisions because, even at bulk-scale, those materials are unregulated. Secondly, the content of existing legislation may, in some instance, be ill-suited to nanomaterials. Thirdly, the particular implementation of those provisions may fail to account for the properties or behaviour of nanomaterials. Existing legislative provisions were never designed with nanomaterials in mind (RCEP, 2007). It is unsurprising, therefore, that their capacity to afford adequate protection may be limited.

The limitations of current legislation are brought into sharp focus by considering their application to food products. The greatest potential difficulty arises in relation to the Novel Foods Regulation (EC) No. 258/97. Pre-market approval is required for novel foods and novel food ingredients, but not for those that are deemed by a national food assessment body (FSA) to be *substantially equivalent* to comparable traditional foods. Substantial equivalence between new and existing foods is determined by a range of factors, such as their composition, nutritional value and intended use; although there is no explicit provision in the Regulation that *particle size* or the unique *properties* of novel foods should be taken into account. This creates the possibility that novel foods or food ingredients containing nanomaterials will be deemed to be substantially equivalent to their existing bulk-scale counterparts, and thereby escape the need for pre-market approval, even though they may pose a greater risk to human health.

The European Commission has recently presented proposals for a new, amended Regulation on Novel Foods (COM (2007) 872). One of the proposed Recitals seeks to clarify whether foods comprising nanomaterials are ‘novel’ and therefore subject to market entry control. ‘Novel food’, the Commission suggests, should include ‘foods modified by new production processes, such as nanotechnology and nanoscience’. The fact that amendments such as this are under consideration is encouraging. Some caution, however, should be expressed in respect of its *technology*-based approach to regulation. A *product*-based approach – in which the novelty of nano-foods is determined on a case-by-case basis according to their individual properties, functions and hazards – remains preferable, not least because process distinctions are not well recognised in the world trade treaties such as GATT.

Generally, food additives legislation (adopted under the framework of the food additives Directive 89/107/EEC, e.g. Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs, 95/2/EC on food additives other than colours and sweeteners, and 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners) is sufficiently broad to encompass the use of nanomaterials. Some aspects of that legislation, however, may be problematic. Directive 95/2/EC, for example, prohibits the use of certain additives in quantities above prescribed maximum levels. Although these maximum levels might be suitable for additives composed of bulk-scale materials, they are not necessarily so for materials at nano-scale. Legislation in this area tends to overlook particle size as a determining factor in the toxicity of substances. The new food additives Regulation (EC) No. 1333/2008 addresses this issue (see Article 12). We welcome this initiative as it presents an obvious solution to track developments in the use of nanomaterials as food additives.

Although the food additives Directive (89/107/EEC) does not set out specific criteria for the assessment of nanomaterials, it contains a number of ‘safety net’ provisions which require that foods are continually observed and re-evaluated in light of changing conditions of use or new scientific information. Umbrella safety legislation (such as the General Food Regulation (EC) No. 178/2002 and the (UK) General Product Safety Regulations 2005) provide an additional layer of regulation, prohibiting the placing of unsafe foods or products on the market. The capacity of these provisions to afford adequate protection against potential harm from with nanomaterials, however, will ultimately depend on whether there are suitable procedures for the identification, characterisation and assessment of risks. These procedures are still lacking. Moreover there are questions about how far a general food safety law might actually deter risk taking conduct.

Q.3 Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

The capacity of current regulations adequately to control the *present*, let alone the next, generation of nanotechnologies and nanomaterials is limited. As applications of nanotechnologies and nanomaterials develop, and become increasingly *dissimilar* to conventional (regulated) technologies and materials, gaps in current legislation will only grow to be more pronounced. Before the capacity of regulations to address future applications of nanotechnologies can be properly examined, it is necessary to gain a clear idea of what those future applications actually entail. Whilst we do not consider it necessary to impose overarching nano-specific legislation (giving effect to a moratorium, for example), current regulations will, in our opinion, need to be amended to account for more sophisticated nano-based products and processes. Moreover these will need to be adapted to cover not merely foodstuffs but also packaging and materials used in food preparation.

Public engagement

Q.1 What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

Broadly speaking, the available evidence on public awareness in countries such as the USA and UK shows that awareness of the existence of nanotechnology in general has changed little from a low level a few years ago (Currall, King et al. 2006; Kahan, Slovic et al. 2007; Scheufele, Corley et al. 2007). For example, in 2006, 42% of Americans surveyed had not heard of nanotechnology (Peter D. Hart Research Associates 2006), with this actually increasing to 49% in 2008 (Peter D. Hart Research Associates 2008). However, research on attitudes towards specific potential applications of nanotechnologies demonstrates that there may be significant concern about food applications, particularly where nanoingredients are actually present within foods rather than simply used within packaging materials. A survey for the Woodrow Wilson Institute indicates that only 7% of Americans would buy nanofood now, with 29% not wanting to buy it at all, and 62% wanting more information on risks and benefits, vs 12%, 73% and 13% for food containers (Peter D. Hart Research Associates 2007). Evidence from research in Switzerland suggests that people may be hesitant to buy foods which either contain nano-additives or use packaging which contains nanomaterials or nanostructures (Siegrist, Cousin et al. 2007). This research also indicates that trust in institutions is a key factor in determining perceptions of such technologies. Survey data from Germany also indicates that mistrust of regulators and industry could be particularly significant with respect to nanofoods, as low trust of these groups is correlated with high rates of rejection of the use of nanoadditives in food (Halliday 2007). Further, research from recent public engagement events in the UK indicates that, in general, the public are perhaps more concerned about the extent of scientific uncertainty surrounding risk, rather than about the nature of risks that have to date been identified (Gavelin, Wilson et al. 2007, 39).

Q.2 How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

Other evidence indicates that whether the public trusts or mistrusts the ability of regulators and industry to handle risks and uncertainties is based on experiences of previous technology controversies (e.g. Macoubrie 2006, 235-6; (Pidgeon, Harthorn et al. 2009), and on whether these controversies have been amplified by a lack of transparency from industry and regulators, both about risk and about scientific uncertainty. Although the assumptions behind public engagement activities have shifted in large part away from “deficit” models of public information about science, some commentators have observed that these models risk being replaced by a “trust deficit” model. For these commentators, unless the purpose and practice of engagement is altered, its purpose risks becoming merely about convincing the public, envisaged as “end-user consumers”, of the potential future benefits of a technology (e.g. Kearnes and Wynne 2007). To counter these effects, the aim of future public engagement exercises on nanotechnology must focus on transparent discussion of scientific uncertainty over both benefits *and* risks. Unfortunately, to date the food industry has manifested a low degree of transparency regarding the presence of nanomaterials in food and food packaging (Schelke 2006). In certain areas such as flavourings, competitive forces may militate against greater openness.

Q.3 What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

There is evidence from research done on public attitudes to GM foods to suggest that demonstration of technological benefits alone is not enough to persuade people to consume modified food (Cox, Koster et al. 2004). There is reason to suspect that similar attitudes may be evident in relation to “nanofoods”. Trying to win public trust by stressing potential benefits may therefore be ineffective, as well as reproducing “deficit” models of engagement in new forms. It has also been argued that new technologies (with GM as a prime example) act as condensation points for the expression of broader public concerns, about e.g. the wider social responsibilities of industry (Kearnes, Grove-White et al. 2006, 300-301). Given that mistrust, in a UK context, is strongly correlated with experiences of controversies over BSE and GM, the importance in the future of the relationship between factors like mistrust and how both risks *and* uncertainties are communicated is difficult to overemphasise.

Q.4 Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

Concerns which are sometimes expressed over exposure to risk turn out, on further investigation, to be about the *imposition* of risk, i.e. about the social context through which risk is distributed. Recent research shows that, as well as demanding information about the state of scientific uncertainty, publics are concerned with the management of consent to bear risk, and the moral issues which underlie issues of consent (Shrader-Frechette 2007). How marketing is used as a conduit for product information features again and again in recent consumer research as an object of concern (e.g. Federal Institute for Risk Assessment (Germany) 2006, Which? 2008, 10). Labelling and other marketing information provides a vital means of allowing people to make decisions about consenting to bear risk and uncertainty, and thus may be a key factor (amongst others) to establishing the social legitimacy of some uses of nanotechnologies.

Conclusion

In general terms we would stress that the Regulatory framework is not water-tight. It is capable of adaptive management since food is generally well regulated and those engaged in food production have strong incentives to ensure that food is safe. While work is already underway at a European level as a beginning of this process, progress to date has been slow. In part this is because of the difficulty of regulating in the absence of agreed definitions, metrics, processes of characterisation etc. However, this should not be used as an excuse to delay regulatory reform.

As for public engagement, this is not easy as a formal exercise amidst a low level of recognition of nanomaterials. However, there are strong messages demonstrating the importance of a continuing form of dialogue with the public and processes of transparent dealings. Without this, distrust of nanotechnologies and their regulation might quickly develop.