

A close-up photograph of a microscope's objective lenses, showing the intricate details of the metal and glass components. The lighting is dramatic, with strong highlights and deep shadows, creating a sense of precision and scientific inquiry.

STEPTOE & JOHNSON LLP

Regulation of Nanotechnology in Food

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EXAMPLES OF NANOTECHNOLOGY IN FOOD

➤ Food Packaging

- ✓ Including ‘Active’ or ‘intelligent’ packaging

➤ Food Processing: Taste and Texture

- ✓ For example, nanoparticle emulsions to improve texture (trickling agents) and reduce fat content

➤ Functional Foods

- ✓ Nanocapsules enclosing nutrients such as vitamins or Omega 3 fatty acids (‘nanocentricals’) for release into body when required

EXISTING LEGAL FRAMEWORK – POSITIONS OF INSTITUTIONS

- June 2008 Commission Communication on Regulatory Aspect of Nanomaterials/Staff Working Document:
 - ✓ ‘Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. Protection ... needs to be enhanced by improving implementation of current legislation. ‘Specially mentions:
 - Regulation 258/97 (Novel Foods – nano ingredients and technologies).
 - Regulation 1935/2004 (Food Contact Materials).
 - Directive 89/107 (Food Additives – now repealed).
 - Directive 2002/46 (Food Supplements).
 - Directive 1925/2006 (Fortification/Addition of vitamins and minerals)

EXISTING LEGAL FRAMEWORK – POSITIONS OF INSTITUTIONS

✓ Suggested solution:

- need for review and amendment of implementing standards, technical guidance (particularly re risk assessment and test methods) to assess appropriateness to nanomaterials
- in some (exceptional) cases, amendment of current legislation ‘may’ be necessary

✓ Scientific knowledge base needs to be improved first

EXISTING LEGAL FRAMEWORK – POSITIONS OF INSTITUTIONS

- April 2009 European Parliament resolution on regulatory aspects of nanomaterials:
 - ✓ Wholesale amendment of existing framework necessary:
 - ‘Clear regulatory and policy framework that explicitly addresses existing and expected applications of nanomaterials’ (especially in food sector)
 - ✓ Call on Commission to review all relevant legislation within 2 years (2011)
 - ✓ ‘Deplores the absence of a proper evaluation of the *de facto* application of the general provisions of Community law in the light of the actual nature of nanomaterials’
 - ✓ ‘Solution not improved implementation of existing legislation when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks’

EXISTING LEGAL FRAMEWORK – POSITIONS OF INSTITUTIONS

- ✓ Introduce comprehensive definition of nanomaterials into relevant Community legislation
- ✓ Duty of care on manufacturers placing nanomaterials on the market
- ✓ Commission to compile before June 2011 publicly available inventory (respecting CBI) of different types/uses of nanomaterials in EU
- ✓ Labelling of nano ingredients (see later)
- ✓ Urgent development of adequate testing protocols to assess hazards of and exposure to nanomaterials

EXISTING LEGAL FRAMEWORK – POSITIONS OF INSTITUTIONS

- October 2009 Commission Communication: 2nd implementation report re Nano Action Plan for Europe:
 - ✓ Nanotechnology currently underpins many practical applications and has the potential further to enhance quality of life and environmental protection and boost Europe's industrial competitiveness
 - ✓ Following publication of regulatory review (also requested by EP) in 2011, the Commission may propose regulatory changes
 - ✓ Specific nanomaterial provisions in novel foods, additives legislation 'at the request of EP'
 - ✓ 'Surveying the market for nano products, including their safety aspects'
 - ✓ 'Stepping up the research effort on safety assessment'
- New Action Plan (2010-2015) under development

CURRENT REGULATION OF NANOTECHNOLOGY IN FOOD – EXISTING FRAMEWORK

- Regulation of products or processes incorporating nanotechnology, not of nanotechnology itself
- General principle of food law: ‘Food shall not be placed on the market if it is unsafe’ (Article 14(1), Regulation 178/2002)
- Existing ‘precautionary approach’ prior approval food legislation (process/product specific)

For example:

- ✓ (Existing) Novel Foods (Regulation 258/97)

CURRENT REGULATION OF NANOTECHNOLOGY IN FOOD – EXISTING FRAMEWORK

- ✓ Food supplements (Directive 2002/46)
- ✓ Fortification (Regulation 1925/2006)
- ✓ New food additives Regulation 1333/2008 (later)

- Non-food specific chemicals prior approval legislation:
 - ✓ REACH (Regulation 1907/2006) since 1 June 2007
 - ✓ Dangerous Substances Directive (Directive 67/548) (largely replaced by REACH)

SUGGESTED DEFINITIONS

- Ongoing calls for comprehensive, internationally agreed definition
- Precondition to establishing market uses
- UK House of Lords Select Committee Report on Nanotechnologies and Food (January 2010):
 - ✓ change in functionality (how substance interacts with the body), not 'below X nm' should be the key
 - ✓ detailed list of 'properties that are characteristic of the nanoscale'
 - ✓ distinguish between naturally occurring and engineered nanoparticles

DRAFT DEFINITION FOR FOOD USE

- Novel Foods Definition of engineered nanomaterial (Council Common Position Article 3(2)(c)):
 - ✓ ‘intentionally produced material that has one or more dimensions of the order of 100 nm or less or that 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 of the nanoscale

Properties that are characteristic of 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’

EMERGENCE OF REGULATION OF NANOTECHNOLOGY IN FOOD

- Recent developments in food legislation to extend existing framework to accommodate nanotechnology
- UK House of Lords Select Committee Report on Nanotechnologies and Food (January 2010):
 - ✓ engineered nanomaterials used in food must be subject to a formal EFSA risk assessment
- Nanotechnology provisions in vertical (application specific) legislation (including food)

EMERGENCE OF REGULATION OF NANOTECHNOLOGY IN FOOD

- Novel Foods Regulation Proposal (EP Plenary Sitting 2nd Reading, July 2010) :
 - ✓ ‘Novel food should include foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food’ (Recital 6, Art. 3(2)(a)(iii) Proposal)
 - ✓ Specific process should be approved through safety assessment showing food safe (EP)

EMERGENCE OF REGULATION OF NANOTECHNOLOGY IN FOOD

- ✓ Need for ‘systematic’ evaluation of food containing engineered nanomaterials, irrespective of whether nanomaterials thought to cause changes in food properties (Council)
- ✓ Definition of ‘engineered nanomaterial’ (Council Common Position Article 3(2)(c)) (see later)
- ✓ Need for internationally agreed definition of ‘engineered nanomaterial’
- ✓ Recognition of need for adaptation of definition to technical and scientific progress (EP)
- ✓ Urgent need for appropriate and specific risk assessment test methods for engineered nanomaterials (EP, Council)
- ✓ Labelling (see later)

EMERGENCE OF REGULATION OF NANOTECHNOLOGY IN FOOD

- New Food Additives Regulation 1333/2008
 - ✓ Food additives produced through nanotechnology requires separate new entry in positive list from non-nano version already on list (Article 12)
- Active and Intelligent Food Contact Materials and Articles:
 - ✓ ‘Nanoparticles, ...should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology. Therefore, they should not be covered by the functional barrier [authorisation exemption] concept’ (Recital 14)

EMERGENCE OF REGULATION OF NANOTECHNOLOGY IN FOOD

- Recast of rules on plastic food contact materials (Draft PIM)
 - ✓ Mentions substances deliberately engineered to particle size which show discrete functional physical and chemical properties
 - ✓ No functional barrier evaluation/authorisation exemption for substances in nanoform

RISK ASSESSMENT OF PRODUCTS ENABLED BY NANOTECHNOLOGY

- Case-by-case risk assessment of nanoparticles necessary
- 2009 SCENIHR Opinion on Risk Assessment of Products of nanotechnologies:
 - ✓ ‘procedure for assessing potential risks of manufactured nanomaterials still under development’
 - ✓ not yet ‘sufficient scientific information available to characterise the possible harmful effects on humans and the environment’
 - ✓ need to characterise nanomaterial as produced (SDS), as used in biological systems (distribution can change considerably characteristics due to particle aggregation), and as actually used in specific product
 - ✓ ‘general lack of high quality exposure data’

RISK ASSESSMENT OF PRODUCTS ENABLED BY NANOTECHNOLOGY

- February 2009 EFSA opinion on the Potential Risk Arising from nanoscience and nanotechnologies on Food and Feed Safety:
 - ✓ ‘The risk assessment of ENMs must be performed on a case-by-case basis’
 - ✓ ‘The available data on oral exposure to specific ENMs and any consequent toxicity are extremely limited’
 - ✓ Under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty. This situation will remain so until more data or and experience with testing of ENMs becomes available
- House of Lords Report:
 - ✓ Urgent need for behaviour of nanomaterials in gut

REPORTING/INVENTORIES

- 2009 Milieu Report commissioned by Commission proposes Commission mandatory nanomaterials register
 - ✓ information from producers/importers required to understand what is on market and assess exposure
- UK Food Standards Agency propose (follow House of Lords recommendation):
 - ✓ mandatory confidential database of nanomaterials researched in food industry
 - crucial information for risk assessment of nanomaterials
 - legislation required

REPORTING/INVENTORIES

- ✓ publicly available (online) list of foods and food packaging containing nanomaterials (those given positive Opinion by EFSA)
 - Difficult to gauge precisely extent of nanotechnology use in food sector – definition?
 - Food industry should avoid secrecy: GMO comparison
 - ‘exactly the type of behaviour that may bring about the public reaction [industry] is trying to avert’
 - secrecy breeds mistrust
 - Balance industry confidentiality concerns with need to gain consumer confidence

➤ Labelling:

✓ Novel Foods Regulation Proposal:

- Labelling stipulated in authorisation decision – case by case (Council)
 - Labelling to state produced with nanotechnology (EP)
 - ‘(nano)’ to appear next to nanomaterial ingredient on label (EP)
- ✓ will consumer understand significance?
- perceived as mandatory warning or marketing claim

CONCLUSIONS

- Regulatory framework need to balance economic potential with both ensuring safety and gaining public trust (GMO history)
- Existing food legislative framework being extended to cover nanotechnologies specifics
- For nano-specific risk assessment, verify or develop:
 - ✓ adequate risk assessment tools
 - ✓ ability to know what nanotechnology is being used in food/researched
- Development of agreed definition and adopted amendments of revised Novel Food Regulation a crucial next step