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Nanofood: Legal and Regulatory Challenges

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NANOFOOD: LEGAL AND REGULATORY CHALLENGES

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ABSTRACT

Nanotechnology will have a significant impact on food production in a variety of ways, both directly and indirectly. The growth and complexity of nanotechnology in food applications poses new challenges for the existing food regulation as well as the regulatory authority. This article seeks to examine the legal and regulatory challenges posed by the nanotechnology applications in the food industry. This article reviews some of the relevant legislation in the U.S. and E.U. in dealing with nanofood and the industry. This article also provides an assessment on the adequacy of those laws and identifies the possible gaps and weaknesses in them.

I. INTRODUCTION

In 2003, Nobel Laureate and nanotech entrepreneur Richard Smalley expressed his frustration with what he viewed as exaggerated concerns over the safety of nanotechnology and stated: "[a]fter all, we're not advising that you eat nanotech stuff." The reality is that "[a]bout the time Dr. Smalley was telling consumers not to worry, the nanotech market for food and food processing was estimated to be in excess of $2 billion and projected to surge to more than $20 billion by 2010."[1] "Nanotechnology is moving out of the

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1. ACTION GROUP ON EROSION, TECHNOLOGY AND CONCENTRATION, DOWN ON THE FARM: THE IMPACT OF NANO-SCALE TECHNOLOGIES ON FOOD AND AGRICULTURE,

laboratory and into every sector of food production. Manufactured nanomaterials are already used in some food products, nutritional supplements, many packaging and food storage applications and some agriculture inputs."[2] More will be entering the market.

II. NANOTECHNOLOGY AND FOOD INDUSTRY

According to the International Union of Food Science and Technology (IUFoST), worldwide commercial foods and food supplements containing added nanoparticles are becoming available. "Estimates of commercially available nanofoods vary widely; nanotechnology analysts estimate that between 150-600 nanofoods and 400-500 nanofood packaging applications are already on the market."[3] The IUFoST's examples of food-related nano-products include:

- nanoparticles of carotenoids that can be dispersed in water, allowing them to be added to fruit drinks providing improved bioavailability;
- a synthetic lycopene has been affirmed GRAS ("generally recognised as safe") under US FDA procedures;
- nano-sized micellar systems containing canola oil that claimed to provide delivery systems for a range of materials such as vitamins, minerals or phytochemicals;
- a wide range of nanoceutical products containing nanocages or nanoclusters that act as delivery vehicles, e.g. a chocolate drink claimed to be sufficiently sweet without added sugar or sweeteners;
- nano-based mineral supplements, e.g. a Chinese Nanotea claimed to improve selenium uptake by one order of magnitude;
- patented 'nanodrop' delivery systems, designed to administer encapsulated materials, such as vitamins, transmucosally, rather than through conventional delivery systems such as pills, liquids or capsules; and
- an increasingly large number of mineral supplements such as nano-silver or nano-gold.[4]

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at 3 (Nov. 2004), *available at* http://www.ecolomics-international.org/biosan_nano_etc_nov04_down_on_the_farm.pdf.

2. GEORGIA MILLER & DR.RYE SENJEN, FRIENDS OF THE EARTH, AUSTRALIA, EUROPE & U.S.A, OUT OF THE LABORATORY AND ON TO OUR PLATES, at 9 (2008), *available at* http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf .

3. *Id.* at 10

4. INTERNATIONAL UNION OF FOOD SCIENCE & TECHNOLOGY, NANOTECHNOLOGY AND FOOD, at 3 (Dec. 2007), *available at* http://www.iufost.org/reports_resources/bulletins/documents/IUF.SIB.Nanotechnology.pdf.

The Friends of the Earth is of the view that [n]anotechnology has potential applications in all aspects of agriculture, food processing, food packaging and even farm and food monitoring:

- methods to enable foods such as soft drinks, ice cream, chocolate or chips to be marketed as 'health' foods by reducing fat, carbohydrate or calorie content or by increasing protein, fibre or vitamin content;
- production of stronger flavourings, colourings, and nutritional additives, and processing aids to increase the pace of manufacturing and to lower costs of ingredients and processing;
- development of foods capable of changing their colour, flavour or nutritional properties according to a person's dietary needs, allergies or taste preferences;
- packaging to increase food shelf life by detecting spoilage, bacteria, or the loss of food nutrient, and to release antimicrobials, flavours, colours or nutritional supplements in response and
- re-formulation of on-farm inputs to produce more potent fertilisers, plant growth treatments and pesticides that respond to specific conditions or targets.[5]

A recent report by Helmut Kaiser Consultancy has estimated that nanofood market would have grown to US$7 billion in 2006, and would reach US$20.4 billion by 2010.[6] Around the globe, over 400 companies, giant and start-up, research, develop, and produce nanofood-related products.[7] "Five out of ten of the world's largest food companies are aggressively exploring the potential of the really small to make really big improvements in packaging, food safety, and nutrition. Similarly, in agriculture, some of the world's largest makers of pesticides, fertilizers, and other farm inputs and technologies are betting on nanotechnology to bring unprecedented precision to crop and livestock production."[8] "Several companies which were hesitant about revealing their research programmes in

5. *See* FRIENDS OF THE EARTH, *supra* note 2, at 11.

6. Helmut Kaiser Consultancy, *Nanotechnology in Food and Food Processing Industry Worldwide*, http://www.hkc22.com/nanofood.html (last visited Apr. 11, 2009).

7. Qasim Chaudhry et al., *Applications and Implications of Nanotechnologies for the Food Sector*, 25 FOOD ADDITIVES & CONTAMINANTS 243 (2008), *available at* http://pdfserve.informaworld.com/567173__791090932.pdf

8. JENNIFER KUZMA & PETER VERHAGE, NANOTECHNOLOGY IN AGRICULTURE AND FOOD PRODUCTION: ANTICIPATED APPLICATIONS, at 7 (2006), *available at* http://nanotechproject.org/process/assets/files/2706/94_pen4_agfoods.pdf. The big companies include Altria, Nestle, Kraft, Heinz and Unilever. Kraft Foods started the first notechnology laboratory in 1999 and is Nanotek consortium, involving 15 universities worldwide and national research laboratories was established in 2000. They are busy working towards "programmable food." An American company has claimed to have created the "Holy Grail of chewing-gum design" - chewing gum with real chocolate in it. *Id.*

nanofood, have now gone public announcing plans to improve existing products and develop new ones to maintain market dominance."[9] It is also widely anticipated that the number of companies applying nanotechnologies to food will increase dramatically in the near future."[10] "The number of patent applications relating to nanotechnology applications in food is growing rapidly."[11]

III. APPLICATIONS OF NANOTECHNOLOGY IN THE FOOD INDUSTRY

"Although nanotechnology applications for the food sector are relatively recent, there have been rapid developments in this area in recent years."[12] Broadly, the currently known and projected applications of nanotechnology for the food sector fall into the following main categories:

- Where food ingredients have been processed or formulated to form nanostructures,
- Where nano-sized, nano-encapsulated or engineered nanoparticles additives have been used in food;
- Where nanomaterials have been incorporated to develop improved, "active", or "intelligent" materials for food packaging;
- Where nanotechnology-based devices and materials have been used, e.g. for nanofiltration, water treatment, nanosensors for food safety and traceability.[13]

The Action Group on Erosion, Technology and Concentration (ETC) is of the view that "[n]ano-scale technologies will take food engineering 'down' to a new level, with the potential to change dramatically the way food is produced, grown, processed, packaged, transported and even eaten."[14] The current and anticipated nanotechnology's applications in the food industry include: smart packaging, nanoparticles as food ingredients and additives, and interactive/programmable food/drink.

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9. Tiju Joseph & Mark Morrison, *Nanotechnology in Agriculture and Food*, NANOFORUM, April 2006, at 10, *available at* http://www.nanoforum.org/dateien/temp/nanotechnology%20in%20agriculture%20food.pdf?1107200604022.

10. *See* Chaudhry et al., *supra* note 7.

11. INSTITUTE OF FOOD SCIENCE & TECHNOLOGY (IFST), INFORMATION STATEMENT: NANOTECHNOLOGY, at 3 (2006), *available at* http://www.ifst.org/uploadedfiles/cms/store/ATTACHMENTS/nanotechnology.pdf.

12. *See* Chaudhry et al., *supra* note 7, at 243.

13. *Id.* at 243-244.

14. ACTION GROUP ON EROSION, *supra* note 1 at 45.

"It is expected that nanotechnology is going to change the whole packaging industry."[15] Engineering at the nanoscale has the potential to create new opportunities for the packaging industries, and various applications of the technology including:

- improved barrier properties;
- better temperature performance;
- thinner films for flexible packaging; and
- nanoscale pigments for inks.[16]

> Nanotechnology enables designers to alter the structure of packaging materials at the molecular level. For example, plastics can be manufactured with different nanostructures to gain various gas and moisture permeabilities to fit the requirements of specific products such as fruits, vegetables, beverage and wine. As a result, the shelf-life and flavour and colour of the products can be improved. Nanostructured films and packaging materials can prevent the invasion of pathogens and other microorganisms and ensure food safety. Nanosensors embedded in food packages will allow the determination of whether food has gone bad or show its nutrient content. By adding certain nanoparticles into packaging material and bottles, food packages can be made more light- and fire-resistant, with stronger mechanical and thermal performance and controlled gas absorption.[17]

Tiju Joseph and Mark Morrison argue that "developing smart packaging to optimise product shelf-life has been the goal of many companies."[18] "Such packaging systems would be able to repair small holes/tears, respond to environmental conditions, . . . and alert the customer if the food is contaminated."[19] "Nanotechnology can provide solutions for these, for example, *modifying* permeation behaviour of foils, increasing barrier properties, . . . improving mechanical and heat-resistance properties, developing active antimicrobic and antifungal surfaces, and sensing as well as signalling microbiological and biochemical changes."[20] "Packaging becomes

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15. Nurhan Dunford, Oklahoma State University, Food and Agricultural Products Research and Technology Center, *Nanotechnology and Opportunities for Agricultural Food Systems*, 139 FOOD TECH. FACT SHEET 1, at 2, *available at* http://www.fapc.okstate.edu/files/factsheets/fapc139.pdf.

16. The UK. Food Standard Agency, *Draft FSA Regulatory Review on Nanotech. In Food: Issue For Comment* 8(2006), available at http://www.food.gov.uk/multimedia/pdfs/int060401a.pdf.

17. *See* Dunford, *supra* note 15, at 139-2.

18. Joseph & Morrison, *supra* note 9, at 7.

19. *Id.*

20. *Id.* at 7- 8 (emphasis added).

part of the food" and is known as "interactive packaging."[21] As the CEO of Food Standards Australia New Zealand, Steve McCutcheon, puts it, "the food takes in chemicals from the packet as it sits on the shelf."[22] He said, "[a]t the moment, the shelf life of prepacked salad vegetables is fairly short, but with the application of this technology we understand that you could actually package fresh salads, and they would be fresh still after the 30-day period on the shelf."[23]

According to the IUFoST, indeed,

> Nanocomposites are already available as packaging or in coatings on plastic bottles to control gas diffusion and prolong the lifetime of various products. Nanotechnology is already being used worldwide to produce anti-microbial food contact materials (FCMs) commercially available as packaging, or as coatings on an ever increasing number of products such as food containers, chopping boards and refrigerators.[24]

"The polymer composites incorporating clay nanoparticles are among the first nanocomposites to emerge on the market as improved materials for food packaging."[25] "The nanoclay mineral used in these nanocomposites is montmorillonite, . . . which is a relatively cheap and widely available natural clay derived from volcanic ash/rocks."[26]

> The financial outlook for nanotechnology enabled packaging looks buoyant. The current packaging market stands at USD $1.1 billion and it is predicted to increase to USD$3.7 billion by 2010." With "this, the Smart Packaging industry is growing faster than predicted as is already showing sign of maturity. Research by the financial firm Frost and Sullivan, found that today's consumers demand much more from packaging in terms of protecting the quality, freshness and safety of foods, as well as convenience. They conclude that this is one of the main reasons behind the increased interest in innovative methods of packaging.[27]

According to the Friends of the Earth, "[b]etween 400 and 500 nano-packaging products are estimated to be in commercial use now, while nanotechnology is predicted to be used in the manufacture of 25% of all packaging within the next decade."[28] "Packaging will increasingly become a service trying to meet multiple funct-

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21. Simon Lauder, *Nanotechnology a 'Bigger Concern' than GM Foods*, ABC NEWS, Nov. 29, 2007,,http://www.abc.net.au/news/stories/2007/11/29/2104922.htm (last visited Apr. 11, 2009).
22. *Id.*
23. *Id.*
24. INTERNATIONAL UNION OF FOOD SCIENCE & TECHNOLOGY, *supra* note 5, at 2..
25. Chaudhry et. al., *supra* note 7 at 245.
26. *Id.*
27. Joseph & Morrison, *supra* note 9, at 8.
28. MILLER & SENJEN *supra* note 2, at 15.

ions . . . and "[a]ccording to Helmut Kaiser. . . , traditional 'packing' is to be replaced with multi-functional intelligent methods to improve the food quality . . ."[29] and it is "estimated that in the next decade nanotechnology will impact 25 percent of the food packaging market."[30]

> Another important application of nanotechnology is the addition of nanoparticles to the existing foods. One of the leading bakeries in Western Australia has been successful in incorporating nanocapsules containing tuna fish oil in their top selling product 'Tip-Top' Up bread. The microcapsules are designed to break open only when they have reached the stomach, thus avoiding the unpleasant taste of the fish oil. The Israeli Company Nutralease utilizes Nano-sized Self-assembled Liquid Structure (NSSL) technology to deliver nutrients in nanosized particles to cells.[31]

Other items available on the market include products called Canola Activa oil, Nanotea, Nanoceuticals Slim Shake, Novasol, Aquanova, Bioral and many more. "Nestle and Unilever are reported to be developing a nano-emulsion based ice-cream with a lower fat content that retains a fatty texture and flavour."[32]

"A number of chemical companies are researching additives which are easily absorbed by the body and can increase product shelf life."[33] Some have managed to produce and market their products. "BASF, for example, produces a nano-scale version of carotenoids, a class of food additives that imparts an orange colour and that occurs naturally in carrots and tomatoes."[34] BASF also produces and "sells its nano-scale synthetic carotenoids to major food & beverage companies worldwide for use in lemonades, fruit juices and margarines. [B]ASF's carotenoid sales are US $210 million annually."[35]

Looking into the future, it is possible that smart/interactive/functional food or drink would be served for our breakfast, lunch or dinner. The Helmut Kaiser Consultancy states:

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29. *See* George Reynolds, *Future Nanopackaging Market Worth Billions, Says Study*, http://www.foodproductiondaily.com?packaging/Future-nanopackaging-market-worth-billions-says-study (last visited Apr. 11, 2009) (emphasis removed).

30. Michael R. Taylor, *Assuring the Safety of Nanomaterials in Food Packaging: The Regulatory Process and Key Issues*, The Project on Emerging Nanotechnologies, June 25, 2008, at 14.

31. Joseph & Morrison, *supra* note 9, at 10.

32. MILLER & SENJEN *supra* note 2, at 15.

33. Joseph & Morrison, *supra* note 9, at 10.

34. ACTION GROUP ON EROSION, *supra* note 1, at 45.

35. *Id.*

> Tomorrow we will design food by shaping molecules and atoms. Nano-scale biotech and nano-bio-info will have big impacts on the food and food-processing industries. The future belongs to new products, new processes with the goal to customize and personalize the products. . . . Functional food will benefit firstly from the new technologies, followed by standard food, nutraceuticals and others.[36]

The Wageningen University, in the Netherlands, is the host to BioNT, the world's leading biotechnology centre for food and health innovations. Its director, Frans Kampers, says the foundations are already in place for making programmable drinks and other foods, although he says the science still has a way to go.[37] He explains:

> We envisage that it is possible to make nanoparticles that contain, for instance, two flavours, and that these nanoparticles break up when they encounter specific enzymes in the mouth. These flavours would add together and create a new sensation. It might be a different flavour, or a mixture of two flavours, but it could also be something that happens in your mouth; a sizzling sensation for instance. Programming it after the flavours have been added will be a lot tougher though. I don't yet know what mechanism could be used for that.[38]

> Building on the concept of 'on-demand' food, the idea of interactive or programmable food is to allow consumers to modify food depending on their own nutritional needs or tastes. The concept is that thousands of nanocapsules containing flavour or colour enhancers, or added nutritional elements, would remain dormant in the food and only be released when triggered by the consumer.[39]

This smart or functional food/drink will remain dormant in the body and deliver nutrients to cells when needed.

IV. POTENTIAL RISKS TO HUMANS

"Nanotechnology opens up a whole universe of new possibilities for the food industry, but the entry of manufactured nanoparticles into food chain may result in an accumulation of the toxic contaminant in foods and adversely affect human health."[40] Small particles can go where other particles cannot reach and their surfaces

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36. Helmut Keiser Consultancy, *supra* note 8.

37. Sally Palmer, *The Nano Diet*, BBC FOCUS MAGAZINE ON SCIENCE, TECHNOLOGY, FUTURE, 2007, at 40.

38. *Id.*

39. Joseph & Morrison, *supra* note 9.

40. See Chi-Fai Chau, Shiuan-Huei Wu and Gow-Chin Yen, *The Development of Regulations for Food Nanotechnology*, TRENDS IN FOOD SCIENCE & TECHNOLOGY, 2007, at 273.

could be designed to target release of drugs or nutrient but, in introducing such particles, the prime consideration has to be on the benefits and potential risks. The Woodrow Wilson International Center for Scholars argues:

[T]here are many reasons why we need to be better prepared for the arrival of food and agriculture applications of nanotechnology:

- Experience has shown that any risks or benefits involved with integrating new technologies into food and agriculture processes are greatly magnified given their potentially far-reaching effects on humans, animals, rural communities, and the environment;
- Public perceptions and acceptance of agri-food nanotechnology will greatly influence widely these applications enter society, [and]
- Food and agri-business concerns are at the vanguard of commercialising nanotechnology innovations, and their success or failures could affect future commercialisation of nanotechnology products in all industries.[41]

Nanofood has to learn from GMO food. First, the rush to commercialise first and respond to consumer questions later has proven a major problem for an industry. "Another lesson . . . is that given the complexity of the technology, a failure to go thoroughly explore potential risks and to openly and candidly discuss them with the public can do great harm, even if the actual problems involved end up posing little, if any, real threat."[42] Grassroots opposition can substantially impair an industry. The consumers' trust is the determining factor. Trust, in turn, is difficult to gain and easy to lose. This means that early preoccupation with potential risks is critically crucial for a sustainable and successful technology development.[43] "Consumers are entitled to expect any changes in food composition or packaging materials that involve nanotechnology to be necessary and safe, the appropriate toxicity testing to have been done and the results to be freely available in the public domain."[44] The most important lesson from the case of GM food is that uncertainties should be openly acknowledged. As stated by James Wilsdon, "An ability to

41. KUZMA & VERHAGE, *supra* note 8, at 8.

42. *Id.* at 14.

43. Abu Bakar Munir and Siti Hajar Mohd.Yasin, *The Next Big Thing is Really Small: Legal and Regulatory Challenges*, THE LAW REVIEW (Malaysia), 118, 139 (2007).

44. INSTITUTE OF SCIENCE AND TECHNOLOGY, *supra* note 11, at 3.

accept uncertainty - to say 'we're not sure - is an essential component of the new approach."[45]

"The main likely route of entry of micro—or nano-sized particles to the gut is through consumption of food and drinks."[46] "The main risk of consumer exposure to nanoparticles from food packaging is likely to be through potential migration of nanoparticles into food and drinks."[47] The British Royal Society and the Royal Academy of Engineering in 2004 "recommend[ed] that chemicals in the form of nanoparticles or nanotubes be treated as new substances."[48] The British Government, in general terms, acknowledges "that chemical[s] in the form of nanoparticles or nanotubes may exhibit different properties to the bulk form of the chemical."[49] In the words of the Government, "sometimes this is beneficial and sometimes it may be potentially hazardous" [50]

The Society recommended that "ingredients in the form of . . . nanoparticles . . . undergo a [full] safety assessment by the relevant scientific advisory body before they are [permitted for use] . . . in products."[51] Again, the Government agrees with this recommendation and pledges, "[t]he DTI and other relevant departments will discuss with our European partners the most effective mechanisms for referral to the relevant scientific advisory committees and for responding to their advice to ensure the safety of manufactured [free] nanoparticles in cosmetics and other consumer products".[52]

According to the European Scientific Committees on Consumer Products (SCCP), "[n]anoparticles may enter the human body via several routes but the evaluation of exposure is limited. The probability of penetration depends on the size and surface properties of particles and on the anatomical structure of the specific sites of the exposure routes."[53] More importantly, however, the SCCP's

45. Vuk Uskokovic, *Nanotechnologies: What we do not know*, TECHNOLOGY IN SOCIETY, 53 (2007).

46. Chaudhry et al., *supra* note 7, at 7.

47. *Id.*at 246.

48. The Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and* Uncertainties , 86(2004).

49. HM GOVERNMENT, RESPONSE TO THE ROYAL SOCIETY AND ROYAL ACADEMY OF ENGINEERING REPORT - NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES, at 14 (2005).

50. *Id.*

51. *Id.* at 6.

52. *Id.*

53. THE EUROPEAN SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS (SCCP), PRELIMINARY OPINION ON SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS, at

report states that "[n]anoparticles may exhibits a potential oxidative capacity associated with their particulate state, [which] is more pronounced in nanoparticles than in larger particles because of their larger surface area and their specific psycho-chemical properties." Hence, nanoparticles can induce local (lungs, gut, and skin) oxidative stress and subsequent health effects.[54]

The Friends of the Earth argues:

> Nanotechnology is an emerging field, with a small number of peer-reviewed studies published to date. It is often suggested by nano proponents that we do not yet know enough about the behaviour of nanoparticles to determine whether they pose enhanced risks to human health. However, the existing body of toxicological literature suggest clearly that nanoparticles have a greater risk of toxicity than larger particles.[55]

The European Scientific Committee on Emerging and Newly-Identified Health Risk (SCENIHR) opined:

> [I]t is likely that exposure to manufactured nanoparticles will become more common. The overall potential risks are likely to increase if no control actions are taken . . . . Among the main factors that underpin this increased potential risk are the ability for nanoparticles to reach tissues that larger particles do not, the unknown effects associated with highly persistent reactive nanoparticles, and the modified toxicokinetics of these nanoparticles compared to conventional bulk materials. [56]

The British Government in 2005 wrote that "[t]here is insufficient evidence to determine whether nanoparticles adversely affect the gut"[57] and "no data exists on the dose of nanoparticles likely to reach other organs such as bone marrow, spleen, liver, heart and the placenta/foetus."[58] Peter HM Hoet, Irene Bruske-Hohlfeld and Oleg V Salata who reviewed quite extensively the research findings

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27(2007), *available at* http://europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_0_099.pdf.

54. *Id.* at 32.

55. GEORGIA MILLER, FRIENDS OF THE EARTH, NANOTECHNOLOGY AND HEALTH: THE BIG RISKS POSED BY SMALL PARTICLES, *available at* http://nano.foe.org.au/filestore2/download/123/Nanotoxicity%20and%20health%20-%20Issue%20Summary%20May%202006.pdf.

56. SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY-IDENTIFIED HEALTH RISKS (SCENIHR) OPINION ON THE APPROPRIATENESS OF THE RISK ASSESSMENT METHODOLOGY IN ACCORDANCE WITH TECHNICAL GUIDANCE DOCUMENTS FOR NEW AND EXISTING SUBSTANCES FOR ASSESSING THE RISKS OF NANOMATERIALS , at 27 (2007), *available at* http://ec.europa.ed/health/Ph_Risk/Committees104_Scenihr/docs/scenihr_0_004c.pdf.

57. HM GOVERNMENT, CHARACTERISING THE POTENTIAL RISKS POSED BY ENGINEERED NANOPARTICLES, at 32(2005), available at http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-nsreport.pdf.

58. *Id.* at 33.

on the potential entry points of nanoparticles into the human body and their health effects have concluded:

> Particles in the nano-size range can certainly enter the human body via lungs and the intestines; penetration via the skin is less evident. It is possible that some particles can penetrate deep into the dermis. The chances of penetration depend on the size and surface properties of the particles and also on the point of contact in the lung, intestines or skin. After the penetration, the distribution of the particles in the body is a strong function of the surface characteristics of the particles . . . . [E]ach nanomaterial should be treated individually when health risks are expected.[59]

V. REGULATION UNDER THE U.S FEDERAL FOOD, DRUG, AND COSMETICS ACT (FFDCA)

The FFDCA was enacted to safeguard public health and prevent deceit of the purchasing public. Indeed, the Supreme Court has established that "the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors".[60] "Section 331(a) of the FDCA prohibits the introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded."[61] Under section 342, a food is "adulterated" if it meets any one of the following criteria: (1) "it bears or contains any poisonous or deleterious substance which may render it injurious to health; . . . (2) it bears or contains any added poisonous or added deleterious substance . . . that is unsafe; . . . (3) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."[62] Further, food is considered adulterated if it is, or it bears or contains an unsafe food additive or it is, or it bears or contains, an unsafe colour additive.[63] "Through these provisions, Congress empowered FDA to set requirements to assure that firms are producing foods that are safe, unadulterated, and wholesome, in-

59. Peter HM Hoet, Irene Bruske-Hohfeld & Oleg V. Salata. *Nanoparticles - Known and Unknown Health Risks*, 2 J. OF NANOBIOTECHNOLOGY 12 (2004), *available at* http://www.jnanobiotechnology.com/content/2/1/12.

60. *U.S. v. Park*, 421 U.S. 658, 671 (1975) (citing *Smith v. California*, 361 U.S. 147, 152 (1959)).

61. 21 U.S.C. § 331 (1938).

62. 21 U.S.C. § 342 (1938).

63. *Id.*

cluding the authority to control conditions at the earliest stages of food production."[64]

> If a food is adulterated, the FDA and FSIS have a broad array of enforcement tools. These include seizing and condemning the product, detaining imported product, enjoining persons from manufacturing or distributing the product, or requesting a recall of the product. Enforcement action is usually preceded by a Warning Letter from FDA to the manufacturer or distributor of the adulterated product.[65]

The authority of the FDA under the Act is depending on, first, whether the added substance "may render it injurious to health" and secondly, if the substance or the food additive or colour additives is "unsafe".[66]

> Under sections 201(s) and 409 of the FFDCA, "any substance added to food 'directly or indirectly' is a food additive unless the substance is 'generally recognized as safe' (GRAS) for its intended use, is a pesticide, or is otherwise excluded from the definition of food additive. [F]ood additives include those substances added directly to food, substances that may become components of food as a result of their use in processing, and components of food contact materials that can reasonably be expected to migrate to food."[67]

"Both FDA regulations and legal precedent have defined 'added' substance broadly" to cover a situation where "a naturally occurring substance 'is increased to abnormal levels through mishandling or other intervening acts'." A substance is "added" to a food even if it derives in part from man and in part from nature. The FDA is only required to show some portion of the substance is attributable to the acts of man and that the total amount may be injurious to health.[68] Putting nanomaterial into the food as an ingredient, or as food additive or as colour additives or if nanoparticles from food packaging migrate into food and drinks would mean a substance has been added.

"GRAS uses of food ingredients do not require premarket authorization by FDA." In other words, a food additive is subject to premarket approval from the FDA only if it is not "generally recog-

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64. Center for Science in the Public Interest, *Citizen Petition*, at 7(2006), *available at* http://www.cspinet.org/new/pdf/fda_Produce_Petition.pdf.

65. Food & Culture Encyclopedia, *Adulteration of Food*, *available at* http://www.answers.com/topic/adulteration-of-food (citation omitted).

66. 21 U.S.C. § 342 (1938).

67. ANDREW C. VON ESCHEN, U.S. FOOD AND DRUG ADMINISTRATION, NANOTECHNOLOGY: A REPORT OF THE U.S. FOOD AND DRUG ADMINISTRATION, *available at* http://www.fda.gov/nanotechnology/taskforce/report2007.html

68. *See* Chaudhry et al., *supra* note 7.

nized as safe."[69] There are two questions here; firstly, whether nanofood "may render it injurious to health," and secondly, whether nanofood deserves GRAS status. If the answer to the former is positive, nanofood would be deemed adulterated. If the answer to the latter is positive, nanofood does not require premarket approval. On the other hand, if nanofoood does not deserve GRAS status, the FDA will have to approve the additive before the product can be put on the market. In short, premarket authorization of nanofood is very much dependent on the GRAS status.

The FDA states, "FDA's authority over products subject to premarket authorization is comprehensive and provides FDA with the ability to obtain detailed scientific information needed to assess the safety and, as applicable, effectiveness of products, including relevant effects of nanoscale materials."[70] However, at the same time, the FDA acknowledges that "[w]here products are not subject to premarket authorization, manufacturers generally are not required to submit data to the FDA prior to marketing, and agency oversight capacity is, therefore, less comprehensive."[71]

The Woodrow Wilson International Center for Scholars (WWICS) advocates that the FDA "establish criteria and provide guidance to the industry about when nanomaterials are not the same as materials that are already listed in FDA's GRAS . . . food additive and food packaging regulations."[72] FDA should also work with the food industry to ask "companies to voluntarily submit their safety data" on food uses of nanotechnology.[73] The Center argues that the "FDA should not, however, have to rely on voluntary industry compliance in order to obtain data. [T]he agency needs legal authority to require disclosure of specified information."[74]

On the FFDCA itself, the WWICS argues that while there are gaps in the legal framework there is no need to have a new law governing nanotechnology. The Center in its report states, "[N]anotechnology does reveal gaps in FDA's legal tool kit. While there is not a need to start from scratch in providing FDA the legal

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69. VON ESCHEN, *supra* note 67.

70. NANOTECHNOLOGY: A REPORT OF THE U.S FOOD AND DRUG ADMINISTRATION NANOTECHNOLOGY TASK FORCE, at 32 (2007), *available at* http://www.fda.gov/nanotechnology/taskforce/report2007.pdf.

71. *Id.* at 33.

72. J. Clarence Davies, *Nanotechnology Oversight: An Agenda for the New Administration*, at 14 (2008), *available at* http://201.58.186.238/process/assets/files/6709/pen13.pdf

73. *Id.* at 15

74. *Id.*

tools it require [sic] to regulate the products of nanotechnology, those gaps do need to be filled if FDA is to provide the oversight people expect."[75] The gaps include "[F]DA's inability to acquire information about nanotechnology products early enough in their development to prepare properly for their regulation, and . . . inadequate authority for post-market adverse event reporting."[76]

VI. EUROPEAN REGULATION: AN OVERVIEW

There are several important pieces of legislation governing food safety in Europe: (1) Regulation 178/2002, (2) Regulation 258/97, and (3) Regulation 1935/2004.

1. Regulation 178/2002 of The European Parliamentand of The Council of The European Union [77]

The Regulation (EC) No 178/2002 elaborates the general principles and requirements of food law in the European Union. It establishes the European Food Safety Authority (EFSA), specifies procedures in matters of food safety, and provides assurance of a high level of protection of human health and consumers' interests in relation to food. Article 14 of this Regulation, on the general requirements of food law, provides that "[f]ood shall not be placed on the market if it is unsafe."[78] "Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; or (b) unfit for human consumption."[79] Meanwhile, Article 17 places the responsibility for ensuring that food is safe on the food business operators.[80]

Article 7 of the Regulation requires provisional risk management measures to be taken in the case of uncertainty. It provides that "[i]n specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection . . . may be adopted, pending further scientific information

75. Michael R Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?*, at 3 (2006), *available at* http://www.Nanotechproject.Org/File_Download/Files/PEN5_FDA.Pdf.

76. *Id.* at 7.

77. 2002 O.J. (L 31) 1.

78. Regulation 78/2002, art. 14(1), at 10.

79. Regulation 78/2002, art. 14(2)(a) and (b), at 10.

80. Regulation 78/2002, art. 17(1), at 11.

for a more comprehensive risk assessment."[81] This provision is relevant to the current status of nanofood, where there is the possibility of harmful effect, coupled with scientific uncertainty about it.

Article 19 provides additional safeguards. It places the obligation on business operators to withdraw food from the market. The article provides that "if a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the marke . . . ."[82] This is passive regulation.

2. Regulation (EC) 258/97

This Regulation[83] covers novel foods and novel food ingredients, which are particularly relevant to nanofood. Article 1 defines novel food as "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community" prior to May 1997 and which fall under one of the defined categories. Two of the categories are relevant to nanofood: (1) foods and food ingredients with a new or intentionally modified primary molecular structures[84] and (2) "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."[85]

> Considering the current and projected applications of nanotechnologies in food, it is unlikely that most nano-structured food products (at least in the foreseeable future) would fall under the first category, i.e. they would not necessarily have a different molecular structure compared to normal processed food. "There is, however, a strong likelihood that they would fall under the second category."[86]

Article 3 of the Regulation requires that "foods and food ingredients... must not present a danger for the consumer, [or] mislead the consumer."[87] The control over nanofood can be divided into

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81. Regulation 78/2002, art. 7(1), at 9.
82. Regulation 78/2002, art. 19(1).
83. Regulation 258/97, art. 1(2)(a).
84. Regulation 258/97, art. 1(2)(a)
85. Regulation 258/97, art. 1(2)(f).
86. Chaudhry, et.al., *supra* note 7, at 252.
87. Regulation 258/97, art. 3(1).

parts: notification and authorization before entering the market, labelling and postmarket monitoring. Under Article 4, anyone who wishes to place product on the market for the first time will have to "submit a request to the Member State,"[88] which includes "an initial assessment"[89] and provision of relevant documents listed in Article 4 and 6. If necessary, competent authority can order additional assessment.[90] If additional assessment is required "an authorization decision shall be taken in accordance with the procedure provided for in Article 13."[91] The decision made should "define the scope of authorization" and shall establish, where appropriate: ". . . the conditions of use of the food or food ingredient, . . . the designation of the food or food ingredient, and its specification, . . . and specific labelling requirements as referred to in Article 8."[92]

Article 12, indirectly, provides for the monitoring of nanofood which is already on the market. It also empowers the European country to restrict the trade or use of a food or a food ingredient. This article provides that:

> [W]here a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, the Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States . . .[93]

This Regulation in article 8 imposes labelling requirements. It has to be noted that nanofood labelling is 'additional' under the Regulation and the target of labelling here is the 'final consumer.' There are four types of information which should be included in the labelling:

> "(a) any characteristics or food property such as composition, nutritional value or nutritional effects, [or] intended use of the food, which renders nanofood no longer equivalent to an existing food or food ingredient . . . ,
>
> (b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

88. Regulation 258/97, art. 4(1).
89. Regulation 258/97, art. 4(2).
90. Regulation 258/97, art. 7(2).
91. Regulation 258/97, art. 7(1).
92. Regulation 258/97, art. 7(2)
93. Regulation 258/97, art. 12(1).

> (c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;
>
> (d) the presence of an organism genetically modified by techniques of genetic modification . . . ."[94]
>
> A novel food or food ingredient is deemed to be no longer equivalent . . . if scientific assessment, based upon appropriate analysis of existing data can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics. In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained.[95]

3. Regulation 1935/2004

EU Regulation 1935/2004[96] is the main Regulation governing the composition, properties and use of FCMs in Europe.

> The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about unacceptable change in the composition of the food or deterioration in its organoleptic properties.[97]

The Regulation applies "to all materials and articles, including active and intelligent food contact materials and articles."[98]

Article 3 provides for the general requirement that may have direct implication on the nanofood packaging industry and manufactures. It provides that "[m]aterials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practices so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food . . . ."[99] Thus, it places an obligation not to produce food packaging or FCM that may transfer its constituents into food in quantities which could "endanger human health or . . . bring about an unacceptable change in the composition of the food . . . or bring about a deterioration in the organoleptic characteristics . . . ."[100]

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94. Regulation 258/97, art. 8(1).
95. Regulation 258/97, art. 8(1).
96. Regulation 1935/2004, 2004 O.J. (L 388) 1.
97. Regulation 1935/2004, art. 1.
98. Regulation 1935/2004, art.1(2).
99. Regulation 1935/2004, art. 3(1).
100. Regulation 1935/2004, art. 3(1).

This brings up two points. First, "[i]t is not clear whether the need to establish the inertness of packaging will lie with the supplier of the nanoparticle materials, the manufacturer of the packaging or packaging components or the retailers of these materials and/or the foods on which they have been used."[101] Second, this provision attaches a qualification of quantities large enough to endanger human health.[102] "This implies, therefore, that the transfer rate and the properties of the substance are known. In the case of nanocomponents this may not always be the case."[103]

Another provision which is relevant to nanofood is Article 4(2). It provides that before any substance can deliberately be incorporated into active and intelligent materials which would be released into the food or the environment surrounding the food an authorization from the European Food Safety Authority (EFSA) is required.[104] Specific measures may also be adopted.[105] These specific measures include "specific limits on the migration of certain constituents . . . ," "an overall limit on the migration of constituents into or on to food," "additional provisions of labelling," etc.[106] The labelling of active and intelligent material must include "information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component[s] . . . ."[107] Article 24 specifically obliges the Member States to carry out "controls in order to enforce compliance with [the] Regulation.[108] "[A] Member State, as a result of new information or a reassessment of existing information . . . [can] temporarily suspend or restrict application" of any material if the use of the material endangers human health.[109]

Some scholars have argued that most applications of nanotechnology in food and FCMs "will be subject to some form of approval process [under the relevant EU legislation] before being permitted for use."[110] They, however, pointed out that:

> [(1)] [c]urrent legislation pertaining to food ingredients, food additives and FCMs does not differentiate between substances produced routinely

101. INSTITUTE OF SCIENCE AND TECHNOLOGY, *supra* note 11, at 8.
102. Chaudhry, et. al., *supra* note 7.
103. *Id.*
104. Regulation 1935/2004, art. 4.
105. Regulation 1935/2004, art. 5.
106. *See* Regulation 1935/2004, art. 5.
107. Regulation 1935/2004, art. 159(1)(c).
108. Regulation 1935/2004.
109. Regulation 1935/2004, art. 18(1).
110. Chaudhry, et.al, *supra* note 7, at 251.

> by 'standard' manufacturing methods and those developed by nanotechnology . . .; [(2)] [t]here is a lack of clarity in the definition of novel foods under relevant regulations that may lead to uncertainty as to whether (and when) a food processed at nano-scale should be considered a novel food; [(3)] [t]here is a lack of information on the extent of migration of nano components from nanotechnology derived FCMs; [and (4)] [t]here is a lack of knowledge of the possible health effects of nanosized food ingredients and additives to enable adequate risk assessment.[111]

VII. CONCLUSION

"Generally recognized as one of the 21ST century 'mega' technologies, nanotechnology may revolutionize the food industry in the coming years."[112] One day, possibly nanofood will be everywhere. "Perhaps, in the future customers will ask for healthy Nano Flake instead of Corn Flakes.[113] Globally, countries, companies and universities recognize the potential of nanotechnology in the food industry. Whatever the impacts of nanotechnology on the food industry and products entering the market may be, the safety of food will remain the prime concern. However, research and safety assessments are apparently lagging behind the forward movement into nanotechnology and nanofood. There has been backlash and calls to say no to nano and nanofood.

As with any new developments, the management of potential risks is not the sole responsibility of the politicians and legislators. Scientists, technologists, industrialists have a primary responsibility to ensure the safety of the products they develop. It is essential to ensure that before manufactured free nanoparticles are introduced directly into foods or used in FCM, such use should have undergone an appropriate, proportionate pre-market safety evaluation.[114] Equally essential is to ensure that the rules and regulations protect consumers and at the same time do not hamper the technology. The existing legal framework will need to be reviewed in making sure that nanoparticulate materials in nanofood are covered and to reflect the possibility that these nanocomponents may have greater toxicity than materials in the larger size range.

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111. *Id.* at 254.

112. Thomas Bratschi, et. al., *Nano-Food: Science-Fiction or Business Opportunity?*, 3 EXCELLENCE IN FOOD 1, 3 (2006), *available at* http://www.innovationsgesellschaft.ch/image/publication_en/study%20introduction%20English.pdf.

113. On the back of Kellogg's Toppas packaging in Germany write-up on the advantages of nanotechnology was printed. *Id.*

114. INSTITUTE OF SCIENCE AND TECHNOLOGY, *supra* note 11, at 17.