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FOOD MICRO SYSTEMS

REPORT ON ETHICAL ISSUES REGARDING MICROSYSTEMS IN FOOD

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FoodMicroSystems aims at initiating the implementation of microsystems & smart miniaturised systems in the food sector by improving cooperation between suppliers and users of microsystems for food/beverage quality and safety.

The project runs from September 2011 to August 2013, it involves nine partners and is coordinated by ACTIA (Association de Coordination Technique pour l'Industrie Agro Alimentaire, France). More information on the project can be found at http://www.foodmicrosystems.eu.

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ETHICAL ASPECTS

Dr David Coles

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Task 3.3 Outline

Especially in applications of advanced technologies in areas like food emotions tend to get hot quickly. There are many different dilemmas that are associated with the use of technologies to modify food or create new food products, many of which are ethical. These issues are very regional and are often interlinked with religious and cultural aspects. In some cases economic links can also be identified. It would probably require a large-scale project of its own to make a comprehensive inventory of all the issues in this area, which is clearly out of scope of this project. The task will therefore limit itself to studying the literature and identifying the main issues with respect to ethics and implementations of technologies in food;

1 Executive Summary

Various ethical issues can be associated with the use of micro and nanosystems applied to agrifood production. These can be linked to the ethical concepts of autonomy, beneficence, non-malfeasance and justice. Examples include ensuring safety, effective risk assessment, transparency, consumer benefits and choice, animal welfare and environmental protection. Micro and nanotechnology applications are currently covered by a range of legislative instruments originally designed for other purposes. Specifically for nanotechnology risk assessment procedures are also in most cases not specific to nano-materials. This results in considerable uncertainty as to the nature and extent of any potential risks from the use of nano-materials, particularly in the food industry. There are also currently no requirements for nano-materials used in agrifood production to be labelled. This may result in ethical issues for these systems that will actually reach the consumers or the environment. For microsystems these would be either through microsystems and other nano-enabled functionality integrated in the final product or, more frequently its packaging, or through nanoparticles added somewhere during production, or parts of broken sensors or other production tools. This report argues that adherence to the ethical principles above means that consumers need to be made aware through labelling of any products that have nanotechnology involved in their production and specific risk assessments need to be established in order to reduce uncertainties and so that consumers and other stakeholders are able to make informed choices. Few ethical issues specifically related to food packaging can be identified.

2 Introduction

All new technologies have the potential to raise ethical issues and generate ethical concerns amongst stakeholders; although whether or not this occurs is contingent on characteristics of the technology in question (e.g. see Frewer et al, 2011; Gupta et al, in press; Hoban, 1997). Key issues, which are relevant to discussion of ethics, food and new technologies including microsystems, are food safety, risks and benefits (to human health, the environment, and in terms of socio-economic impacts), including the extent to which the benefits (and risks if any) are equitably distributed (for example, across food producers in different countries, or between producers and consumers), consumer choice, and potentially issues of data protection and privacy. These can be considered from an ethical perspective in the way in which they impinge on fundamental ethical principles of non-malfeasance, beneficence, autonomy and fairness.

This report focuses on potential ethical issues that might arise from food-related developments in microsystems related to nanotechnology. Of the proposed microsystems, nanotechnology applications raise issues related to the invisibility of the products, uncertainties in relation to potential harms and the problems in identifying contamination (see D3.2.2); other ethical issues relate to the perception of privacy risks.

If a micro or nano system is thought of as one in which stimulation to a sensor causes a response or change this can cover a vast range of possible implementations. In addition to the microsystems considered in this project, where much of the focus is on ICT-related applications, one can consider other less "sophisticated" examples such as an enzyme to be a microsystem in which an active site (sensor) detects the presence of a protein or other chemical which then causes the enzyme to change shape in order to form an attachment to (for example) a cell membrane, which may in turn cause the release of a chemical transmitter or hormone which travels to another site in the body (transmission of information). This then causes an action or response. Even a simple nano component such as nano-silver causes changes in microbial membranes which result in death of the cell, although in this case the nano component is largely passive. Nano-capsules (as described below) change their surface properties to release chemicals or drugs in a targeted way in response to sensing the presence of particular protein structures or other chemicals. Another practical example might be an active nano-sieve able to detect the presence of certain proteins (for example a pathogen or other microorganism) which causes the nano-sieve to change shape to bind to or otherwise prevent the passage of the microorganism while still allowing passage of other large molecules. However, these are mainly scientific distinctions in the use of micro and nano systems in the food chain. From an ethical perspective, as discussed below, there are very few ethical issues specifically in relation to the use in food, food production, processing or packaging, of sensors that detect and convey information about physical or chemical properties including DNA and the presence of pathogens although there may be examples, such as Radio Frequency Identification (RFID) devices, where privacy and data protection could become ethical issues. As we will see, the ethical issues related to the potential for use of such microsystems lies in the use of nano and other similar materials in such sensors where, because of the unknown risks, uncertainty in regulation and inconsistency in assessment procedures there is potential for their use or disposal to cause harm to humans, animals, the environment and future generations. This leads to the ethical issues of autonomy, which requires openness and transparency in communicating the presence of such materials anywhere in the food chain, to enable consumers to come to an autonomous decision on a risk/benefit balance and to beneficence, non-malfeasance and justice in terms of potential for contamination by, absorption of or disposal of waste materials. These issues are no different whether we are dealing with active nano-based microsystems or more “passive” nano-materials. The results from the focus group studies (Task 3.2) confirm that peoples’ concerns are mainly about chemical contamination of the food with nanoparticles. This ethical analysis and discussion is not therefore addressing only more complex active microsystems but considers the much broader and more generic use of nanotechnology in the food chain. It therefore identifies a wide range of current and future potential food and agriculture related applications and provides an analysis of potential ethical issues adopting the principles of an ethical matrix. From this point, issues of particular relevance to the use of microsystems based on nanotechnology in the food industry including in packaging can be identified.

2.1 Developments in miniaturization related to Food:

Nanotechnology is the manufacture and use of materials and structures at the nanometre scale (a nanometre is one millionth of a millimetre). Many large scale manufacturers of foods and agricultural products have already invested heavily in nanotechnology R&D (Scriens and Lyons 2007) and indeed nanotechnology is already being used in some countries in the production of agricultural products as well as processed foods and drinks and in food packaging. There is currently very little regulation that relates specifically to applications of nanotechnology in any field of application, and particularly in relation to food. Regulators therefore rely instead on a whole range of other relevant current regulation designed principally with applications other than nanotechnology in mind. This approach is set out in the European Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research. The relevant European regulations that need to be considered extends from REACH, (the EC Regulation No. 1907/2006 on Chemicals, aimed at preventing harm to humans or the environment), through the Waste Framework Directive 2008/98/EC to the Novel Foods Regulation (EC) No. 258/97). See Table 1 below for a more detailed list.
Nanotechnology covers and is relevant to a very wide range of food-related applications (Frewer, Fischer et al, 2011). There is therefore no definitive list of foods or food contact products that involve nanotechnology and it is extremely difficult to estimate how widespread is the use of nanotechnology in food and agriculture (Jones, House of Lords Evidence 2009) Below a number of key areas of nanotechnology application in the field of food and agriculture are provided, together with some specific examples within each area.

Agricultural practice

There has been significant investment in agricultural applications of nanotechnology which are largely intended to address some of the limitations and challenges facing large-scale, chemical and capital intensive farming systems (Scrinis and Lyons, 2007). Objectives include improvement of the efficiency of soils and other growing media and facilitating targeted delivery of both nutrients and pesticides. Specific current and potential applications designed to improve the fertility and capacity of soil and other growth substrates, include the fine tuning and more precise micro-management of soils,; more efficient and targeted use of inputs such as fertilisers and other soil additives (Scrinis and Lyons, 2007); use of nano-iron and carbon nano-tubes for soil and water remediation and purification (Karn et al, 2009). New sub-stances are also being formulated for more effective pest control, including smart pesticides some of which would have the capacity to respond differentially to a range of pests including targeted action through smart sensors and smart delivery nano-systems (Rai and Ingle 2012) including increased effectiveness by concentrat-ing action (or “swarming”) around the target pest. The great advantage of such a system is that much less pesticide would be needed as its action is able to be auto-matically focussed on the site of attach y the pests. More interactive agricultural application is the incorporation of nano-sensors into livestock to facilitate animal tracking, drug-delivery systems or to detect presence of certain substances such as drugs, growth hormones etc. when animals are marketed (Nguyen et al, 2012). A further possibility is the use of nanotechnology in nano-induced changes to plants and animals for the development of new crop and animal traits and behaviours (e.g. developing service animals as human assisters – for use in detection of drugs, chemi-cals, explosives etc.). Work has also been carried out on the use of nano-encapsulation as a method of facilitating vaccination of fish stocks. The encapsulated vaccine is released into the water but only released from the micro-capsule once ingested by the fish (Nielsen et al 2011)

Research on the nano-modification of seeds (precision GM) is still in its very early stages but has the potential to enable very precise genetic modification of seeds (Scrinis and Lyons 2007). This precision GM could then potentially also be extended to animals.

Food manufacture and processing

Many large scale manufacturers of foods and agricultural products have already in-vested heavily in R&D and indeed micro and nanotechnology is already being used in some countries in the production of agricultural products as well as processed foods and drinks (Scrinis and Lyons, 2007) and in food packaging. In the manufacture and preparation of food nano-sieves are already in use for nanofiltration applications (Erikkson 1988), use of nano-materials to create non-fouling surfaces in food prepa-ration prevents clogging of processing machines and therefore reduces the need for both cleaning and machine downtime and so lowers production costs. Nanosensors can also be used in the production process to monitor food quality and provide feedback to adjust processes accordingly. Research is also underway to develop fi-brillar protein aggregates as meat replacers and nanotechnology may be one route to enable fibrillar proteins to be constructed to imitate meat. Nanotechnology can also improve the texture of foods such as making them taste creamier (e.g. texture of dairy products such as yogurts and ice-cream),

Food packaging

The application of nanotechnology enabled microsystems to food packaging is of great interest to manufacturers and retailers and is an area where nanotechnology-derived materials have already been introduced to improve mechanical and barrier properties. Packaging applications includes use of nano-silver as a microbicide to extend the freshness of food and prevent contamination (Maillard and Hartemann 2012). Nano-materials can also be used to improve the barrier properties of packaging to regulate the passage of gases and moisture through the packaging to extend shelf life and maintain quality and freshness (Sozer and Kokini 2009). Nanotechnology can also improve the biodegradability of packaging (Sozer and Kokini 2009), and together with the development of stronger and less bulky nano-packaging; this could generate less waste. Within the context of microsystems, nanosensors are also being developed to detect the ripeness of packaged products or the presence of pathogens or breakdown products (Kuswandi et al, 2011). A further development of this approach could also be used to signal whether the packaged food is displayed or stored at the optimum environmental conditions such as correct temperature or pressure. These systems may be in the form of buttons on the packaging which change colour to act as an indicator or warning or could be RFIDs which could be interrogated remotely to aid stock control.

Food Products, supplements and additives

Nano-encapsulation (foodstuff is encapsulated in a nano-material that protects it from gut digestive juices until it reaches its target which it identifies by surface interaction) and increased bioactiviation (where a nano-substrate can be used to optimise the way a bioactive ingredient is presented to its target) are important elements in the development of novel foodstuffs, particularly functional foods and nutriceuticals for the delivery of drugs to specific sites or for oral vaccines. Increased bioavailability through nanocrystals would enable e.g. omega-3 fatty acids, phytosterols, flavours, antimicrobial components, antioxidants and carotenoids such as β-carotene and lycopene to be absorbed more effectively where they are needed. Targeted nutrition increases the rate of uptake of nutrients during digestion while nano-encapsulation could also reduce the uptake of e.g. fats, thus allowing delivery of the flavour of fats without their calorific or other undesirable effects. An alternative nanotechnology approach could modify flavour delivery so that non-fatty foods might taste fatty. Although not functioning as active systems sending and receiving information these applications are equally relevant of the ethical considerations. Some delivery systems for biologically active compounds are already available in some countries. For example in Germany nanotechnology is used in foods and dietary supplements to produce *inter alia,* nano-green tea, to improve the bioavailability of selenium from the leaves, “Canola Active” cooking oil with microencapsulate phytosterols to reduce absorption of cholesterol, nano-vitamins and nano-coenzymes (Sekhon 2010).

2.2 Potential risks of nanotechnology

It is well-established that as particles approach the nano-scale their properties can change. Microsystems built with the use of nanotechnologies may release nanoparticles into the food or the environment. Where these are new substances the changes can be highly unpredictable as can be their impact on humans, other animals and the environment. Because of their very small size, nanoparticles can cross biological barriers. Therefore they have the ability to enter cells and organs, including crossing the blood-brain barrier and may interact with normal biological processes in an unpredictable manner. Because very little work has been done on risk assessment specifically directed at nano-materials, it is not known how the human body responds to these chemicals. However, the evidence for health risks of ultrafine and nanoparticles after inhalation has been increasing over the last decade (Kreyling et al, 2006, Penyala et al, 2008). There is the possibility that many of the nano-materials such as nano-silver may bio-accumulate in food (from nano-packaging or from accumulation in plants and animals used in food production), or in the human body (Pronk 2009). Because of the wide range of activity and use of nanomaterials, including their properties as microbicides, pesticides and activation catalysts, there are potentially real and unknown risks from their use. This is particularly relevant because of the lack of nano-related risk and toxicity assessments. It is also clear that risk assessment (RA) procedures used in other related regulatory instruments are not always appropriate for the special characteristics of many nano-materials.

Nanomaterials may also produce a significant risk to the environment (Klaine et al 2008). Use of nano-silver in packaging could lead during waste disposal, to its leaching and accumulation into the environment where it would continue to kill microorganisms in the environment. This could prove a major problem for water treatment installations and for other microbial activity in the environment. (Fabrega et al, 2011). Use of nano-iron and carbon nanotubes in the remediation of soils involves putting them directly into the environment and while it is not clear how fixed they would be to the soil being treated, the soil itself would be subject to movement through the environment with the consequent accumulation of the nanomaterials in other areas including water courses (Boxall et al 2007). As there is evidence that carbon nanotubes in particular could have similar heath-impact properties to asbestos this presents a clear uncharacterised risk which may have greater negative consequences than the soil pollutants they are designed to remove. This particular case is of particular concern as in the U.S. carbon nanotubes are already incorporated into some packaging materials to detect microorganisms, toxic proteins and food spoilage (ElAmin, 2007). One of the rationales for the use of nano-particle pesticide applications lies in their improved capacity for absorption into plants compared to larger particles. As such, while they may not be washed off as readily, thereby increasing their effectiveness, this does pose a new order of risks to consumers of these products as the pesticides would be more persistent (Belfield, 2005). Farm workers and rural residents are also being exposed to these nano-pesticides, without any requirement for safety testing or regulation of nano-scale formulations of already approved chemical pesticides (Lyons and Scrinis, 2009). The size and dissolvability of nanoparticle pesticides may also mean they contaminate soils, waterways and food chains across a wider geographical area, while nano-encapsulated pesticides may release their toxins in other environments or in the stomachs of other living organisms (Scrinis and Lyons 2007). There is some evidence that exposure to nanoparticles (Titanium oxide) reduces reproductive output in zebrafish and that in trout they cause damage to the gills (Federici et al, 2007). Nano-encapsulated vaccinations of fish involve release of the nanoparticles carrying the vaccine into open or semi-open aquatic systems where their dispersal patterns and subsequent destination is likely to be unpredictable.

While nanotechnology is increasingly used in food manufacture, very little work has been done to assess the risk of contamination of food products with nano-materials used in processing such as nano-filtration, non-fouling surfaces, or catalytic processes. Risks associated with use of nanotechnology to improve texture in food products appear not to have been assessed. Where nanotechnology is incorporated in food products for use in the European Union, these have to comply with the EC Regulation on Novel Foods. This would apply to the use of nano-encapsulation, increasing bio-activation and bio-availability products that currently incorporate nanotechnology. Where nanosensors are used in food packaging, food processing or even incorporated into animals or plants at the production or growth stage, thought has to be given to their eventual disposal and breakdown. Is it practical to remove nanosensors from animals or plants when they enter the food chain? How will practical solutions be found for removing and disposing of nanosensors used in food processing plants and they deteriorate?See also the book *Nanotechnology in the Agri-Food Sector: Implications for the Future, Frewer et al (Eds). 2011*

2.3 Regulation of Nanotechnology

Applications of nanotechnology are extremely diverse. This is one of the reasons why there are currently no specific regulations on nanotechnology applications either in Europe or elsewhere. Within Europe, nanotechnology applications are deemed to be covered by existing legislation. This is also true for food-related applications. As a result there are a large number of regulations that may need to be taken into account. There is also a requirement to assess whether the existing regulation needs to be modified for nanotech applications (European Commission Recommendation of 07/02/2008).

Regulations covering nanotechnology in food in Europe include:

Table 1

Regulatory Instrument	Title	Purpose
REACH	*Regulation (EC) No 1907/2006 on Chemicals*	Emphasis is on preventing harm to humans or the environment – based on the precautionary approach).
Health and Safety Directive	Safety and Health of Workers Directive 89/391/EE	Regulation of exposure of workers to potentially hazardous substances
Novel Foods Regulation	EC Regulation 258/97	If Nanotechnology is used to develop novel foods and processes, approval is required under this Regulation to ensure products are safe.
General obligation to provide safe food	EC Regulation 178/2002	Established the European Food Safety Authority and lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.
General Product Safety Directive	Directive 2001/95/EC	A general product safety requirement, containing provisions on the general obligations of producers and distributors, and on the enforcement of Community product safety requirements to ensure consumers safety and health.
The IPPC Directive	EU Council Directive 2008/1/EC	Relates to Integrated Pollution Prevention and Control (IPPC) in respect of release of pollutants into the environment.
The Seveso II Directive	Directive 96/82/EC	Prevention and control of chemical accidents.
The Water Framework Directive	Directive 2000/60/EC	Protects rivers, lakes, estuaries, costal waters and groundwater and ecosystems in relation to their water needs; promotes sustainable water and progressive reduction of pollution of groundwater, reduction of discharges, emissions and leaching of hazardous substances.
Waste Framework Directive	Directive 2008/98/EC	This Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use.
EC Communication on Regulatory Aspects of Nanomaterials	COM(2008) 366 final	To promote an integrated, safe and responsible approach to use of nanotechnology and ensure that applications and use of nanosciences and nanotechnologies comply with the high level of public health, safety, consumers and workers protection, and environmental protection

The EC Communication on Regulatory Aspects of Nanomaterials (2008) states that:
"The regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained"
"When an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. The risk management measures and operational conditions will have to be communicated to the supply chain."
The Commission in 2008 proposed amendments to the regulation on Novel Foods which *inter alia* includes a legal definition of nano-materials and their mandatory labelling. However the European Council and the European Parliament (EP), have been unable to agree on amending the existing Regulation (mainly because of a failure to agree on a related issue of foods derived from cloned animals).
The Opinion of the European Food Standards Authority's (EFSA) Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety (2009) states that:
Specific uncertainties apply to the difficulty to characterize, detect and measure ENMs (Engineered NanoMaterials) *in food/feed and biological matrices and the limited information available in relation to aspects of toxicokinetics and toxicology. There is limited knowledge of current usage levels and (likely) exposure from possible applications and products in the food and feed area. The risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterization) is considered applicable for ENMs. However, risk assessment of ENMs in the food and feed area should consider the specific properties of the ENMs in addition to those common to the equivalent non-nanoforms. It is most likely that different types of ENMs vary as to their toxicological properties. The available data on oral exposure to specific ENMs and any consequent toxicity are extremely limited; the majority of the available information on toxicity of ENMs is from in vitro studies or in vivo studies using other routes of exposure. The risk assessment of ENMs has to be performed on a case-by-case basis. Current toxicity-testing approaches used for conventional materials are a suitable starting point for risk assessment of ENMs. However, the adequacy of currently existing toxicological tests to detect all aspects of potential toxicity of ENMs has yet to be established. Toxicity-testing methods may need methodological modifications. Specific uncertainties arise due to limited experience of testing ENMs in currently applied standard testing protocols. Additional endpoints presently not routinely addressed may need to be considered in addition to traditional endpoints. For hazard characterization, the relationship of any toxicity to the various dose metrics that may be used is currently discussed and several dose metrics may need to be explored in addition to mass. The different physicochemical properties of ENMs compared to conventional dissolved and micro/macroscale chemical counterparts imply that their toxicokinetic and toxicity profiles cannot be fully inferred by extrapolation from data on their equivalent non-nanoforms.*

It is clear from this Opinion how little regulation is in place that can readily and appropriately be applied to food-related nanotechnology applications. This situation makes it difficult for developers and manufacturers in knowing just what if any regulations they need to comply with and what risk assessments if any, are appropriate. It is also therefore a formula for potentially increased and unknown risks for the consumer and the environment. The increasingly rapid development of nanotechnology applications in this area mean that some form of appropriate and consistent governing regulation and assessment is urgently needed (Kreyling et al, 2006). Failure to implement such a scheme could result in wholesale consumer rejection of nanotechnology in food and agriculture applications.

A number of initiatives have been launched with the objective of establishing a more coherent approach to risk assessment for nanotechnology applications. Examples of such initiatives include: Euro-NANOTOX www.euro-nanotox.at (launched 2007), BioNanoNet; www.euro-nanotox.at (launched 2009) and the OECD-Database on Research into the Safety of Manufactured Nanomaterials http://webnet.oecd.org/NANOMATERIALS (launched 2009). However a coherent standardisation of risk assessment of nanotechnology applications and use is still some way off.

3 Ethical Issues related to Micro and nanosystems and Food

The 2010 EU EuroBarometer (EB) found that Europeans *"know little about nanotechnology, are not excessively concerned about risks and believe nanotechnology should be encouraged."* (Eurobarometer 2010).

However, the EuroBarometer only asked about nanotechnology in general terms and did not refer to nanotechnology in relation to food. While consumers may approve of a technology in some fields (e.g. medicine) they may be much less approving if it is used in relation to food. This clearly has been the situation in the case of biotechnology and genetic modification. Generally most people appear positive towards nanotechnology. For example, meta-analysis of 22 surveys conducted in Canada, United States, Europe and Japan between 2002-2009 showed that the members of the public who perceive greater benefits outnumber those who perceive greater risks by 3 to 1 (Satterfield, et al., 2009). Several authors have suggested that many of the public concerns discussed in the literature on biotechnology in food are being raised in qualitative and quantitative studies on nanotechnologies for food (Mehta, 2004; Rogers-Brown, 2011). On one hand, nanotechnologies are generally perceived to be beneficial. However, many people express concerns about nanotechnological modifications of food. Indeed experts are of the view that food-related applications of nanotechnology may be the most problematic in terms of societal acceptance. To date the empirical evidence for this is somewhat mixed, in particular in the context of concrete applications with tangible benefits (Gupta et al, 2012). For example, Fischer at al (in press) found considerable intra-individual variation in attitudes to food-related nanotechnology after the provision of balanced risk-benefit information about risk and benefit. Gupta et al, (in preparation), report that consumer acceptance is high for food-related applications with concrete and tangible benefits.

There may be ethical issues associated with the introduction of a novel food technology, in so much as labelling and consumer choice needs to be embedded in the process of introduction. This was certainly not the case with the introduction of GM foods into Europe, and contributed to societal rejection. This can be avoided in the case of foods made with nanotechnology. However, it may also be the case that most consumers are not aware of the degree to which nanotechnology is already involved in the food chain, the scope of its application in agriculture and the manufacture and supply of food products, nor indeed the potential risks and the limited extent to which these are currently assessed and to which implementations of the technology regulated. It is tempting to again draw a cautionary parallel with the situation of GM food products at the very end of the 20th century (Kearnes et al, 2006) when a number of products were already available for sale to consumers but little or no information had been provided on potential risks, nor was consideration given to how consumers might benefit from the incorporation of GM ingredients into foodstuffs.

There has been some discussion about how relevant it is to apply ethical considerations to nanotechnology and whether indeed there is a need to develop an ethics model specifically for nanotechnology and its application in for example microsystems. The general consensus appears to be that nanotechnology does not constitute a “special case” for ethical consideration but that the normal ethical analysis approach of autonomy, non-malfeasance, beneficence and justice can be effectively applied to nanotechnology issues (Ebbesen et al. 2006, Kuzma and Besley 2008).

It is useful to apply an Ethical Matrix analysis (Mepham 2000) to the broad categories of application of nanotechnology to see how the ethical principles of autonomy (self-determination), non-malfeasance (no harm), beneficence (do good) and justice (fairness) apply to different stakeholders, animals and the environment (See Tables 2 – 5). While this has limitations in analysing and weighing the ethical issues associated with a technology it is helpful in identifying the sort of issues that may need to be considered (Schroeder and Palmer 2003). A more detailed analysis could be carried out on individual applications which might be a useful inclusion in the risk assessment process.

Ethical Matrices for Nanotechnology applied to Agriculture and Food

Table 2

Area of Application	Stakeholder / Entity	Autonomy	Non-Malfeasance	Beneficence	Justice
	System developer	Freedom to develop applications, in compliance with any applicable regulation	Has a responsibility to test for and minimise any potential harm to other stakeholders Avoid exploitation of the market and warn stakeholders of any risks.	Profit from successful applications.	A clear and consistent regulatory framework and risk assessment process to facilitate product development and minimise risk of market failure.
	Farmer	Freedom to choose whether or not to adopt based on evidence and without pressure from processors or distributors	Responsibility to use nano products responsibly, in accordance with regulations and to avoid harm to animals or damage to environment through waste products	Profit from improved products and yields. Improved and more efficient farming practice.	Improve welfare of animals and enhance environmental sustainability
Agricultural Practice	Processor	Freedom to choose whether to select raw materials and processes that make use of nano-technology	Responsibility to avoid use of supplies that have caused harm to animals and their welfare or to the environment. To ensure that products and processes are tested to avoid harms to consumer health.	Ability to profit from use of nanotechnology applications in processing.	A clear and consistent regulatory framework including safety and labelling requirements
	Consumer	To be informed by producers when nano-technology is used in producing foodstuffs and provided with sufficient information to make an informed choice.	To be provided with information about any risks to health and information and facilities to dispose of nano-packaging materials and other nano-waste in a safe	Ability to benefit from better quality food and greater health benefits without fear of unknown risks.	Any potential risks should be outweighed by potential benefits for the consumer. A clear, consistent and transparent regulatory framework.

			and sustainable way		
	Animals	Optimum quality of life and freedom of movement	Not to be harmed by nanotech application or bioaccumulation	Improvement in feed and welfare	Respect and maintainence of “telos”
	Environment	Maintenance of sustainable natural environment	Appropriate assessment of environmental risks and measures in place to minimise or eliminate contamination, bioaccumulation or leaching of nano-materials from treated soils, pesticides or animal products into the wider environment	Use of nano-materials to improve environmental conditions and promote sustainability.	Measures in place to prevent secondary contamination of other land by migration of nano-materials.
	Future Generations	Health and environment should not be jeopardised by current use of nanotechnology	Health and environment should not be jeopardised by current use of nanotechnology	Enhanced environmental conditions and food production plus advances in human health and nutrition and animal welfare.	Future health and environment should not be jeopardised by current use of nanotechnology

Table 3

Area of Application	Stakeholder / Entity	Autonomy	Non-Malfeasance	Beneficence	Justice
Manufacture and Processing	System developer	Freedom to develop applications, in compliance with any applicable regulation	To test for and minimise any potential harm to other stakeholders Avoid exploitation of the market and warn stakeholders of any risks.	Profit from successful applications.	A clear and consistent regulatory framework and risk assessment process to facilitate product development and minimise risk of market failure.
	Farmer	Freedom to choose whether or not to adopt based on evidence and without pressure from processors or distributors	Responsibility to use nano products responsibly, in accordance with regulations and to avoid harm to animals or damage to environment through waste products	Increased profit from improved processing of produce to enhance flavours, delivery and shelf life.	Improve welfare of animals and enhance environmental sustainability
	Processor	Freedom to choose whether to select raw materials and processes that make use of nanotechnology	Responsibility to avoid use of supplies that have caused harm to animals and their welfare or to the environment. To ensure that products and processes are tested to avoid harms to consumer health.	Ability to profit from use of nanotechnology applications in processing. Cleaner more efficient machinery.	A clear and consistent regulatory framework including safety and labelling requirements
	Consumer	Be informed by manufacturers when nanotechnology is used in foodstuffs and their processing and provided with sufficient information to make an informed purchasing choice.	To be provided with information about the nature of any nanomaterials used, any risks to health and information and facilities to dispose of nano-packaging materials and other nano-waste in a safe and sustainable way	Ability to benefit from better quality food and greater health benefits without fear of unknown risks.	Any potential risks should be outweighed by potential benefits for the consumer. A clear, consistent and transparent regulatory framework for nanotechnology applications for food.
	Animals	Optimum quality of life and freedom	Not to be harmed by nanotech applications or by bio-	Improvement in feed and welfare	Respect and maintainence of “telos”

		of movement during manufacture and processing	accumulation.		
	Environment	Maintenance of sustainable natural environment	Appropriate assessment of environmental risks and measures in place to minimise or eliminate contamination, bioaccumulation or leaching of nanomaterials from treated soils, pesticides or animal products into the wider environment	Protection and promotion of environmental sustainability and prevention of nanotech waste being distributed or leached into the environment.	Measures taken to regulate the disposal of nanowaste and protect the environment.
	Future Generations	Future health and environment should not be jeopardised by current use of nanotechnology	Regulatory system should ensure that future health, environment and animal welfare should not be jeopardised by current use of nanotechnology	Enhanced environmental conditions and food production plus advances in human health and nutrition and animal welfare.	Future health, environment and animal welfare should not be jeopardised by current use of nanotechnology

Table 4

Area of Applica-tion	Stakeholder / Entity	Autonomy	Non-Malfeasance	Beneficence	Justice
	System developer	Freedom to develop applications, in compliance with any applicable regulation.	To test for and minimise any potential harm to other stakeholders from nano-materials. Warn stakeholders of risks and uncertainties associated with individual products.	Profit from successful applications.	A clear and consistent regulatory framework and risk assessment process to facilitate product development and minimise risk of market failure.
	Farmer	Freedom to choose whether to supply produce for use with nano-packaging.	Responsible use of nano products in accordance with regulations and to avoid harm to animals or damage to environment through waste disposal.	Improved profits from longer shelf life of produce.	N/A
Packaging	Processor	Freedom to choose whether to use particular nano-technology products in packaging	To ensure that products and processes are appropriately tested and to avoid use of nano-packaging materials that may cause harm to human health or to the environment. To provide appropriate labelling on packaging.	Ability to profit from use of nanotechnology applications in packaging.	A clear and consistent regulatory framework including safety and labelling requirements
	Consumer	Packaging should be labelled to indicate use of nanomaterials and identify the specific nano-products used together with its purpose in	To be provided with information about the nature of any nano-materials used, any risks to health and information and facilities to	Ability to benefit from better quality, longer lasting food and greater health benefits without fear of unknown risks.	Any potential risks should be outweighed by potential benefits for the consumer. A clear, consistent and transparent regulatory framework for

		order that consumers can make an informed purchasing choice.	dispose of nano-packaging materials and other nano-waste in a safe and sustainable way		nanotechnology applications for food.
	Animals	N/A	N/A	N/A	N/A
	Environment	Maintenance of sustainable natural environment	Appropriate assessment of environmental risks and measures in place to minimise or eliminate contamination, bioaccumulation or leaching of nano-materials from waste packaging into the wider environment	Protection and promotion of environmental sustainability and prevention of nanotech waste being distributed or leached into the environment.	Measures taken to regulate the disposal of nano-packaging and protect the environment.
	Future Generations	Future health and environment should not be jeopardised by current use of nanotechnology	Future health and environment should not be jeopardised by current use of nanotechnology including accumulation of nano-materials in the biosphere and environment	Enhanced environmental protection and food production and storage.	Future health and environment should not be jeopardised by current use of nanotechnology.

Table 5

Area of Application	Stakeholder / Entity	Autonomy	Non-Malfeasance	Beneficence	Justice
Products	System developer	Freedom to develop nanotech applications, in compliance with any applicable regulation.	To test for and minimise any potential harm to other stakeholders from nano-materials. Warn stakeholders of risks and uncertainties associated with individual products.	Profit from successful applications.	A clear and consistent regulatory framework and risk assessment process to facilitate product development and minimise risk of market failure.
	Farmer	Freedom to choose whether to supply raw materials to producer of foods incorporating nanotechnology.	Responsible use of nano products in accordance with regulations and to avoid harm to animals or damage to environment through waste disposal.	Improved profits from expanded use of products	N/A
	Processor	Freedom to choose whether, within a consistent regulatory framework, to use nanotechnology in the development of food products.	To ensure that all products are rigorously tested. To avoid use of nanotechnology in foods that may be suspected of causing harm to human health or to the environment. To provide appropriate labelling on packaging.	Ability to profit from use of nanotechnology in food products and to develop new products.	A clear and consistent regulatory framework including appropriate assessment, safety and labelling requirements
	Consumer	Foods containing nano-materials or created using processes involving nanotechnology should be clearly labelled as such. The specific nano-materials used should be	To be provided with information about the nature of any nano-materials used, any real or potential risks to health and information and facilities to dispose of nano-packaging	Ability to benefit from better quality, longer lasting food and greater more targeted health and nutrition benefits without fear of unknown risks.	Any potential risks should be outweighed by potential benefits for the consumer. A clear, consistent and transparent regulatory framework for nanotechnology applications

		identified in order that consumers can make an informed purchasing choice.	materials and other nano-waste in a safe and sustainable way		for food together with appropriate labelling requirements.
	Animals	N/A	Use of nanotechnology in feedstuffs should be clearly identified.	Improved and better targeted health and nutrition.	Use of nanotechnology in the production of animal feeds should be clearly identified.
	Environment	Maintenance of sustainable natural environment	Appropriate assessment of environmental risks and measures in place to minimise or eliminate contamination, bioaccumulation or leaching of nano-materials from waste food and packaging into the wider environment	Protection and promotion of environmental sustainability and prevention of nanotech waste being distributed or leached into the environment.	Measures taken to regulate the disposal of nano-materials in waste food and packaging and protect the environment.
	Future Generations	Future health and environment should not be jeopardised by current use of nanotechnology	Future health and environment should not be jeopardised by current use of nanotechnology including accumulation of nano-materials in the biosphere and environment	Enhanced food products, better flavours, and environmental protection.	Future health and environment should not be jeopardised by current use of nanotechnology.

The most prominent area of ethical concern for nanotechnology as it impacts on food and agriculture is that of non-malfeasance (‘do no harm’) i.e. the safety of the food or process. This is particularly important because of the level of unknown risk associated with this technology and the potential for unforeseen consequences to humans, biological organisms and the environment, including risks to future generations. The very extensive range of potential applications of nanotechnology, and the fact that the European Commission and its associated bodies such as EFSA also acknowledge that existing regulatory instruments and risk assessment processes are not wholly appropriate and may need to be modified for nanotechnology applications, possibly on a case by case basis, is another factor indicating the need for a cautionary, and possibly a precautionary approach to implementation of nanotechnology innovations in food and agriculture in particular. However to date there appears to be something of a "free-for-all" in the way in which industry implements the use of nano particles and nano and microtechnology enabled systems in agriculture, food processes and products with very little attention currently being given to the use of a precautionary approach to safety issues.

There are a large number of claims about the ability of nanotechnology applied to food and agriculture to "do good" (beneficence) and there does appear to be evidence that nanotechnology does have the potential for significant benefits from "Farm to Fork". However these claims of potential benefits of themselves cannot justify the use of these nanotechnology applications without some understanding of the magnitude and likelihood of any potential risks. Risk/benefit balance is of course an important ethical consideration. Manufacturers, processors and producers should ensure that there is minimal risk to end-users and consumers, animals, the environment as well as to future generations. Some degree of risk or potential for harm may however be acceptable if there is an even greater potential for the application to be of benefit (beneficence – to 'do good'). However there must be complete transparency and risk communication about both potential risks and benefits to consumers so that a free and informed choice is possible. For example, from the perspective of the consumer, there is little justification for developing a nano-process if it does not produce a higher quality or less expensive product for consumption. However it might be considered to be justified in situations where it produces much greater quantities of food to alleviate serious shortages.

The ethical principle of Justice (fairness) requires that where there does exist a potential for risk, there should be fairness in the way in which, and by whom, these risks are borne. First of all, fairness requires that those exposed to such risks should be aware of them. Also where there is a benefit arising from the application then it should be clear to whom any such benefit would accrue. Application of the principle of fairness also means that those who are subject to the greatest risk should also have the potential to receive the greatest benefit. For example, it would not be ethically just or fair if the benefits of a new technology were enjoyed by the manufacturer (for example in terms of increased profits, greater efficiency etc.) while all the risks accrued to the consumer, even if these were very small or uncertain. Indeed the European consumers' rejection of first generation GM products arose primarily because they perceived that any benefit would accrue to industry and producers while any risks, whether real or potential that might exist would be borne by the consumer (Frewer et al, 2011). However unlike first generation applications of genetic modification to food and agriculture, developers of food-related nanotechnology applications claim that many of the products and processes will have real benefits for the consumer. While there does indeed appear to be evidence that nanotechnological applications have the potential to achieve many of the claimed benefits such as improved quality in food products, flavour enhancement and better and more targeted delivery and bioavailability of nutrients, there still remains potential risks which are largely unknown (Singh and Nalwa 2007). This therefore raises the ethical issue of autonomy and the right of the consumer to choose whether they wish to be exposed to unknown potential risks. The principle of autonomy is the capacity of a rational individual to make an informed, uncoerced decision. For an individual to have the capacity to make an informed decision they first need to be provided with the necessary information. In the context of nanotechnology and food this means having the means to assess the risks and benefits (whether real, perceived or unknown) associated with the application of the technology used to create the food. In order for the decision to be uncoerced the individual also needs the capacity to make a choice and indeed be aware that there is a choice to be made. At present it would appear that many developers of nanotechnology applications in food are utilising processes and bringing products to the market without making the consumer aware that nanotechnological processes or substances are involved (Scrinis and Lyons 2007). One of the reasons for this is that regulations requiring such disclosure do not currently exist and there is lack of clarity amongst any regulations that may be applicable as these do not refer specifically to nanotechnology applications. It would therefore appear that the principle of autonomy could be being violated in the case of the consumer.

Similarly there appears to be very little information provided to farmers for example, on the nanotechnology constituents of pesticides or soil enhancement products. Although nano-pesticides might reduce the burden of traditional pesticides on the environment it is possible that they may create new kinds of contamination of soils and waterways due to enhanced transport, longer persistence and higher toxicity (Kah et al, 2012). As this potential risk is currently unknown, growers and producers of food can only have autonomy if they have sufficient information for them to make a choice as to whether they wish at the current state of knowledge, to use such products on their land and/or animals.

A key issue here is that there is no requirement for products derived from nanotechnology, or from processes that involve use of nanotechnology, to be labelled as such. Therefore in most cases consumers and other users may well be unaware of the extent to which nanotechnology is involved in the agriculture and food production system.

Over the last century or so there have been a number of technologies which one might identify as having significantly transformed the food industry or have the potential to do so. These would include *inter alia* mechanisation, information technology (IT), development and use of polymers (plastics etc.) in packaging and processing and the use of artificial additives in food. Use of mechanisation and IT are essentially benign, although they have significantly altered practices in the food and farming industry which has had an impact in other areas such as housing and employment. Use of polymers in packaging in particular has had enormous benefits in terms of lightness, shape, convenience etc. but has also presented us with a significant problem in terms of unrecyclable waste which is only in recent years beginning to be addressed as consumer awareness of the problem has grown. However, these innovations were introduced in terms only of their benefit with it would appear, no reference being made to any potential harms. In the case of inorganic artificial additives regulation has increased steadily to the stage when such components are now carefully assessed and controlled. This may be because they can have a direct and even deadly impact on human health. As a result they are subject to rigorous risk assessment and it is also a requirement that they be clearly identified in products through mandatory labelling. A similar situation exists for any foods or processes involving or sourced from genetically modified products. Relatively few GM products are licenced for use in the European Union and even in those countries where there are no restrictions on the sale of GM products, the great majority of consumers, including many of those willing to consume GM-derived products believe that foods should be labelled to indicate whether GM products are involved in their production (Frewer et al 2012). Surveys on the use of nanotechnology applications in food indicate that its use in food packaging is assessed by consumers as less problematic than nanotechnology foods themselves. However, perceived control is considered to be an important factor influencing consumer perceptions as is the importance of naturalness. Opposition to or acceptance of nanofood is very much related to trust in governments and the regulatory system (Siegrist et al. 2008; Vandermoere et al 2011)

Use of nanotechnology in the food industry seems to be much closer to artificial food additives and GM than to the other technologies mentioned above in that like artificial additives, nanotechnology involves the introduction of manufactured chemical substances to food and food processes or like GM technology, causes changes to the characteristics of foods or food sources, in addition to creating the possibility of unknown potential risks to human health, the environment and future generations. This suggests that manufacturers should indicate whether nanotechnology has been involved in the processing or production of their products and in particular whether they contain nanotech ingredients. This would enable the consumer for example to make an informed autonomous choice. For example it would enable them to decide whether they wished to purchase foodstuffs that had been grown in soils treated with nano-soil enhancers such as carbon nano-tubes or nano-pesticides, products packaged using nano-materials such as nano-silver with uncertain waste disposal characteristics or foodstuffs which themselves contain nano-materials, which may present a potential and unknown risk of bioaccumulation of nanomaterials.

It may seem to be not in the interests of producers or distributers to highlight the presence of nano-materials in case consumers choose not to purchase the product. However following the major consumer reactions as they perceived they were not fully informed on food chain processes, particularly BSE and genetically modified foods, most manufacturers now recognise the importance of an open and ethical approach to informing the consumer and providing them with sufficient information to enable them to make an informed choice.

Central to informing the consumer is the principle of adequate and appropriate labelling to enable consumers to identify both ingredients and processes related to the production of their food.

3.1 The case for effective labeling of the use of nanotechnology in food production and packaging

Food labelling is a key instrument in facilitating consumer autonomy. It enables the consumer to choose what food and food ingredients they wish to eat. Labelling is important for all food products but with both modern food processing and more particularly innovative technologies there is a particular need for the consumer to be fully informed on both ingredients and processes. This is especially relevant where consumers may have either ethical, safety or sustainability concerns about foods created by particular technologies and or processes.

The European Commission is of the opinion that current EU legislation does not meet all policy needs in relation to labelling. One of the difficulties is that of providing consumers with all the information they need to make an informed choice on labels of limited size, particularly for small products. Some consumers require much more information than others. Ideally consumers and other stakeholders should be able to access information about the ingredients (e.g. whether it contains nuts or other allergens, meat products, GM or nano-material), processes (e.g. use of growth hormones, GM feed, nano-sensors or control systems, nano-enhanced soil or pesticides, nano-based non-fouling surfaces, nanopackaging etc.), nutrition (e.g. high fat, sugar and salt levels and the origin of the food to enable them to make choices based on for example, Fair Trade, country of origin, fair trade and other socio-political considerations that may be important to them.

Clearly it is difficult to see how all this information might be included on a simple package label, particularly for small food items. A means of providing back-up information for those who want it may be one approach. New technologies provide opportunities for such innovative new labelling technologies and some of these are already in use. For example, Radio Frequency Identification (RFID) tags, are a wireless non-contact tag system that responds to an electromagnetic field to provide information to a scanner for the purposes of automatic identification and tracking. Many of these tags require no battery and are powered by the electromagnetic fields used to read them (Fig 1).

Fig. 1 – Radio Frequency Identification Tag (RFID)

A large amount of information is able to be stored in a RFID and each tag can have a unique identifier. Many supermarkets already provide customers with hand scanners that enable them to read and record prices while shopping. It would be a simple matter to enable these scanners to read the information on the RFID and display this for the consumer when required. In addition, as most current scanners are already linked to a customer loyalty card, the consumer could have any particular preferences, such as low fat, low salt, avoidance of particular ingredients because of allergies, vegetarian products, packaging materials used, country of origin, whether the product contains GM products or nano-materials etc., stored on their loyalty card so that when this is swiped on entering the store, preferences are transferred to the hand scanner. Information and alerts (e.g. an audible signal and message announcing "This product contains nuts") could then be displayed on the hand scanner as the product is scanned. A simple app on a smartphone could perform the same function. This approach has been successfully piloted in the context of allergenic ingredients, for example (see Voordouw et al, 2012). However, the use of RFIDs could be considered a "double-edged sword" as it is increasingly likely that RFIDs themselves will develop into microsystems containing nanocomponents which will be used for a much broader range of information and communication applications. This would result in them being in the interesting position of having to alert consumers to the presence of any nanomaterials which they themselves may contain.
Bar codes (Fig 2) or datamatrix codes (Fig 3) are an alternative method of labelling which could also provide the same information to consumers. The technology would be different as the information would either have to be stored in a database on the store hand scanner or be available on the internet for use with a smartphone app or dedicated personal scanner. As bar codes already exist on all products this technology would be readily introduced.

Fig.2 – Bar Code

1 25002 74135 0

Fig 3 - Datamatrix Code

3.2 Privacy Issues

The use of personalised scanners does raise some issues of privacy and data protection. Stores would have access to consumers' personal preferences in more detail than they currently have through loyalty cards. In addition it could provide companies access to information on their customers' medical conditions. It would be important that only essential information was stored and that this is properly secured and encrypted.

RFIDs in particular can also give rise to privacy issues as they are individually identifiable and so can be used to track where the product goes. E.g. who bought it and what did they do with the packaging? With some products (e.g. RFIDs on clothing) they can be used to track the person. It would therefore be important to ensure that appropriate provisions are in place under the implementation of the Data Protection Directive 95/46/EC, to ensure consumers' privacy is secured. Similar issues may emerge as more microsystems are developed which can communicate or be interrogated remotely which could provide information on for example, what people do with their waste and how and where it is disposed of. Linkages to loyalty cards for example would result in consumers being individually identifiable. It is therefore important to consider ways in which such systems may be disabled after leaving the store for example.

Labelling of foodstuffs in the EU is currently covered by a number of Directives and Regulations (Table 6).

Table 6

Legislation	**Purpose**
Directive 2000/13/EC	Governing the labelling, presentation and advertising of foodstuffs
Directive 2001/101/EC	Amendment relating to labelling of meat
Directive 2003/89/EC	Labelling of ingredients present in foodstuffs
Novel Foods Regulation (EC) No. 258/97	Rules for the authorisation of novel foods, ingredients and processes

One or more of these regulatory instruments may need to be amended to take account of use of nanotechnology in food and agriculture. However it will first be necessary to establish an agreed definition of what constitutes "nanotechnology" in relation to its application in foods.

4 Conclusions

The original intention of this study was to consider ethical issues associated with the use of nanotechnology with a particular focus on the area of smart nano enabled microsystems in food packaging. However, following analysis, it became clear that while nanotechnology applied to food production generally raises many ethical issues, few of these directly apply specifically to active microsystems or nanotechnology in packaging. One issue, that of consumer choice related to packaging as opposed to the foods contained by it, does raise the question of whether packaging materials should be labelled to indicate whether they are produced using nanotechnology or contain embedded nano-materials, in line with requirements for consumer autonomy. It is also necessary to evaluate whether the putative benefits of applying nanotechnology to packaging outweigh the potential risks. Other than these two issues, and some considerations of privacy issues in relation to microsystems that transmit information or can be interrogated, there is little ethical basis for questioning the use of microsystems and nanotechnology in food packaging. The important problem of there being no clear and consistent risk assessment framework for nanomaterials applies not only to nanotechnology packaging but to all uses of nanotechnology whether food-related or otherwise.

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