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Proceedings of a workshop on “Nanotechnology for the agricultural sector: from research to the field”

Prepared by Claudia Parisi,

Mauro Vigani and Emilio Rodríguez-Cerezo

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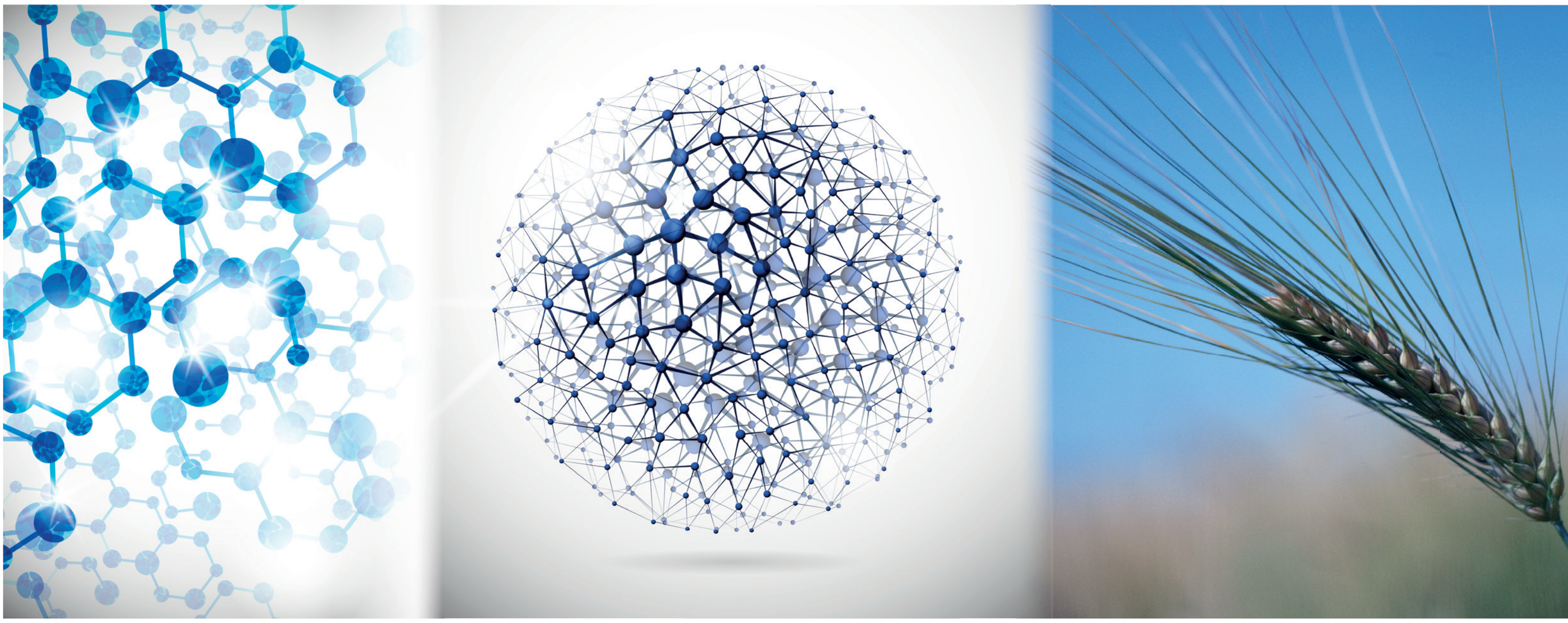

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Abstract

Innovation is at the centre of the EU's growth strategy for the coming decade (EU2020). New technologies and their adoption by EU farmers are essential in maintaining European agriculture competitive in a global world. Nanotechnology represents an innovative technology in many areas of applications and is showing a great potential in the agricultural sector, in particular for the development of more precise and effective methods for disease diagnosis and treatment in crop plants.

The Institute for Prospective Technological Studies (IPTS) of the European Commission's Joint Research centre (JRC) organised an International Workshop on "Nanotechnology for the agricultural sector: from research to the field" in Seville on 21st and 22nd November 2013. The purpose of the workshop was to review the state-of-the-art of R&D of nanotechnology for the agricultural sector and to analyse possible markets and commercial pipeline of products with applications in crop production. This workshop brought together leading scientists, key stakeholders and experts, in order to promote the presentation of research and industry results and the discussion of experiences.

The JRC Scientific and Policy Report provides the proceedings of the November 2013 workshop, which covered the following topics:

Session 1: Overview of nanotechnology applications with a focus on agricultural nanotechnology
Session 2: Nanotechnology research activities in the agricultural sector
Session 3: Case-studies on developing industrial applications of agricultural nanotechnology
Session 4: Developments in nanotechnology risk assessment and regulation
Session 5: Socio-economic issues of agricultural nanotechnology

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List of Abbreviations

CEN	European Committee for Standardization
CLP	Classification, Labelling and Packaging
COPA-COGECA	European Committee of Professional Agricultural Organisations & General Confederation of Agricultural Cooperatives
DAFNE	Department of Agriculture, Forest, Nature and Energy - University of Tuscia (Italy)
DG	Directorate General
DG ENTR	European Commission Directorate General for Enterprise and Industry
DG ENV	European Commission Directorate General for the Environment
DG SANCO	European Commission Directorate General for Health & Consumers
EC	European Commission
ECPA	European Crop Protection Association
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPA	Environmental Protection Agency
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FIC	Food Information to Consumers
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FP7	Seventh Framework Programme
GM	Genetically Modified
GMO	Genetically Modified Organism
ICCA	International Council of Chemical Associations
ICT	Information and communications technology
IFT	Institute of Food Technologists
IGO	International Governmental Organization
IHCP	Institute for Health and Consumer Protection
ILSI	International Life Sciences Institute
IoN	Institute of Nanotechnology
IPTS	Institute for Prospective Technological Studies
IRMM	Institute for Reference Materials and Measurements
ISO	International Organization for Standardization
JPO	Japan Patent Office
JRC	Joint Research Centre
KET	Key Enabling Technology
NAARM	National Academy of Agricultural Research Management
NGO	Non-Governmental Organization
NIA	Nanotechnology Industries Association
OECD	Organisation for Economic Co-operation and Development
PCS	Photon Correlation Spectroscopy
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIKILT	Dutch Institute for Food Safety
RIPoNs	REACH Implementation Projects on Nanomaterials
SAP	Super Absorbents
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
TEM	Transmission Electron Microscopy
TFEU	Treaty on the functioning of the EU
US	United States of America
USPTO	United States Patent and Trademark Office
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPN	Working Party on Nanotechnology
XRD	X-ray Diffraction

Executive summary

Introduction

Innovation is at the centre of the EU's growth strategy for the coming decade (EU2020). Nanotechnology is recognized by the European Commission as one of the six key enabling technologies (KETs) that shows applicability in several different sectors such as medicine, biotechnology, electronics, materials science and energy technologies. Nanotechnology makes use of phenomena and fine-tuning of materials at atomic, molecular and macromolecular scales, where properties differ from those at a larger scale. The innovation in this sector is pulled by manufacturers and producers because of the beneficial new properties of nanomaterials, attracting large-scale research investments.

Among the different sectors, applications of nanotechnologies for the food industry (applied to food processing, distribution, packaging, and functional food) have been largely investigated. On the other side, the potential of nanotechnologies for agriculture is, for the largest extent, still unrevealed. However, agriculture can potentially benefit from nanotechnologies in different ways, allowing EU farmers to maintain the competitiveness in a global world.

The purpose of the "Workshop on Nanotechnology for the agricultural sector: from research to the field", held at JRC-IPTS (Seville) on 21st and 22nd November 2013, was to review the state-of-the-art of R&D of nanotechnology for the agricultural sector and to analyse possible markets and commercial pipeline of products. The scope is on nanotech-based products with applications in crop production. This workshop brought together leading scientists, key stakeholders and experts, in order to promote the presentation of research and industry results and the discussion of experiences.

Overview of nanotechnology research activities in the agricultural sector

Technical innovation in agriculture is of extreme importance, in particular to address global challenges such as population growth, climate change and the limited availability of important plant nutrients such as phosphorus and potassium. Nanotechnology applied to agricultural production could play a fundamental role for this purpose and research on agricultural applications is ongoing for largely a decade by now. Both scientific publications and patents are showing a growing trend. The application of nanomaterials in agriculture aims in particular to reduce applications of plant protection products, minimize nutrient losses in fertilization, and increase yields through optimized nutrient management. Despite these potential advantages, the agricultural sector is still comparably marginal and has not yet made it to the market to any larger extent in comparison with other sectors of nanotechnology application.

New devices and tools, like nanocapsules, nanoparticles and even viral capsids, are examples of uses for the detection and treatment of diseases, the enhancement of nutrients absorption by plants, the delivery of active ingredients to specific sites and water treatment processes. The use of target-specific nanoparticles can reduce the damage to non-target plant tissues and the amount of chemicals released into the environment. Nanotechnology derived devices are also explored in the field of plant breeding and genetic transformation. The potential of nanotechnology in agriculture is large, but a few issues are still to be addressed, such as increasing the scale of production processes and lowering costs, as well as risk assessment issues. In this respect, particularly attractive are nanoparticles derived from biopolymers such as proteins and carbohydrates with low impact on human health and the environment. For instance, the potential of starch-based nanoparticles as non-toxic and sustainable delivery systems for agrochemicals and biostimulants is being extensively investigated.

Nanomaterials and nanostructures with unique chemical, physical, and mechanical properties (e.g. electrochemically active carbon nanotubes, nanofibers and fullerenes) have been recently developed and applied for highly sensitive bio-chemical sensors. These nanosensors have also relevant implications for application in agriculture, in particular for soil analysis, easy bio-chemical sensing and control, water management and delivery, pesticide and nutrient delivery.

In recent years, agricultural waste products have attracted attention as source of renewable raw materials to be processed in substitution of fossil resources for several different applications. Nanocomposites based on biomaterials have beneficial properties compared to traditional micro and macro composite materials and, additionally, their production is more sustainable. Many production processes are being developed nowadays to obtain useful nanocomposites from traditionally harvested materials. For example, it is possible to use chemical-mechanical processes to obtain nanofibers with enhanced thermal properties for the production of thermoplastic composites, starting from wheat straw and soy hulls.

Commercial applications of nanotechnology in the agricultural sector

From a commercial perspective, existing agro-chemical companies are investigating the potential of nanotechnologies and, in particular, whether intentionally manufactured nano-size active ingredients can give increased efficacy or greater penetration of useful components in plants. However, the nano-size so far did not demonstrate to hold key improvements in products characteristics, especially considering the interest of large scale production and the costs involved in it.

Some specific nano-products for the agricultural sector have been put on the market by technology-oriented SMEs, like soil-enhancer products that promote even water distribution, storage and consequently water saving. However, the commercial market application of these products is so far only achieved at small scale, due to the high costs involved in their development. These costs are normally compensated by higher returns in the medical or pharmaceutical sectors, but so far there are no such returns in the agricultural sector. Research continues in the commercial agro-chemical sector to evaluate potential future advantages.

Companies are also facing challenges derived from the definition of nanomaterials that is adopted by the EU. One crucial point related to the EU definition is the possibility that non-active substances already used for many decades in commercial products formulations will fall within the scope of the nano definition, although not intentionally developed as nanoparticles or having specific nano-scale properties. Nanoscale formulants (e.g. clay, silica, polymers, pigments, macromolecules) have been used for many decades and are also ubiquitous in many daily household products. The concern is that the need for labelling of products that are already on the market since decades results in a scenario, in which the technology is stigmatized, preventing further and innovative applications of nanotechnology in agriculture.

Nanotechnology risk assessment and regulation in the EU and worldwide

The EC developed in 2011 a Recommendation (2011/696/EU) on the definition of nanomaterial, which will be reviewed in the light of new experience and of scientific and technological developments:

> *A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm -100 nm.*

The definition of nanomaterial is the first filter to define and measure the impact of this technology, but it is complex to provide a technical and shared definition, given that national and global organisations utilise different criteria.

In order to implement the EC's Recommendation for a definition of nanomaterial, some important tools need to be developed, such as guidance documents and validated methods for size measurement, taking also into consideration the measurement of nanomaterials in complex matrices (food, cosmetics, etc.). The European Commission's Joint Research Centre Institute for Health and Consumer Protection (JRC IHCP) is actively involved in research into safety, identification and detection of nanomaterials. An important activity by the JRC IHCP in collaboration with the Dutch institute for food and feed safety RIKILT, is also the creation of an inventory of current and prospective applications of nanotechnologies in the areas of food and feed (including food contact materials) for the European Food Safety Authority (EFSA).

In October 2012, the EC adopted the Communication on the Second Regulatory Review on Nanomaterials, which assesses the adequacy and implementation of EU legislation for nanomaterials and lists the Commission's actions in the field of nanomaterials. Regarding the safety issues, this Communication reports a key statement which regards nanomaterials as similar to chemical substances in that some may be toxic and some may not. The hypothesis that smaller means more reactive, and thus more toxic, has not been substantiated. According to EFSA, risk assessment should take into consideration the physico-chemical properties of nanomaterials as manufactured as well as present in the food/feed matrix. Generally, a case-by-case approach is recommended by the EC, while specific safety aspects related to nanomaterials still require further investigation. There are specific hazards that could potentially be linked to the nano-size of the materials, but methods for hazard identification and exposure assessment are still to be developed, validated and standardized.

Due to the variety of applications of nanotechnology, different pieces of legislation are concerned in the EU, including both horizontal legislation and product-specific legislation. The most comprehensive horizontal piece of legislation relevant to nanomaterials is the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals REACH, which addresses chemical substances, in whatever size, shape or physical state. Substances at the nanoscale are therefore covered by REACH and its provisions apply. Among product-specific legislation, some already explicitly address nanomaterials (cosmetics, food additives, provision of food information to consumers, and biocides) while others do not (toys, electrical equipment and waste & environmental legislation).

Since certain products are already available to consumers, and other products may follow soon, there is a need of a clear and internationally harmonized definition of nanomaterials for the food chain. At international level, there are several activities in place on risk analysis of nanomaterials in the food and agriculture sectors, in particular by the governments of Australia/New Zealand, Canada, China, the EU, Japan, Switzerland and the US. Overall, definitions of nanomaterials developed in different countries result in different risk management measures. So far, apart from the EU, no country has set a regulatory framework for the mandatory labelling of nanomaterials in food.

According to FAO/WHO, many progresses have been made in the last years in the development of national and international risk assessment and risk management approaches that identify and implement strategies to address potential hazards associated with the use of nanotechnology-related products or techniques. However, data gaps, in particular related to the characterization of nanomaterials, continue to exist and the global knowledge will benefit from information exchange at international level between scientists from academia and industry and authorities.

Socio-economic issues of agricultural nanotechnology

The emergence of nanotechnology applications in consumer products has also raised a number of ethical and societal concerns in some countries, starting from health and environmental safety, to consumer perception and intellectual property rights.

There are many socio-psychological factors influencing the societal response to the introduction of a new technology. For the case of nanotechnology it is important to identify these factors among different stakeholder groups. From different studies about consumer acceptance of nanotechnology products, it appears that the public opinion is generally not negative. The public seems to be unconcerned about many applications of nanotechnology with the exception of areas where societal concern already exists such as pesticides.

As for many emerging technologies, intellectual property in nanotechnology, and in particular freedom to operate, constitute relevant issues for the development of new products. The number of patent applications in nanotechnology has increased more than tenfold during the last 20 years, demonstrating a great potential for commercial applications. Patenting on nanotechnology in general presents some important concerns. Nanotechnology is pervasive in different fields of applications and nano-based inventions could infringe existing granted patents in those fields. This risk of overlapping patents can also have consequences for the agri-food sector. Moreover, patent holders could lock-up huge areas of technology. There are indeed already over 3,000 patents worldwide for potential agrochemical usage of nanotechnology but they are most likely patents with broad claims, filed with the scope of guarantee freedom to operate in the field in case of future commercial developments.

In developing countries nanotechnologies can have important applications in several agri-food areas, such as food security, input delivery, rice production systems, agri-biotechnology, healthcare of animals, precision farming, food industry and water use. However, the main factors limiting the development of these applications are low investments in manpower training and in research infrastructure. Despite these potential uses of nanotechnology and progress being exhibited in some successful business models on products based on nanotechnology, the issues of safety of its application to humans and the environments need to be addressed. Risk management strategies should be put in place in parallel to the technological developments and also through development of stable governance models in the entire production and consumption system through continued interaction with all the stakeholders: governments, producers, users, and consumers.

Session 1: Overview of nanotechnology applications with a focus on agricultural nanotechnology

This session describes the main applications of nanotechnology in the different sectors, with a focus on agriculture, and highlights the current concerns related to the correct definition of this technology, its safe use and its potential economic impact.

Presentation S1-1: Nanotechnology in the EU – an overview

Mark Morrison, *Institute of Nanotechnology, UK*

The definition of nanotechnology is the first filter to define and measure the economic impact of this technology, but it is complex to provide a technical and shared definition, given that national and global organisations utilised different criteria. Indeed, each organization involved (from ISO to Patent Offices, and from National and International funding bodies to Industrial Associations) has presented its own definition of nanotechnology. While broadly similar, they can vary in certain key respects. For instance the definition of nanomaterials recommended by the European Commission (EC) is based on a certain percentage of nanoparticles:

> *A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm -100 nm*[1]*.*

Conversely, according to the International Council of Chemical Associations (ICCA), the definition should focus on weight distribution. Additional issues such as how to deal with agglomerated nanoparticles further complicates the matter.

When talking about product development, nanotechnology can be involved directly, (e.g. when final product functionality and novelty strongly depend on nanotechnology), or indirectly (when nanomaterials affect the production process but may not be present in the final product). Therefore, the economic impact of nanotechnology can differ depending on the specific product. For this reason, three definitions are being used by the OECD's Working Party on Nanotechnology (WPN):

- *Nanotechnology products*: nanotechnology is fundamental, the key functionality would not otherwise exist e.g. novel batteries.
- *Nano-enabled products:* products whose key functions hinge on exploiting size-dependent phenomena underlying nanotechnology, but where nano-materials may constitute a small percentage of the final product.
- *Products that utilise nanotechnology*: nanotechnology has improved or enabled more efficient or cost effective production or processing, but the final product may not contain nanomaterials and its functionality may not have been enhanced by nanotechnology e.g. anti-fouling coatings for food processing equipment.

The impact of nanotechnology can be measured through input indicators (e.g. public investment, infrastructure or number of graduates), output indicators (e.g. publications, patents or product sales) and impact indicators (e.g. number of companies, number of jobs, growth of market or volume share). However, the data collection depends very much on the definition adopted of nanotechnology. To complicate more the analysis, several companies do not see themselves as belonging to the nanotechnology world, although their products (even traditional products) could fall under the definition if taken literally. It is therefore difficult to attribute the correct parts of the business to nanotechnology and also to identify if government funding is attributed to nanotechnology.

Within the scope of the FP7 project ObservatoyNANO (http://www.nano.org.uk/news/1747), coordinated by the Institute of Nanotechnology (IoN), which is involved in many different initiatives in the field of nanotechnology, ten broad sectors of nanotechnology application were selected and analysed, including medicine, transport, environment, materials and also agrifood. The project ObservatoryNANO produced several reports, briefings and factsheets on economic, safety, ethical and regulatory aspects of nanotechnology.

According to ObservatoryNANO bibliometric analysis, the EU has the highest number of publications in the nanotechnology field, but it is losing the lead during the last years, especially because of the growing trends of China and South Korea. A lot of research activities in the field of nanotechnology have been identified throughout Europe, being Berlin the city where the highest number of publications has been produced.

In the framework of ObservatoryNANO, also the number of patents involving nanotechnology was analysed, and the details are provided in Presentation S5-2. According to the patent landscape, the US is the leading country in number of patents but again China and South Korea are gaining ground.

ObservatoryNANO provided a very comprehensive map of nanotechnology companies in the EU, including companies manufacturing products or delivering services utilizing nanotechnology (identified through patent and publication searches and by participation in nanotechnology projects in the Framework Programme). In this mapping exercise, nanotechnology was taken in its broader sense, despite the companies' own conception. In this way, over 1,500

1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.

companies were identified through publications and patents, most of them based in Germany.

The IoN is involved in several different projects, including the following examples:

- FP7 NanoCelluComp: Production of composite materials with high mechanical strength using nanofibres derived from waste from processed vegetables.
- FP7 CLIP: Development of low cost copper-based conductive inks for different types of printing technologies.
- FP7 NanoValid: Development of reference methods for hazard identification, risk assessment and life-cycle assessment of engineered nanomaterials.
- FP7 NMP-DeLA: Nanosciences, nanotechnologies, materials and new production technologies deployment in Latin American countries.
- FP7 NanoDefine: Development of an integrated approach based on validated and standardized methods to support the implementation of the EC recommendation for a definition of nanomaterial.
- FP7 EU NanoSafety Cluster: analysis of the impact of nanotechnology in different environmental systems, and industry and product areas. The EU is very active in the field of safety studies, but there are still big challenges to be faced, such as the high variability of physico-chemical properties in different materials and the knowledge gap in the life cycle.

Nanotechnology can have a direct or indirect impact on the development and manufacture of particular processes or products. To illustrate this we will look at two value chains as examples: the 'green' car, and the production of jam. The green car can include a number of different materials, components, and systems which have been enabled by nanotechnology, such as the battery, the tyres, displays, the bodywork and chassis. The jam contains no engineered nanomaterials; however, the production process may include the employment of nanostructured coatings in the food processing equipment. The issue is how to measure the value of nanotechnology to the final product. These two value chain emphasise the importance of assessment of the full value chain, rather than focusing on individual stages, and of having a thorough knowledge of these issues at each stage of the value chain before starting the collection of economic data.

In conclusion, the impact of nanotechnology is a complex issue because of its non-homogeneous definition, of the direct and indirect nature of its impact and, consequently, of the difficulty in data collection. It is therefore important for any investor (governments included) to know what their money will achieve to calculate the investment return. Data collection from the market side must have the value chain at its core, and not only considering the final products but also the information on different stages. Mapping the innovation pathways and linkages between different organizations involved at different stages is also fundamental to understand how companies are brought into the field of nanotechnology and what data is really needed.

Presentation S1-2: Agricultural applications of nanotechnology

Thomas Bucheli, ***Agroscope, Institute for Sustainability Sciences, Switzerland***

The global number of scientific publications related to nanotechnology has shown an exponentially growing trend until today. The same trend can be observed for publications related to the application of nanotechnology for agricultural production. However, compared to other fields of nanotechnology application, like water and energy, agriculture is still a marginal sector. Nevertheless, fundamental nanotechnological knowledge gained in other emerging topics, such as environmental monitoring and drug delivery techniques, may over time find their applications in agriculture as well[2].

Different options exist for the application of nanotechnology in the agri-food sector, in particular for food-based applications (packaging), animal husbandry (detoxification and nanomedication) or both sectors (tagging and barcode), and for crop-based applications (plant genetic modification and nanomaterials from plants), environment-based applications (pollutant remediation, water purification and water retention) or both (plant protection products and fertilizers), plus applications that are common to all these sectors (e.g. nanosensors). Numerous research projects are being carried out in all these fields[3].

Currently, several programmatic areas are being investigated at NIFA (US National Institute of Food and Agriculture)[4] and are showing high promises. They include in particular nanosensors, tools for identity preservation and tracking of products and smart treatment of delivery systems.

By analysing the scientific publications related to the application of nanotechnology in the agri-food sector in developing countries[5], what emerges is that the main

2 Chen, H.C., Roco, M.C., Son, J.B., Jiang, S., Larson, C.A., Gao, Q., 2013. Global nanotechnology development from 1991 to 2012: patents, scientific publications, and effect of NSF funding. J. Nanopart. Res. 15, 1951.

3 Kuzma, J., VerHage, P., 2006. Nanotechnology in Agriculture and Food Production: Anticipated Applications. Project on Emerging Nanotechnologies. http://www.nanotechproject.org/process/assets/files/2706/94_pen4_agfood.pdf. Wilson International Center for Scholars, Washington, DC

4 http://www.nifa.usda.gov/ProgViewOverview.cfm?prnum=16500

5 Cozzens, S., Cortes, R., Soumonni, O., Woodson, T., 2013. Nanotechnology and the millennium development goals: water, energy, and agri-food. J. Nanopart. Res. 15, 2001.

applications for agricultural production are pesticide formulations and nanosensors.

A meta-analysis of assessments on nanotechnology in agriculture performed by Forsberg and de Lauwere[6] illustrates the need for greater integration in the evaluation of nanotechnology in food and agriculture. According to authors, assessments should be based on their point of departure, with regard to values, narratives, and the framing of the topic and there is a need for more specific analysis, addressing topics in their complexity rather than only generic assessments.

Other studies describe nanotech in agriculture as an application with little future[7], since the agri-food sector is a low profit industry with little public funding and nanotech applications are bound to encounter tremendous regulatory hurdles in parallel with the opposition of NGOs (Non-Governamental Organisations).

The number of patents, publications and google hits about nanotechnology for pesticides and fertilisers are showing an exponential growth in the last years. According to literature, there are many opportunities in the application of nano-scale pesticides and fertilizers, in particular to avoid unwanted losses due to the way of application, volatilisation or chemical reactions, excretion by the plant, microbial degradation, etc[8]. Nanotechnology can contribute to minimise these losses thanks to a more stable emulsion, better leaf coverage, lower application rates, precise application, UV-protection and controlled release.

By analysing patents on applications of nanomaterials for plant protection products and fertilisers, what emerges is that most patents are on plant protection products, in particular fungicides and insecticides. Patents can be divided between the ones claiming the additive (most patents) and the active ingredient. Additive functions may aim to controlled release, including dispersion aid, transport media, protecting agent and photocatalyst. Nanomaterials employed in these applications can be divided in solid and non-solid. Most patents and scientific papers refer to non-solid nanomaterials such as lipids, polymers and emulsions.

Some examples of nanomaterials include, among many others, silver nanoparticles as active ingredients in fungicides[9], TiO_2 nanoparticles as additives (photocatalysts) in pesticides like imidacloprid[10], ZnO nanoparticles as active ingredients in fertilizers[11] and hydroxyapathite urea-coated particles as additives in fertilizers for controlled release[12].

Most patents are owned by private companies, mainly multinational ones. Industrialised countries like the US and Germany are emerging as the strongest in producing patent applications, while China is clearly leading in scientific publications and Korea also shows a relevant publication activity (like the US).

Interestingly, although all patents and publications have been identified because of their reference to nanomaterials and nanotechnology, a closer analysis of the actual size of the particles described reveals that 50% of the papers deal with particles above the nano-size range.

Not many products are already available on the market. As an example, in Canada polymer nanoparticles have been developed that are less than 10nm in size and hold active pesticide ingredients to be delivered to plants[13]. These particles show the advantage of coating leaves evenly and improve plant penetration.

The development of manufactured nanomaterials and their presence on the markets make it necessary to evaluate their environmental and health impacts. Yet many questions regarding the fate of these materials in the environment have still to be answered. Analysing the intentional and enhanced input of nanomaterials into agricultural ecosystems, in comparison with other potential nanoparticle input sources, such as sewage sludge, direct application of nanoparticles through plant protection products may increase fluxes to soil by up to three orders of magnitude. The most important environmental compartment for agricultural production is the soil, therefore more studies should investigate the behaviour and the effects of nanomaterials in natural soils under environmental conditions.

In the EU, nanoparticles are considered as a specific form of substances and are therefore regulated under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) as illustrated in Session 4. In the EU, there are specific regulations dedicated to plant protection products and fertilisers (Reg. EC No 1107/2009 and Reg. EC No 2003/2003, respectively) but they do not specifically address nanoparticles.

6 Forsberg, E.M., de Lauwere, C., 2013. Integration Needs in Assessments of Nanotechnology in Food and Agriculture. Nordic Journal of Applied Ethics 7, 38-54

7 Busch, L., 2008. Nanotechnologies, food, and agriculture: next big thing or flash in the pan? Agric Hum Values 25, 215-218.

8 Gogos, A., Knauer, K., Bucheli, T.D., 2012. Nanomaterials in Plant Protection and Fertilization: Current State, Foreseen Applications, and Research Priorities. Journal of Agricultural and Food Chemistry 60, 9781-9792.

9 Kim, H., Kang, H., Chu, G., Byun, H., 2008. Antifungal effectiveness of nanosilver colloid against rose powdery mildew in greenhouses. In: Rhee, C.K. (Ed.), Nanocomposites and Nanoporous Materials Viii, pp. 15-18.

10 Guan, H.N., Chi, D.F., Yu, J.C., Li, X., 2008. A novel photodegradable insecticide: Preparation, characterization and properties evaluation of nano-imidacloprid. Pesticide Biochemistry and Physiology 92, 83-91.

11 Milani, N., McLaughlin, M.J., Stacey, S.P., Kirby, J.K., Hettiarachchi, G.M., Beak, D.G., Cornelis, G., 2012. Dissolution Kinetics of Macronutrient Fertilizers Coated with Manufactured Zinc Oxide Nanoparticles. Journal of Agricultural and Food Chemistry 60, 3991-3998.

12 Kottegoda, N., Munaweera, I., Madusanka, N., Karunaratne, V., 2011. A green slow-release fertilizer composition based on urea-modified hydroxyapatite nanoparticles encapsulated wood. Current Science 101, 73-78.

13 http://www.vivecrop.com

In the US, nanopesticides are regulated by the EPA (Environmental Protection Agency)[14] and are identifiable in its website since July 2011, seeking for public comment regarding how such products should be regulated and incorporated into their existing Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registration of new pesticide products.

In Switzerland, nanomaterials in plant protection products submitted for registration must be declared by describing its composition, shape, particle size, surface area, aggregation status, coatings and functionalization[15], but no such products have yet been submitted.

In conclusion, research on applications of nanotechnology in agriculture is ongoing for largely a decade by now, but it is still comparably marginal and has not yet made it to the market to any larger extent in comparison with other sectors of nanotechnology application. The number of publications and patents on nanotechnology applications in plant protection products and fertilizers is currently rather low, but steadily increasing. Nanomaterials offer the potential to improve conventional products and, at the same time, the nanotech industry seems to show responsibility: most products this far are analogues to natural materials, non-persistent and biocompatible. Knowledge gaps are largely obvious: scientists and legislators are aware of the risks and take measures in a rather timely manner.

14 http://www.epa.gov/pesticides/regulating/nanotechnology.html

15 Ordinance concerning the placing of plant protection products on the market; SR 916.161

Session 2: Nanotechnology research activities in the agricultural sector

This session describes recent research activities and applications of nanotechnology for agriculture. First the session will review the use of nanodevices as delivery systems to specific plant tissues for crops fertilization and protection. Nanodevices can also be used in agriculture to detect relevant molecules or compounds, such as low level of pesticides residues and soil nutrients. Finally, agriculture is not only a field of application of different nanotechnological devices, but it can also be a mean for the sustainable production of nanomaterials to be employed in agriculture or other fields.

Presentation S2-1: Nanomaterials as smart delivery systems for disease and pest control in plants

Alejandro Perez-de-Luque, *University of Sheffield, UK*

The most relevant nanodevices for plant protection are nanocapsules and nanoparticles, both at a scale ranging from 0.1 to 1,000 nm.

A nanocapsule is composed by a shell that contains an active compound, like an agrochemical product for the protection of the plant against pests or diseases. The shell can be constituted by different elements, such as polymers, lipids, viral capsids or nanoclays. Its main function is to protect the active compound until it is released, but it can also improve the solubility and the penetration of the compound into the plant tissues. Depending on the specific characteristics of the shell, the active compound can be released slowly and gradually, or completely after the shell opening is triggered by certain circumstances (e.g. pH changes or enzymatic degradation).

Nanoparticles have a solid core or a matrix that can be composed by different materials (such as metals or polymers) and is surrounded by linkers and biomolecules. Due to the small size, the ratio between surface area and volume is increased in the nanomaterials (compared with bulk forms), improving the biochemical reactivity and conferring unusual and valuable physical properties (e.g. superparamagnetism).

An example of application of nanocapsules for plant protection is the use of nanodisks for delivering amphotericin B, an important antimicotic. The nanodisk is a matrix composed by a bilayer of phospholipids containing the molecules of amphotericin inside[16]. This structure protects amphotericin molecules against the degradation by external agents (e.g. pH or light) while improving its solubilisation.

While medical applications are intended to protect or cure one individual at a time, plant protection in agriculture is a massive treatment for thousands of plants. Therefore, it is important that the active compound is applied in relatively small doses to cover large plant surfaces. The characteristics of the product must thus be designed taking into account these wide treatments, and also if the mechanism of action is systemic or by contact.

An important aspect concerning plant protection products involves the way in which they are absorbed by the plant and their translocation within the plant tissues and organs. The formulation of the product varies if the absorption of the active ingredient takes place through the leaves or the roots. Absorption through the roots could be easier due to their biological role for nutrient assimilation, but the advantage of getting absorption through leaf tissues is that they are more easily available for field treatments. However, the knowledge about how these mechanisms work with nanomaterials is still to be improved. Magnetic carbon-coated nanoparticles can be tracked and used to analyse nanomaterials behaviour moving all along the plant structure[17]. They are easily detectable and their magnetic properties allow their accumulation in tissues by way of using magnetic fields.

The use of nanocapsules and nanoparticles for plant protection products offers important advantages. Since active compounds are protected in capsules, they are not degraded by external agents or the crop plant itself, and are not involuntarily dispersed into the soil, allowing the use of a reduced amount of active compounds for plant treatments and consequently causing a lower environmental impact. Other environmental benefits of using nanodevices, e.g. nanoclays, derive from the potential reduction of leaching and further water contamination. Additionally, thanks to the protective capsule, it is possible to use also labile chemical products for plant protection, which can be less harmful to the environment and are currently not employed in agriculture because of their quick degradation. Finally, nanoparticles linked with biomolecules with specific affinity (e.g. antibodies or aptamers) guarantee the selectivity and specificity of targets.

Along with these benefits, nanodevices for plant protection currently show also some constraints. First of all, there are not yet sufficient studies on the potential toxicity of

16 Tufteland et al. (2009) Nanodisks protect amphotericin B from ultraviolet light and oxidation-induced
damage. *Pest Manag Sci* 65: 624–628.
Pérez-de-Luque et al. (2012). Effect of amphotericin B nanodisks on plant fungal diseases. *Pest Manag Sci* 68: 67-74

17 Cifuentes et al. (2010). Absorption and translocation to the aerial part of magnetic carbon-coated nanoparticles through the root of different crop plants. *J Nanobiotechnol* 8: 26

some nanomaterials (nanosilver, nanogold, etc.) on plants, animals and the environment. Potentially, if nanomaterials accumulate in vegetal and animal tissues, they can end up into the food chain. It is therefore fundamental to guarantee their safety and to correctly inform the consumers. However, the use of non-toxic materials (starch, chitin or nanoclays versus metals) eliminates such risk. Furthermore, nanodevices are currently very expensive and agriculture would require very large quantities of nanoproducts for a proper application, but to date there are no companies able to produce them at large scale. It might be foreseen that lower production costs due to up-scaled production will allow a greater diffusion of nano-based plant protection products in the future.

Another valuable potential application of nanotechnology related to agriculture is plant genetic transformation. Nanoparticles carrying nucleic acid constructs and with specific ligands to penetrate the cell wall can increase the delivery of nucleic acid vectors into the plant cells, enhancing the development of new genetically modified (GM) plant varieties.

The genetic manipulation through nanoparticles has potential advantages with respect to the transgenesis methods currently used. It is a system applicable to any plant species, while the more conventional *Agrobacterium*-mediated transformation can be applied only to selected species. Additionally, plant transformation through nanotechnology can lead to an increased efficiency in transformation rate with respect to biolistic methods. Moreover, with nanodevices it is possible to aim for both permanent and temporal genetic transformation, including gene silencing. In addition, genetic transformation could also be performed *in vivo* and not only *in vitro* like the other methods, allowing for specific transformation of individual plant organs or parts (fruits, branches, etc.).

As illustrated with its application in disease and pest control, nanotechnology for plant genetic transformation offer very attractive advantages, but commercial applications are not yet mature, and further assessments of the safety of its use have to be conducted.

Presentation S2-2: Starch-based nanoparticles in sustainable agriculture

Giorgio M. Balestra*, University of Tuscia, Italy***

Agricultural nanotechnology can be applied to sustainable production methods such as organic agriculture. Indeed, the Department of Agriculture, Forest, Nature and Energy (DAFNE) at the University of Tuscia in Italy is carrying out a research project for the development of starch-based nanocontainers for the delivery of nutrients, biostimulants and crop protection molecules into the plants tissues. The clear advantage of this approach is that starch is biocompatible, biodegradable and non-toxic for plants, animals and the environment.

The first step to develop starch nanocontainers for sustainable and organic agriculture is to produce starch with improved content of amylose, which is the linear fraction composing starch and determines its functional properties, and therefore easily obtain starch particles with reduced size. This is possible through improved wheat varieties with higher amylose content obtained by molecular mutagenesis techniques.

The second step is the sustainable preparation, functionalization and characterization of starch nanoparticles suitable to be used as nanocontainers. The main approach adopted to produce nanoparticles from starch is based on the acid hydrolysis of starch granules, but these methods have several drawbacks that include long duration, low yield and environmental concerns about the production of toxic waste. To overcome these problems, it is possible to successfully apply ultrasounds as an eco-friendly approach for the production of wheat starch nanoparticles, without the need of any additional chemical reagent. Once nanoparticles are produced, their surface has to be functionalized: their physical-chemical and biological properties must be chemically or enzymatically modulated to obtain the entrapment of molecules to be delivered and released in a controlled way.

Different kind of molecules can be delivered through starch nanocontainers. They can be employed to deliver nutrients into plants tissues at slow release rates for the long-term feeding of plants, and to protect phosphorus and micronutrients (e.g. iron, manganese, zinc) in alkaline soils. Biostimulant compounds can also be slowly released through nanocontainers according to the plant needs, while being protected from microbial degradation before plant uptake. Moreover, starch nanocontainers can be developed for the delivery of plant protection products, e.g. antibacterial active principles, which can also be suitable for organic agriculture (e.g. vegetal extracts, copper) and thereby used in smaller amounts. On horticultural as on stone fruit plants, recent successful experiences (in greenhouse as well as in open field) revealed the great potentiality of these nanocontainers to protect the plants along the time against harmful pathogens.

Overall, the advantages of starch nanoparticles application in agriculture are the following:

- Absence of phytotoxicity;
- Reduction of harmful residues in soils;
- Reduction of chemical compounds use for nutrition/protection of crops;
- High selectivity towards the crops treated;
- High quality and no harmful residues in the final products;
- Low production costs.

Presentation S2-3: Sensors and diagnostic devices to monitor environmental conditions: nanostructures as transducers in biosensors

Nikos A. Chaniotakis, *University of Crete, Greece*

Nanotechnology consists in the creation of novel functional materials, devices and systems through the control and utilization of nano-scale matter which presents unique properties (i.e. physical, chemical, electrical, mechanical, optical and magnetic characteristics) due to its scale.

Some of the peculiar properties of nanomaterials represent specific advantages in the production of sensors and diagnostic devices. The quantum size effects of the nanomaterials result in unique mechanical, electronic, photonic, and magnetic properties. The chemical reactivity of nano-scale materials is different and much greater with respect to macroscopic state, mainly because of the increased surface area per unit mass. The lower scale allows new chemical forms of common chemical elements, such as fullerenes, nanotubes of carbon, titanium oxide, and zinc oxide.

These properties enhance a great variety of nanostructures, all of them with different properties for different applications. The most important nanostructures for sensors and diagnostic devices are fullerenes, nanotubes, nanofibers, nanoparticles, nanocolums, nanocavities, graphene and carbon quantum dots.

An important field of research concerning sensors and diagnostic devices is the analysis of soils, which can have relevant implications also for application in agriculture. This type of research is carried out by the University of Crete, Greece, together with Tufts University in the US for the exploration of distant planets. The extreme miniaturization of the devices permits the analysis of planets soils, overcoming the typical problems of remote sensing, such as large sensors and sample size, the need of maintenance and calibration, the stability and reproducibility of the analyses and the power consumption. Nanomaterials and nanotechnology can provide solutions to these problems by decreasing the sensor and sample size, maximizing the number of sensors and reducing the power consumption. In some cases it is possible also to perform direct soil analysis using chemical microscopes, without sampling, solvents, and reagent delivery.

Bio-silica nanostructures are particularly suited for building diagnostic and sensor devices based on proteins. Bio-silica is produced by marine species (e.g. diatom and sponges) in order to support and protect the unicellular organisms. Such nanostructured material can be used for protein immobilization and stabilization, developing robust biosensors.

Nanomaterial-based nanodevices provide a new horizon for applications. They have already shown their efficiency in some cutting edge technologies, and they will have a very profound effect in emerging technologies in the near future. In particular, agricultural technologies will benefit from direct and easy bio-chemical sensing and control, water management and delivery, pesticide and nutrient delivery and monitoring and food safety for consumer protection.

Presentation S2-4: Bio-nanocomposites from agricultural residues

Ayse Alemdar-Thomson, *FPInnovations, Canada*

Natural fibres from plant and wood are used as reinforcement materials for bio-composite production since the beginning of the 20th century. With their relative high strength, high stiffness, low density and being renewable, these bio-composites are of interest as a replacement for synthetic fibre reinforced composites in an increasing number of industrial sectors, including the automotive industry, packaging, construction and consumer product industries.

There are an estimated 500 million tonnes of agricultural residues such as corn, soybean and wheat, available in North America each year. Only a small percentage is being used in applications such as feedstock and energy production[18]. Most get burned on the field.

Cellulose is a fibrous, semicrystalline and the most abundant biopolymer on Earth. It is the main constituent of plant structures. Plant cell walls consist of rigid cellulosic microfibrils embedded in a soft hemicelluloses and lignin matrix. Cellulose chains are packed in an ordered manner to form compact microfibrils, which are stabilized by both inter-molecular and intra-molecular hydrogen bonds. These microfibrils are formed by elementary fibrils (nanofibres) that are 8-50 nm in diameter and length of a few microns. Because of their crystal structure, nanofibres give strength to the plant stem.

In recent years, significant research has been carried on the production of high strength bio-composites using nanofibres from pulp, plants and agricultural crops

In order to exploit agricultural waste as a source of natural nanofibres, Canadian Universities with the support of Ontario Ministry of Agriculture, Food and Rural Affairs carried out a project with the objectives of isolating nanofibres from wheat straw and soy hulls and of developing a method for incorporating these nanofibres to reinforce bio-based polymers for bio-nanocomposite production. The main goals of this project are to unlock the potential of underutilised renewable material and provide a non-food based market for the agricultural industry by developing environmentally friendly but economically and performance competitive bio-nanocomposites.

18 Alemdar A. and Sain M. (2008) Bio-composites from wheat straw nanofibres: Morphology, thermal and mechanical properties. *Comp Sci Technol* 68:557-565

Within the project, a chemical-mechanical technique for the isolation of cellulose nanofibres from wheat straw and soy hulls has been developed. This method consists in a pre-treatment of the long fibre bundles by acid hydrolysis and alkali treatment, followed by a mechanical treatment of cryo-crushing and defibrillation. The cellulose nanofibres obtained from wheat straw has a diameter of about 20 to 80 nm while it was 20-120 nm for the soy hulls[19]. The nanofibres show improved thermal stability, crystallinity and higher cellulose content with respect to the untreated wheat straw and soy hulls fibres. The reinforcing potential of the nanofibres obtained from wheat straw was investigated in thermoplastic starch and polyvinyl alcohol polymers. It was shown that the nanocomposites had significant improvement in tensile strength and modulus, 145% increase, compared to pure thermoplastic starch. The results of the Dynamic Mechanical Analysis showed that the storage modulus was increased from 112 MPa for the pure thermoplastic starch to 308 MPa with the addition of 10 wt% nanofibre.

The main challenge in adopting this new technology is constituted by increasing the production scale of the nanofibres and their applications in industrial scale. In order to obtain this, one option is to create synergies between the industries that benefit from using natural fibres, such as packaging, automotive, textile and medical, and the potential producers of the natural nanofibres.

19 Alemdar A. and Sain M. (2008) Isolation and characterization of nanofibers from agricultural residues – wheat starw and soy hulls. Bioresource Technol 99: 1664-1671

Session 3: Case-studies on developing industrial applications of agricultural nanotechnology

After the overview provided in Session 2 about R&D activities in the field of nanotechnology applied to agriculture, Session 3 is dedicated to nanotechnology applications of commercial interest by the industry. So far, the nanotechnology applications that seem to drive more commercial interest are mainly in the field of the delivery of agrochemical molecules and the use of nanomaterials for water retention in the soil. However, the concrete potential of nanotechnology in these applications seems to be still unrevealed and industry is facing some challenges related to the adopted definition of nanotechnology and the consequent classification of innovative and traditional products.

Presentation S3-1: Nanotechnology and the crop protection industry

Andrew Fowles, *European Crop Protection Association*

Private companies are investigating whether intentionally manufactured nano-size active ingredients can give increased efficacy or greater penetration of useful components in plants. Indeed, decreasing the particle size and consequently increasing the surface area can be beneficial for parameters like the rate of solubility, the coverage of a leave surface etc. In particular, the use of nano materials as carriers and delivery systems for active ingredients is being researched (in particular solid-liquid formulations). However, the nano-size so far did not demonstrate to hold important product changes of agrochemical interest.

In specific cases, the effects obtainable at macro scale (>1µm) can even be more advantageous than at smaller size, since smaller sizes can result in poorer efficacy due to rapid sunlight degradation because of larger surface area. Indeed, larger size can increase the longevity of a fungicide or improve larvecidal activity of an insecticide. Size matters when, for instance, spraying droplets on crops. By reducing the size of the droplets, the leaf surface coverage improves drastically. However, smaller droplets do also evaporate before. Therefore, there is no trace of nanotechnology there after the treatment.

There are over 3,000 patents worldwide for potential agrochemical usage of nanotechnology but they are most likely patents with broad claims, filed with the scope of guarantee freedom to operate in the field in case of future commercial developments. In reality, today very few, if any, intentionally manufactured nano-sized formulations exist on the market.

Agrochemical large companies are constantly exploring the possibilities offered by nanotechnology, among other innovative technologies. However, at present, no significant data have been obtained in the development and impact of these products. Nanotechnology is not seen by agrochemical industry as a technology that will have a major impact on the crop protection industry in the foreseeable future and so far no agrochemical product is intentionally manufactured as a nanomaterial by these companies. Additionally, nanoparticles usually present higher costs compared to particles of bigger sizes. These costs are normally compensated by higher returns in the medical and pharmaceutical sectors, but so far the agricultural applications require too high investments. Research will anyway continue in the agro-chemical sector to evaluate potential future advantages.

In addition to these considerations, private companies are facing the challenges derived from the definition of nanomaterials that will be adopted. According to the proposed EU nanomaterial definition (see Session 1), particle size is defined by the number of particles and not by their volume (*"50% or more of the particles in the number size distribution").* However, this definition does not take into consideration that, at the nano-scale, there is a fundamental difference between measuring the volume and the number of particles. In fact, a recipe that contains 0.1% nanoparticles by volume can contain ≈ 99.9% nanoparticles by number. Up to date no valid standardized test methods are available for nano-sizing with regard to the current nano definitions.

One crucial point related to the EU definition is the possibility that non-active substances already used for many decades in formulations fall within the scope of the nano definition, although not intentionally developed as nanoparticles. Nanoscale formulants (e.g. clay, silica, polymers, pigments, macromolecules) have been used without issues for many decades and are also ubiquitous in many daily household products. Even many natural products (including milk) may be captured by the EU nanomaterial definition.

What industry would like to avoid with nanotechnology, and especially with products that are already on the market since long time, is the GMO (genetically modified organisms) scenario, in which the technology is stigmatised as harmful or dangerous. In particular, the use of nanotechnology for the application of pesticides (a very sensitive topic itself) could run the same risk.

To cope with the EU definition of nanomaterials, sensitive detection techniques must be employed to identify the nanoparticles, and to determine their size and their number percentage in the material. Several techniques are available to detect particles in the nano-range[20]. Examples of those techniques among others are Transmission Electron Microscopy (TEM), Photon Correlation Spectroscopy (PCS)

20 NanoCap, 2009. Measurement Techniques For Nanoparticles. University of Essex for Nanocap. FP6 Capacity Building project NanoCap from 2006-2009

and X-ray Diffraction (XRD). A few studies have been conducted for nanoparticles detection both in suspensions and dispersions and in solid samples[21]. However, none of these techniques can give reliable, accurate, absolute data relative to the number size distribution. As a consequence, application of the proposed nano-particle definition is currently very problematic[22]. Defined, accurate, absolute test methodology is urgently required.

Presentation S3-2: GEOHUMUS: nanoparticulate products for water absorption and release

Holger Behrens, *Geohumus GmbH, Frankfurt, Germany*

Water is the life blood for all processes that happen in soil. Without water the plant cannot take up nutrients, the soil microbes cannot survive and soil structure deteriorates. For this reason, there is a growing interest in developing soil-enhancer products that promote even water distribution, storage and therefore water saving.

Super Absorbents (SAP) are organic water-retaining materials, similar to that used in nappies, which have so far encountered some shortfalls for use in soil. Eight years ago, the company Geohumus, based in Frankfurt (Germany), decided to integrate the useful properties of SAP with the positive soil mineralisation effects of a nano-scale volcanic rock dust, by combining the two materials at molecular level to form an inseparable new composite. The resulting product, Geohumus, is a soil enhancer in a granular form that demonstrates swelling capacity, perfect long term mineralisation of water (ideal for continuous supply of water) and improved biological activity in soil. According to numerous studies, the use of Geohumus leads to improved root formation, improved aeration of the soil, and improved retention of nutrients and minerals, resulting in faster and better growth of plants, a greater yield and earlier harvest. Tests also confirmed the ability of Geohumus to reduce the density of compacted soils.

Geohumus' soil-like particles are obtained by mixing the rock flours and the clay minerals very early into the polymerisation process. The inorganics are bound to the organic polymer at the smallest possible scale. The components can never separate. This results in unique material properties that are useful for many types of soil applications.

Geohumus represents a very good example of how nanomaterials can improve the useful properties of an agricultural product, in particular for water retention and release. However, in practice the whole Geohumus product is not captured by the nanomaterial definition currently recommended in the EU, since only one component, the clay, is actually at a nano-scale and only constitutes 10% of the product.

The largest application area of Geohumus is for gardening and landscaping, including public greens, nurseries, seed production, turf grass applications and home gardening. Geohumus can also be employed in agriculture, in particular for drip irrigated agriculture, but for the moment farmers' willingness to pay for this product is very low. Therefore, potential applications are only feasible for high–value crops, like e.g. asparagus in Germany, since the cost per hectare can be prohibitive for row crops.

Another potential application of Geohumus is for equine usage, but the application that is attracting the greatest media interest at the moment is for revegetation of soils. Geohumus can indeed help plant growth in sandy soil, as demonstrated with date palm trees and is therefore of potential utility for application in arid countries like e.g. Arab Emirates, although it cannot really tackle desertification.

Several ecotoxicological studies have been performed in collaboration with other German companies and research institutes to guarantee that the use of Geohumus is safe for human health and the environment. In particular, it was demonstrated that Geohumus is safe for aquatic organisms and systems and for terrestrial organisms and soils as result from ecotoxicological analyses performed in compliance with good laboratory practice.

S3: Round table: Statements by stakeholders

David Carlander, *Nanotechnology Industries Association, Brussels, Belgium*

The Nanotechnology Industry Association (NIA) includes within its members both very small and very large industries and covers different elements of the nano-value chain: nanomaterials producers, users and formulators.

Nanotechnology is not an emerging sector only because there are now available new detection methods of nanomaterials that were not available before, but the innovation in this sector is pulled by manufacturers and producers because of the beneficial new properties of nanomaterials. The beneficial potential of nanotechnology is documented at global level, and in particular nanotechnology is recognized as one of the six key enabling technologies (KETs) according to a Communication of the European Commission[23], showing applicability in several different sectors.

21 Anderson, W., Kozak, D., Coleman, V.A., Jamting, A.K., Trau, M., 2013. A comparative study of submicron particle sizing platforms: Accuracy, precision and resolution analysis of polydisperse particle size distributions. *J. Colloid Interface Sci.* 405, 322-330.

22 Linsinger, T., Roebben, G., Gilliland, D., Calzolai, L., Rossi, F., Gibson, N., Klein, C., 2012. Requirements on measurements for the implementation of the European Commission definition of the term 'nanomaterial'. Luxembourg (Luxembourg): Publications Office of the European Union JRC73260.

23 EC, 2012. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 'A European strategy for Key Enabling Technologies - A bridge to growth and jobs'. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0341:FIN:EN:PDF.

NIA carried out a patent analysis on nanotechnology, showing that about 60% of the patents for the agricultural sector have been filed only in the last four years. Among the potential applications of nanotechnology, the most frequent regarding the agricultural sector are related to water treatment, soil remediation and minimization of waste. In addition, there are applications that can directly improve agricultural productivity, such as nano-scale molecules for crop protection and nutrient translocation.

Some nanotechnology applications can also positively affect the agricultural sector indirectly, in particular the ones related to energy and packaging. For example, improved fuel additives and lubricants for agricultural machineries can increase the efficiency of the machineries use while, at the same time, reducing the carbon footprint of the agricultural sector. Moreover, the advances in the food packaging sector can be exploited also to create improved packages used by farmers to reduce the degradation of the products before commercialization.

Despite the potential uses, the regulation of nanotechnology products is still covered by uncertainties. The nanotechnology definition provided by the EC in its recommendation brings some elements of discussion by the industry, in particular the definition of aggregates and agglomerates. Uncertainties in the regulation are detrimental for the companies' activities. According to NIA, nanomaterials do not require a specific regulation, since existing regulations are enough to guarantee a safe production and use of nanomaterials, but currently there are proposals of new regulation.

The ongoing proposals are not suited for the development of nano-products, and a new regulation should be designed in such a way to avoid the stigmatization of nanotechnology, in order to avoid negative effects on public perception. For example, unsuited labelling requirements can be misleading, bringing information in such a way to provoke negative public opinion on nanotechnology.

From a safety point of view, nanomaterials should be considered as any other chemical substances, in the sense that some may be toxic and other not. There are numerous and large research projects going on about how to do risk assessment of nanomaterials, including for the agricultural sector. Very thorough documents have already been published. The industry sector is very active in participating to these research projects, but no consensus has been reached yet at regulation level and companies still face uncertainties regarding how to carry out the risk assessment of new products.

Laurent Schibler, *COPA – COGECA, Brussels, Belgium*

COPA is the European Committee of Professional Agricultural Organisations that represents both the general and specific interests of farmers in the European Union. COGECA is the General Confederation of Agricultural Cooperatives. Due to the novelty of the topic and despite some discussions, especially around new food and food safety, COPA-COGECA has not yet taken a formal position on nanotechnologies.

Maintaining and developing agriculture in Europe will undoubtedly require innovations and nanotechnologies clearly provide exciting applications and real opportunities. Supporting research in this field is thus essential to develop new and efficient applications. However, there is also a clear need for research on the lifecycle of nanomaterials, to analyse their impact on environment and on living organisms. COPA-COGECA supports the need to look into these aspects. The evolution of risk assessment and social perception are essential in order to facilitate the use of nanotechnologies by agricultural cooperatives. Indeed, we should keep in mind that agricultural cooperatives benefit from a very positive image in European countries.

Social acceptance of agro-nanotechnologies at large scale will remain a subject of social debate, due to environmental and safety issues. In this regards, research in the animal sector may probably provide more opportunities than in the plant sector. The social acceptance of the technology will greatly depend on its success in the pioneer sectors. To draw a parallel with GMO, there would be a risk if applications were released firstly in questionable sectors, leading to a general rejection of the technology by the society.

Therefore, it could be worth focusing firstly on the less questionable applications, especially sensors. In cattle for example, there will be opportunities to improve reproduction, which is a key factor for breeding sustainability. Sensors could be used to detect estrus to inseminate the cows at the best time. The signal from this sensor could be incorporated as a part of a central monitoring and control system to improve breeders' work and life. The natural follow up would be to have an implanted semen capsule made of nanomaterial, which could be triggered on demand to fertilize the oocyte. Likewise, pregnancy or some microbial infection could be detected by analyzing the milk using dedicated sensors. Nanotechnology also offers opportunities for antimicrobial material used in the process of semen collection, which could reduce the use of antibiotics.

The use of agriculture products to produce nanomaterials seems also very promising, assuming that it would not compete with feed or food. In this context, the use of waste materials seems promising. However, some countries will probably need to balance such use with the production or green energy and biogas.

COPA-COGECA has not taken a position in terms of nanomaterials regulation. Nevertheless, in the framework of the discussions on novel foods, COPA-COGECA is currently considering the different elements of the proposal.

Paul Leonard, ***European Crop Protection Association (ECPA), Brussels, Belgium***

The EU industry producing crop protection products is currently excited about the potential of nanotechnology applications in the different sectors, including agricultural production, and is very active in performing further research in this field.

Safety is an issue of paramount importance in plant protection products. According to the EU legislation, active ingredients must follow a risk assessment process before being released on the market. Applicants must submit a very thorough dossier for the authorization of new products. Many tests for safety assessment are required, including inhalation studies. In fact, toxicological and environmental dossiers for the authorization of plant protection products are usually bigger than that for pharmaceuticals and can even reach 20,000-40,000 pages. ECPA considers that, under the current procedure for traditional crop protection products, the safety of nanomaterials would also be properly assessed.

ECPA shares the message brought from the EC in the framework of nanomaterials safety that the nano-size does not necessarily imply toxicity, but ECPA acknowledges that there is high perception of risk when referring to the nano-size.

Currently, one big concern of ECPA is the definition of nanomaterials proposed by the EC in its recommendation. This definition is in fact based on the number of particles and can be applied also to traditional components of many plant protection products already on the market, like e.g. silicon dioxide.

There is a big concern by the crop protection industry about the stigmatization of nanomaterials from the public opinion, also related to the classification adopted by the European Commission. In particular, the combination of nanotechnology, food and pesticides has a high potential of arousing public concern. The crop protection industry is afraid of the possibility of a scenario comparable with the rejection of GMOs.

There is currently a big investment in the EU to move away from organic solvents, due to their negative effects on the environment, and promoting more sustainable water-based solutions. However, there is a high possibility that 50% of these new solutions will trigger the nano-definition, although neither industry nor consumers did so far recognize those products as nanoproducts.

Plant protection industry sees the EU initiative of a nano-repository[24] as unfortunate because of its potential to bring the consumers into confusion, by including ingredients that have been used already for decades in plant protection products without being classified as nano before. Nonetheless, the EU industry will comply with its duty by providing the information and material requested.

ECPA favors a positive and informed dialogue in the topic of nanotechnology. For instance, "Science Policy Breakfast" is an initiative in place to give politicians the opportunity to gain insights from scientists into current topics of research and development and support scientifically well-founded political decisions.

24 http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/nanomaterials-repository

Session 4: Developments in nanotechnology risk assessment and regulation

The production and use of commercial products containing nanomaterials, need to be regulated in order to guarantee their safe use. To properly understand the current state of the regulation, which products are covered and how it is applied, a deep knowledge on the unique properties of nanomaterials and on their interaction with the human body and the environment is needed.

This session is dedicated to the regulatory initiatives concerning nanotechnology and the aspects of risk assessment/management of nanomaterials, with a particular focus on the EU regulations.

Presentation S4-1: The European regulatory framework for nanotechnology

Maurits-Jan Prinz, *Directorate General for Enterprise and Industry, European Commission*

Due to the manifold applications and aspects of nanotechnology, a number of DGs (Directorates-General) of the EC carries responsibility for legislation related to nanomaterials.

As illustrated in Session 1, the EC published in 2011 a Recommendation (2011/696/EU)[25] on the definition of nanomaterial:

> *A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm -100 nm.*

The definition is meant to be integrated in the EU legislation, and the EU Agencies, Member States and industry are recommended to use it.

The size range of 1-100 nm is in line with the ISO (International Organization for Standardization) term for nanomaterials. Other properties of nanomaterials were also discussed within the EC but were not considered sufficiently robust to be used in the definition. The definition covers nanoparticles in aggregates and agglomerates, which may exhibit the same properties as the single nanoparticles. In contrast to the EU definition, the ISO definition (TS 80004-1) includes all nanostructured materials, increasing the coverage of the definition to a greater variety of nanomaterials.

In 2014, the definition presented in Recommendation 2011/696/EU will be reviewed in the light of new experience and of scientific and technological developments. One of the aspects of the review that may be under discussion concerns the threshold of 50%. According to the recommendation, a different threshold (between 1 and 50%) may be used in specific cases.

In October 2012, the EC adopted the Communication on the Second Regulatory Review on Nanomaterials[26], which assesses the adequacy and implementation of EU legislation for nanomaterials and lists the Commission's actions in the field of nanomaterials. Additionally, the related Staff Working Document[27] provides an overview of nanomaterials on the market and available information on hazard properties, together with background information on the definition.

Nanotechnology is identified by the Communication of the EC as a key enabling technology[28] with a global market evaluated at around 11 million tonnes and a direct employment of 300,000 to 400,000 jobs (these figure take into account commonly known nanomaterials – i.e. those known to have a particle size between 1-100 nm).

Nanomaterials are classified in three main types: commodity materials like carbon black or synthetic amorphous silica, which represent the largest part of the market (more than 95%) and have been used for decades; newly developed medium volume substances (e.g. nano-TiO2, carbon nanotubes, etc.), some of which are under discussion for safety issues; and, finally, newly developed low volume substances which cover a large variety of substances.

Regarding the safety issues, the EC Communication on the Second Regulatory Review reports a key statement by the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), which regards nanomaterials as similar to chemical substances in that some may be toxic and some may not. The hypothesis that smaller means more reactive, and thus more toxic, has not been substantiated, according to SCENIHR. Additionally, some nanomaterials have been already used for decades. Therefore, a case-by-case approach for the risk assessment of nanomaterials is warranted and specific safety aspects related to nanomaterials still require further investigation.

An important principle in the establishment of legislation with an impact on health or environment is the precautionary principle, referred to in the TFEU (Treaty on the functioning of the EU) This principle denotes that the freedom and rights of individuals, industry and organisations should be balanced

25 EC, 2011. Commission Recommendation of 18 October 2011 on the definition of nanomaterial. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF. Official Journal of the European Union L 275, 38-40.

26 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012DC0572

27 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF

28 EC, 2012. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 'A European strategy for Key Enabling Technologies – A bridge to growth and jobs'. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0341:FIN:EN:PDF.

with the need to reduce the risk of adverse effects to the environment, human, animal or plant health, finding the correct balance so that proportionate, non-discriminatory, transparent and coherent actions can be taken.[29]

Due to the variety of applications of nanotechnology, different pieces of legislation are concerned, including both horizontal legislation (like REACH and CLP, discussed below, and occupational health & safety legislation) and product-specific legislation, of which some already explicitly mention nanomaterials (cosmetics, food additives & food information to consumers, and biocides) while others do not (toys, electrical equipment and waste & environmental legislation). As an example, the Cosmetics Regulation (No. 1223/2009) requires a notification to the EC for products containing nanomaterials and the labelling of all ingredients in the form of nanomaterials.

REACH[30] is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, administered by the EC Directorates-General for Enterprise and Industry (DG ENTR) and Environment (DG ENV). Registration is mandatory for substances (including nanomaterials) produced in more than one tonne per year. The EC is currently assessing regulatory options for REACH, including possible amendments of the REACH Annexes to ensure clarity in the data requirements for nanomaterials.

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP) of substances and mixtures requires manufacturers, importers and downstream users to identify and evaluate hazard information for substances and mixtures that are placed on the market and to classify them accordingly. This classification is also related to the form or physical state in which the substance or mixture is placed on the market, and in which it is most likely to be used. Nanomaterials are covered by the definition of a 'substance' in both the REACH and CLP Regulation.

In parallel with the EC assessment of the current legislation on nanomaterials, some Member States have established or proposed national registries of nanomaterials, while the possibility of creating an EU registry is currently under evaluation by impact assessment. Additionally, many EU research projects related to the safety of nanomaterials (e.g. in the EU NanoSafety cluster, which comprises around 35 FP7 projects) are on-going, such as NANoREG, which is aimed at investigating test strategies and risk assessment criteria for nanomaterials.

Presentation S4-2: Nanotechnologies in food, health and consumer products

Michael Flueh, *Directorate General for Health & Consumers, European Commission*

The EC Directorate General for Health & Consumers (DG SANCO) is responsible for guaranteeing health and safety products to EU citizens. Among the different responsibilities, DG SANCO is also requested to ensure that nanotechnology has no adverse effect on food safety, plant health, cosmetics, medical devices and pharmaceuticals. It takes regulatory actions based on independent scientific advice, and coordinates the Scientific Committees, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).

DG SANCO Scientific Committees[31] provide sound scientific advice on emerging problems related to consumer safety, public health and the environment and they already published two generic opinions on nanomaterials, in 2007[32] and 2009[33]. Additionally, the Scientific Committees have issued two opinions on specific nano-applications: zinc oxide (2012) and titanium dioxide (2013), which represent the first scientific assessment on nanomaterials at global level.

In the published documents, the Scientific Committees conclude that risk assessment has to take into account the physico-chemical characteristics of nanomaterials, and of the final products, and that a case-by-case approach is recommended. There are specific hazards that could potentially be linked to the nano-size of the materials, but methods for hazard identification and exposure assessment are still to be developed, validated and standardized.

EFSA is the EU risk assessment body for food and feed safety and receives mandates from the EC to provide scientific outputs as technical risk assessment guidelines, scientific opinions on specific products and technical and scientific assistance to the European Commission. EFSA published already two scientific opinions[34] [35] on potential risk and risk assessment principles for nanotechnology entering the food and feed chain, but no applications for specific nano-products have been submitted to EFSA so far.

29 Commission of the European Communities, 'Communication from the Commission on the precautionary principle', COM(2000) 1, 2 February 2000

30 EC, 2006. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. Official Journal of the European Union 396, 1-849.

31 http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

32 SCENIHR, 2007. Request for a scientific opinion on scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies. Scientific Committee on Emerging and Newly Identified Health Risks.

33 SCENIHR, 2009. Risk Assessment of Products of Nanotechnologies. Scientific Committee on Emerging and Newly Identified Health Risks.

34 EFSA, 2009. The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. Scientific Opinion. http://www.efsa.europa.eu/en/efsajournal/pub/958.htm. The EFSA Journal (2009) 958, 1-39.

35 EFSA, 2011. Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. Scientific Opinion. http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm EFSA Journal 2011 9, 2140.

According to EFSA's main conclusions, there is still a high degree of uncertainty around nanomaterials' characteristics and the appropriate risk assessment methodology to recommend. In particular, there is still too little information about how to identify and characterize engineered nanomaterials. Consequently, there is little information about their toxicity, use levels and exposure. The risk assessment paradigm (hazard identification + hazard characterisation + exposure assessment + risk characterization) is considered appropriate by EFSA also for nanotechnology, but the detailed risk assessment process is still under development.

As previously illustrated, several legislations concern the nanotechnology applications and are currently under revision. The regulatory developments going on in the food sector include, among others, food information to consumers[36] (FIC), food additives and pesticides.

According to the FIC, all ingredients presented in the form of engineered nanomaterials must be labelled. For this purpose, a clear and agreed legal definition of nanomaterial is fundamental, although it must be adapted to the technical and scientific progress. The exclusion of natural or incidental nanomaterials in the definition is currently under discussion.

Several food additives containing nanomaterials are on the market since long time, even decades (e.g. vegetable carbon E153, calcium carbonate E170, silicon dioxide and titanium dioxide), however, these nanoparticles are not manufactured intentionally.

Two different evaluation processes are performed for existing (i.e. on the market until 2011) and new food additives. EFSA's opinions on food additives take into consideration the particle size of the food additive analysed and therefore, if an existing additive is subject to significant changes in particle size, it will be classified and assessed as a new product.

Data requirements for the submission of dossiers for approval of substances as pesticides were only recently reviewed. EFSA recommended not including specific provisions for these products since hazard identification and exposure assessment are fine tuned. For the moment, EFSA stated that existing international approaches for risk assessment of non-engineered nanomaterials can be applied, but a case-by-case approach is always recommended. Unlike biocides, no labelling is required for nanomaterials in pesticides. This difference in the legislations for pesticides and biocides may cause discrepancy in the cases of products with both uses.

The industry, represented by the European Crop Protection Association (ECPA), expressed its position on the pesticides legislation, stating that no engineered nanomaterials are yet approved and on the market in the EU, while there is a risk that many components of plant protection products on the market be suspected to be nanomaterials according to the definition. Industry recognizes the need for validated methodologies for the analysis of engineered nanomaterials but that the risk assessment procedure should continue to be based on existing studies

Presentation S4-3: Role of JRC-IHCP in Nanotechnology: overview of policy support activities on nanomaterials safety

Hubert Rauscher, ***Institute for Health and Consumer Protection, Directorate General Joint Research Centre, European Commission***

The Joint Research Centre of the EC has seven scientific institutes. Research on nanotechnology is carried out at the Institute for Health and Consumer Protection (IHCP), based in Ispra, Italy; the Institute for Reference Materials and Measurements (IRMM), based in Geel, Belgium; and the Institute for Prospective Technological Studies (IPTS), in Seville, Spain.

The work of IHCP on nanomaterials includes science-based advice to policy makers and addressing scientific challenges for the implementation and amendment of nanomaterials legislation. Major contributions of the IHCP to policy support on nanotechnology include:

- Definition of the term "nanomaterial" – supporting the development and review of the EC Recommendation
- Methodologies for safety assessment
- Information needs for nanomaterials in consumer products (labelling and reporting)
- Provision of tools: characterisation and detection methods for nanomaterials, representative test materials (including a repository of nanomaterials), the NanoHub database, inventory of nanomaterials in food/feed applications, and a web-platform on nanomaterials (first version online since December 2013)

In order to implement the European Commission's Recommendation for a definition of nanomaterial some important tools need to be developed, such as guidance documents and validated methods for size measurement, taking also into consideration the measurement of nanomaterials in complex matrices (food, cosmetics, etc.). In 2012, IHCP published a report[37] describing requirements on measurements for the implementation of the EC definition. Suitable candidate methods and protocols are discussed in the report.

36 http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm

37 Linsinger, T., Roebben, G., Gilliland, D., Calzolai, L., Rossi, F., Gibson, N., Klein, C., 2012. Requirements on measurements for the implementation of the European Commission definition of the term 'nanomaterial'. Luxembourg (Luxembourg): Publications Office of the European Union JRC73260.

Another activity of IHCP is to coordinate projects which are closely related to the implementation of the nanomaterial definition and the safety of nanomaterials. Such projects are often carried out in close cooperation with external experts in the field of nanosafety. One example are the REACH Implementation Projects on Nanomaterials (RIPoNs), launched by the EC in 2009 to provide advice on key aspects of the implementation of REACH with regard to nanomaterials, concerning information requirements, chemical safety assessment and substance identification[38].

The IHCP also has specific policy support activities concerning the assessment of methods and strategies for testing the safety of nanomaterials. Particular challenges for the assessment of nanomaterials are adaptation and development of testing methods for (eco)toxicity, *in-vitro* test methods and nanomaterial specific testing strategies.

The EU legislation on food and cosmetic products will make it obligatory for producers to label products containing ingredients in the form of nanomaterials. These labelling requirements imply the development and validation of analytical methods for the detection and characterisation of nanomaterials in food and cosmetics, which constitutes a major challenge. IHCP is developing methods to determine the chemical composition, morphology, particle size, size distribution and concentration of nanomaterials used in food, consumer products in general (including cosmetics) and in the environment. There is an urgent need also for validated routine methods, but many technical challenges are still to be tackled, like for instance the identification and characterisation of unknown nanomaterials.

IHCP, in collaboration with the IRMM, also collaborates closely with CEN TC 352 and ISO TC 229 (the Technical Committees "Nanotechnologies"), as well as with other international bodies, including the OECD Working Party on Manufactured Nanomaterials. The aim is to develop internationally accepted standards and guidelines in the field of nanotechnology, such as characterisation methods for nanomaterials and test methods for their safety assessment.

In 2009, the IHCP launched the database and information system known as the NanoHub, which is a comprehensive platform dedicated to the management of information on nanomaterials relevant for safety and risk assessment.

Moreover, the availability of representative samples of nanomaterials is of key importance for the reproducibility and the reliability of testing. For this reason, in 2011 IHCP inaugurated a repository of representative nanomaterials, which can serve as international benchmarks for the testing of nanomaterials. The repository brings together the principal materials from the OECD sponsorship programme on the testing of a representative set of nanomaterials, such as titanium dioxide, silicon dioxide, zinc oxide, cerium dioxide, nano-silver, nanoclays and multi-walled carbon nanotubes.

Another important IHCP activity, funded by and carried out for EFSA, is the creation of an inventory of current and prospective applications of nanotechnologies in the areas of food and feed (including food contact materials), in collaboration with the Dutch institute for food and feed safety (RIKILT).

In conclusion, IHCP is bringing together an interdisciplinary team working on the safety of the innovative field of nanotechnology, by combining and integrating three pillars: scientific questions, safety assessment and support to legislation & standardisation.

Presentation S4-4: Risk assessment and management of nanotechnologies in the food and agriculture sectors

Masami Takeuchi, *Food and Agriculture Organization of the United Nations (FAO)*

FAO recognises three fundamental pillars of food security: food quantity (sufficient food for everybody), food safety and nutritional value of food. Food safety is considered as fundamental as food quantity by the international organizations. Any new technologies including nanotechnology need to be explored for its potential for improving food production and nutrition, and at the same time assuring its safe use in the food and agriculture sectors.

Governments, industry and scientific bodies have identified the potential of nanotechnology in the food and agriculture sectors and are investing significantly in its applications. In response to the accelerating development of this technology, FAO and WHO convened an Expert Meeting in 2009 on the applications of nanotechnologies in the food and agriculture sectors[39]. The meeting brought together seventeen experts of food technology, toxicology and communication, focusing the meeting on three main areas: the use of nanotechnology in food production and processing; the potential human health risks associated to this use; and the transparent and constructive dialogue on nanotechnology among stakeholders.

During the Expert Meeting, stakeholders agreed that nanotechnology offers considerable opportunities for the development of innovative products and applications for food and agriculture and that some products may be soon available to consumers. They also recognized the need of a clear and internationally harmonized definition of nanotechnologies for the food chain.

The Expert Meeting acknowledged that the current risk assessment approaches used by FAO/WHO and the Codex

38 http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

39 FAO/WHO, 2010. FAO/WHO Expert meeting on the application of nanotechnologies in the food and agriculture sectors: potential food safety implications. Meeting report. http://www.fao.org/docrep/012/i1434e/i1434e00.pdf

Alimentarius are suitable for engineered nanomaterials used in food and agriculture, but emphasized that additional safety concerns may arise due to the peculiar properties of nanomaterials, which need to be taken into account. FAO and WHO should continue to review its risk assessment strategies, in particular through the use of tiered approaches, in order to address the specific emerging issues associated with the application of nanotechnologies in the food chain. Moreover, the development of validated testing methods and guidance would help addressing specific data gaps.

The Expert Meeting analysed also the general requirements for the engagement of stakeholders, which is considered imperative in the area of food safety to address key interests, priorities and concerns. The FAO/WHO should promote an international forum for continuing the dialogues with stakeholders.

In 2013, FAO and WHO published a report[40] summarizing and analyzing the scientific information on nanotechnology since the 2009 Expert Meeting, and drawing the possible courses of action to be followed by FAO, WHO and other organizations in this matter.

Information on relevant regulations and risk assessment presented in the report were gathered from the websites of national and international institutions, organizations and governments; while information on uses of nanomaterials for food or food packaging/contact materials was collected from a variety of sources: scientific literature, websites, patent databases, market analysis reports and material presented at conferences, workshops and symposia.

The analysis revealed that there are no ”novel” applications for the agri-food sector since 2009. Globally many projects are being carried out on nanotechnology products, but very few in the agri-food sector, the most prominent topic being nanoemulsion in food for increased bioavailability.

About national and international activities on risk analysis of nanomaterials in the food and agriculture sectors, the results of the 2013 report show that there are considerable activities by the governments of Australia/New Zealand, Canada, China, the EU, Japan, Switzerland and the US, while other countries have no specific actions yet (like Malasya, Mexico, South Africa, Indonesia and Brazil). Overall, definitions of nanomaterials developed in different countries result in different risk management measures. So far, apart from the EU, no country has set a regulatory framework for the mandatory labelling of nanomaterials in food.

The report also reviews the relevant activities by international governmental (IGOs) and nongovernmental (NGOs) organizations. According to the retrieved information, many national, regional and international activities are ongoing in the field of nanotechnology, driven in particular by opportunities for research and industry and also safety concerns. Overall, there is in fact a global concern of avoiding the GMO scenario. The most active international organizations are IFT (Institute of Food Technologists), ILSI (International Life Sciences Institute) and OECD (Organisation for Economic Co-operation and Development). IFT in particular is a very active player and already published a few review papers on characterization and safety of food nanotechnology.

Finally, the report presents an overview of the scientific reviews published in the last years addressing risk assessment of nanotechnologies in the food and agricultural sector. This analysis confirms that there are currently insufficient reliable data to allow a clear safety assessment of nano-products. Most scientific literature is focused on labour health and in particular on the effects of the exposure to nanoparticles through inhalation, oral/gut and lungs.

In conclusion, nanotechnology hype steadily continues in research and media, although no new issues or applications emerged for the agri-food sectors since 2009. The definition of what is “nano” (if only based on dimensions or also on new properties) matters a lot and different countries are applying different legal definitions.

There is an increased interest on health risks of nanotechnologies and therefore policies and guidance documents are being published worldwide, despite the limited number of “real products”. The OECD made significant progress in adapting pertinent testing guidance. For the foreseeable future, a tiered and case-by-case approach is recommended. The dialogue with stakeholders and their confidence is fundamental: authorities, IGOs and NGOs run programs that focus on communications and education and several inventories are collecting information on what is happening in the market place.

40 FAO/WHO, 2013. State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors. FAO/WHO technical paper. http://www.fao.org/docrep/018/i3281e/i3281e.pdf.

Session 5: Socio-economic issues of agricultural nanotechnology

The rapid emergence of nanotech applications in consumer products has raised a number of ethical and societal concerns in both developed and developing countries, ranging from their effects on human and animal health and on the environment (as described in the previous session), to consumer perception and intellectual property issues[41].

Presentation S5-1: Societal response to nanotechnology: exploring the future with experts and the public

Nidhi Gupta, *Wageningen University, The Netherlands.*

Analysing the public perception on nanotechnologies is a complex task, due to the large number of applications (food, agriculture, medicine, environment and material science among others) and the different stakeholders involved (the general public, scientists, policy makers, industry, media and NGOs). Moreover, there are many socio-psychological factors influencing the societal response and therefore it is important to identify these factors among different stakeholder groups for the case of nanotechnology. The commercialisation trajectory of different nanotechnology applications is likely to be driven by the opinions of experts regarding societal acceptability of these. If expert views of societal acceptability do not align with those held by the general public, applications that consumers will reject may be introduced initially, and focus public opinion on the negative aspects of nanotechnology. Conversely, applications which are acceptable to consumers may never be commercialised if experts perceive that consumers are likely to reject them. In order to identify these factors, three studies have been conducted at Wageningen University to analyse societal response to specific applications of nanotechnology by incorporating views of both the experts and the general public.

The first study[42] involved structured interviews with experts from five EU countries (The Netherlands, Belgium, Germany, UK and Ireland) on 15 sectors of application of nanotechnologies (including the agri-food sector). The second study analysed societal responses on the same sectors in a consumer sample in the UK. Finally, the third study[43] used a larger sample of experts across five different regions of the world (Northern America, Europe, Australasia, India and Singapore) to provide a comparative account of expert views on societal response to agri-food applications of nanotechnology (targeted drug delivery, water filtration, smart pesticides, nanoencapsulated food and food packaging). Results from the first study show that according to experts the main factors influencing societal responses to different applications of nanotechnology were the extent to which applications are perceived to be beneficial, useful, and necessary, and the extent to which these applications will be perceived as “real” and physically close to the end-user. Perceived risk was less frequently mentioned by experts as a potential factor influencing societal acceptability. Experts indicated that medical nanotechnology applications (targeted drug delivery) and environmental nanotechnology applications (water filtration) will be the most societally acceptable. In contrast, agrifood applications (smart pesticides, nano-encapsulated food and food packaging) will be the least societally acceptable as analogies were drawn between agrifood applications of nanotechnology and GM food.

The second study suggested that consumers differentiate nanotechnology applications based on the extent to which they perceive them to be beneficial, useful, necessary and important. The results also suggest that negative public reactions will be driven by perceptions of fear, concerns about privacy, ethical concerns, and perceived equity regarding to whom the benefits of nanotechnology products will accrue. Of the 15 applications, medical and environmental applications were perceived as the most beneficial, an issue on which experts and consumers agreed. In contrast to the views of experts, food applications were rated as generally beneficial. Consumer perceptions differed from those identified as being influential by experts, insomuch that consumers emphasized fair distribution of benefits as being a determinant of acceptance, but had fewer concerns regarding the potential for physical contact with products made using nanotechnology, and the time to market introduction of nanotechnology products.

The results from the third study suggested that experts thought that perceived risk and consumer concerns regarding contact with nano-particles would lead to public rejection of nanotechnology applications, and perceived benefits would influence societal acceptance. The results were not highly differentiated across different countries, with the exception of India, where perceived risks were considered less relevant compared to the other countries. In general, Australasian and European experts emphasised on potential risks, while Indian, American and Singaporean experts put more emphasis on benefits of nano-applications. Encapsulation and delivery of nutrients in food and smart pesticides were

41 Gruère, G.P., 2012. Implications of nanotechnology growth in food and agriculture in OECD countries. *Food Policy* 37, 191-198.

42 Gupta, N., Fischer, A.R.H., van der Lans, I., & Frewer, L.J. (2012). Factors influencing societal response of nanotechnology: an expert stakeholder analysis. *Journal of Nanoparticle Research*, 14(5), 1-15. doi: 10.1007/s11051-012-0857-x

43 Gupta, N., Fischer, A. R. H, George, S., & Frewer, L. J. (2013). Expert views on societal responses to different applications of nanotechnology: A comparative analysis of experts in countries with different economic and regulatory environments. *Journal of Nanoparticle Research*, 15(8), 1-15. doi: 10.1007/s11051-013-1838-4

thought to be the applications most likely to raise societal concerns, while targeted drug delivery and water filtration were thought most likely to be accepted.

Overall, these three studies indicate that there are similarities as well as differences among the experts and the general public. Both these groups emphasised that perceived benefits and usefulness are likely to influence social acceptability. These similarities point out to the fact that experts are picking from the debates concerning emerging technologies in the past and are able to identify factors found relevant by the general public in case of nanotechnology. However, there were differences among both the groups, where public was found to stress more on ethical issues and the experts stressed more on technical factors such as concern over coming in contact with nanomaterials. The differences between expert and consumer views which have been identified lends further credence to the argument that it is important to incorporate concerns voiced by broader society (the general public or the potential consumers of the products of nanotechnology) into technology development and policy formulation regarding risk analysis and other innovation strategies for nanotechnology (and indeed other emerging technologies). Developing dialogue between technologists and the public as part of technology assessment will ensure that social and ethical issues are addressed early in the development of emerging technologies.

From these studies it appears that the public opinion regarding different nanotechnology applications is generally not negative. In general, the public seems to be unconcerned about many applications of nanotechnology. The exception relates to those areas of application where societal concern already exists such as pesticides. Medical and environmental applications of nanotechnology are most likely to garner positive public response and among different agri-food applications food packaging is considered more acceptable than encapsulated food. Hence, applications with clear benefits and acceptable/low risks should be introduced first into the market, driving the acceptance of other applications to be introduced later on.

Presentation S5-2: Intellectual property in nanotechnology

Leif Brand, *VDI Technologiezentrum - Düsseldorf, Germany*

The biggest wave of patenting in nanotechnology started at the beginning of 2000, inducing leading patent authorities around the world to introduce specific patent classification systems for nanotechnology applications. For example, the United States Patent and Trademark Office (USPTO) introduced "Class 977"; the Japan Patent Office (JPO) introduced "Class ZNM"; and the European Patent Office (EPO) introduced "Y01N classification" within the ECLA-system (transferred to "Cooperative Patent Classification" (CPC) "B82Y"; valid from Jan 1st, 2013).

Each patent class contains different sub-classes dedicated to the specific field of application, such as nano-biotechnology, nano-optics, nano-magnetics, nanotechnology for ICT, for materials and for sensing. The majority of patents related to the agri-food applications are included in the sub-classes nano-biotechnology and nano-materials.

However, for a detailed view, a keyword-based analysis has to be combined with the patent classification approach. Appropriate evaluations have been performed in the framework of the FP7 project "ObservatoryNANO". Based on specific keyword-sets extracted from bibliometric evaluations of the University of Maastricht, the VDI Technologiezentrum conducted extended statistical patent analyses on nanotechology applications. This research addressed nanotechnology in general as well as 10 specific application areas – "agri-food" being one of which - for the period 1972-2011.

Through the EPO Worldwide Patent Statistical Database (PATSTAT), which covers data from 76 patent organizations (including EPO and WIPO), about 200,000 patents were identified on nanotechnology in general. The great majority of these patents (47%) may be assigned to the US, followed by Japan (25%), the EU (20%) and Korea (4%). Within the EU, Germany, France and the UK contribute with the largest fractions. Compared to the US or Japan, other Asian countries like Korea and China did not yet file bigger numbers of patent applications. However, they showed a very strong raise during the last years. Private companies dominate patenting in nanotechnology with a fraction of 71% of the patent applications, followed by public or semi-public research institutes (17%) and academia, i. e. universities (12%). This is in accordance to the suggestion that companies are the most efficient entities with respect to transferring research into application.

Within nanotechnology, the application areas "nano-materials" (54%), "ICT" (36%) and "health / medicine" (14%) are quantitatively dominating patent filing. The "agri-food" sector comes fourth, with a 6% fraction of the total number of nano-related patent applications. Within "agri-food", Europe contributes with about 24%, which is slightly higher than the EU percentage in nanotechnology patents in general.

By combining bibliometric and statistical patent information, the US and Japan emerge as more efficient than Europe with respect to research to application transfer. That holds for both nanotechnology in general and the agri-food sector in particular. Thus, the US contributes with one nano-related agri-food patent application on 26 scientific publications in this sector. With 1/29, Japan reaches a similar rate. Europe, however, contributes with 84 scientific publications per patent application, resulting in a much lower rate. Hence, although Europe´s position in nano-related agri-food research is quite promising, its capability of application transfer is comparably low.

Overall, nanotechnology patent filing has shown a phase of stagnation during recent years. Despite this slowdown in the growth rate, the number of patent applications is still very high. That indicates nanotechnology increasingly evolving from an emerging towards an established technology.

Patenting on nanotechnology in general presents some important issues. Nanotechnology is pervasive in many different fields of applications and innovations and nano-based inventions could infringe existing granted patents in those fields. This risk of overlapping patents can also have consequences for the agri-food sector. Moreover, patent holders could lock-up huge areas of technology, with the consequent risk of a decreased freedom to operate for R&D and application in the field.

Closing Presentation S5-3: Impact of adoption of agri-food nanotechnology

Kalpana Sastry, *Research Systems Management Division, India*

The rising global population and the accelerating economic growth in big developing countries are provoking a clear increase in the demand of food products, both in terms of quantity (especially sought during the green revolution) and quality, and the intensification of agricultural activities. Moreover, the rising demand for non-agricultural uses of natural resources is putting further pressure on the agro-ecosystems worldwide. The diffusion of innovative technologies is fundamental in facing these challenges, not only with the aim of higher agricultural productivity, but also against energy crisis, deterioration of soils, and declining of water resources for drinking and agriculture, all very crucial issues in most developing countries like India, whose economy is mostly agrarian in nature.

A well-developed and innovative agricultural sector is not only necessary for the production of adequate and nutritive food, but also as a source of labour and income for the population. Therefore, agriculture in developing country has to move from subsistence agriculture to market-oriented agribusiness, involving all the rings of the agri-food chain and all these measures could lead to increasing job prospects in the unexploited business opportunities via processed food, packaging, retailing, quality certification and standardization sectors of agricultural production- consumption system.

Nanotechnology is not a single technological field, but comprehends a set of technologies with potential applications for the entire agri production-consumption system, such as materials, electronics, biotechnology, manufacturing, environment, energy, agriculture and food. Applications are not confined to the farm production level, but they can extend across all the steps of the agricultural value chain. Several nanotechnology based innovations are found to have simultaneous applications across sectors like smart treatment delivery systems, pathogen and contaminant detection, identity preservation and tracking.

In order to properly understand the potential of nanotechnology for the agri-food sector, the National Academy of Agricultural Research Management (NAARM), in India, has conducted an analysis of the nanotechnological developments based on publications, patents and products on the market. Within this project two databases were built, one on literature and one on patents in agri-food nanotechnology. These databases with a query-based relational character were used to understand the current trends of science and technology in agri-nanotechnology. This strategy could help formulate a roadmap for strategic decision making.

What emerged from the information collected is that nanotechnologies can have important applications in several agri-food areas, such as food security, input delivery, rice production systems, agri-biotechnology, healthcare of animals, precision farming, food industry and water use. However, the main factors limiting the development of these applications are low investments in manpower training (young scientists) and in research infrastructure.

Food security is a crucial issue especially in developing countries and is strictly related to the agri-food sector. Nanotechnology can positively contribute to food security through four key channels: agricultural productivity, storage and distribution of food, soil health and water security.

Focussing on problem of accessible safe drinking in India, the presentation illustrated the potential of nanotechnology in providing filtration devices and technology keeping local constraints. Currently, there are three companies operating in India that produce nano-silver filters for tap-water. These companies represent a very successful and sustainable business model, since their products are based on nano-particle based filters, and operate with no electricity. The final products are light and very amicable placed for domestic use for small families. One of the products is based on nanoparticles extracted from crop residue like paddy straw. Such innovations which are ecologically friendly solutions and suit local needs and are within economic needs of the consumers are proving to impact Indian rural areas, where income levels are still low and are challenged with no or energy deficient situations.

Despite these potential uses of nanotechnology and prowess being exhibited in some of success business models on products developed based on nanotechnology, especially in developing countries, the issues of safety of its application to humans, environments and ecosystem need to be addressed. Indeed, there are many potential points of human exposure to nanomaterials along the agri-food chain (from workers to consumers), and the threat of possibility of nanoparticles reaching non targeted sites can pose health and environmental problems. Risk management strategies should be put in place in parallel to the technological developments and also through development of stable governance models in the entire production and consumption system through continued interaction with all the stakeholders: governments, producers, users, and consumers.

Annexes

List of participants to the workshop

External participants	
Participant	**Affiliation**
ALEMDAR, Ayse	FPInnovations, Canada
BALESTRA Giorgio M.	University of Tuscia, Italy
BEHRENS, Holger	Geohumus GmbH, Germany
BRAND, Leif	VDI Technologiezentrum, Germany
BUCHELI, Thomas	Federal Office for Agriculture, Switzerland
CARLANDER, David	Nanotechnology Industries Association (NIA), Brussels
CHANIOTAKIS, Nikos A.	University of Crete, Greece
FOWLES, Andrew	Dow, France
GUPTA, Nidhi	Wageningen University, NL
LEONARD, Paul	European Crop Protection Association (ECPA), Brussels
MORRISON, Mark	Institute of Nanotechnology, UK
PEREZ-DE-LUQUE, Alejandro	University of Sheffield, UK
SASTRY, Kalpana R.	Research Systems Management Division, NAARM, India
SCHIBLER, Laurent	COPA-COGECA, Brussels
TAKEUCHI, Masami	FAO, Italy
European Commission	
DELINCÉ, Jacques	JRC IPTS
FLUEH Michael	DG SANCO
KATHAGE, Jonas	JRC IPTS
LUSSER, Maria	JRC IPTS
PARISI, Claudia	JRC IPTS
PRINZ Maurits-Jan	DG ENTR
RAUSCHER Hubert	JRC IHCP
RIZOV, Ivelin	JRC IPTS
RODRÍGUEZ-CEREZO, Emilio	JRC IPTS
TILLIE, Pascal	JRC IPTS
VIGANI, Mauro	JRC IPTS

Agenda of the workshop

Workshop on "NANOTECHNOLOGY FOR THE AGRICULTURAL SECTOR: FROM RESEARCH TO THE FIELD"

21st – 22nd November 2013

European Commission (EC), Joint Research Centre (JRC)
Institute for Prospective Technological Studies (IPTS)
Unit "Agriculture and Life Sciences in the Economy" (AGRILIFE)

Venue: JRC-IPTS, Isla de la Cartuja, Edificio Expo, 1st floor, Room A30, c/ Inca Garcilaso 3, Seville, Spain

AGENDA

DAY 1 21st November 2013		
9:00 – 9:30	Welcome and objectives of the workshop	**Emilio Rodríguez-Cerezo and Claudia Parisi** JRC-IPTS
Session 1	**Overview of nanotechnology applications with a focus on agricultural Nanotechnology** Chair: Emilio Rodríguez-Cerezo (JRC-IPTS)	
9:30 – 10:00	Introduction on Nanotechnology: • Technical definition of Nanotechnology • Examples of nanomaterials • Nanotechnology diffusion in the EU • Main applications of Nanotechnology in different sectors, including agrifood.	**Mark Morrison** Institute of Nanotechnology, UK
10:00 – 10:30	Overview of agricultural applications of Nanotechnology: • Evolution of R&D activities for nanomaterials in agriculture • Classes of nanomaterials and their intended purpose in agriculture • Research priorities for a safe use of nanomaterials	**Thomas Bucheli** Federal Office for Agriculture, Switzerland
10:30 – 11:00	**Coffee break**	

Session 2	**Nanotechnology research activities in the agricultural sector** Chair: Claudia Parisi (JRC-IPTS)	
11:00 – 11:20	Nanomaterials as smart delivery systems for disease and pest control in plants: • Nanocapsules, nanoparticles and viral capsids • Absorption and translocation throughout the plants • Benefits/constraints in crop management and ecotoxicity	**Alejandro Perez-de-Luque** University of Sheffield, UK
11:20 – 11:35	Starch based nanoparticles in sustainable agriculture, possibilities and perspectives: • Wheat modification to improve amylose content; • Sustainable preparation, functionalization and characterization of starch nanoparticles; • Starch nanocontainers for delivering nutrients and biostimulants to plants. • Nanotechnology in pesticide development;	**Giorgio M. Balestra** University of Tuscia, Italy
11:35 – 11:55	Sensors and diagnostic devices to monitor environmental conditions: • Nanostructures as transducers in biosensors • Potential applications of biosensors • Focus on biosensors for pesticide detection	**Nikos A. Chaniotakis** University of Crete, Greece
11:55 – 12:15	Agriculture as a means to produce nanomaterials: • Harvesting natural nanomaterials from waste material • The example of wheat straw and soy hulls • Benefits of biobased materials compared to traditional production	**Ayse Alemdar** FPInnovations, Canada
12:15 – 12:45	Discussion on Session 2	
12:45 – 14:00	**Lunch break**	
Session 3	**Case-studies on developing industrial applications of agricultural Nanotechnology** Chair: Mauro Vigani (JRC-IPTS)	
14:00 – 14:20	Dow R&D and commercial products based on nanotechnologies for agriculture.	**Andrew Fowles** Dow
14:20 – 14:40	GEOHUMUS: nanoparticulate products for water absorption and release.	**Holger Behrens** Geohumus GmbH, Frankfurt, Germany
14:40 – 15:15	Discussion on Session 3	
15:15 –16:00	**Coffee break**	
16:00 – 16:40	Round Table: Statements by stakeholders	**David Carlander** NIA - Nanotechnology Industries Association Brussels, Belgium **Laurent Schibler** COPA – COGECA Brussels, Belgium **Paul Leonard** European Crop Protection Association (ECPA) Brussels, Belgium
16:40 – 17:00	Final discussion of Day1	
20:30	**Departure to dinner from Hotel NH Plaza de Armas**	

DAY 2 22nd November 2013		
Session 4	**Developments in Nanotechnology Risk Assessment and Regulation** Chair: Emilio Rodríguez-Cerezo (JRC-IPTS)	
09:00 – 09:20	The European regulatory framework for Nanotechnology: • EU definition of nanomaterials • Second regulatory review • Legal framework: REACH & CLP • Other Initiatives	**Maurits-Jan Prinz** EC - DG ENTR
09:20 – 09:40	Nanotechnologies in food, health and consumer products: • Nanotechnologies in food, health and consumer products: risk assessment studies and regulations involved • Role of DG SANCO • Opinions of EFSA, SCENHIR and SCCS.	**Michael Flueh** EC - DG SANCO
09:40 – 10:00	Role of JRC-IHCP in Nanotechnology: • Research on Nanotechnology at the EC-JRC • The repository of nanomaterials • Detection of nanomaterials in food and consumer products	**Hubert Rauscher** EC - JRC-IHCP
10:00 – 10:20	FAO/WHO State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors: • Relevant activities at the national/regional level and by international governmental and nongovernmental organizations • Scientific reviews addressing risk assessment of nanotechnologies in the food and agriculture sectors	**Masami Takeuchi** FAO
10:20 – 10:50	Discussion on Session 4	
10:50 – 11:30	**Coffee break**	
Session 5	**Socio-economic issues of agricultural Nanotechnology** Chair: Claudia Parisi (JRC-IPTS)	
11:30 – 11:50	Public perception of Nanotechnology-derived products: • Factors influencing societal response of nanotechnology • Focus on Agrifood sector	**Nidhi Gupta** Wageningen University, NL
11:50 – 12:10	Intellectual property in Nanotechnology: • Statistical Patent Analysis in nanotechnology, with a focus on agricultural sector • Relevant patent applications in the EU • Current intellectual property issues in nanotechnology	**Leif Brand** VDI Technologiezentrum - Düsseldorf, Germany
12:10 – 12:50	Impact of adoption of Agrifood Nanotechnology: • The issue of food security in developing countries and the impact of new technological developments in agriculture • Potential of nanotechnology for enhancing food security • The case of India	**Kalpana Sastry** Research Systems Management Division, NAARM, India
12:50 – 13:20	Final discussion and conclusions of the workshop	
13:20 – 14:30	**Lunch break**	

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