

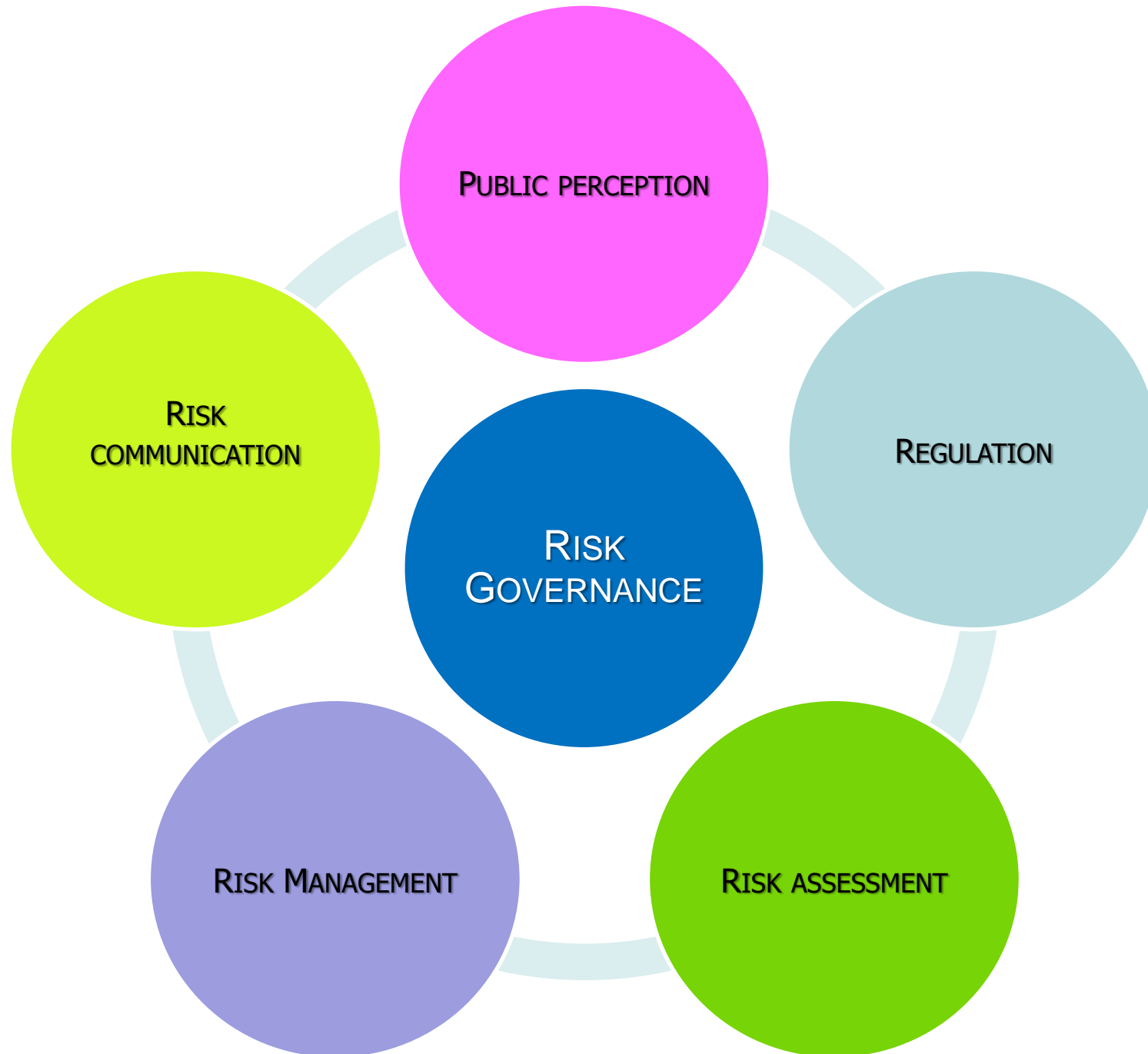
ILSI India Symposium on Nanotechnology

Risk Governance of Nanomaterials in Food

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Nanomaterials in Food

- Risk governance of nanomaterials
- Example applications of nanomaterials in food/feed
- Specific aspects need considering for nanomaterials in food
- Questions/answers



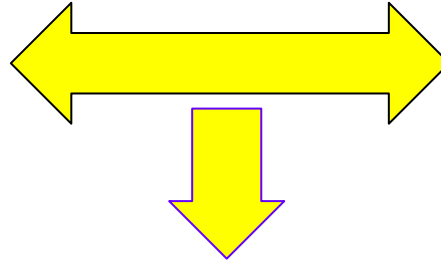


Governance





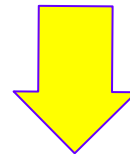
Cosmetics



Medicines



**Supplements
Nutraceuticals
Cosmeceuticals
Health Foods**



**Agriculture,
Food,
Packaging**

Sector Applications

New emerging area.
Current level of applications is still marginal.

- Cosmetics and personal care products
- Paints & coatings
- Catalysts & lubricants
- Security printing
- Textiles & sports
- Medical & healthcare
- Food and nutritional supplements
- Food packaging
- Agrochemicals
- Veterinary medicines
- Water treatment
- Construction materials
- Electrical & electronics
- Fuel cells & batteries
- Paper manufacturing
- Weapons & explosives

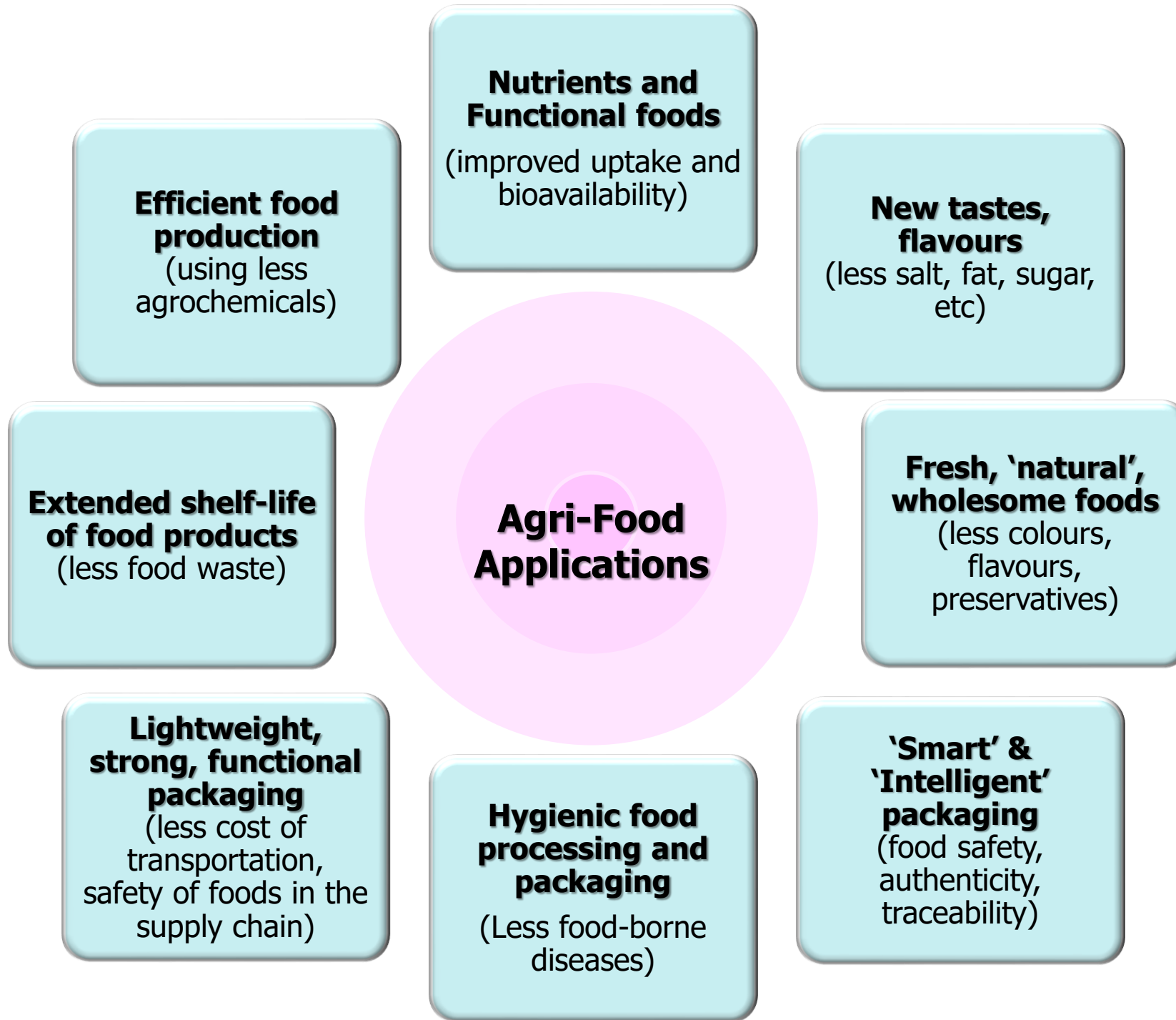
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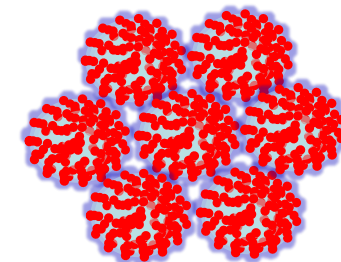
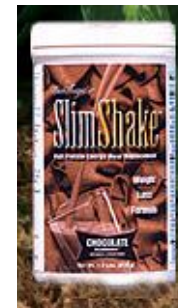
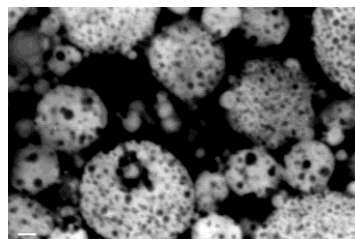
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Example Applications

- **Inorganic materials:**
e.g. calcium, magnesium, selenium, iron, zinc, silver, gold, platinum
- **Organic materials:**
nutraceuticals, supplements, vitamins, antioxidants, preservatives, etc.
- **Agrochemicals**
biocides, pesticides, veterinary medicines
- **Food packaging**
improved, active, intelligent packaging



Application Trends

- Improved/active food packaging \Rightarrow smart/intelligent packaging
- Supplements \Rightarrow Health-foods \Rightarrow Food and drink products \Rightarrow Animal feed
- Pesticides \Rightarrow fertilisers and other agrochemicals
- Coatings (processing machinery, food products)
- Water treatment



REGULATION

Regulation of Nanomaterial Risks

The European Approach

- Definitions, guidance on risk assessment of nanomaterials;
- Pre-market authorisation - risk assessment, labelling;
- Risk assessment by industry
- Scientific assessment/advice by EFSA

The EU Regulation of Nanomaterials in Food/Feed

- Food Additives [Regulation 1333/2008] requires risk assessment for new and already authorised additives when there is a "significant change in the production methods or in the starting materials used, or if there is a change in particle size, for example through nanotechnology". Also, where flavourings and enzymes are obtained from new production processes giving rise to significant changes in production process.
- Food Packaging [Regulation (EU) N°10/2011] on measures for plastic materials and articles: from 1 May 2011, nanomaterials can only be used if listed in its Annex I and explicitly authorised and mentioned in the specifications in Annex I. Also, [Regulation (EC) N°450/2009 for active and intelligent materials and articles]: "substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale".
- Food Information Regulation [(EU) No 1169/2011] requires labelling for any nanomaterial used in food products.
- Novel Foods [Regulation (EU) 2015/2283] requires safety assessment and authorisation for any nanomaterial before being used in foodstuffs. Safety assessment of novel foods is carried out by the EFSA.

The EU Regulation of Nanomaterials in Food/Feed

- The use of nanomaterials in food/feed products is specifically regulated under the EU Novel Food Regulation (EU) 2015/2283, which:
 - provides a regulatory definition (provisional – pending alignment with the EU Recommendation 2011*);
 - requires risk assessment and novel food authorisation for any use of nanomaterials in food/feed products;
 - designates EFSA to evaluate risk assessment dossiers, and to verify that appropriate and up-to-date methods have been used to assess safety.

* "Nanomaterial" means 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.



Main Safety Questions

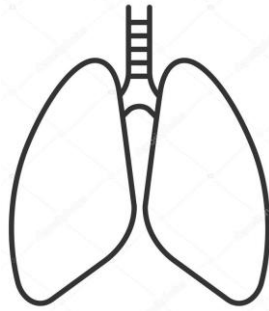
Whether oral exposure to a nanomaterial via food/drinks can lead to:

- absorption of insoluble or poorly-soluble nanoparticles in the body?
- greater uptake and bioavailability of nanoparticles than the conventional form?
- translocation of systemically available nanoparticles from the GI tract to other parts of the body?
- potential interaction/interference of the nanoparticles with cellular/organ moieties/functions?
- potential adverse effects on consumer health from short/long (repeated) exposures?



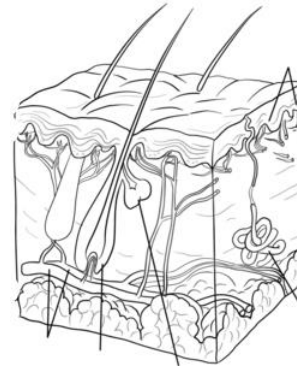
Nanoparticles

Inhalation



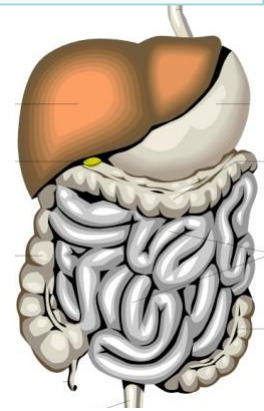
Nanoparticles not cleared through phagocytosis/ lung clearance may translocate to other organs.

Dermal



Limited studies so far. Intact skin is potentially a good barrier to (nano)particles.

Oral



Limited studies so far. Translocation may be possible for nanoparticles that remain intact in the GI tract

Main routes of exposure

Potential for systemic effects

Titanium dioxide: E171 no longer considered safe when used as a food additive

Published: 6 May 2021



Contents

FAQ – EFSA 2021 safety assessment of titanium dioxide (E171)

How to contact us

Related topic(s)

EFSA has updated its safety assessment of the food additive titanium dioxide (E 171), following a request by the European Commission in March 2020.

The updated evaluation revises the outcome of EFSA's previous assessment published in 2016, which highlighted the need for more research to fill data gaps.

Prof Maged Younes, Chair of EFSA's expert Panel on Food Additives and Flavourings (FAF), said: "Taking into account all available scientific studies and data, the Panel concluded that titanium dioxide can no longer be considered safe as a food

Risk Assessment of Nanomaterials in the EU

Food contact materials:

- Positive EFSA opinions where lack of migration of nano-additives to food/simulants is demonstrated (silicon dioxide; carbon black; titanium nitride).

Food additives:

- First examples are currently undergoing risk assessment by EFSA.

Pesticides, fertilisers:

- No regulatory risk assessment in the EU yet.

Cosmetic ingredients (SCCS Opinions) e.g. TiO₂, ZnO, SiO₂, Carbon black,

- Positive opinions where lack of dermal penetration is demonstrated – indicating absence of systemic availability
- Negative opinions where indications of adverse effects after inhalation exposure



PUBLIC PERCEPTION

Public Perception of Nano Foods

Public perception of foods is often inconsistent:

- willing to eat a lot of unhealthy (high fat, high sugar) traditional foods, but averse to novel foods.
- Especially sensitive to anything perceived as 'unnatural', 'not wholesome', or 'unduly over-processed'

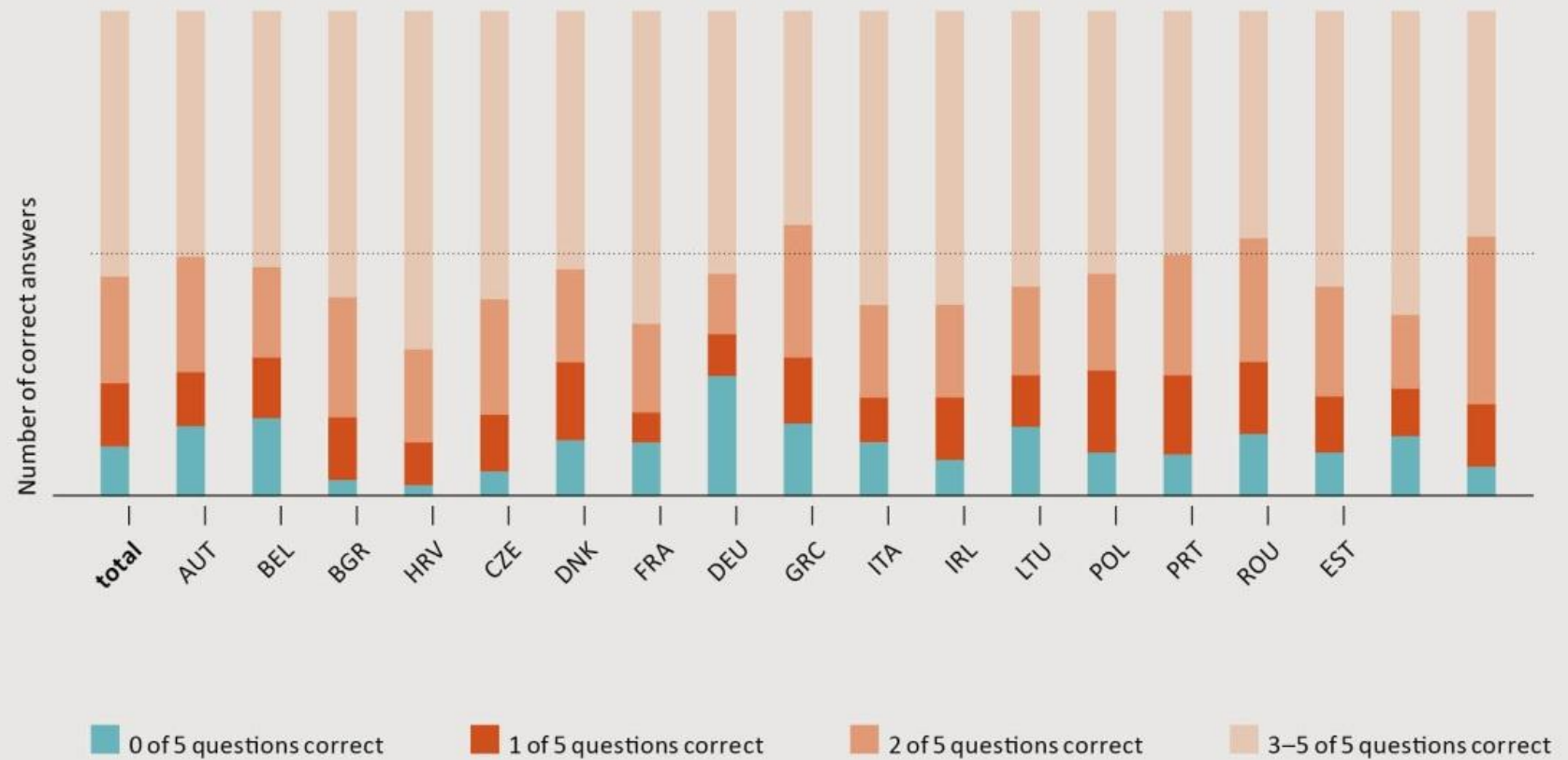
The debate about nanotechnology in food is almost where it was over a decade ago. The same questions remain:

- What exactly is nanotechnology?
- Who benefits from this technology?
- What could be the risks?
- Who will be responsible if something goes wrong?

Public Perception of Nano Foods

- Public sensitivities are generally heightened regarding the use of new technologies in producing/ processing food.
- Like any new technology, nanotechnology will not receive an automatic acceptance by general public.
- The debacle over GM foods shows that uncertainties due to lack of knowledge/clear communication can raise concerns over real and perceived risks.
- Nano-foods also opened up a similar debate, with calls for a moratorium or an outright ban on the use of nanotechnologies for food.
- Surveys of public opinion in the EU have shown that, whilst the consumer opinion is conducive to other applications of nanotechnology, it is not entirely favourable to applications for food

Level of knowledge of Nanotechnology Total numbers, N=6779



EU project *NanOpinion* (2014) surveyed 15,000 people in 26 cities in 18 EU countries



RISK
COMMUNICATION

Improved Packaging:

- mechanical properties - flexibility, durability, temperature/ moisture stability
- barrier properties against water, gases, taint



Active Packaging:

- antimicrobial packaging to keep food fresh for longer



Smart/Intelligent Packaging:

- nano(bio)sensors to indicate quality of foodstuffs;
- nano(bio)switch to release preservatives

Nano-coatings:

- antimicrobial and self-cleaning food contact surfaces



Improved packaging:

✓ Food remains fresh for longer and this will cut food waste.

✗ May be seen as benefiting the industry if packaging is used to extend product sell-by date – consumer will get less fresh product.

Active packaging:

✓ Safety against food-borne diseases.

✗ May be seen as a cover for hiding non-hygienic practices during food processing.



RISK
GOVERNANCE

A carefully designed science-led strategy
to engage/educate public on:

Societal benefits



Health and environmental risks



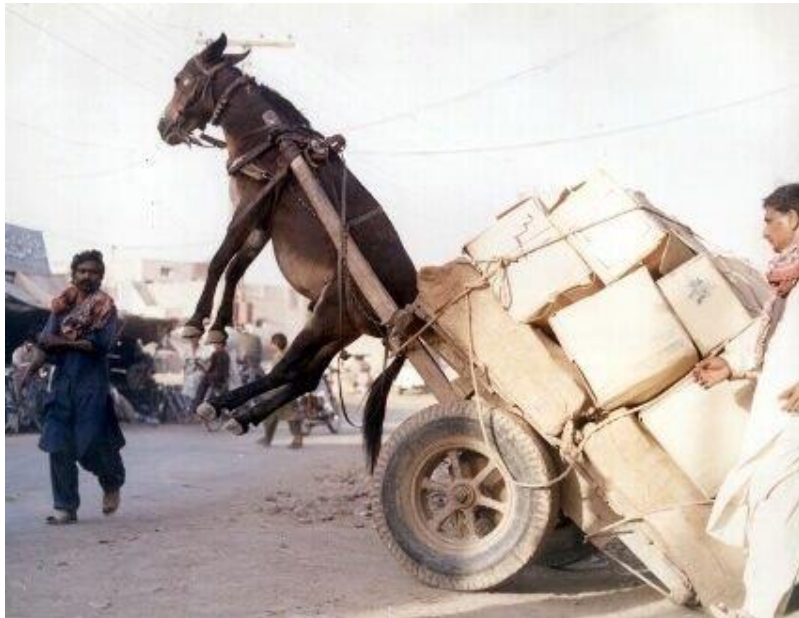
Balanced regulation



Communication



'Licence to produce' by the public

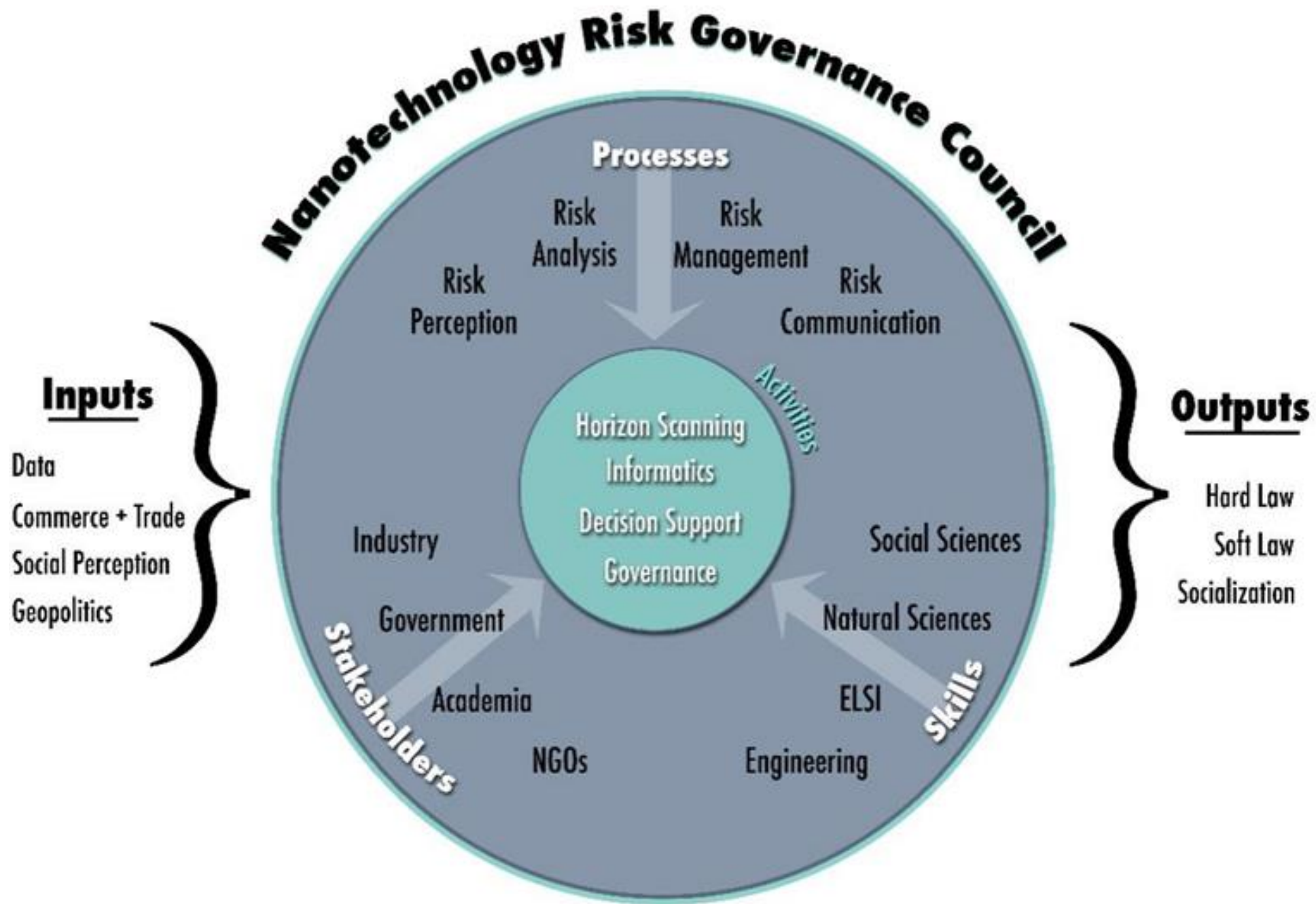




Risk Governance of Nanomaterials

3 European projects working together to develop frameworks for risk governance framework and a risk governance council along with supporting infrastructure for data, tools & instruments





Summary

- A lot of prospects for nanotechnology-driven innovations in the agri-food/nutrition sectors;
- Current level of applications is marginal. Growing applications for nano-sized vehicles for delivery of nutrients and supplements; nanopesticides/fertilisers
- Concerns over consumer safety of insoluble/poorly-soluble nanomaterials
- Several technological challenges in regard to risk assessment
- Science based effective communication needed to address real/perceived risks
- Nanotechnology developments are not happening any regulatory vacuum – regulatory systems are in place for assessment/management of risks
- Work underway on the development of nano risk governance frameworks/council under EU projects

Food Additives and Contaminants, March 2008; 25(3): 241–258

Review



Applications and implications of nanotechnologies for the food sector

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(Received 8 August 2007; accepted 14 December 2007)

Abstract

A review of current and projected nanotechnology-derived food ingredients, food additives and food contact materials is presented in relation to potential implications for consumer safety and regulatory controls. Nanotechnology applications are expected to bring a range of benefits to the food sector, including new tastes, textures and sensations, less use of fat, enhanced absorption of nutrients, improved packaging, traceability and security of food products. The review has shown that nanotechnology-derived food and health food products are set to grow worldwide and, moreover, a variety of food ingredients, additives, carriers for nutrients/supplements and food contact materials is already available in some countries. The current level of applications in the European food sector is at an elementary stage; however, it is widely expected that more and more products will be available in the EU over the coming years. The toxicological nature of hazard, likelihood of exposure and risk to consumers from nanotechnology-derived food/food packaging are largely unknown and this review highlights major gaps in knowledge that require further research. A number of uncertainties and gaps in relevant regulatory frameworks have also been identified and ways of addressing them proposed.

Keywords: *Nanotechnology, nanoparticles, food, food additives, food packaging, consumer safety, regulatory frameworks*

2nd Edition

Nanoscience & Nanotechnology Series

Nanotechnologies in Food

Edited by Qasim Chaudhry, Laurence Castle
and Richard Watkins

