Evidenced-based Regulation of Food Nanotechnologies

A perspective from the European Union

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Drawn from research undertaken with Qasim Chaudhry and Anna Gergely

1. Background

- Agri-food landscape is *extremely* dynamic in nature, from farm to fork
- Global food retail sector alone valued at around $4 trillion annually
- Value of this sector predicted to only increase in time
- Obvious target area for new technologies & innovation that can improve processes and products

1. Background: Why nano in food?

- External pressures (consumers, regulators & shareholders)
- Nanotechnologies = whole new array of possibilities
- Manipulation of properties, generation of novel functionalities
  - nano-sizing of agrochemicals (↑efficiency,↓'cides)
  - organic carrier systems
  - nano-scale processing of food materials
- Widely anticipated, *but* still emergent and marginal

"As for packaging, nanotech is already being used in the US to stop beers going flat. Plastic beer bottles used by brewer SABMiller contain flaky nanoparticles of clay, which fill up much more space in the walls of the bottle than molecules of plastic." (Sanderson, 2013)

i.e. slows down the rate at which the beer goes flat at.

"The use of nanoparticles in sunscreens and cosmetics, and the use of nanoparticles to improve the *nutritional benefits of food were the applications where information recalled was least positive*…." (Australian Government, 2012).

2. Potential risks of nano in foods?

- Range of potential concerns
- Real or potential risk versus a perceived one
  - natural nanoscale food materials that are digested/ assimilated in the GI tract, and are not biopersistent should not pose any additional nano-specific risk
  - main concern: insoluble, indigestible and biopersistent nano additives (e.g. some metals/oxides), and functionalised nanomaterials in food and drinks
  - food packaging → would need to first have migration
  - agrochemicals (worker exposure, consumer exposure)

2. Potential risks of nano in foods?

Most important determinant of a nano-related risk:

- Whether nanoparticles added to food can remain, translocate from the GI tract, and reach other parts of the body, in insoluble particle form.

- Regulatory frameworks must be able to differentiate between the various applications on the basis of available scientific evidence (i.e. no-, low- or high risk)

3. Definitional debate & food

"…there is no nano in any food on the European market at this time…" (Industry representative, 2010),

“"The application of nanotechnologies in the food industry is at an early stage, *and to the best of our knowledge the UK food and drink manufacturing industry does not currently use engineered nanomaterials in food products, their processing or their packaging*." So says the UK's Food and Drink Federation, which represents food manufacturers.

Nestlé says that it is keeping a watchful eye on developments in food nanotechnology, but not doing any of its own research. Heinz takes the same line, saying that it is monitoring the field but not actively participating.” (Sanderson, 2013)

"…any regulatory definition of nanomaterials proposed at a European level, in particular in the Novel Foods Regulation, should not include a size limit of 100 nm but instead refer to "the nanoscale" to ensure that all materials with a dimension under 1000 nm are considered]" (House of Lords 2010:112).

- HofL favoured an approach based on a change in functionality (how the substance interacts with the body) rather than an approach relying on size range alone

The EU Approach

Food Information Regulation (Regulation (EC) No 1169/2011)

Article 2 defines an engineered nanomaterial to mean:

> "any intentionally produced material that has one or more dimensions of the *order of 100 nm or less* or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, *which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale*".

Contrast this to the definition in the Cosmetic Regulation (Regulation (EC) No 1223/2009):

> Article 2(1)(k), “nanomaterial" means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”.

US Position: FDA draft guidance

"FDA will ask:

(1) whether an engineered material or end product has at least one dimension in the nanoscale range (approximately 1 nm to 100 nm); or

(2) whether an engineered material or end product exhibits properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer" (FDA draft guidance, June2011).

4. Regulating food nanotechnologies

European Union

- General food laws (Regulation (EC) No 178/2002): cross cutting measures designed to ensure that food is safe
- Producer placing it on the marker is liable for its safety (vis-à-vis the US's Federal Food, Drug and Cosmetic Act)

4. Regulating food nanotechnologies

Food Information Regulation (Regulation (EC) No 1169/2011):

- Article 18: nano labelling requirements (analogous to the Cosmetic Regulation)
- i.e. cocoa (nano)…
- Responsibility for labelling & safety testing falls on industry (operator, or importer)
- Regulation acknowledges that nanomaterial definition may need to be adjusted in line with technical / scientific progress (Article 2(2)).

4. Regulating food nanotechnologies

European Union

- Novel Foods and Novel Food Ingredients Regulation (Regulation (EC) 258/97):
  - a novel food is defined as a food or food ingredient not having a significant history of human consumption within the Community prior to May 1997 …
  - Article 1(f): "Foods and food ingredients to which has been *applied a production process not currently used*, where that process gives rise to *significant changes* in the composition or structure of the foods or food ingredients which affect their *nutritional value, metabolism or level of undesirable substances.*"

4. Regulating food nanotechnologies

United States

"FDA does not categorically judge all products containing nanomaterials or otherwise involving application of nanotechnology as intrinsically benign or harmful. Rather for nanotechnology-derived and conventionally manufactured food products alike, FDA considers the characteristics of the finished product and the safety of its intended use" (FDA 2012:13).

5. Conclusion

- Regulatory guidance on potential risks and risk assessment issues has become increasingly available both in the EU and the US (& other jurisdictions)
- Entry into force of the new labelling regime in the EU will create some transparency about what is on the market
- But compliance, and enforcement? → how practicable is it to ensure the objectives are met?
- Moreover, question of compliance if/when the definitions evolve?
- Impact of this approach v utilization of guidance for other countries?

Thank you.