AnimalfreeResearch

Mind the gap

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Some EU-Activities

- EU: 1st and 2nd review of REACH with respect to the adaptation to nanomaterials

- Report of the EC in September 2011: the EU, Canada and Australia have adopted an approach…to adapt regulations for nanotechnologies

The conclusion was, that EU legislation was inadequate and that nanomaterials should be explicitly addressed

→ modifications of some REACH Annexes envisaged

Some EU-Activities

- Definition of nanomaterials in October 2011, review foreseen in December 2014 (and for this definition you need the proper measuring techniques for determining particle size and size distribution…)

- As of 11 July 2013, a new Cosmetics Regulation (EC No 1223/2009) has been fully implemented which includes specific provisions for nanomaterials (definition, requirement for notification, labelling and reporting).

- Regulation (EU) No 1169/2011 states that all food ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients (transition period until 2014).

Some Swiss activities

- Action Plan (2008) on risk assessment and risk management of synthetic nanomaterials

-states that the scientific basis for a risk assessment is lacking and that these gaps are to be closed

-intends to create a regulatory framework

-as a first step, the self-responsibility of industry is to be supported

-changes in legislation are to take place when the required approaches and risk assessments are available (if necessary)

- Publication of the ‘Precautionary matrix’, the ‘Guidelines for safety data sheets’ and reports on ‘Nanoparticles at workplaces’ as a joint effort between the Federal Office for the Environment and the Federal Office of Public Health

Some Swiss activities

- At the end of 2010, the results of an initiative promoted by the Swiss Federal Office of Public Health (FOPH) with key nanotechnology stakeholders were published (NANO Dialogue Platform).

- Issues related to the need for a definition of nanomaterials, labeling within foods, cosmetics, chemicals, and waste regulations were considered

There has been a unanimous agreement on the need for a coherent approach on regulatory matters between Swiss and EU regulations.

…this just in…

On 11.09.2013 the Swiss National Council refused a motion to regulate nanotechnologies on a legal basis (specifically, food and cosmetics) and to create an inventory on existing products. They argued that nanomaterials can be controlled with the existing regulations concerning chemicals, food and feed and medical approaches. The declaration of nanomaterials for food products is intended to be adopted in the course of the revision of the respective legislation in 2015.

The Green Party, who submitted the motion, is arguing that the public is indeed extremely sceptical towards the new technology, especially with regards to food, and that scientific literature indicates that there are serious knowledge gaps concerning a thorough risk assessment.

Max Frisch responded to the question where he would want to be when the world ends:

„In Switzerland. Everything happens later there.“

The National Research Programme 64: Opportunities and risks of nanomaterials

18 projects, 5 years (Dec 2010 – Dec 2015), 12´000´000 CHF

- Aim: strengthen and perpetuate the leading role of Switzerland in nanomaterials research
- Deepen knowledge on possible risks
- Establish toxicity testing and innovative risk assessment approaches
- Describe ecological risks and interactions, modifications of nanomaterials
- Assist in establishing a basis for legislators
- NRP is part of a network between other national and international scientific programmes, authorities, politics and legislators

Goals of our project

Establish ITS in Nanotoxicology as proof of principle before the implementation of according legislation and the beginning of animal testing on a regular scale

Why ITS?

Approaches that integrate different types of data and information into the decision-making process. In addition to the information from individual assays, test batteries, and/or tiered test schemes, integrated testing strategies may incorporate approaches such as weight-of-evidence and exposure/population data into the final risk assessment for a substance.

Goals of our project

Contribute!! to development of feasible ITS and acceptance by authorities

ITS accepted e.g. in REACH and OECD
(NRC report 2007)

- characterization!!
- exposure data
- as reasonable and cheap as possible
- With as few animal tests as possible

Rely strongly on the inclusion of the NRP projects to establish ITS in regular testing approaches in Switzerland and use the network to approach and convince authorities

Which existing in vitro methods are suitable???

- Plenty of validated methods! Suitability for nanomaterials? None are validated
- Methods specifically developed for nanotoxicity testing (inhalation), none validated
- How do you validate for nanomaterials? Is it at all reasonable to do so? Is there time for such a process?
- Does an ITS in itself have to be validated? For each material in itself? For groups? Which groups?

On the other hand, if you use animals, you also need a testing strategy (categorization of nanomaterials)

What is required?

- Find an approach to deal with changing characteristics, and thus hazard, of NM during their life cycle.
- Integrate exposure, material properties, biopersistence, biokinetics (ADME/ADCE) as well as primary effect and apical effect testing into a concern- driven testing strategy that can be applied to an individual NM but also includes guidance for grouping of NM.
- Use grouping as an integral part of the testing strategy

- *Characterization of test materials*
- *Behavior of nanoparticles in culture medium*
- *Uptake and subcellular distribution*
- *Need of in vitro biokinetic and metabolic studies*
- *Need to study absorption via different routes*
- *Endocytic pathways and biopersistence (Hartung and Sabbioni 2011)*

Questions, questions…

- Is classical toxicology at all relevant for nanomaterials? E.g. dose-response curves?
- According to what criteria should grouping be done?
- Is a validation necessary?
- Is grouping feasible? What criteria are the basis?

The concept of transparency: what is the public supposed to do with all the information? How do you explain the need for a special labelling of a food product to manufacturers and consumers if there is no special issue with these materials?

Outlook (1)

- ITS for nanomaterials in food
- ITS for occupational health

Food: development of an in vitro system for assessing the interactions of nanoparticles with the intestinal mucosa/immune system)

Occupational health:

- risk analysis of inhalable nanoparticles in vitro
- Distribution of nanoparticles and crossing of the blood-brain barrier; interactions with (brain) cells
- Tracking and oxidative stress in human volunteers
- immunomodulation of nanoparticles in the lung
- Transplacental transport

Outlook (2)

- Make contact with the respective project leaders and ask for their cooperation
- Make contact with the Swiss Federal Laboratories for Materials Science
- Aim for international contacts (European NanoSafety Cluster)
- Develop strategies according to existing ITS and/or results from literature in order to establish mechanisms of possible toxic effects

- Test for relevance (in vivo?)

- Prepare proposals for authorities, emphasize that these basic questions have to be answered in vitro

Thank you for your attention!

Collaboration:
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Thank you!