

Nanotechnology in animal feeds: The approach of the legislators in the USA and the EU

Dragan Momcilovic¹ & Wolfgang Trunk²

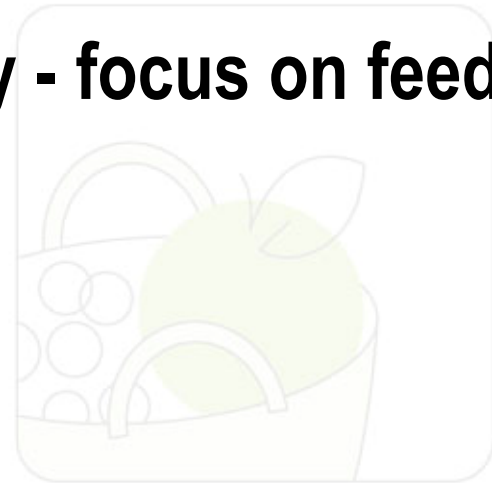
¹ PhD, DVM, DACT, Food and Drug Administration,
Center for Veterinary Medicine, Rockville, USA

² PhD, European Commission, DG for Health and
Consumers, Feed Unit, Brussels, Belgium

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Outline

- I. Introduction
- II. FDA/CVM's role
- III. **EU approach on nanotechnology - focus on feed**
 - EU strategy and action plan
 - Policy debate
 - Feed applications
- IV. **Challenges to tackle for**
 - Science/Research
 - Politics/Regulators
- V. **Résumé**



III-I EU strategy and action plan

1. EU strategy for nanotechnology (nT) 2004

- nT seen as potential to enhance quality of life and industrial competitiveness in Europe.
- “Integrated, safe and responsible approach”
- Stakeholder-involvement, eg CIAA code of practice for the responsible use of nanomaterials (nms) for the food industry

2. EU nT action plan 2005-2009

- Boosting R&D,
- Continuous market survey
- Cooperation within COM and international dialogue
- More direct, focused and continuous societal dialogue

III-II Policy debate

1. Definition “engineered nMs”

Many different definitions on in the debate containing generally the following element: “intentionally produced material that has one or more dimensions of the order of 100 nm or less”

2. Notification of n-products

- “Food containing nMs need a pre-marketing authorisation” - notification implicit but what if industry does not claim n-application?
- Watchdog groups have inventories with hundreds of consumer products made with nT, growing at a rapid pace BUT
- *stricto sensu*: “No definition – no notification”

III-II Policy debate

3. Authorisation

- Required (EP) for “food additives, food enzymes, flavourings ... to which is applied a new production process ... which give rise to significant changes in the composition or structure (*Reg. 1333/2008 on food additives names even particle size*) of the food such as engineered nMs).
- nMs present in food packaging should be entered on a list of approved nMs, accompanied by a migration limit ... into the food products contained in such packaging.”

4. Labelling

- EP: ... all ingredients present in the form of nMs in substances, mixtures or articles should be clearly indicated in the labelling of the product (e.g. followed by the word 'nano' in brackets)
- COM + Council: possibility to decide additional labelling requirements on a case by case basis only

III.III Feed applications

1. Regulatory framework

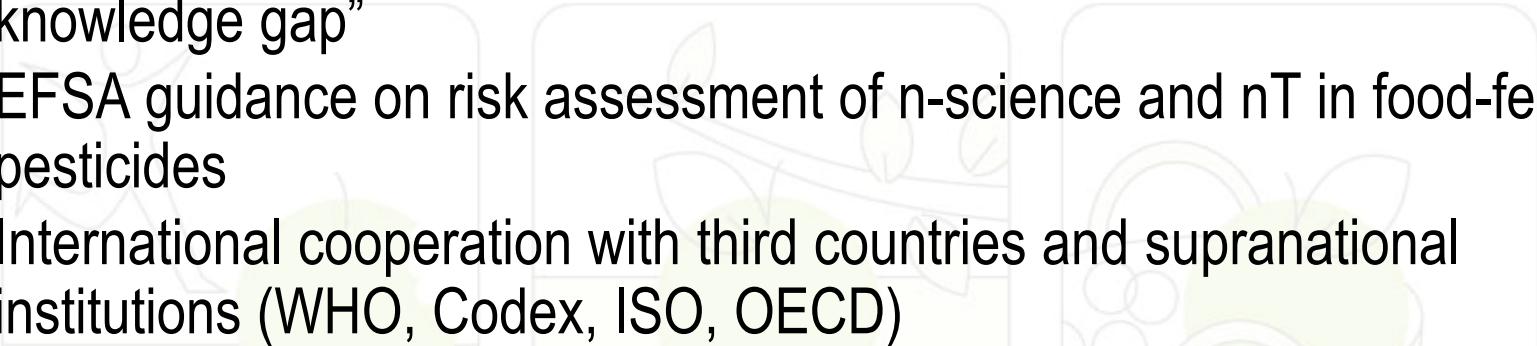
- Like in other areas: NO n-specific provisions in Community law - current legislation covers in principle the relevant risks relating to “nMs”
- EFSA (02-09) on “Potential risks arising from n-science and nT on food and feed safety”
- Additives: The particle-size of a substance has to be addressed in the product description and safety chapter of the application dossier &
- Acute inhalation toxicity studies shall be performed if particles or droplets with a diameter of less than 50 μm constitute more than 1 % of weight.

III-III Feed applications

2. Concrete products

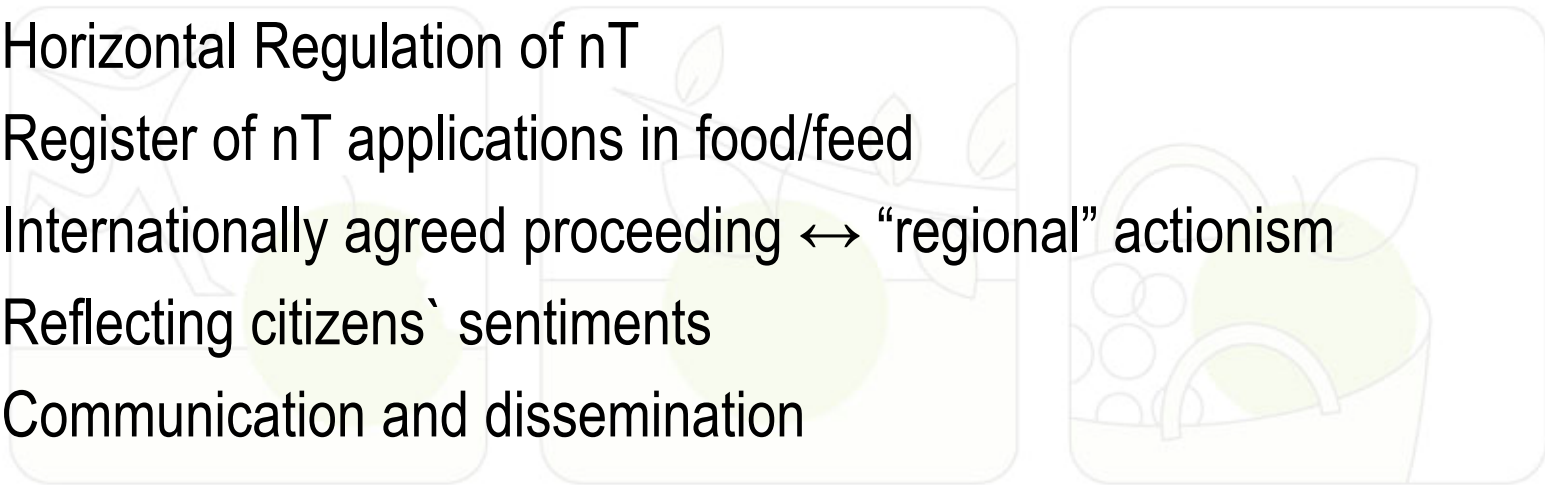
- Dietary supplements (vitamins, flavourings, trace elements) with claims such as “better nutrient absorption” or “inhibiting absorption of undesirable substances” – “n-drops added to the feed acting as carrier of substances insoluble in water or fat. These supplements are meant to be sprayed inside the mouth, swallowed as pill/capsule or added to drinking water.
- “Organo-clay (modified structure of montmorillonite by increasing the interlayer space by inserting an seaweed/algae extract)
 - interlayer space is thus expanded 10 times more
 - surface area of clay from 1 cm²/g to 800 cm²/g
 - potential to absorb mycotoxins (e.g. aflatoxin, T-2, DON, ZEA, trichothecenes) and heavy metals better”.

Challenges Science/Research

- "no data, no market": for all applications of nMs in products with potential health, environmental or safety impacts over their life cycle - "Bridging the knowledge gap"
 - EFSA guidance on risk assessment of n-science and nT in food-feed-pesticides
 - International cooperation with third countries and supranational institutions (WHO, Codex, ISO, OECD)
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Challenges Politics/Regulators

- new COM NT Action Plan for 2010-2014
- Horizontal Regulation of nT
- Register of nT applications in food/feed
- Internationally agreed proceeding ↔ “regional” actionism
- Reflecting citizens` sentiments
- Communication and dissemination



Résumé

- nT promising “new technology”
- Huge interest in society, science, economy and thus politics
- Missing Transparency → scepticism in citizens
- Lessons to be learnt from GMO
- Applications in feed still very limited
- Current regulatory framework in US and EU able to tackle evaluation of nMs but more specific consideration useful
- Knowledge gaps in plenty of areas related to nT are big chance for science community
- Political challenges and solutions depend on how science can abandon uncertainty