Regulatory Aspects applicable to Nanomaterials in Food

Belgium Presidency Symposium
Nanotechnologies in Food
Brussels 24 November 2010

Eric Poudelet

Director

European Commission, DG Health and Consumers

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

How EU Legislation addresses nanomaterials in Food?

- An adapted legal frame
- A systematic scientific risk assessment
- An EU pre-market authorisation system
- Ensuring consumer information

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Legal Frame for Nanomaterials in Food

- Current EU legislations do cover « in principle » nanomaterials (COM report 2008)
- On-going revision of some food legislations is addressing specifically nanomaterials (additives, novel foods, FCM)
- EU pre-market approval regime
- If already authorised substances but under nano form, new scientific risk assessment required
- Need of an EU definition for legal purpose

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Legal requirements for nanomaterials in food

- Specific legislations apply depending types of food ingredients (additives, novel foods, vitamins and minerals, food contact materials)
- Harmonised legislations
- Non harmonised legislations

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Harmonised legislations I

Provisions addressing nanomaterials:

- **Food additives**: « Significant change in production methods or in the starting materials used, or if there is a change in particle size, for example through nanotechnology » Regulation 1333/2008 on food additives

- **Food contact materials (plastic):** currently similar provisions than food additives. Nanomaterials can only be used after explicit pre-market authorisation from 2011.

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Harmonised legislations II

Provisions addressing nanomaterials:

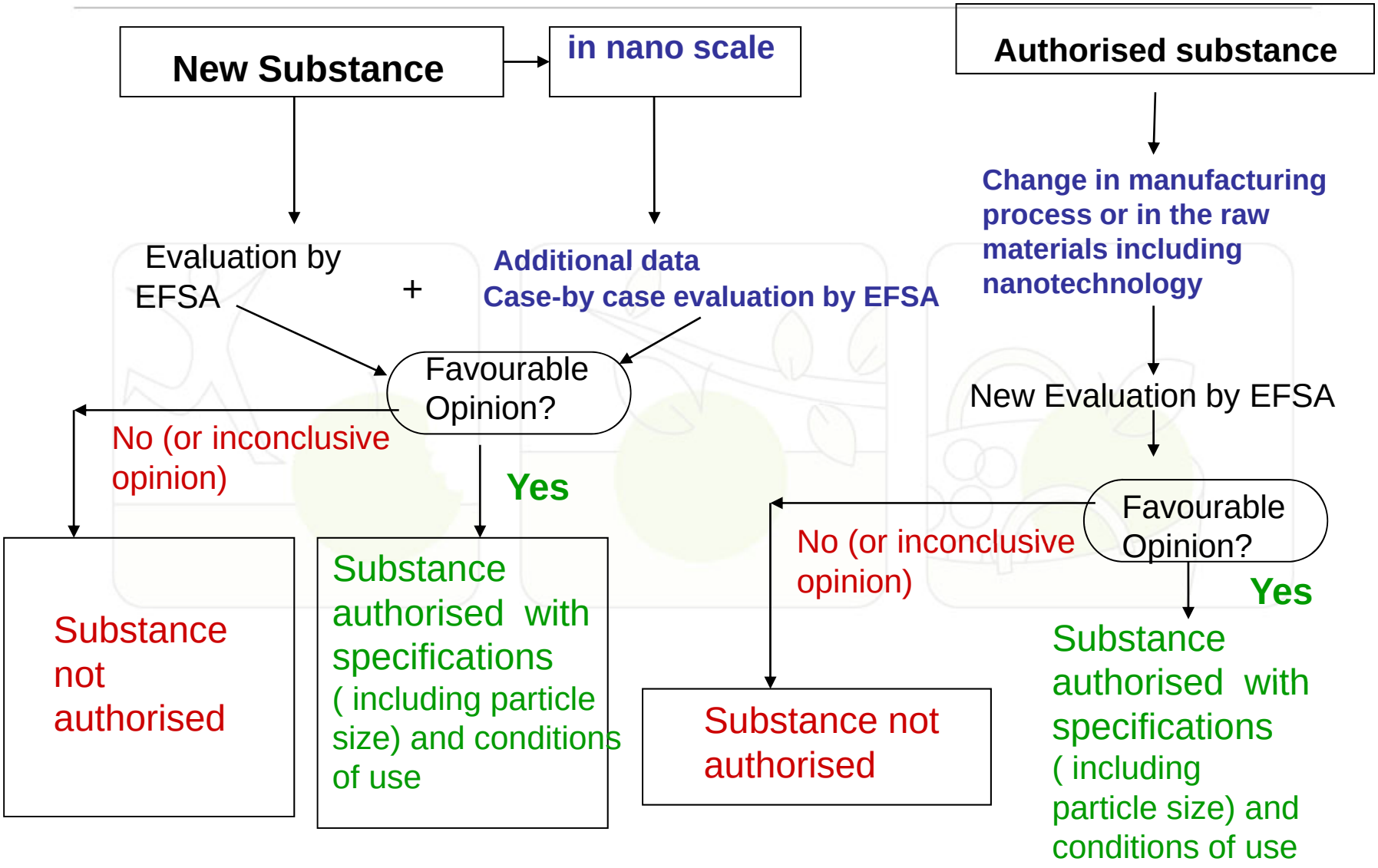
- **Novel foods**
  - « New production process giving rising to significant changes in the composition or structure of the food » Regulation 258/97 on Novel Food
  - « food containing or consisting of engineered nanomaterials" draft Novel Food revision
- **Vitamins and minerals** (no specific provisions pending revision but to verify if novel food authorisation is required)

Non harmonised legislations

- National competences for substances other than vitamins and minerals for:
  - Food supplements
  - Food fortification
- Member States:
  - May adopt national measures (lists of authorised or forbidden substances, conditions of use)
  - Shall notify them to Commission

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General



EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

EU nanomaterial definition

- Existing EU definition for cosmetics (2008)
- Draft EU definition for Novel Food Revision
- Draft EU Inter-Services definition
  - Legal consistency amid same sector (food) and across industrial sectors
  - Draft definition under public consultation (completed 18 November)

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Draft Inter-Services Definition

"Nanomaterial" means a material that meets at least one of the following criteria:

- consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1 % of their number size distribution;
- has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm;
- has a specific surface area by volume greater than 60 m2/cm3, excluding materials consisting of particles with a size lower than 1 nm.
- Particle: means a minute piece of matter with defined physical boundaries.

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Food safety Risk Assessment

- EU risk assessment performed by EFSA
- Methodology
  - General risk assessment methodology does apply (EFSA opinion 2008)
  - Assessment on a case by case basis (no common risks)
  - EFSA mandate for elaborating EU guidelines for risk assessment of nanomaterials in food, feed and pesticides (April 2011)

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

EU Risk management

- No EU authorisation without an EFSA scientific risk assessment establishing that substance under nanoform is safe
- Full risk assessment of food safety aspects (even for substances already authorised under their conventional form)
- Other risks (protection of environment / safety of workers) addressed by other EU relevant legislations
- Pre-market authorisation system already applies precautionary principle

EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Labelling of nanomaterials

- To ensure consumer information and freedom of choice for food products containing nanomaterials
- General food labelling directive rules apply to all food and food ingredients (different from specific legislations)
- On-going legislative revision (Food Information proposal) with introduction of a mandatory labelling requirement for all foods containing « engineered nanomaterials »
- Labelling would apply at level of list of ingredients

Conclusions

- On going revision of specific food legislations addresses explicitly the use of nanomaterials in all foods. A Commission report to the EP / Council on regulatory review will be adopted in 2011
- EU regulatory definition to be finalised and adopted. Possibility to update it according to scientific and international developments
- Other initiatives at international level (OECD, FAO/OMS, Codex Alimentarius)
  - Revision of international standards (ISO)
  - International guidelines for risk assessment?
  - Inventory of consumer goods containing nano on the market?