

# EU Nano Food Policy Plate

Brussels, 10 April, 2018

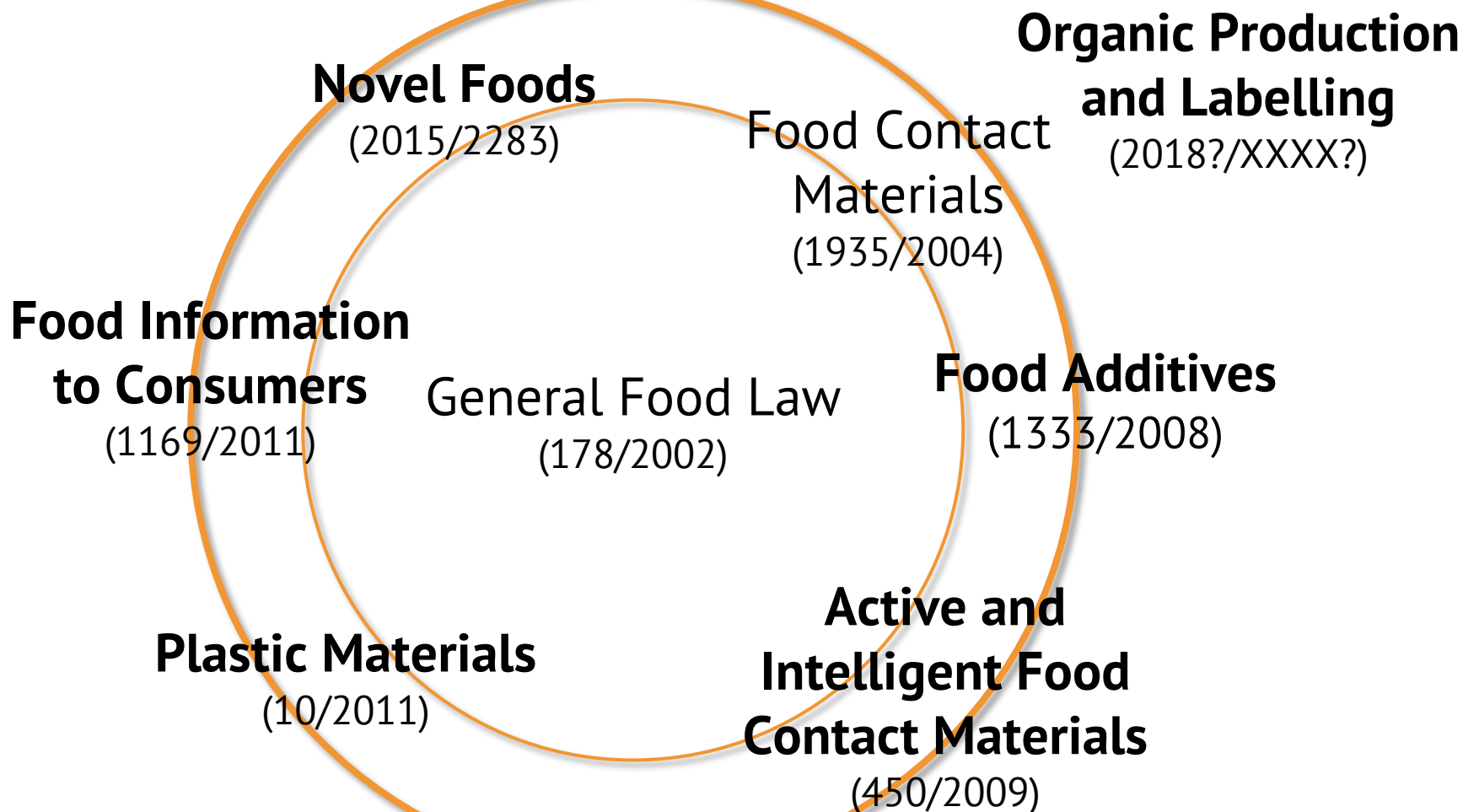
**Dr David Carlander**  
NIA Director Regulatory Affairs

# Nano in food – Examples from the market

Nanomaterial	Application	Countries
Calcium	Fortified foods	S. Korea, China, Malaysia and others
Silver	Supplement, Food contact	USA, Germany, China
Zinc, Copper, Gold	Supplement	USA, Spain
TiO <sub>2</sub>	Supplement, Food contact	Japan, Germany
SiO <sub>2</sub>	Supplement	USA, Japan, Germany
Aluminosilicate clays	Additives, Food contact	Several countries

[Survey from ILSI NanoRelease Food Additive project]

Type/description	Company
Emulsion	Aquanova
Emulsion	Solgar
NanoSOF	Nanoxyn Alpha
Mucolyxir®	AllergyResearchGroup
naNOX9® Next Gen uses Nitrosigine®	MuscleTech
Encapsulation	SupremeVitamin
Nanocetrical Solutions	Nanocetrical Solutions
Enteric-coated capsule	Counter Aging Wise CAW
A liposome made with phosphatidylcholine	Lipolife
Nano Particulated Amino Acid Complex'	BioTechUSA
Phytosome	Indena S.p.A
Nanocolloidal	RBC Life
Micro and nano encapsulation	EatNano
Nano phospholipid emulsion	EatNano
Emulsion	DSM
Liposome	Encapsula Nano Sciences



- Adopted Nov 2015, and applies from 1 Jan 2018
- Novel food defined as not consumed to a significant degree before 15 May, 1997, and falls within one of ten listed categories
  - **‘Food consisting of engineered nanomaterials’** (Art 3.2.a.VIII)
- Centralised Authorisation Procedure:
  - Safety Assessment by European Food Safety Authority
- Generic authorisations replace individual authorisations
- EU Positive List of authorized novel foods to be established by 1 January 2018



- Engineered nanomaterials require authorisation before being used in food
- Applicants need to demonstrate the scientific appropriateness of the test method [Article 10.4]
- EU legal definition of engineered nanomaterials is now in the Novel Food Regulation [Article 3.2.f]

(f) 'engineered nanomaterial' means 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.

Properties that are characteristic of the nanoscale include:

(i) those related to the large specific surface area of the materials considered; and/or

(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

Replaces the same definition currently in Regulation (EU) 1169/2011 Food Information to Consumers

- The application shall include (among several points)

*When test methods are applied to engineered nanomaterials [...] an explanation shall be provided by the applicants of their **scientific appropriateness for nanomaterials** and, where applicable, of the **technical adaptations or adjustments** that have been made in order to respond to the **specific characteristics of those materials**. [Article 10.4]*

- Around 150 completed applications 1997-2015
- Around 60 current applications
- Around 300 notifications 1997-2016, following Article 5 of (EC) No 258/97 (Substantially equivalent to existing foods or food ingredients)

## Applications under Regulation (EC) N° 258/97 of the European Parliament and of the Council

With regard to genetically modified foods and food ingredients (former categories a and b of Article 1(2) of Regulation (EC) No 258/97) Regulation (EC) No 1829/2003 applies, as from 18 April 2004 (marked yellow).

Genetically modified foods and food ingredients for which the scientific assessment was finalised before 18 April 2004 pursuant to Article 46 of Regulation (EC) No 1829/2003 and therefore an authorisation has to be granted under Regulation (EC) No 258/97.

### PART 1: COMPLETED APPLICATIONS

Ref. No	Applicant	Description of Food or Food Ingredient	Initial Assessment Carried out
1	Katholieke Universiteit Leuven Laboratory of Plant Physiology B - 3001 Heverlee	<i>Stevia rebaudiana</i> (plant and dried leaves)	Hoge Gezondheidsraad RAC - Esplanadege verdieping Pachecolaan 19 bus B - 1010 Brussel
2	Belovo srl Zone industrielle, 1 B - 6600 Bastogne	Phospholipides from egg yolk	Hoge Gezondheidsraad RAC - Esplanadege verdieping Pachecolaan 19 bus B - 1010 Brussel

## NOTIFICATIONS PURSUANT TO ARTICLE 5 OF REGULATION (EC) N° 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

With regard to genetically modified foods and food ingredients which do no longer fall under the scope of Regulation (EC) No 258/97 (former category b of Article 1(2)) see register pursuant to Article 28 of Regulation (EC) N° 1829/2003 as from 18 April 2005 (marked yellow)

	Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
1	AgrEvo UK Limited Chesterford Park Saffron Walden UK - Essex CB10 1XL	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	"Report on oil from a genetically modified (GM) glufosinate ammonium tolerant oilseed rape" (ACNFP) <sup>1</sup> (UK)	9 June 1997	24 June 1997
2a	Plant Genetic Systems N.V. Jozef Plateastraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all	"Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape" (ACNFP) <sup>1</sup> (UK)	10 June 1997	24 June 1997 again 28 July 1998



- The legal definition is different from the European Commission 2011/696/EU Recommendation
- The European Commission shall **adjust the definition of engineered nanomaterials to 'technical and scientific progress or to definitions agreed at international level'** [Article 31]

## Updated European regulation spells uncertainty for food nanomaterials

22 February 2016 Andrew Williams

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The head of the industry association representing the European nanotechnologies sector has broadly welcomed amendments to an EU-wide regulation governing nanomaterials in food, but warns that questions over the exact definition of nanomaterials could lead to continued uncertainty.

The updated regulation classes any food as a nanomaterial if more than half of its constituents are nano-sized.



Under the new regulation, producers will need to submit new nanomaterials to the European Food Safety Authority for assessment © Shutterstock

David Carlander, director general at the Nanotechnology Industries Association, admits that while it is possible that the development and use of nanomaterials in food will be 'somewhat hampered' by the updated novel foods regulation, he believes that clearer requirements on what is required from producers means that uncertainties are reduced. In the long run this may actually increase the use of nanomaterials in foods. 'However, the complications and difficulties in using the definition of a nanomaterial are still not fully understood, and therefore we are still likely to see uncertainties on practical aspects of nanomaterials in the novel foods regulation,' he adds.

[<http://www.rsc.org/chemistryworld/2016/02/european-regulation-nano-materials-food>]

STATUS	APPLICANT	SUBJECT	PETITIONER	PUBLISHING DATE
In progress	EFSA	Public consultation on the Guidance for risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1 on human and animal health		
Finished	Spain	Request for the evaluation of active substance: <b>Selenium nanoparticles</b>	Samtack SL	12/01/2018
Finished	EFSA	2016 Annual report of the <b>Nanotechnology Network</b>		16/12/2016
In progress	EFSA	Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed		
Finished	EFSA	2015 Annual report of the <b>Nanotechnology Network</b>		11/01/2016
Finished	Germany	Request for a scientific opinion on the <b>presence of plastic microparticles and nanoparticles in food, with particular focus on seafood</b>		23/06/2016
Finished	EFSA	2014 Annual report of the <b>Nanotechnology Network</b>		19/02/2015
Finished	The Netherlands	Request for the evaluation <b>of Zinc oxide nano particles</b>	BYK Chemie GmbH	02/03/2016
Finished	The Netherlands	Request for safety evaluation of <b>zinc oxide, nano particles for use as an additive in plastics</b>	TNO Triskelion on behalf of Umicore Zinc Materials	13/04/2015
Additional data request	Spain	Request for safety evaluation of Nano-Hexadecyltrimethylammonium Bromide modified Montmorillonite Organoclay for use as additive in plastics	Itene	
Finished	United Kingdom	Request for the evaluation of additive : <b>copolymer in Nanoform</b> of methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl acrylate, butadiene	Keller and Heckman LLP on behalf of Arkema France	17/02/2015
		Request for the evaluation of Additive : <b>Copolymer in nanoform</b> of ethyl acrylate, methyl methacrylate, butadiene, styrene and either not crosslinked or crosslined with divinyl benzene or 1,3-butanediol dimethacrylate	Keller and Heckman LLP on behalf of Arkema	16/04/2014

STATUS	APPLICANT	SUBJECT	PETITIONER	PUBLISHING DATE
Finished	EFSA	CFT/EFSA/FEED/2012/01: Inventory of food additives/food contact materials/feed additives applications in the area of nanotechnologies.		17/07/2014
Not accepted	Spain	Submission of documentation by the company Nanobiomatters Industries S.L. in order to assess the safety of the substance 02Block®4x4C1,33, intended to come into contact with food.	NanoBioMatters Industries S.L.	
Finished	EFSA	Annual report of the EFSA Scientific Network for Nanotechnologies in food and feed safety 2012		05/12/2012
Finished	EFSA	Annual report of the EFSA Scientific Network for Nanotechnologies in food and feed safety 2013		13/12/2013
Finished	United Kingdom	Titanium nitride, nanoparticles		28/03/2012
Finished	EFSA	Public consultation on: Guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed		10/05/2011
Finished	EFSA	Establishment and operation of the EFSA Scientific Network for Nanotechnologies in food and feed safety		15/02/2012
Finished	European Commission - DG SANCO	Guidance on risk Assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food, feed, and pesticides		10/05/2011
Finished	European Commission - DG SANCO	Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment		05/03/2009
Finished	European Commission - DG SANCO	Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment		05/03/2009
Finished	European Commission - DG SANCO	Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment		05/03/2009
Finished	Germany	Titanium nitride, nanoparticles	Fraunhofer Institut	16/12/2008

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