


Bioagricert srl - Organismo di controllo e certificazione		
	OPERATOR DECLARATION - NANOMATERIALS AND NANOTECHNOLOGIES – IFOAM STANDARD 2014	Master 260 Rev. 01
Red. RS	Ver. RAQ	Approvazione CC 30-03-2016

The operator is committed to quickly communicate any change of information contained in this form

COMPANY		BAC code	
Address			
Country			

Operator declaration (Ifoam - 7.3.7 Intentional manufacture or use of nanomaterials in organic products is prohibite)	
Name of Operator certified	
Address of Operator	

Kind of operations (Please specify the type of activity by placing an X in the box of interest)	Production	Livestock	Aquaculture	Processing	Production of inputs material

I declare that organic products was produced/manufactured without Intentional use of Nanomaterials and Nanotechnologies (7.3.7)

Based on the evidence in my possession (MSDS – Material safe data sheet; Labels and technical doc of products/equipments; Manufacturer declaration)
I declare that organic products was produced/manufactured with:

Control Points	Please answer YES/NA	Nanomaterials Status	If YES, Please specify the evidence
2.3.5 - 7.2.1 Agricultural inputs such as growth promoters, pesticides and fertilizers		Free of nanomaterials	
2.3.5 - 7.2.1 - Nutritional supplements, food additive, processing aids (Ifoam standard TABLE 1) and non-organic raw materials		Free of nanomaterials	
7.3.7 - 7.3.8 - Equipment surfaces and utensils that might come into contact with organic products shall be free of nanomaterials, unless there is verified absence of contamination risk.		Free of nanomaterials and have not been treated with nanomaterials	
2.3.5 - 7.5.1 - Packaging materials, and storage containers, or bins		Free of nanomaterials and have not been treated with nanomaterials	

Additional declaration:
Moreover, I declare that No nanomaterials and Nanotechnologies have been used/are used in the production and processing of conventional product.


Operator's Commitment	I undertake to inform Bioagricert immediately if this declaration is modified, or if any information comes to light which would undermine its accuracy. All evidences referring this declaration will be provide to Bioagricert if requested and will be provide to Bioagricert inspector during the inspection.
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The undersigned takes responsibility for the accuracy of this declaration

Date, _____ Place _____

Signature and stamp _____

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Ifoam – 2014

Definition of Nanomaterials:

substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (*approximately 1-300 nm*) because of very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition.

Ifoam requirements – 2014

2.3.5	The use of nanomaterials is prohibited in organic production and processing, including in packaging and product contact surfaces. No substance allowed under this standard shall be allowed in nano form.
7.2.1	All ingredients used in an organic processed product shall be organically produced except for those additives and processing aids that appear in Appendix 4 . Regional or other exception <i>In cases where an ingredient of organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic raw materials, provided that:</i> <i>a. they are not genetically engineered or contain nanomaterials</i>
7.3.7	Intentional manufacture or use of nanomaterials in organic products is prohibite
7.3.8	Equipment surfaces and utensils that might come into contact with organic products shall be free of nanomaterials, unless there is verified absence of contamination risk.
7.5.1	Operators shall not use packaging material that may contaminate organic products. This includes reused bags or containers that have been in contact with any substance likely to compromise the organic integrity. Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, fumigant, or nanomaterials are prohibited.

IFOAM Position Paper - Nanotechnologies & Nanomaterials - Approved by the IFOAM World Board on April, 15, 2011

Concerns Regarding the Use of Nanotechnologies

Nanotechnology is a field of research and development and has various commercial applications in the food and agricultural sector, such as in:

- manufacture of agricultural inputs such as growth promoters, pesticides and fertilizers;
- nutritional supplements and food additives;
- equipment used for food processing, which enter into contact with food;
- food packaging; and
- surface treatments

At the moment, in most countries, nanomaterials are not subject to any specific regulation and therefore are not differentiated from the non-nano version of the same materials when it comes to safety testing, regulations and labeling.


Guidance for Organic Operators and Organic Standard Owners

Manufactured nanomaterials are intentionally transformed in new and novel ways that renders them unnatural or 'synthetic' by most common forms of understanding. As such, they should be considered as inputs excluded from the organic method, even if they are identical in name and chemical composition to natural and permitted substances and materials.

IFOAM considers that the use of nanotechnology and nanomaterials in food and agriculture is not compatible with the Principle of Care, which calls on us to manage organic systems in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment and to reject unpredictable technologies.

Hence IFOAM recommends that organic standard setters prohibit the use of nanotechnologies on the generic level for the time being and adopt clear definitions and approaches to ensure that intentionally manufactured nanomaterials are not used in organic production and processing, including in products, in packaging and on food contact surfaces, and that contamination of organic products by such materials is avoided as much as possible. **IFOAM calls all organic producers, handlers and certifiers to refuse the use of nanomaterials and to increase their vigilance, education and information about the presence of nanomaterials in purchased inputs as these are not necessarily labeled as such and may be named as commonly accepted materials.**

However, nanomaterial contamination that is beyond the control of the organic producers should not lead to decertification.

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HOW TO VERIFY THE PRESENCE / ABSENCE OF NANO MATERIALS

Some examples and guidelines

Food and Food Contact Materials

EU Regulation 1169/2011 "on the Provision of Food Information to Consumers" establishes the principles, requirements and responsibilities governing food information to consumers, and in particular food labelling (European Parliament and Council 2011a). It contains specific provisions for nanomaterials, including a definition of "engineered nanomaterial". It specifies that besides information such as nutrition values, allergens or country of origin, all ingredients present in the form of ENMs shall be clearly indicated in the list of ingredients.

Food or vitamins, minerals and other substances containing or consisting of "engineered nanomaterials".

Some of the particulate food additives, which have been in use for years such as anticaking powders (SiO₂, CaCO₃), may contain a fraction of particles at nanoscale. Previously authorised food additives are considered as new additives if there is a significant change in production methods or in the starting materials used, or if there is a change in particle size, for example through nanotechnology. They therefore need to be (re-)evaluated and authorised.

Concerning calcium carbonate (E170) EFSA concluded that "*the available data are sufficient to conclude that the current levels of adventitious nanoscale material within macroscale calcium carbonate would not be an additional toxicological concern*" (EFSA Panel on Food Additives and Nutrient Sources added to Food 2011). The re-evaluation of silicon dioxide (E551) is expected to be completed by 2016 (European Commission (DG SANCO) 2013).

Food additives already included in the Union lists by Regulation 1129/2011 and which could be in the form of "engineered nanomaterial" in the final food are being discussed to be excluded from mandatory qualifying as "nano" in the list of ingredients

Food contact materials (FCM) and articles are covered by Regulation (EC) No. 1935/2004, however, there are special measures for specific FCMs. The revised EU "Plastic Food Contact Materials" Regulation 10/2011 (amended and corrected by Regulation 1183/2014) (European Parliament and Council 2011a) refers specifically to NMs, stating that substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications of Annex I of the regulation.

For addressing the potential risks of substances in non-plastic FCMs, such as inks, coatings and adhesives, the EC plans to issue a consultation on policy options early 2014.

Novel Food

The use of nanotechnology in food production is covered by the Novel Food Regulation.

Nanomaterials used as novel food, food additives, food supplements or in food contact materials have to undergo an EU-wide authorisation which is based on a risk assessment. Risk assessment and authorisation for the macromaterial do not cover nanoforms. Engineered nanomaterials in food have to be indicated in the list of ingredients with the word "nano" in brackets (from the end of 2014).

Biocidal Products

Biocidal Products Regulation (BPR) (EU) No 528/2014 - From 1 September 2013 the name of all (not only "active") NMs contained in biocidal products is required to be followed by the word "nano" in brackets.