

## Response to EFSA consultation on its Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health

*These comments were submitted via the electronic submission platform provided by EFSA  
(<http://registerofquestions.efsa.europa.eu/roqFrontend/consultation/doc/105>) on 4 March 2018.*

### Abstract

Avicenn welcomes EFSA Guidance on risk assessment (RA) of the application of nanosciences and nanotechnologies in the food and feed chain, part I: there are strong and legitimate societal expectations for better information, RA and risk management for nanoparticles (NP) in consumer products, especially in food and agriculture, and this guidance is a step towards the right direction.

As a citizen organisation, we do not have the required expertise to make scientific comments, however we would like to insist on the necessity for EFSA and other stakeholders to better improve nanofood RA, as well as consumer exposure assessment, and consumer safety and information regarding NP in food, which are not sufficiently guaranteed today.

Indeed, tests on food products made by French NGOs since 2016 [1] and by the French General Directorate for Competition Policy, Consumer Affairs & Fraud Control (DGCCRF) since 2017 [2], have shown that manufacturers do not properly label food products that yet do contain NP, thus violating FIC Reglementation No 1169/2011, in spite of safety red flags and calls for stopping the massive use of NP in food, starting with TiO<sub>2</sub> and SiO<sub>2</sub> NP, coming not only from NGOs but also from researchers [3].

So far, proper RA and risk management measures have not been taken before marketing, in defiance of the laws and the precautionary principle. Avicenn, as a watchdog and conveyer of the questions, concerns & propositions from NGOs and citizens, will therefore support all the efforts aiming at improving consumer information and protection, for which a proper RA is necessary.

Without the European-wide nano register that the European Commission has refused to create, some relevant data for RA are hard to collect, and traceability of nanomaterials is not ensured. But in the last weeks, DGCCRF announced that they will continue their market investigations, promote the implementation of controls in all European Member States, and sanction operators violating FIC regulation. A major French consumer organization also filed several complaints against manufacturers for failure to comply with FIC legal obligation to report [nano] on packaging [4]. Meanwhile, a growing number of brands and distributors are removing TiO<sub>2</sub> NP (and/or E171) from their products: William Saurin, Mars, Lutti, Verquin, Saint Lucia, Picard, Manufacture Cluizel, Motta, Malabar, Carrefour, Leclerc, Auchan, Systeme U, and more are yet to come [5].

[1] Cf.

- <http://veillenanos.fr/wakka.php?wiki=2016JuinEnqueteApeNanoAlimentation>
- <http://www.60millions-mag.com/kiosque/bonbons-gateaux-stop-aux-nanoparticules>

- <https://kiosque.quechoisir.org/magazine-mensuel-quechoisir-566-fevrier-2018>
- <https://www.foodnavigator.com/Article/2018/01/23/Four-manufacturers-face-Paris-High-Court-legal-complaint-over-undeclared-nanoparticles>

[2] Cf. <https://www.economie.gouv.fr/dgccrf/controle-presence-nanoparticules-dans-produits-alimentaires-et-cosmetiques-par-dgccrf>

[3] Cf. Among other scientific publications :

- <https://www.nature.com/articles/srep40373>
- <https://particleandfibretoxicology.biomedcentral.com/articles/10.1186/s12989-017-0202-8>
- See more : <http://veillenanos.fr/wakka.php?wiki=NanoAlimentationRisques>

[4] Cf. <https://www.quechoisir.org/action-ufc-que-choisir-nanoparticules-dissimulees-9-plaintes-de-l-ufc-que-choisir-contre-des-fabricants-de-produits-alimentaires-et-de-cosmetiques-n50840/>

[5] See the green list compiled by Agir pour l'Environnement:  
<https://infonano.agirpourenvironnement.org/liste-verte>

## Section 122

(lines 480-482) : « In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number–size distribution threshold of 50% may be replaced by a threshold between 1 and 50% »

→ we were told that this possibility could disappear in the coming revised recommended definition ; this would be very damaging and we hope that the 50% threshold will be lowered, to be replaced by a threshold that should not exceed 10% (as a reminder, SCENIHR proposed 0,15% in 2010:  
[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenih\\_r\\_o\\_030.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_030.pdf))

## Section 123

we approve that this Guidance is applicable to assess materials whose particles median sizes are significantly greater than 100 nm but for which « a small fraction (<50%) is always expected to be present with at least one dimension below 100 nm » (lines 557-560)

## Section 421

We would like to add one parameter to the listed requested parameters (where relevant): the function(s) of the material (e.g, the expected properties for which a company would want to use it). This information is key to risk/benefits analysis.

## Section 422

Given the results of the tests made in France by consumer watchdogs on food products (see above), safety of TiO<sub>2</sub> (E 171), SiO<sub>2</sub> (E551) and other food additives must be further investigated, not only via documentary analysis and reviews of the literature but also via real tests made on real marketed products (not only a small sample).

## Section 63

When it comes to pointing out the potential risks of nanomaterials, we often hear, rightly, "be careful, do not generalize". Regarding grouping/read-across, the same precaution is needed: scientific knowledge is far too embryonic at that stage to "generalize" safety assumption from one nanomaterial to another.

## Conclusion

2480-2483: "Particularly for the fraction of particles in the size range 1 nm – 100nm, the fraction should be specified, e.g. > 10 % taking in account the measurement uncertainties of available methods. The SC recommends that such a threshold, be established for controls or labelling enforcements. "

We advocate for a threshold that does not exceed 10% (as a reminder, SCENIHR proposed 0,15% in 2010: [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenih\\_r\\_o\\_030.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_030.pdf))

2484-248 : "Currently, there is no agreed definition of nanopesticide (see Appendix E). This is needed to identify any relevant active substances and formulations that may be required to undergo nanospecific safety assessment."

We strongly approve this statement.

3633-3636 : The French register R-nano and agricultural professionals actually indicate nanosized co-formulants, introduced to modify the mode of action of the active ingredient.

3640-3644 : We advocate for a definition whose threshold and limits in number and in size are established in relation to their specific properties (for example systemic capacity = crossing or not the plant walls, resistance to leaching by the rains, duration of effectiveness = remanence...)

3921-3922 : We strongly support the following bullets :

- It is advisable that a pesticide active substance or formulation should be considered within the scope of this Guidance if it is: o in the form of a nanoparticle as such (neat or surface modified), or is contained in a nanoparticle carrier; o in the form of nanosized droplets in an emulsion, or in solid lipid particles; o nanoencapsulated in a natural or synthetic polymer shell
- Risk assessment of a nanopesticide should consider both the individual components (the active substances and co-formulants), as well as all the components together that form the nanopesticide entity.
- For nanopesticide active substances and formulations, the likelihood and extent of the absorption through skin, lung, and gastrointestinal tract (if relevant) should be determined whilst mimicking the potential exposure scenarios, giving due considerations to the nanoaspects.