



3rd Expert Group on Regulation (EU) No 1169/2011 on the provision of food information to consumers

Short minutes of the meeting held on April 12th 2013 in Brussels

Topic: Preparation of a Commission Delegated Regulation on the adaptation of the definition of 'engineered nanomaterials' laid down in Regulation (EU) No 1169/2011 on the provision of food information to consumers

The Commission (DG SANCO and the Joint Research Centre) and representatives from the following Member States were present: AT, BE, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LU, LV, NL, RO, SE, SI, UK. Croatia, candidate country at the time, was also present.

Background:

This was the 3rd meeting of the Expert Group on the provision of Food information to consumers and the 3rd time that the adaptation of the 'engineered nanomaterials' definition was discussed.

Meeting:

Following the discussion of the 2nd meeting, the Commission outlined the main elements of the revised adaptation of the definition as follows:

- Coverage of newly authorised food additives only (i.e. exclusion of food additives **already** authorised prior to the establishment of the Union list referred to in Regulation (EC) No 1333/2008, e.g. silicon dioxide);
- **Set 50% as the threshold value in the particle number based size distribution** and indicate that this threshold should be lowered in the future following technological developments as regards detection methods;
- Introduce a definition of 'manufactured material' which is defined as 'material not occurring in nature' and link it with the definition of 'substances which occurring in nature' to be found in Regulation (EC) No 1907/2006 (REACH Regulation);
- Limit the concept of 'engineered nanomaterials' to **'intentionally manufactured' only**.

Overall, the MSs supported the general approach, as presented.

SPECIFIC ISSUES:

- **Coverage of only new food additives:**
This view was supported by some MSs, others expressed serious reservations because it would reduce the level of consumers' information, and others questioned whether there is a need to explicitly refer to food additives. The Commission explained the rationale behind the proposed wording.
- **The number size distribution threshold set at 50% - possibility to lower it in light of technological developments:**

Certain MSs asked the Commission the reasons for adapting the threshold from 10% in the previous proposals to 50%. The Commission explained that in view of the



absence of detection methods to quantify particle size distribution below 50% and also taking into account previous discussions, it would be extremely difficult (even impossible) to detect and determine such value. However, the 50% threshold should be reconsidered in light of technological developments. This should be reflected in a recital in the delegated act. The JRC supported the Commission's rationale.

Aiming to ensure enforcement, the majority of the MSs supported the 50% threshold given the current availability of detection methods.

- **Inclusion of fullerenes, graphene flakes and single wall carbon nanotubes below 1nm as provided in the Commission Recommendation**

The Commission explained that in light of the previous discussions, it proposes to explicitly state that fullerenes, graphene flakes and single wall carbon nanotubes below 1nm will be considered as 'engineered nanomaterials', in accordance with the Commission Recommendation, although for the time being there are no food applications of these substances. The proposal was supported by the MSs.

- **Alternative proposal (explicit reference to 'solid particles' + intentionally manufactured) put forward by the Commission during the meeting**

The Commission invited the members of the Expert Group to consider the following alternative proposal which had been discussed in the meeting of 6 March 2013. The alternative proposal makes an explicit reference to **solid particles** and includes a definition of intentionally manufactured. This proposal would make it clear that milk and mayonnaise are excluded from the scope. Finally, in support of this proposal, the Commission also referred the Expert Group members to the Commission Staff Working Paper accompanying the Commission Communication on the Second Regulatory Review on Nanomaterials (dated 3.10.2012, SWD(2012)288 final) which **clarifies that nano-emulsions do not match the EU definition of 'nanomaterials'** as laid down in the Commission Recommendation 2011/696/EU. Therefore, micelles are not covered by the Commission Recommendation. Overall, MSs seemed open to this alternative suggestion.

Finally, the Commission explained that carriers and substances which are not food additives but are used in the same way and with the same purpose as carriers are excluded from the obligation to be labelled in the list of ingredients and therefore they are not relevant for the definition of 'engineered nanomaterials'.

OTHER COMMENTS:

- **Review of the Commission Recommendation on the definition of 'nanomaterial' - 18 Oct. 2011**

The Commission gave a short presentation on the issue. It also informed the members of the Expert Group that the Commission Recommendation will be reviewed in 2014.

- **Consultation of stakeholders:**

The Commission informed the members of the expert group that on 26 April 2013, the Commission will inform the Advisory Group on the Food Chain and Animal and



Plant Health on the developments concerning the adaptation of the definition of 'engineered nanomaterials' in the FIC Regulation.
In addition, a **special Working Group of the Advisory Group** will be convened for 22 May 2013 to discuss more in detail with stakeholders.