Novel foods

2008/0002(COD) - 11/10/2010 - Commission opinion on Parliament's position at 2nd reading

Out of the European?s Parliament?s 104 amendments to the Council?s position, the Commission can accept 34 of these, either in full or in part. On the other hand, it rejects 70 amendments.

As regards the amendments accepted by the Commission, they concern in particular:

- Nanotechnologies: the Commission supports the principle of a regulatory definition of "engineered nanomaterials" in order to clarify which products would require a pre-market approval under the Novel Food Regulation. This definition, based on science, must be enforceable by food business operators and Member State control authorities. Should science provide new information about the elements to be considered in the draft definition before the final adoption of the text, the Commission will submit appropriate changes to that definition to the co-legislators. The Commission agrees with the need to adapt the regulatory definition of "engineered nanomaterials" to the scientific progress and international developments through delegated acts. As regards, the labelling of nanomaterials in foodstuffs, the Commission can accept the principle of a mandatory and systematic labelling of all foods and food ingredients containing nanomaterials. This labelling requirement would apply at the level of the list of ingredients and to all food ingredients containing engineered nanomaterials covered by the above mentioned definition. The Commission considers that the labelling requirement should preferably be done within the framework of the proposal for a Regulation of the European Parliament and the Council on the provision of food information to consumers in order to provide a coherent approach to the labelling of engineered nanomaterials in all foods.
- Precautionary principle, protection of animal welfare and environmental and ethical aspects: the primary objective of the Novel Food Regulation is to ensure the food safety through a systematic EU risk assessment and authorisation procedure prior to getting market access and the free circulation of goods within the EU. However the Commission supports the inclusion, where applicable, of the objectives related to the protection of animal health, animal welfare, the environment and consumer protection.
- Traditional foods from third countries: the Commission can agree with the requirement for a 25 year period of consumption in third countries to demonstrate the history of safe food use of traditional foods from third countries. This comes in addition to the necessity to submit relevant data required to establish the safety of these foods.
- Animal testing: the Commission agrees that repetition of tests on vertebrates should be avoided as much as possible. Therefore, the possibility for an applicant to refer to the results of animal test studies made by a prior applicant against financial compensation can be provided, including when data protection has been granted. However, such possibility does not mean that the prior applicant has the obligation to grant access to its data in all cases.
- Adaptation to the Lisbon Treaty: as regards the adaptation of the definition of "engineered nanomaterials" to scientific and technical progress and to definitions agreed at international level, the Commission considers that the recourse to the "ordinary legislative procedure" for its revision would prevent this definition to reflect the best state of science and can agree with its revision through delegated acts. As regards the modalities for the delegation and revocation of power to the Commission for adopting delegated acts and for objections to delegated acts, the Commission can support the EP amendments (as regards the duration of the delegation, the modalities for the revocation of the delegation and the modalities for raising objections to delegated acts).

Amongst the amendments rejected by the Commission, the following may be highlighted:

- Cloning: following extensive discussions at both EP and Council levels, the Commission considers that the Novel Food Regulation is not the appropriate legal frame for addressing globally the cloning issue for food production. In particular, the production and marketing of products other than food (reproductive materials) cannot be covered by the Novel Food Regulation which deals exclusively with the pre-market authorisation of food products.
- Nanotechnologies: the Commission does not agree with the EP assumption that the general methodology used for the risk assessment of foodstuffs would not be applicable for that of nanomaterials in food and that, until specific test methods are developed, no food with nanomaterials should be put on the EU market. The Commission is committed to only approve the marketing of food containing nanomaterials for which the food safety has been established.
- Data protection: the Commission considers that, in dully justified cases concerning genuine innovative products for which data protection has been granted, these novel foods could benefit from an individual authorisation and 5-year period of exclusivity on the EU market. As only generic authorisations are granted through Article 7 of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, the authorisation procedure with data protection clearly derogates from the common authorisation procedure and shall therefore be kept separate in the Novel Food Regulation and therefore amendments the EP amendments on this issue cannot be accepted. The synchronisation of the data protection periods which may be granted both under Novel Food Regulation and under Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods would provide an improved benefit for the placing of the market of such products. However, as the data to be assessed are under both Regulations are of totally different nature and have to be examined by different EFSA panels, the matching of the periods of data protection cannot be ensured in practice and therefore amendments regarding this cannot be accepted.
- Adaptation to the Lisbon Treaty: the Commission considers that the possibility to adopt further criteria to clarify the definitions related to sub-categories of novel foods and to traditional foods from third countries should be kept. Its removal implies that it could be done only through the "ordinary legislative procedure". The Commission considers that the determination of these criteria is a measure aimed at supplementing non essential elements of the Regulation, which should be adopted through delegated acts.

Other issues: several amendments on other issues (such as the procedures applicable for determining the status of a food, the setting up of EU lists of authorised novel foods, the rules for the transitional period or the update of Regulation n° 1331/2008 on the common authorisation procedure) do not provide further improvements to the text and thus should be rejected.