EUROPEAN COMMISSION

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Mr Jean-Pierre BEL
President of the Sénat
Palais du Luxembourg
15, rue de Vaugirard
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Dear President,

The Commission would like to thank the Sénat for its Reasoned Opinion on the proposal for a regulation of the European Parliament and of the Council on novel foods {COM(2013) 894 final}.

As to the observations made by the Sénat regarding the compliance of the proposal with the principle of subsidiarity, the Commission would like to put forward the following clarifications:

The principal objective of the proposal is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

To authorise a new novel food, the proposal foresees a centralised authorisation procedure which would take 18 months whereas the current decentralised procedure takes on average 3 years.

In the current system under Regulation (EC) No 258/97[1]*, the Member States are not at equal footing as the application to place the novel food on the market is addressed to the Member State of the applicant's choice, which is in charge of verifying the application and carrying out the initial safety assessment.*

The procedure as proposed in the proposal would reduce the costs and administrative burden for food business operators. It would also reduce the administrative burden of the Member States as they no longer have to make the first safety assessment.

The Member States would be fully involved in the decision-making process. In fact, although all the applications would be addressed to the Commission and all the safety assessments would be carried out by the European Food Safety Authority (EFSA), the Member States would be informed of all the steps of the procedure by the Commission.

[1] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

The authorisation decisions would be taken by the Commission on the basis of the vote in the Standing Committee where all Member States are represented. This way the centralised procedure would guarantee that all novel foods submitted to the authorisation procedure would be evaluated for safety in an equal way by EFSA with positive implications regarding the objective to protect human health and consumers' interests.

Today in the current system a Commission decision is only taken in the case where one or more Member States have submitted objections.

In addition, the current system of individual authorisation would be replaced by a generic authorisation. In accordance with the provisions that are in place today, authorisation is granted to the applicant (individual authorisation). Furthermore, another applicant could notify to the Commission placing on the market of food which is substantially equivalent to the authorised food. The present proposal would, by removing this simplified procedure and instead foreseeing a generic authorisation, significantly reduce the administrative burden for the Member States, food business operators and the Commission.

For the reasons mentioned above, the objectives of the legislation on novel foods could be better achieved and the administrative and financial burdens to the parties involved could be reduced by the centralised procedure as proposed in comparison with the current procedures in place.

The Commission hopes that these clarifications address the concerns and issues raised by the Sénat and looks forward to continuing our dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President