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Committee on Sanitary and Phytosanitary Measures

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NEW EU LEGISLATION ON NOVEL FOODS

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 29 February 2016, is being circulated at the request of the Delegation of the European Union.

1 THE REGULATION

1.1. Regulation (EU) 2015/2283 on novel foods was adopted on 25 November 2015. The new Regulation makes it easier for food businesses to bring new and innovative foods to the EU market, while maintaining a high level of food safety for European consumers. The new rules will apply from **1 January 2018**.

1.2. The general criteria for the definition of a novel food remain **unchanged**: novel foods are foods and food ingredients not consumed in the European Union to a significant degree before 15 May 1997 (i.e. before the entry into force of the original Regulation on novel foods¹).

1.3. The **main improvements** introduced by the new Regulation are the following:

- a. **The authorization procedure** will be streamlined by centralising authorizations at EU level and granting generic authorizations. The European Commission will process all the applications and will grant the authorizations, which will be generic. As a result, all food business operators will be able to place an authorised novel food on the market, as long as its conditions for use and labelling requirements are respected.
- b. **Safety evaluations** will be carried out by the European Food Safety Authority (EFSA). The European Commission will consult EFSA on the applications and base its authorization decisions on the outcome of EFSA's evaluations.
- c. **Efficiency and transparency** will be improved by establishing deadlines for the safety evaluation and authorization procedure, thus reducing the overall time required for approvals.
- d. **Faster and more proportionate safety assessments** for traditional foods from third countries. To facilitate trade in novel foods which are traditional foods in countries outside the European Union, the new Regulation introduces a simplified assessment procedure. If the traditional food in question can historically be demonstrated to be safe and there are no safety concerns raised by EU member States or EFSA, it will be allowed to be placed on the EU market on the basis of a notification from the applicant.
- e. **Promotion of innovation** by granting an individual authorization for five years based on protected data. Specific data protection provisions are included in the new Regulation.

¹ Regulation (EC) No 258/97.

2 EFSA GUIDANCE

2.1. Following the adoption of the new Regulation on Novel Foods, the European Commission requested EFSA to update and develop **scientific and technical guidance** for the preparation and presentation of applications for authorization of novel foods and for notifications of traditional foods from third countries.

2.2. On 18 February 2016, EFSA launched an **open consultation** on two draft guidance documents. **The first document** specifies the requirements that applicants need to meet when submitting applications for the authorization of novel foods.

2.3. **The second document** addresses the preparation and presentation of a notification for authorization of traditional foods from third countries. This document aims to assist applicants in preparing and presenting the data on the history of safe food use in a third country.

2.4. The EFSA public consultation, to which all interested parties are invited to submit written comments, is open until 21 April 2016. Further information on the public consultation is available at the following EFSA's website: <http://www.efsa.europa.eu/en/press/news/160218b>.

2.5. EFSA also invites stakeholders to a **meeting on the two draft guidance documents** to be held on 11 April 2016 in Brussels. Registration for the meeting is open until 14 March 2016. The meeting gives stakeholders, international organisations, academic institutions, NGOs and representatives of the private sector the opportunity to exchange views with EFSA experts on both documents. More information on the event is available at following EFSA's website: <http://www.efsa.europa.eu/en/events/event/160411>.

2.6. More information about novel foods is available on the European Commission's website: http://ec.europa.eu/food/safety/novel_food/index_en.htm.
