USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 2/5/2014
GAIN Report Number: E14011

EU-28

Post: Brussels USEU

Proposal for a New Novel Foods Framework Regulation

Report Categories:
FAIRS Subject Report
Approved By:
Cynthia Guven
Prepared By:
Hilde Brans

Report Highlights:
On December 18, 2013, the European Commission presented its long-awaited proposal for a revision of the current Novel Foods Regulation 258/97. An earlier attempt to revise the current novel foods rules failed in March 2011when the European Parliament and Council could not reach agreement on how to regulate food from animal clones. Separate legislation on animal cloning was presented on the same day as the novel foods proposal. The main objectives of the novel foods proposal are to introduce an EU centralized authorization system, an EU positive list of novel foods, a simplified authorization procedure for traditional foods from third countries and to update the current provisions in line with new technological and scientific developments. This report provides an overview of the main changes to the current Novel Foods Regulation.

Proposal for a New Novel Foods Framework Regulation

On December 18, 2013, the European Commission presented a long-awaited proposal for a revision of the current Novel Foods Regulation 258/97. An earlier attempt to revise the rules on novel foods failed in March 2011 when the European Parliament (EP) and Council could not reach agreement in conciliation[1] over the amendments on animal cloning introduced by the EP. Although the EP and Council disagreed on introducing mandatory labeling requirements for all foods from animal clones and offspring, they did agree on the need for separate legislation for animal cloning outside of the scope of the novel foods regulation. The Commission presented the proposals on animal cloning on the same day as the novel foods proposal in order to avoid the introduction of any cloning-related amendments to the latter. For more information on animal cloning see our website http://www.usda-eu.org/topics/animal-cloning/.

With this new proposal, the European Commission actually picks up where the EP and Council left off in March 2011. Most of the provisions in the new proposal were already agreed upon during the EP and Council negotiations on the previous proposal for a revision. The main objectives of the novel foods proposal are to replace the current mutual recognition system with an EU centralized authorization procedure, to establish a simplified authorization process for traditional food with a history of safe use from third countries, the establishment of an EU list of authorized novel foods and to update the current provisions for novel foods in line with new technological and scientific developments.

This report provides an overview of the main changes to the current Novel Foods Regulation.

New Definition of a "Novel Food"

Article 2.2(a) of the draft regulation defines "novel food" as any food not used for human consumption to a significant degree within the EU before May 15, 1997. This includes in particular:

- Food to which a new food production process not used before May 15, 1997, is applied, changing the composition and structure of the food
- Food containing or consisting of "engineered nanomaterials" as defined in the "Food Information to Consumers" Regulation 1169/2011
- Vitamins, minerals and other substances produced with a new production process or containing or consisting of engineered nanomaterials
- Food used exclusively in food supplements before May 15, 1997, intended to be used in foods other than food supplements

[1] Conciliation is the final phase of the Co-decision process wherein representatives from the Council and European Parliament along with the relevant Commissioner work, within a prescribed timeframe, to agree on a 'joint text' or compromise on a proposed regulation

- "Traditional food" from a third country, derived from primary production, with a history of safe food use (25 years) in a third country.

Union List of Novel Foods

The European Commission will establish and update a "Union list of novel foods". Only novel foods included in the Union list will be allowed on the EU market. The list will also specify the conditions of use and indicate, where applicable, the end date of the data protection (see "Data Protection"). A novel food will only be approved for use and entered into the Union list if it does not present a risk to public health, is not nutritionally disadvantageous when replacing a similar food and is not misleading to the consumer. Already authorized novel foods will automatically be included in the Union list.

New Authorization Procedure for Novel Foods

A new EU centralized authorization procedure would replace the current mutual recognition system where applications for a pre-market authorization must be submitted to an individual Member State's food assessment body which then evaluates the application. The initial assessment report is sent to the Commission who then circulates it to all Member States for comments and objections. If an objection is raised, the Commission asks the European Food Safety Authority (EFSA) to carry out an additional assessment. Based on EFSA's safety assessment, the Commission then takes an authorization decision. Authorizations under the current system are applicant-linked (see "Data Protection").

One of the main objectives of the proposal is to establish a faster and more efficient authorization procedure. Article 9 of the draft novel food regulation sets out a new centralized authorization procedure. The new procedure would start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission screens the applications and may ask EFSA to deliver a scientific opinion. EFSA would have to deliver its opinion within nine months from the date of receipt of a valid application. Within nine months from the date of publication of EFSA's opinion, the Commission then submits a draft "implementing act" authorizing the novel food to a regulatory committee. The current role of the Member States' national authorization bodies is eliminated under the new authorization procedure.

Data Protection

Under the current rules, novel food authorizations are "individual" authorizations granted to an applicant. Other applicants may notify the Commission that they want to market a product that is "substantially equivalent" to an already authorized novel food. A simplified authorization applies if the claimed equivalency can be substantiated by scientific evidence.

Under the new rules, novel food authorizations will be generic. Generic authorizations would avoid the resubmission of a new application by other companies for the same novel food. Once a novel food is authorized and entered into the Union list, all companies can sell it. However, Article 24 of the draft regulation provides for a 5-year data protection under certain conditions. On an applicant's request and supported by verifiable documentation, newly developed scientific evidence and proprietary data may not be used for the benefit of another application for a period of maximum 5 years after the novel food has been authorized.

Data protection will not apply to traditional foods from third countries.

Nanomaterials

Nanomaterials intended for food use need a novel food authorization. The definition of "engineered nanomaterials" however is set out in Article 3 (t) of the EU's "Food Information to Consumers" Regulation 1169/2011. The Commission is developing test methods to assess the safety of engineered nanomaterials.

Labeling Requirements

Novel foods will be subject to the EU's "Food Information to Consumers" Regulation 1169/2011 which enters into force in December 2014 and other relevant labeling requirements set out in EU food law. For every authorized novel food, additional requirements may be established for the description of the food, its source and its conditions of use.

Traditional Food from Third Countries

The draft novel foods regulation introduces a new simplified procedure to allow the marketing of traditional foods from third countries. A traditional food may be allowed on the basis of a notification if a history of safe food use can be demonstrated by the food business operator. A history of safe use means that the food has been consumed for at least 25 years as part of a normal diet within a large part of the third country's population. If the Member States or EFSA do not present reasoned safety objections based on scientific evidence, the food may be included in the Union list. In case a reasoned safety objection is presented, EFSA will be asked to carry out a safety assessment but a simplified EU authorization procedure, i.e. with shorter deadlines, will apply. Traditional foods from third countries will only be considered for inclusion in the Union list if they are derived from primary production. Articles 13 through 17 of the draft regulation set out the approval procedures.

Implications for U.S. Products

Under the current rules, a novel food authorized by one Member State can in theory be marketed in all the other Member States. In practice, however, the unclear status and different categorization of a product or substance creates problems for business operators. A product or substance may be categorized as a novel food in one Member State and as a medicinal product in another Member State in which case mutual recognition does not apply. The "novel foods catalogue" published on the Commission's website is not legally binding.

The draft regulation sets out a procedure to determine the status of a novel food based on only one criterion, i.e. the date of May 15, 1997. Article 4 stipulates that food business operators should verify whether or not the food they want to market in the EU falls within the scope of the novel foods regulation. In case of doubt, they should consult a Member State and provide information to help determine to what extent the food in question was used in the EU before May 15, 1997. For cases where insufficient or no information is available, the Commission will establish a procedure involving the Commission, the Member States and the food business operators. This additional procedure based on a

historical date rather than safety seems to defeat the claimed simplification of the current rules. Also, the new regulation will not remedy the different categorization of products in the Member States.

Next Steps

The proposal has to be adopted under the ordinary legislative procedure (co-decision). Under this procedure, both the EP and Council have up to three readings to reach agreement on the proposal. Commission officials expect the proposal to be adopted in one reading but the elections for a new EP in May 2014 could slow down the process. Detailed information on the legislative procedure can be found on our website.

The novel foods proposal was notified to the WTO on December 20, 2013 (Notification G/SPS/N/EU/64). Post recommends submitting comments.