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New EU Novel Foods Regulation Adopted

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Report Highlights:
A new EU Regulation on Novel Foods was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation will apply from January 1, 2018. This report provides an overview of the main elements of the Novel Foods Regulation.

NEW EU NOVEL FOODS REGULATION ADOPTED

A new EU framework regulation 2015/2283 on Novel Foods was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Regulation 2015/2283 will repeal the current Novel Foods Regulations 258/97 and 1852/2001. Most provisions of the new Novel Foods Regulation will apply from January 1, 2018. However, detailed rules for the implementation of several provisions in the new Novel Foods Regulation still need to be adopted by the European Commission. This report provides an overview of the main elements of the new Novel Foods Regulation.

Expanded Definition

A novel food is defined as food that has been not consumed to a significant degree in the EU before May 15, 1997 **AND** falls within at least one of the 10 categories listed in Article 3 of the new regulation:

- Food with a new or intentionally modified molecular structure
- Food consisting of, isolated from or produced from microorganisms, fungi or algae
- Food consisting of, isolated from or produced from material of mineral origin
- Food consisting of, isolated from or produced from plants or their parts obtained by non-traditional propagating practices if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances
- Food consisting of, isolated from or produced from animals or their parts obtained by non-traditional breeding techniques
- Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae
- Food resulting from a new production process if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances
- Food consisting of engineered nanomaterials
- Vitamins and minerals and other substances used in accordance with Food Supplements Directive 2002/46/EC obtained by a new food production process or containing engineered nanomaterials
- Food used exclusively in food supplements within the EU before May 15, 1997, intended to be used in foods other than food supplements

An Information and Guidance Document on "human consumption to a significant degree" is posted on the Commission's website http://ec.europa.eu/food/safety/novel_food/catalogue/index_en.htm.

The Commission may decide on its own initiative or upon request by a Member State, by means of an implementing act, whether or not a particular food falls within the novel food definition. The Novel Foods Regulation does not apply to genetically modified foods, food enzymes, food additives, food flavorings and extraction solvents used in the production of foodstuffs or food ingredients.

Status & Responsibility

Article 4 of Regulation 2015/2283 puts the responsibility of verifying whether a food falls within the scope of the Novel Foods Regulation with the food business operators. In case of doubt, food business operators should consult the competent authority of the Member State where they first intend to market their product. Article 4 also provides for a consultation procedure to determine the status of a food or food ingredient. The procedural steps for this new consultation process which would include time limits and means of making the status publicly available still need to be adopted by an implementing act (examination procedure).

New Authorization procedure

Article 10 of Regulation 2015/2283 introduces a new centralized authorization procedure with fixed time limits. Under the new procedure, applications for authorizations must be submitted to the European Commission. The Commission then has 1 month to verify the validity of the application before forwarding to the European Food Safety Authority (EFSA) for a safety assessment. EFSA must deliver a scientific opinion within 9 months from the date of receipt. Within 7 months from the date of publication of EFSA's opinion, the Commission must submit a draft proposal authorizing the novel food to the Standing Committee on Plants, Animals, Food and Feed (PAFF). Authorizations will be granted through "implementing acts" (examination procedure) which means that the European Parliament will not be able to veto them. If no EFSA opinion is requested, the 7-month period starts from the date on which the Commission receives a valid application.

Applications for an authorization must include:

- Name and address of the applicant
- Name and description of the novel food
- Description of the production process
- Detailed composition
- Scientific evidence demonstrating there is no human health risk
- Analysis method(s) where appropriate
- Proposal for the conditions of intended use and specific labeling requirements or a justification why these elements can be omitted

Article 13 requires the Commission to adopt by January 1, 2018, an implementing act (examination procedure) that sets out the administrative and scientific requirements for novel food applications. The implementing act would set out rules for the content, drafting and presentation of applications, arrangements to verify the validity of an application and the type of information to be included in EFSA's opinion.

Generic authorizations will replace individual, applicant-linked, authorizations. Member States will be able to suspend or temporarily restrict the marketing and use of any novel food in case of an alleged health risk. The Commission will then examine the Member State's protective measure and take a decision.

Who Should Apply?

According to Article 3 of Regulation 2015/2283, any Member State, third country or interested party which may represent several interested parties can submit an application for authorization to the Commission.

EU Positive List

Article 6 of Regulation 2015/2283 requires the Commission to establish an EU list of authorized novel foods by January 1, 2018. The list will initially include novel foods that have already been authorized under Regulation 258/97. As of January 1, 2018, only authorized novel foods included in the positive list may be marketed in the EU. Updates (adding, removing or changing the specifications) of the EU positive list will be done through implementing acts (advisory procedure). The list would also include, where appropriate, the conditions of use, additional labeling requirements and post-market monitoring requirements.

Food from clones

Until separate legislation on cloning is adopted, food from clones but not offspring will continue to fall within the scope of the Novel Foods Regulation.

Engineered nanomaterials

Engineered nanomaterials require a novel food authorization before being used in food. Applicants will have to demonstrate the scientific appropriateness of the test methods used to test the nanomaterials for which they request an authorization. The definition of engineered nanomaterials currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation.

Traditional food from third countries

Articles 14-20 of Regulation 2015/2283 set out specific rules for "traditional foods from third countries". A new notification procedure would allow traditional foods from third countries with a demonstrated safe history of use of at least 25 years onto the EU market provided no safety concerns are

raised by Member States or EFSA within 4 months of the notification.
Notifications should include:

- Name and address of the applicant
- Name and description of the traditional food
- Detailed composition of the traditional food
- Country or countries of origin
- Documented data demonstrating the safe history of use in a third country
- Proposal for the conditions of intended use and specific labeling requirements or a justification why these elements can be omitted

If a duly reasoned safety objection is submitted to the Commission, the food will not be allowed on the EU market. In such case, the applicant may submit an application which will need to be assessed by EFSA within 6 months from the date of receipt. Within 3 months from the date of publication of EFSA's opinion, the Commission must present a draft implementing act (examination procedure) authorizing the traditional food to the Standing Committee on Plants, Animals, Food and Feed (PAFF).

Article 20 requires the Commission to adopt by January 1, 2018, an implementing act (examination procedure) that sets out the administrative and scientific requirements for applications for authorization of traditional foods from third countries. The implementing act would set out rules for the content, drafting and presentation of the notification/application, arrangements for verifying the validity of notifications/applications, arrangements for submitting duly reasoned safety objections and the type of information to be included in EFSA's opinion.

Data Protection

As a general rule, authorizations will be generic. Article 26 of Regulation 2015/2283 provides for a 5-year data protection under the following conditions:

- Newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made
- The initial applicant has exclusive right of reference to the proprietary scientific evidence of scientific data at the time the first application was made
- The novel food cannot be assessed by EFSA without the submission of proprietary scientific evidence or scientific data by the initial applicant

Transitional Measures

Article 35 of Regulation 2015/2283 sets out transitional measures for novel food authorizations. Foods that do not fall within the scope of the current Novel Foods Regulation 258/97 and are lawfully

marketed in the EU may fall within the scope of the new Novel Foods Regulation 2015/2283 in which case they will need a novel food authorization.

Implementing Acts

Detailed information on the procedure to adopt implementing acts can be found in GAIN report "How the European Union Works – A Guide to EU Decision-Making".

By January 1, 2018, the Commission needs to adopt the following implementing acts:

- Implementing act setting out a consultation procedure (Article 4.4)
- Implementing act establishing the EU positive list (Article 8)
- Implementing act setting out administrative and scientific requirements for applications for authorization of novel foods (Article 13)
- Implementing act setting out administrative and scientific requirements for notifications/applications for authorization of traditional foods from third countries (Article 20)
- Implementing act on the confidentiality of applications for updates of the EU positive list (Article 23)

Potential Effect on U.S. Exports

As there is no legal distinction between "novel" and other foods in the United States, exporters may be unaware that a food which is currently lawfully marketed in the EU may fall within one of the new categories established by Regulation 2015/2283. There may also be uncertainty about which food business should submit an application for an authorization: the food business producing novel product "X" or the food business processing product "X" or using product "X" as an ingredient.

Food and food ingredients derived from plants obtained by New Breeding Techniques (NBTs) may also fall within the scope of the new Novel Foods Regulation. Currently, the European Commission is carrying out a legal analysis of a group of NBTs in order to evaluate whether or not they fall within the scope of the EU's GMO legislation. Food and food ingredients obtained through NBTs that do not fall within the scope of the GMO legislation would need a novel food authorization if there is a significant change to the composition or structure of the food affecting its nutritional value (e.g. vitamin levels), metabolism (e.g. increased allergy risk) or level of undesirable substances (e.g. toxins).

U.S. exporters should always check with their EU importers, who are responsible for putting products that comply with EU legislation on the EU market, whether a novel food authorization may be needed.