

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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New EU Novel Food Regulation Applicable as of January 1 2018

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FAIRS Subject Report

SP2 - Prevent or Resolve Barriers to Trade that Hinder
U.S. Food and Agricultural Exports

Approved By:

Jennifer Lappin

Prepared By:

Hilde Brans

Report Highlights:

The EU's new Novel Food Regulation 2015/2283 became applicable on January 1, 2018. It introduces a new centralized authorization procedure as well as a fast-track notification procedure for traditional foods from third countries and provides for the establishment of an EU positive list. In December 2017, the European Commission published three implementing regulations establishing the EU list of Novel Foods and setting out administrative and scientific requirements for applications as regards to content, drafting and presentation.

New EU Novel Food Regulation Applicable as of Jan 1. 2018

The EU's new [Novel Food Regulation 2015/2283](#), adopted in November 2015 and published in Official Journal L 327 of December 11, 2015, became applicable on January 1, 2018. "Novel food" is defined as food that has not been consumed to a significant degree in the EU before May 15, 1997, and falling with one of the 10 categories listed in Article 3 of the new regulation such as, for example, chia seeds. An overview of the main changes is provided in [GAIN report "New EU Novel Food Regulation Adopted."](#) Regulation 2015/2283 required the European Commission to adopt by January 1, 2018, detailed rules for the implementation of the provisions detailed below:

- Establishment of the EU positive list of authorized novel foods (Article 8)
- Administrative and scientific requirements for applications for authorization of novel foods (Article 13)
- Administrative and scientific requirements for notifications/applications for authorization of traditional foods from third countries (Article 20)

EU Positive List of Novel Foods

On December 30, 2017, the European Commission published [Implementing Regulation 2017/2470](#) setting out the long-awaited list of authorized novel foods. The list currently contains novel foods that were authorized under the previous rules such as, for example, rooster comb extract and oil extracted from squids. Regulation 2017/2470 specifies the conditions of use, maximum levels and labeling requirements for each novel food. Novel foods that are not included in the list may not be marketed in the EU. Under the new rules, authorizations are generic and no longer applicant-linked. This means that any food producer can use a novel food included in the EU positive list when following the conditions and specifications set out in regulation 2017/2470.

Novel Food Applications

Article 10 of Novel Food Regulation 2015/283 introduces a new centralized authorization procedure with fixed time limits that the Commission and the European Food Safety Authority (EFSA) must respect (see [GAIN report "New EU Novel Food Regulation Adopted"](#) for detailed information). [Commission Implementing Regulation 2017/2469](#), published on December 30, 2017, sets out administrative and scientific requirements for applications as regards to content, drafting and presentation.

Traditional Foods from Third Countries

Novel Food Regulation 2015/2283 introduces a new fast-track notification procedure that allows traditional foods from third countries with a demonstrated safe history of use of at least 25 years to enter the EU market. Foods from third countries which are regarded novel foods in the EU will only qualify as "traditional foods" if they are derived from primary production. For example, juice derived from an exotic fruit not consumed in the EU before May 15, 1997, that has been part of a regular diet in a third country would qualify as a "traditional food". [Commission Implementing Regulation 2017/2468](#) sets

out administrative and scientific requirements for applications for authorizations of traditional foods from third countries as regards to content, drafting and presentation of the notification.

Related Reports

- [GAIN report “New EU Novel Food Regulation Adopted”](#)
- [EU Food and Agricultural Import Regulations and Standards \(FAIRS\) Report](#)

Useful Links

- FAS/USEU website: <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/novel-foods/>
- European Commission website: https://ec.europa.eu/food/safety/novel_food/legislation_en