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New EU Law on Novel Food Status Determination

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Report Highlights:
On April 9, 2018, a new EU law enters into force that sets out a procedure to determine the "novel food status" of a particular food. Commission Implementing Regulation 2018/456 maps out a consultation procedure that food business operators have to follow in order to verify whether or not a food they intend to market in the EU for the first time, falls within the scope of the EU's Novel Food regulation 2015/2283.

New EU Law on Novel Food Status Determination

On April 9, 2018, a new EU law enters into force that sets out a procedure to determine the "novel food status" of a particular food. Commission Implementing Regulation 2018/456 maps out a consultation procedure that food business operators have to follow in order to verify whether or not a food they intend to market in the EU for the first time, falls within the scope of the EU's Novel Food regulation 2015/2283. The EU's most common reason for rejecting imports of products in the categories dietetic food, food supplements and fortified food is the presence of unauthorized novel food ingredients and other unauthorized substances.

Context: Novel Food regulation 2015/2283, in force since January 1, 2018, defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997 (e.g. chia seeds and rooster comb extract). It required the European Commission to establish a procedure to determine whether or not a food or food ingredient is "novel." Implementing Regulation 2018/456 specifies the different procedural steps of this verification process.

Consultation Process

Food business operators are responsible for verifying whether a food or food ingredient is "novel" before putting it on the EU market. In order to verify the status of a specific food, a food business operator must submit an electronic consultation request to only one "recipient Member State," even if it intends to market the food in several Member States.

Implementing regulation 2018/456 outlines the following procedural steps:

Submitting a request: A consultation request submitted to a recipient Member State must include a cover letter, a technical dossier and supporting documentation. Food business operators must use the template provided in Annex II to regulation 2018/456 to draft the technical dossier.

Checking the validity of a request: The recipient Member State examines the validity of the consultation request (no time limit). It may set deadlines for food business operators to provide additional information and then informs the Commission and the other Member States of its final decision on the validity of the consultation request.

Conclusion on the status: Within four months of its decision on the validity of a consultation request, the recipient Member State must conclude whether the food is novel or not. If it lacks sufficient evidence to do so, it may request food business operators to provide additional information. The timeline for providing additional information is set at four months, extendable in exceptional cases to maximum eight months. When the recipient Member State reaches its conclusion on the novel food status, it will notify the food business operator as well as the Commission and the other Member States.

Notification: The recipient Member State's notification will include the name and description of the food concerned, a statement indicating whether the food is "novel, not novel or not novel only in food supplements" and the novel food category in which the food falls.

Publication: Following the recipient Member State's notification, the Commission will publish the information on its dedicated website.

Confidentiality
Food business operators may request the recipient Member State to treat certain information submitted as part of the consultation request as confidential. However, confidentiality will not apply to the name and address of the applicant, the name and description of the food and the summary of the studies provided.

U.S. Exports

Post strongly advises U.S. exporters to verify whether their products or food ingredients fall within the scope of the EU's Novel Food regulation before exporting to the EU. Products are not only checked at import but also at all further stages of marketing. Member States report infringements of EU food law through the EU's Rapid Alert System for Food and Feed (RASFF). The 2016 RASFF report shows that the main issues in the categories dietetic food, food supplements and fortified food concern unauthorized substances and unauthorized novel food ingredients.

A Novel Food Catalog is available on the Commission website. In case of doubt on the status of a specific product, U.S. exporters should work with their importers in order to submit a consultation request. The Commission will publish contact details of the Member States' competent authorities on its dedicated website by May 1, 2018.

U.S. exporters should be aware that the consultation procedure only covers how the status of a specific food is determined but does not grant authorizations. Products that receive a novel food status must still pass through the EU's Novel Food authorization procedure (for more information see GAIN report "New EU Novel Food regulation applicable since January 1, 2018").

Related Reports

- GAIN report: New EU Novel Food regulation applicable as of January 1, 2018
- GAIN report: EU-28 Food and Agricultural Import Regulations and Standards (FAIRS)
- GAIN report: Exporting food supplements to the European Union
- GAIN report: New EU Novel Food regulation adopted
- GAIN report: New EU rules on dietetic food