CLIENT ALERT

Revised EU Novel Foods Regulation Simplifies Approval Process, Increases Food Innovation, and Maintains High Food Safety Standards

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The European Parliament and the Council of the European Union (Council) reached political agreement on an updated EU Regulation for novel foods on November 16, 2015. The revised regulation would ease requirements for new and innovative foods to enter the EU market and maintain high food safety standards.

The current EU novel food regulation dates back to 1997, and a revision was deemed necessary to keep pace with scientific and technological advances. In March 2011, the European Commission and Parliament failed to reach an agreement because of ethical and safety concerns related to animal cloning. The EU Commission circulated a revised proposal in December 2013 that included bans on using and importing cloned animals and on marketing food derived from cloned animals.

The revised regulation continues to define "novel food" as food that had not been consumed in the European Union "to a significant degree" before May 1997, when the first regulation took effect. "Novel food" includes both newly developed, innovative food and food produced using new technologies and production processes, such as nanomaterials, insects, and new colorants. In addition, as mass tourism and migration boosts EU interest in foods that have not been part of traditional EU diets, novel foods increasingly include food that is regularly consumed in other parts of the world. To be approved for sale within the European Union, novel food must not present a risk to public health, must not be nutritionally disadvantageous when replacing a similar food, and must not be misleading to the consumer. The revised EU novel food regulation requires the European Commission to establish and maintain the official list of novel foods that have been approved for sale within the European Union.

According to the European Commission, the revised regulation introduces more appropriate procedures for assessing and approving novel foods for sale in the EU. In particular, the revised regulation introduces food safety assessment procedures that should help reduce the waiting period from more than three years to an average of 18 months. The revised regulation also reduces administrative burdens by replacing the current requirement that a novel food be approved by each Member State in which it is sold with a single, EU-wide authorization. As a result, once a novel food is authorized and added to the EU list, it may be sold anywhere in the EU. In addition, approvals for novel foods will no longer be company-specific, so once a novel food is approved, it is approved for all companies that wish to sell it in the EU.

Under the revised regulation, the European Food Safety Authority (EFSA) will conduct a scientific risk assessment for each novel food proposed for sale in the EU market, and the European Commission will manage the files for each novel food application, present the proposal for approval of novel foods that EFSA determines to be safe, and list all approved novel foods.

The revised regulation also enhances the transparency of the approval process and reduces the need for duplicative testing, especially on animals, by allowing any interested party to submit scientific information to the European Commission and the EFSA regarding a novel food application.

The revised EU novel food regulation still has to be formally adopted by the European Parliament and the Council before its publication in the Official Journal of the EU, after which it will take roughly two years to be implemented.

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