



**COUNCIL OF
THE EUROPEAN UNION**



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Council agrees on new rules for novel foods

The Council today¹ approved a political agreement² on a draft regulation concerning novel foods (10754/09 + ADD 1).

The main objective of the draft regulation is to stimulate the development and placing on the EU market of safe innovative foods and to ensure a high level of food safety and of human health protection.

The new regulation includes in particular the following provisions:

¹ The agreement was reached at a Coreper meeting on 16 June 2009 and confirmed, without discussion, at the Agriculture and Fisheries Council meeting in Luxembourg.

² The United Kingdom and Greece abstained, the Commission voted against.

P R E S S

- The **authorisation procedure is streamlined** by switching to a centralised EU-level procedure. According to the Council's political agreement, all applications for the approval of novel food must be submitted to the Commission and then transmitted to the European Food Safety Authority (EFSA) for a risk assessment. The final decision to include a novel food in the EU list of authorised novel foods is made by the Commission via the committee procedure.¹ As under the existing legislation, the Council wants novel foods to be authorised only if they do not present a danger for consumers, do not mislead them and are not nutritionally disadvantageous for them.

- An accelerated authorisation procedure is introduced for **traditional food from third countries** (i.e. food derived from primary production which has been part of the customary diet for at least 25 years in a large part of the population of a third country). EFSA must give its opinion within six months (rather than nine months under the normal procedure), and the Commission is to submit any proposal for an update of the list of traditional foods within three months (rather than nine months under the normal procedure).

- The **definition of novel food and the scope of the regulation** are clarified. According to the Council's political agreement, the new regulation explicitly applies to food produced from animals obtained by a cloning technique, and the scope of the regulation is extended to food from the offspring of cloned animals. The Council invites the Commission to report on all aspects of food from cloned animals and their offspring within one year after the entry into force of the regulation and to submit, if appropriate, a proposal for a specific legislation on this topic. Furthermore, food containing or consisting of engineered nanomaterials is explicitly included in the scope of the regulation. The general definition of novel food remains unchanged, i.e. food not used for human consumption to a significant degree within the Community before 15 May 1997 (when the current regulation entered into force).

¹ Currently, an application must be made to a single member state which submit it to its competent national food assessment body for initial safety assessment. This is then sent to the other member states and the Commission for comments. If neither the Commission nor the member states raise any objection, the applicant may place the product on the market; otherwise an authorisation decision by the committee procedure is required.

- The new regulation allows applicants to request the **protection of scientific data** on newly developed innovative foods for a period of five years, with the aim of stimulating innovations in the food sector.

So far, more than 30 novel foods have been authorised for use in the EU, such as "rapeseed oil high in unsaponifiable matter", "rye bread with added phytosterols/phytostanols", "milk type products and yoghurt type products with added phytosterol esters", "coagulated potato proteins and hydrolysates thereof" and "phospholipids from egg yolk".

The Council's common position will be adopted at a forthcoming meeting once the text has been finalised. It will then be sent to the European Parliament for a second reading.
