Speeding up authorisation of novel foods

In December 2013, the European Commission presented a proposal to clarify the definition of novel foods, take into account new technologies in food-making, and streamline and speed up the authorisation process. The proposal also seeks to make it easier for traditional foods from countries outside the European Union (EU) to enter the EU market. A compromise following negotiations in trilogue is awaiting a vote in the October III plenary session.

Context

Innovation and product development is fast in the food sector, with new products and ingredients coming onto markets, including new, exotic products imported from non-EU countries. To make sure that novel products are safe for consumers, a procedure is in place for assessing their safety and authorising them. As the current EU legislation covering novel foods dates back to 1997, updating the rules is considered necessary to keep up with technological developments over the past 20 years. Foods and food ingredients which were not consumed in the EU to a significant degree before the entry into force (15 May 1997) of the current Novel Food Regulation (EC) No 258/97 ('the current Regulation') are considered to be 'novel'.

Examples of authorised novel foods include fat spreads with added phytosterols or phytostanols (to help reduce cholesterol), chia-seeds (used for centuries in South America, authorised in the EU since 2009 as an ingredient in bread products), as well as fruit juices produced using a new high-pressure technique. In addition to innovative food, traditional foods from non-EU countries need to be assessed and authorised as novel foods in the EU, which has been seen as a non-tariff trade barrier by some third countries.

The approval of a novel food product can be long and costly, taking on average three years and costing on average €20 000 to €45 000, though it can range from just a few hundred euros up to a million, depending on the type and quality of scientific information required. This can be a deterrent to small companies and investors, especially if consumer acceptance of the new product is not guaranteed. In addition, in most cases the product has to be assessed twice, because the Member States tend to challenge each other's assessments and raise safety objections to the initial assessment conducted by a first Member State's competent authority. In such instances (about 80% of cases so far) an additional assessment by the European Food Safety Authority (EFSA) is required.

An earlier attempt to update the novel food regulation was made in 2008, but the procedure lapsed because the European Parliament and the Council could not reach an agreement over specific rules on cloning. The dossier was one of the eight legislative procedures that went to the conciliation stage in the last parliamentary term.

Commission proposal

The Commission presented its new proposal on novel foods in December 2013. The most significant changes compared to the 1997 Regulation are the removal of the specific categories of foods falling within the scope of the regulation (such as food consisting of, or isolated from, micro-organisms, fungi or algae), a centralised authorisation process (where applications are submitted to the European Commission instead of Member States' authorities, and EFSA carries out the risk assessment), introducing a system of generic authorisation instead of applicant-based authorisations (where each company has to introduce its own application), and a simplified notification procedure for traditional foods with a history of safe use in non-EU countries. The proposed definition of novel foods also includes food containing 'engineered nanomaterials', as defined in Regulation (EU) No 1169/2011 on the provision of food information to consumers (the 'Food Information Regulation').

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An example: food made from insects

The use of insects for food is not regulated precisely in the EU at the moment. There are no safety assessments done according to the rules required by the current Regulation on any insects used as a food ingredient. Most Member States have so far prohibited the use of insects as food, and the use of processed insects from which parts (e.g. legs, wings or head) have been removed, is forbidden. However, Member States have different interpretations as to whether this applies to whole insects, and some Member States are more tolerant than others: for example, in the United Kingdom, bags of whole mealworms, crickets and grasshoppers are sold; a Dutch supermarket chain sells insect burgers and nuggets, and a Belgian supermarket chain offers burgers with buffalo worms, and vegetable spreads made with mealworms. The proposed new regulation would explicitly bring insects under the scope of the Novel Foods Regulation. The Commission has asked for advice from EFSA in order to assess the safety aspects of edible insects, and EFSA's scientific opinion was published on 8 October 2015.

Trilogue agreement

The Committee on the Environment, Public Health and Food Safety (ENVI) adopted its report in November 2014 (rapporteur: James Nicholson, ECR, United Kingdom). Interinstitutional negotiations were held between December 2014 and June 2015. The Committee of Permanent Representatives (Coreper) approved the compromise text on 10 June and the ENVI Committee on 25 June 2015.

At Parliament's insistence, food derived from cloned animals will provisionally be retained in the scope of the Novel Foods Regulation until specific legislation on cloning (currently under discussion in the Parliament and Council) is in force. Food categories were re-introduced in updated form and some new categories added, such as food produced from cell or tissue culture (so called 'lab meat') and food resulting from a new production process which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances.

Food consisting of engineered nanomaterials will also be considered a novel food under the new regulation. The definition of nanomaterial will be deleted from the Food Information Regulation and moved to the Novel Foods Regulation, which is considered to be the appropriate legislative framework for including such a definition. The most up-to-date test methods should be used to assess their safety. The Commission will be empowered to adapt the definition to technical and scientific progress or international definitions by means of delegated acts (this means that either the Council or the Parliament can veto the changes proposed by the Commission under Article 290 TFEU).

The new regulation facilitates the entry into the EU market of traditional foods from third countries. Following a notification to the Commission, a traditional food – with a history of safe use over at least 25 years in the customary diet of a significant number of people in at least one third country – can be placed on the EU market, unless EFSA or Member States submit reasoned safety objections within four months. If there is scientific uncertainty over safety, the precautionary principle should be applied. EFSA should be requested to render its opinion in every case where a novel food is liable to have an effect on human health. Duplication of animal testing should be avoided, where possible, to reduce animal welfare and ethical concerns with regard to novel food applications.

Transparency is improved by requiring the Commission to publish a summary of all new applications and a list of rejected applications. The EU list of authorised novel foods will be publicly available. It will include all of the, approximately, 86 novel foods already approved, and will be updated by the Commission through implementing acts. To speed up the process, the Commission has seven months to decide on whether a novel food is allowed to be placed on the market. It has one month to refer the case to EFSA, if it considers this necessary.

Stakeholders

The food industry, represented by FoodDrinkEurope, is, in general, favourable to the new regulation, with the exception of the Nanotechnology Industries Association, which recently claimed the proposed changes are unworkable. The European consumer organisation, BEUC, sees the compromise text as a 'mixed bag', welcoming the update and the centralised procedure, but regretting that EFSA is not performing safety assessments systematically, but only if the Commission asks for them.

The agreed text is due to be voted by Parliament at the October III plenary session and then has to be formally approved by the Council.