# Briefing

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# Updating rules on novel foods to keep up with scientific advances


**SUMMARY**

To protect public health, new foods or food ingredients ('novel foods') require safety assessment and authorisation before they can be placed on the EU market.

The current authorisation process covering novel foods is seen by the food industry as complex, expensive and time-consuming. In addition, stakeholders agree that updating the current Novel Foods Regulation, which dates back to 1997, is urgently needed to reflect scientific and technological advances.

In December 2013, the Commission presented a revised proposal on novel foods. Questions related to cloning have been left out of the proposal, as disagreement concerning food derived from cloned animals led to the failure of the previous attempt at revision of the Regulation in 2008.

The main changes in the new proposal are: the removal of the former novel food categories; a centralised authorisation process; a shift from applicant-based to generic authorisations; and a simplified procedure for traditional foods from third countries.

Interinstitutional trilogue negotiations started in December 2014; the Committee of Member States' Permanent Representatives (Coreper) approved the resulting compromise text on 10 June, and the EP's Committee on Environment, Public Health and Food Safety (ENVI) followed suit on 25 June 2015. The text is expected to be voted in plenary in October 2015.


**In this briefing:**




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## Introduction

'Novel Foods' are foods or food ingredients which were not used for human consumption to a significant degree in the European Union before 15 May 1997 (date of entry into force of the current Novel Foods Regulation). Novel food can be innovative, newly developed food, produced using new technologies; or food that is traditionally consumed in other countries, but not in the EU.

To protect public health, any new food or food ingredient requires safety assessment and authorisation before it can be placed on the EU market. Up to the beginning of 2015, nearly 180 applications for authorisation had been introduced (approximately 7-10 per year), and around 80 novel foods authorised. Six products have been rejected (in most cases on the basis that the applicant did not provide enough information), and about 20 applications withdrawn.

**Examples of authorised novel foods:**

- fat spreads and dairy products with added phytosterols or phytostanols (to help reduce cholesterol)
- a novel chewing gum base
- noni juice (an exotic fruit juice)
- coriander seed oil
- rapeseed protein
- high pressure fruit juice (produced using new production techniques)
- UV-treated yeast
- synthetic vitamin $K_2$

For a novel food to be authorised it has to fulfil the following criteria: it must not pose a risk to human health, its use must not mislead the consumer; and, if it is intended to replace similar food, it must not be nutritionally disadvantageous for the consumer. The authorisation sets out the specification, the conditions for use and the labelling requirements for each novel food.

The six Member States that received the majority of applications for authorisation were: the United Kingdom (45 applications); Ireland (22); Netherlands (21); Belgium (16); Finland (15); and France (14).

The ongoing legislative procedure is the second attempt to revise the Novel Foods Regulation. The first, unsuccessful, attempt, begun in 2008, failed in March 2011 in the conciliation committee, when the Council and the Parliament could not agree on the labelling of products from cloned animals and their offspring. As a result, the Commission decided to remove the cloning issue from the Novel Foods Regulation and to deal with it in a separate proposal.[1]

## Current legislation and problems related to it

The current legislation consists of two legislative acts: the current Novel Foods Regulation, i.e. Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients (laying down the general principles for authorisation), and Commission Regulation (EC) No 1852/2001 (laying down detailed rules concerning public and protected information provided by the applicants).[2] Stakeholders have identified several problems with the current procedures and highlighted the need to update the framework.

A company that wants to introduce a new food or ingredient into the market must first apply for authorisation from the competent authority of a Member State. A national food assessment body makes an initial safety assessment and sends it to the Commission, which circulates it to other Member States. The national authority also decides if an additional assessment by the European Food Safety Authority (EFSA) is needed. If additional assessment is not deemed necessary, and there are no objections

from the Commission or other Member States, the company is allowed to place the product on the market.

If, however, other Member States raise objections to the initial safety assessment carried out (which until now has happened in the majority – around 80% – of cases), the application has to be assessed and authorised at EU level. In this case, EFSA normally carries out an additional assessment and the Commission draws up an authorisation decision, to be approved by the Member States' experts in the Standing Committee on Food Chain and Animal Health (SCOFCAH). In most cases, applications thus have to be **assessed twice.** This makes the procedure complex and expensive for applicants, as well as time-consuming (taking, on average, three years).

The **costs** of submitting a novel food application vary according to the fees charged by the Member State authorities, as well as data requirements set for applications, and whether further data is required following 'safety objections' raised by other Member States. A Commission Staff Working Document (Annex II) on impact assessment of possible establishment of fees for EFSA estimates that the average cost for applicants of submitting a novel food application is between €20 000 and €45 000. The costs can differ significantly according to the type and quality of the scientific information required, ranging from a few hundred to a million euros.[3]

In the current Regulation, **uniform safety assessment criteria** apply for all kinds of food, whether innovative novel ingredients or traditional food used in third countries. Non-EU countries have claimed this is an unjustified trade barrier to their traditional foods and is not proportionate to the potential risks, given that these foods already have a history of safe use.

Under the current system authorisation is granted to an **individual applicant**, meaning that only one specific applicant is authorised to market the novel food in the EU. If other companies want to use the same or similar ingredient ('substantially equivalent' to a similar product already on the EU market), they have to introduce an additional application.[4]

## Commission proposal for a new Regulation

In December 2013, the Commission presented a revised proposal on novel foods. The aim was to update the Regulation to take into account rapid scientific and technological developments in the food sector, as well as to streamline and speed up the authorisation procedure to encourage innovation. According to the Commission, the proposal was based on the points of agreement between the Parliament and the Council found in conciliation in March 2011.

### Main changes and points of discussion in the 2013 proposal

*Definition and scope*

There has been some discussion on whether the date of 15 May 1997 should be retained as the threshold for determining if a product is to be considered as novel. There is general agreement; however, among EU and national authorities, consumer organisations and industry stakeholders; that there would be little value in changing it, and that for the sake of consistency and continuity the date should be kept.

The current Regulation covers only new foods and food ingredients falling within the specific categories mentioned (e.g. foods to which a new production process is applied). In the 2013 proposal, the Commission **removed these categories**, replacing them with a

reference to the general definition of food (included in Regulation (EC) No 178/2002 laying down general principles and requirements of food law).

Food industry representatives warn against the consequences of removing these categories. As highlighted in a workshop held in the European Parliament in October 2014, this would broaden the definition and extend the scope to all new foods and ingredients not used before 1997. This could mean that even foods already legally on the market could be challenged (by competitors in the food industry for example). This would cause legal uncertainty for operators – and shake consumer confidence, if products already on sale were to be withdrawn for further assessment. For these reasons, stakeholders, industry, and consumer representatives, recommend re-introducing the categories in an updated form.

*Authorisation process*

To address the problem of the lengthy authorisation process, the Commission proposes a **centralised procedure**, where individual Member States would no longer carry out initial safety assessments. Instead, all applications would be submitted to the Commission, which may then ask EFSA for a scientific opinion on risk assessment. The aim is to shorten the approval process from the current average of three years to 18 months.

FoodDrinkEurope, representing Europe's food and drink manufacturers, welcomes the proposal, noting that the revised regulation should stimulate innovation in the food and drink industry by simplifying and streamlining the regulatory framework and facilitating market access for novel foods.

Stakeholders point out that clear deadlines need to be set for all steps to speed up the process in practice. Moreover, EFSA's ability and resources to take on these new tasks is questioned. It has been suggested that, in the transitional period, EFSA should use the expertise of Member State authorities with experience of conducting such safety assessments.

*From applicant-based to generic authorisations*

Under current rules, authorisation is granted to the applicant (individual authorisation). The Commission proposes to change this to a **generic authorisation**, to avoid repeated new application submissions by several companies for the same novel food. This is expected to benefit small and medium-sized enterprises (SMEs) in particular. The food industry stresses, however, that adequate data protection provisions are needed to maintain incentives for companies to continue investment in research and product development. The proposed regulation thus allows that, by way of derogation, individual authorisations with data protection may be granted for a maximum period of five years.

*Traditional foods from third countries*

To facilitate access to the EU market, a simple notification procedure is foreseen for **traditional foods from third countries** with a history of safe use over at least 25 years. The European Consumer Organisation (BEUC) is wary of this provision, however, pointing out that the fact that a food has been consumed for many years is not a guarantee of its safety, and that clear criteria on 'history of safe use' should be defined.

The Commission has argued that strict conditions apply and that there is still a 'safety net' provided by Member States: if a Member State or EFSA presents reasoned safety

objections, the product has to undergo an EFSA assessment followed by an EU authorisation procedure.

*Nanotechnology*

The proposed definition of novel foods in the new Regulation would also include food containing or consisting of 'engineered nanomaterials', as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

There is, as yet, no accurate definition of nanomaterial in the EU. In its Recommendation on nanomaterial definition, the European Commission recommends a definition of 'nanomaterial' as material where 50% or more of the particles are less than 100 nanometers in size.[5]

EFSA's Scientific Committee, in its opinion on nanoscience and nanotechnologies in food and feed safety, notes that the data currently available are limited, and the lack of test methodologies makes risk assessment of nanotechnology products both difficult and highly uncertain. According to EFSA, the present state of knowledge still presents many gaps preventing risk assessors from establishing the level of safety. In view of the current uncertainties, EFSA proposes that a lower nanoparticle threshold of 10% should be considered for food-related applications, instead of the 50% currently proposed in the Recommendation.

**Nanotechnology**

Nanotechnology is a field of applied sciences dealing with manipulation of matter at atomic and molecular scale (less than 100 nanometers). This emerging technology could have important applications in the food and feed sector in the future. Nanotechnologies can be used in the food industry, for example in food packaging, or to improve taste of food, to reduce sugar or salt content or to slow down microbial activity.

This view is supported by the European Consumer Organisation, which underlines that the precautionary principle must be applied to protect consumers and the environment. BEUC considers the 50% threshold to be too high in light of ongoing uncertainty over safety. The Commission argues that it is currently impossible to detect such small amounts of nano particles. Therefore a 50% threshold should be used as the starting point, which could be gradually reduced as scientific progress increases detection possibilities.

As with other new technologies, the potential risks of nanotechnology for food safety and public health are still hard to assess. Some nanomaterials, for example, may have the potential to enter the human body through the skin or through mucous membranes (e.g. in the respiratory or alimentary tract), possibly causing health risks. Research continues at EU, as well as international level, in order to improve methods for safety assessment. The European Commission's Joint Research Centre (JRC) participates in the OECD Working Party on Manufactured Nanomaterials, and, following calls from the European Parliament and the Council, the JRC also hosts a Web Platform on Nanomaterials to make information on nanomaterials easily accessible.

## European Parliament

**The 2008 proposal**

The first attempt to revise the Novel Foods Regulation in 2008 ended in failure: based on the fact that cloning is a new production process, food from cloned animals falls under the scope of the current Novel Foods Regulation. In an attempt to introduce specific rules on cloning, the European Parliament and the Council failed to reach an agreement in the conciliation committee in its final meeting in March 2011. The proposal was not adopted and thus the 1997 Regulation remains in force.

In its position at second reading, adopted in July 2010, the Parliament voted to exclude foods derived from cloned animals from the scope of the Regulation, and asked the Commission to put forward a separate legislative proposal to prohibit placing foods derived from cloned animals and their descendants on the EU market.

Concerning nanomaterials, the Parliament called for all ingredients present in the form of such materials to be clearly indicated in the list of ingredients, followed by the word 'nano' in brackets. In view of the various definitions of nanomaterials used at international level, the Commission was asked to adjust and adapt definitions to technical and scientific progress by means of delegated acts.[6] The Parliament requested that foods produced with the aid of nanotechnology should not be included in the EU list of authorised novel foods until specific methods for safety assessment were approved.

The Parliament demanded ethical and environmental aspects to be considered as part of the risk assessment. It also insisted that post-marketing monitoring would be required for all novel foods to monitor possible adverse effects, and that a review be made five years after authorisation.

**The 2013 proposal**

On 2 December 2014, the Committee on the Environment, Public Health and Food Safety (ENVI) adopted its report on Parliament's position at first reading (rapporteur James Nicholson, ECR, United Kingdom).

Members adopted amendments re-introducing the former food categories and introducing new ones, thereby including:

- food with a new or intentionally modified primary molecular structure;
- food containing, consisting of, or produced from micro-organisms, fungi and algae;
- new foods containing, consisting of, or produced from plants, except for plants with a history of safe food use within the EU and obtained by traditional propagating practices;
- food derived from **cloned animals or their descendants**;
- food containing, consisting of, or obtained from **cellular or tissue cultures**;
- food consisting of, isolated from, or produced from animals or their parts, including whole animals, such as **insects**, except for food from animals obtained by traditional breeding practices and with a history of safe food use within the EU.

The old Novel Foods Regulation covers food from clones, while the new one would not. To avoid a 'legal vacuum' in case the previous Regulation is repealed before new provisions are in place, Members insisted that cloning should be mentioned explicitly in the Regulation until separate legislation on the issue is adopted.

Members added that, in addition to not posing a risk to human health, the product should not pose a risk to **animal welfare** or to the environment. Its **use, presentation and labelling** should not mislead the consumer, and it should be possible to ensure the **traceability** of the materials used in its manufacture.

Foods to which new production processes are applied (such as foods produced using **nanotechnologies**) should not be included in the EU list until specific methods for risk assessment have been approved by EFSA.

Members also asked for more specific **deadlines**: the Commission should verify the validity of an application within one month; and, if an opinion from EFSA is requested,

forward a valid application to EFSA within a month. The Commission should be empowered to adopt delegated acts in order to update the list of authorised novel foods with a time limit of six months from receiving the EFSA opinion.

**Trilogue negotiations**

Interinstitutional negotiations were held between December 2014 and June 2015. The issues which proved to be difficult to negotiate were nanotechnology, cloning and parliamentary scrutiny over the list of authorised novel foods.

The trilogue reached an agreement on nanotechnology, setting a 50% threshold content for nanoparticles to be defined as 'nano'. The threshold would be lowered progressively, through delegated acts, as advances in technology make it possible to detect smaller amounts.

It was agreed that food from cloned animals would be retained under the Novel Foods Regulation during the transitional period until the two separate proposals currently being discussed come into force.

MEPs also wanted Parliament to have scrutiny over the EU list of authorised novel foods, by empowering the Commission to add new products on the list by the way of delegated acts. As delegated acts can be vetoed either by the Parliament or the Council, the Parliament would have been able to veto new products, if considered necessary. This demand was not, however, accepted by the Council, as according to the Council and the Commission this would have countered the purpose of the revised Regulation, which was to speed up the authorisation process.

**Next steps**

The Committee of Permanent Representatives (Coreper) approved the compromise text on 10 June and the ENVI Committee subsequently did so on 25 June 2015.

A vote in plenary could take place in October 2015. If the compromise agreement is not accepted by Parliament, the EP will conclude its first reading, and a second reading would then be required.

## Main references

Novel foods – Complementary Impact assessment reviewing and updating the European Commission's 2008 Impact Assessment for a Regulation on Novel Foods, European Parliamentary Research Service, Ex-Ante Impact Assessment Unit, July 2014.

Proceedings of the workshop on Novel Foods, European Parliament, Directorate General for Internal Policies, Policy Department A, February 2015

## Endnotes

[1] The two legislative proposals (Directive of the European Parliament and of the Council on the cloning of animals for farming purposes (2013/0433(COD)) and accompanying Council Directive on the placing on the market of food from animal clones (2013/0434(APP)) are currently being discussed in the European Parliament and in the Council.

[2] Genetically modified foods also originally belonged under the Novel Foods Regulation, but are now regulated separately under Regulation (EC) No 1829/2003 on genetically modified food and feed.

[3] The working document concludes that the introduction of fees for EFSA should be abandoned. One of the reasons cited is the system of generic authorisations predominant in the area of food legislation: the applicant submitting the authorisation file would have to pay a fee, but all operators would benefit from the authorisation. Currently EFSA does not charge fees for conducting an additional risk assessment due to safety objections raised.

[4] In these cases, a simplified 'notification' procedure is used, where the 'substantial equivalence' is assessed and confirmed by a national food assessment body.

[5] The definitions set in the Recommendation were to be reviewed by December 2014, but this has not yet been done.

[6] Delegated acts can be vetoed either by the European Parliament or the Council. In February 2014, the Parliament rejected the Commission proposal for a delegated act amending the definition of 'engineered nanomaterials' by excluding natural and incidental nanomaterials from the definition, as it considered that this could lead to existing nanomaterials not being labelled.

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