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Explanatory document
REVISION OF REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 JANUARY 1997 CONCERNING NOVEL FOODS AND NOVEL FOOD INGREDIENTS

This explanatory document serves as background information to the general public, stakeholders and the Member States.

Your input is important and will contribute to identifying the likely positive and negative impacts of the proposed policy options, enabling the Commission to design its legal proposal based on an informed judgement.

This document adheres to the standards laid down in the Communication from the Commission COM (2002) 704 final "Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission".

Novel foods are foods that were not consumed to significant degree in the EU before 15 May 1997 (date of entry into force of the Regulation) and thus go under a pre-market safety assessment and authorisation. Since 1997 the EC has received around 65 applications and in the recent years, 7-10 applications per year (as at 31.1.2006). Novel foods can be divided in three main groups: traditional food from 3rd countries (e.g. noni juice), newly developed innovative foods (e.g. phytosterols) and food produced by new technologies with impact on food (e.g. GM food in the past, high pressure fruit juice). For novel food legislation and approvals, see:
http://europa.eu.int/comm/food/food/biotechnology/novelfood/index_en.htm.

1. OBJECTIVES, CONTEXT AND SCOPE OF THE CONSULTATION

1.1 Objectives of the consultation and of the proposal

The purpose of this consultation is to ensure the participation of the general public, stakeholders and the Member States in the design of the future legislative proposal, which intends to introduce changes to the existing Novel Food Regulation EC No 258/97.

The objectives of the proposal are to:

- to ensure a high level of public health protection and secure the functioning of the internal market on foods by streamlining the authorisation procedure, developing a more adjusted safety assessment system as well as clarifying the definition of novel (including new technologies with impact on food) and the scope of the Regulation,
- improve the efficiency and application of the system as well as the implementation of the Regulation,
- empower consumers by providing more specific information about novel foods as appropriate,
- improve legal clarity by making necessary changes and updating the legislation.

1.2 Context and scope of the consultation

1.2.1 The issue

In line with the overall Commission goals on Better Regulation a revision of the Novel Food Regulation is needed, in order to clarify the legislation after removal of GM food from the scope of the Regulation, to create a more favourable environment for innovation for the food industry and to facilitate internal and external trade. The consumer benefits from a wider choice of safe novel foods.

Experience on the implementation of the Regulation has been gained since 1997, when it came into force. A consultation with stakeholders, including competent authorities, and an independent review by external consultation company were carried out 2002-2003. The review based on an internet consultation on the Commission Discussion paper on the implementation of the Novel Food Regulation 258/97. Various issues were identified and different policy options for each issue were discussed, see:
http://europa.eu.int/comm/food/food/biotechnology/novelfood/initiatives_en.htm.

The main issues for the impact assessment are considered to be the following:

- At present traditional food, which was not on the EU market before 1997 but with information on safe use outside the EU, goes through the same rigorous safety assessment as any newly developed innovative food. This is perceived by, for example third countries as unjustified barriers to trade for their traditional foods.

- The product authorisation procedure takes too long. It is also in some cases difficult to predict for the applicants due to the lengthy decentralised system.

- The authorisation decision is presently only addressed to the applicant, so that others do not have the right to market the product. Therefore, an additional separate administrative procedure (simplified procedure) is at present needed for others to market the same food.

- Repetitive work and administrative burden is caused by authorising the same substances under different legal frameworks.

In order to improve the quality and coherence of this new policy development, the Commission will carry out an impact assessment on the various policy options.

1.2.2. Types of impact

Depending on the issue, the following impacts will be examined.

Economic impact:
Impact on competitiveness, markets and trade (including third countries)
Impact on the administrative burden imposed on business and authorities

Impact on innovation and research
Impact on employment and jobs

Social impact:
Impact on consumer rights (information)
Impact on public health and food safety
Impact on third countries, in particular local communities and indigenous groups

Environmental impact in both EU and 3rd countries.

1.2.3. Target groups of the consultation

The questionnaire will be addressed to the general public, stakeholders and the Member States. The following key stakeholders will be informed of the internet site (http//www.cc.cec/home/dgserv/markt/ipm_en.htm):

– Advisory Group on the Food Chain and Animal and Plant Health;
– competent authorities of the Member States;
– food industry
– 3rd country authorities.

2. GENERAL ISSUES FOR CONSULTATION

2.1 General information on novel foods

In order to collect information on the economic value of novel foods questions are asked on the size and value of novel food markets as well as imports and related employment in 2000-2005. To be able to evaluate the administrative burden, information is requested on costs of novel food applications as wells as research and innovation costs in the food industry.

2.2 Legal Instrument

For ensuring a proper functioning of the internal EU market, it is necessary that food safety regulations are harmonised. The Novel Food Regulation adopted in 1997 contributed to the harmonisation of food safety regulation in the EU. Therefore, without a harmonised Novel Food Regulation the concept of mutual recognition of foods on the EU market before 1997 could be discontinued. Deregulation could also encourage the introduction of different national authorisation procedures, which were in place in some Member States before the Novel Food Regulation came into force. Non legislative action based on e.g. good practice code or guidelines could lack protection and legal certainty. The General Food Law (Regulation 178/2002), which lays down general food safety provisions, was adopted in 2002. It made food business operators responsible for the safety of food but it does not require a pre-market safety assessment of foods.

3. SPECIFIC ISSUES FOR CONSULTATION

In this part, the main issues and their various policy options with possible impacts for future legislative proposal are described.

1. Adjusted safety assessment and management for traditional food from 3rd countries?

Option 1 *No changes 'One size fits all'*

At present, uniform criteria (and guidelines) apply for the safety assessment of all kinds of foods, e.g. from traditional foods from 3rd countries to newly developed innovative foods. The system is simple and straightforward to administrate. However, the requirements are not always proportional to potential risks and therefore unnecessary requirements and administrative burden can be created for the applicants. This is perceived for example by third countries as unjustified barriers to trade for their traditional foods.

Option 2 *Adjusted safety assessment for traditional food from 3rd countries*

An adjusted safety assessment by creating different criteria and guidelines for different kinds of foods by maintaining the safety level could lead to a more proportional and rational system of food safety assessments. The data on safe food use outside the EU should be taken better into account.

Option 3 *Adjusted safety assessment and management for traditional food from 3rd countries*

To further adjust the procedures for traditional foods from 3rd countries with reliable data on safe food use, the authorisation procedure could be simplified. If the European Food Safety Authority (EFSA) does not express serious concerns in its assessment opinion, the Commission could consult Member States whether they have objections to the authorisation. Where no objections are presented, the applicant could be informed by the Commission of the positive outcome. In case of objections the general authorisation procedure (comitology procedure) could apply.

Option 4 *No pre-market safety assessment and authorisation for traditional food from 3rd countries*

The repeal of the pre-market safety assessment and authorisation for traditional foods entering the market after 15 May 1997 would be a major simplification and probably welcomed by 3rd countries. Food business operators placing such a food on the market would be responsible for ensuring that the food is safe according to the general food law. However, there is food potentially unsafe around the world. Without a pre-market safety assessment for novel food, the general safety level of foods would decrease. The internal market of foods could be affected by measures that might be taken by Member States.

2. Safety assessment and authorisation procedure

The Commission recently presented a Proposal for a Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings, which defines a common authorisation procedure for these food categories. This is the first building block of a horizontal legal act which will harmonise the authorisation procedures for all the approvals in the food area. In the revision of the Novel Food Regulation the Commission has the intention to pursue this harmonising of the authorisation procedures (including the decision, see point 3) in this common horizontal act.

Option 1 *No changes (Decentralised assessment and authorisation procedure)*
Option 2 *Centralised risk assessment and authorisation procedure*

In the present risk assessment system the initial risk assessment is carried out by a Member State's competent assessment body. The application is assessed (EFSA) and authorised on the EU level only if objections have been raised. In practice, however, this has mostly been the case. Therefore, the system has been time consuming with administrative burden, as the applications were assessed at least twice. A centralised risk assessment and authorisation procedure could streamline and increase the efficiency and predictability (especially with deadlines) of the assessment and authorisation system of novel foods.

3. Authorisation decision

Option 1 *No changes*: *Authorisation linked to the applicant (only applicant able to market)*
Option 2 *Generic authorisation (all companies able to market in the EU and abolishment of the simplified procedure)*
Option 3 *Generic authorisation + data protection for certain foods*
Option 4 *Different types of authorisations (generic and for certain foods applicant linked)*

An authorisation generally addressed to the EU (new food products authorised as generics or a positive list) would allow food industry to market the authorised products. At the same time, the present notification system of substantially equivalent foods to existing foods (simplified procedure) would no longer be needed and could be abolished. On the other hand, more innovative products with considerable product development could be protected by an authorisation linked to the applicant ('brand specific authorisation') or simply by data protection.

4. Submission of application for several food uses

Option 1 *No changes*: *separate applications for different food uses*

As presently, for a substance for different food uses (e.g. additives, flavourings, extraction solvents or novel foods) separate applications need to be presented under the respective legal frameworks.

Option 2 *One application for all new foods for different uses*

If an applicant decides to apply for approval of a novel food and at the same time to apply for approval for other food uses covered by other sectoral legislation (e.g. additives, flavourings, extractions solvents) one single application could be submitted. The advantage would be one application and risk assessment submitted in conformity with the future common authorisation procedure in the food area to be laid down in a horizontal legal act. The requirements and criteria of the specific sectoral legal frameworks would be respected.

4. SUBSEQUENT POLICY DEVELOPMENT STAGES

The Commission shall undertake an impact assessment on the proposal introducing changes in the present legislation on novel foods. This impact assessment will be published on the SANCO website at the following address: http://europa.eu.int/comm/dgs/health_consumer/index/_en.htm.

The Commission intends to prepare a legislative proposal in 2007.