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Accompanying document to the

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON NOVEL FOODS AND AMENDING REGULATION (EC) NO XXX/XXXX [COMMON PROCEDURE]

SUMMARY OF THE IMPACT ASSESSMENT

[COM(2007) 872 final]
[SEC(2008) 12]

SUMMARY IMPACT ASSESSMENT

for a Regulation replacing Regulation (EC) No 258/97 on novel foods and novel food ingredients

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The main stakeholders concerned with the Revision of Regulation 258/97 on novel foods and novel food ingredients were consulted in 2002 - 2007.

A Commission Inter-Service Group on the impact assessment was set up, and the Commission carried out, with the general public, an Interactive Policy Making (IPM) online consultation in order to collect information and data on the possible impacts of the main issues under consideration for the revision of the Regulation in 2006.

The impact assessment results were scrutinised by experts from the Member States, from different Commission Directorate-Generals' represented in the Inter-Service Group and from other relevant stakeholder groups in the working group of the DGSANCO Advisory Group on the Food Chain and Animal and Plant Health as well as by the European Commission Impact Assessment Board (IAB), which gave its opinion on 16 February 2007.

2. PROBLEM IDENTIFICATION

Regulation (EC) No 258/97 on novel foods and food ingredients concerns food that was not consumed to a significant degree in the EU before 15 May 1997 (date of entry into force of the Regulation) and thus has to undergo a pre-market safety assessment and authorisation. Novel foods are in practice newly developed innovative foods and food produced by new technologies with possible impact on food, as well as exotic traditional foods from outside the EU.

The main issues with potential economic and social impacts were identified as follows:

- Adjusted safety assessment and management for traditional food from third countries.
- Safety assessment and authorisation procedure.
- Authorisation decision.
- Submission of application for several food uses.

Furthermore, there is a need for legal clarifications and updating.

3. OBJECTIVES

The core objective is to revise and update the Novel Food Regulation 258/97 in order to:

- Ensure food safety, protect human health and secure the functioning of the internal market for food by streamlining the authorisation procedure, developing a more adjusted safety assessment system and clarifying the definition of novel food, including new technologies with an impact on food, and the scope of the regulation;
- Improve the efficiency and transparency of the system and the implementation of the Regulation;
- Empower consumers by informing them about food;
- Achieve legal clarity by making any necessary changes and updating the legislation.

The in-depth impact assessment has been carried out on four major policy actions.

4. POLICY ACTIONS

Policy Action 1: Adjusted safety assessment and management for traditional food from third countries

Current problems:

At present, uniform criteria apply for the safety assessment of all kinds of food, including traditional food from third countries and newly developed innovative food. However, the requirements are not always proportional to the potential risks, which mean that the costs of application could be considered disproportionate. This is perceived, for example, by third countries as unjustified barriers to trade in their traditional food with a history of use.

Policy options:

- Option 1: No change 'One size fits all': Keeping the present system of uniform criteria for the safety assessment of all kinds of food.
- Option 2: Adjusted safety assessment for traditional food from third countries: Taking history of safe food use outside the EU better into account.
- Option 3: Adjusted safety assessment and management for traditional food from third countries: In addition to option 2, if the European Food Safety Authority (EFSA) and the Members States do not express serious concerns in their safety assessments, the applicant would be informed by the Commission of the positive outcome, otherwise the comitology procedure would apply

- Option 4: No pre-market safety assessment and authorisation for traditional food from third countries.

Analysis of impacts:

Impact on public health and food safety and consumer rights

Developing an adjusted safety assessment or management procedure for traditional food from third countries does not have a significant impact on public health and food safety. The responses underline the importance of a documented history of safe food use, ascertaining possible undesirable effects and clear guidelines and criteria. The omission of a pre-market safety assessment and authorisation for traditional food from third countries would have an adverse impact on public health and food safety. As regards impact on consumer rights, the options concerning an adjusted safety management procedure and abolishing the requirements for third countries were viewed as beneficial.

Impact on employment and jobs

- (no significant impacts expected)

Impact on administrative requirements imposed on business

A better adjusted safety assessment or management system would lead to a decrease in the administrative burden imposed on business. It is clear that removing the requirement for pre-market safety assessment and authorisation for traditional food would eliminate the administrative burden.

Impact on competitiveness, markets, trade and invest flows (including third countries)

According to the consultation results the development of better adjusted safety assessment or management system would have a beneficial impact on the economic parameters. Research shows that market interest and demand for biodiversity products and services is growing, giving countries rich in biodiversity a comparative advantage. However, developing countries often lack the capacity to turn this into a competitive advantage, meaning traded volumes of biodiversity goods remain relatively low. Abolishing all requirements would also be beneficial. However, there is a danger of measures at EU level being replaced by different measures by some food operators and in some Member States. Option 4 could also lead to a loss in confidence in the safety of food products from third countries with possible negative economic impacts.

Impact on innovation and research

A better adjusted safety assessment or management system for traditional food from third countries is surprisingly expected to increase innovation and research efforts leading to e.g. an improved economic situation. Doing away with the requirements for traditional food from third countries is even seen as further improving the situation. According to one international food company, strict requirements are a hindrance to innovation, including for EU companies.

Environmental impact (EU and third countries)

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Socio-economic impact (third countries in particular) (in particular local communities and indigenous groups)

According to the consultation results, the most significant impact of developing a better adjusted safety assessment or management system is expected in the socio-economic field. Abolishing the requirements for traditional food from third countries could further improve the situation.

Conclusion:

For traditional food from third countries, a procedure setting out essential criteria and guidelines, that would allow food with a history of safe food use to be subject to an adjusted safety assessment and management procedure, should be introduced.

Policy Action 2: Safety assessment and authorisation procedure

Current problems:

At present the initial risk assessment is carried out by a Member State's competent assessment body within three months of receiving the application. The initial assessment report is circulated to the other Member States. If no objections are presented within the 60 days commenting period, the Member State's competent authority informs the applicant that it may place the novel food product in question on the market. The application is assessed and authorised at EU level only if objections have been raised. In practice, this is generally what has happened. So the system has proved to be time-consuming and has imposed a high administrative burden, as applications are assessed twice.

Policy Options:

- Option 1: No change: The present decentralised assessment and authorisation procedure would continue.

- Option 2: Centralised risk assessment and authorisation procedure

Analysis of impacts:

Impact on public health and food safety and consumer rights

The switch from a decentralised to a centralised assessment and authorisation procedure is seen as having a positive impact on public health and food safety and on consumer rights. This was not expected because in practice, for most of the applications, the initial assessment at national level already is followed by an additional safety assessment at EU level. Some Member States and a consumer organisation underline the importance of the Member States' and stakeholders commenting on the applications.

Impact on employment and jobs

According to the consultation results the centralised assessment and authorisation system is expected to have a positive impact on employment and jobs. For R&D based companies, providing a better environment for innovation could increase new product development and the number of new products entering the market. This in turn could lead to increased employment and new jobs.

Impact on administrative burden

The switch to a centralised procedure was seen as very beneficial. Time and costs for authorities and applicants alike would be reduced. It is suggested that deadlines would need to be shortened and laid for the various steps in the procedure.

Impact on competitiveness, markets, trade and investment flows (including third countries)

A centralised authorisation procedure, incorporating deadlines and a reduced administrative burden, is expected to work in favour of new product development. Enhanced competitiveness and higher investments could increase trade in novel food. A beneficial impact, including for third countries, is expected since a more transparent and harmonised procedure would give equitable access to the EU market.

Impact on innovation and research

The economics and attractiveness of new product development would increase with a more efficient and less time-consuming centralised authorisation procedure. As a result, the impact of option 2, on innovation and research, is viewed as beneficial. A more efficient approval system is likely to encourage innovation.

Environmental impact (EU and third countries)

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Socio-economic impact (third countries in particular) (in particular local communities and indigenous groups)

According to the consultation results, creating a centralised assessment and authorisation procedure for novel food is viewed to have a positive socio-economic impact due to the more general positive economic impacts.

Conclusion:

The decentralised procedure should be replaced by a centralised procedure at EU level. The safety assessment should be carried out by EFSA, and the authorisation decision taken by comitology procedure, combined with time limits to be respected.

Policy action 3: Authorisation decision

Current problems:

At present the authorisation decision is linked to the applicant, thus allowing initially only this applicant to market the novel food in the EU and making it necessary to have an additional administrative notification procedure (simplified procedure). This allows food to be marketed in the EU which is substantially equivalent to food already authorised in the EU. This system is held in high regard by industry, but it causes multiple work for a food that has already been authorised.

Policy Options:

- Option 1: No change: Applicant-linked authorisation. Only applicant able to market, others by simplified procedure.

- Option 2: Generic authorisation: All companies able to market in the EU and simplified procedure abolished.

- Option 3: Generic authorisation (option 2) and data protection for certain foods.

- Option 4: Different types of authorisations: generic and applicant-linked. Simplified procedure abolished. Innovative novel foods based on considerable product development could be protected by an authorisation linked to the applicant.

Analysis of impact:

Impact on public health and food safety and consumer rights

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Impact on employment and jobs

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Impact on the administrative burden

The administrative burden is expected to decline in all scenarios (options 2-4) compared to the present situation. Generic authorisation is expected to cut the administrative burden for the authorities and for the food industry since the present simplified procedure would be abolished. Generic authorisation is also seen as simplifying access to the EU market for traditional food from third countries.

Impact on competitiveness, markets, trade and investment flows (including third countries)

According to the consultation results changing the type of authorisation decision was generally viewed as beneficial (options 2-4) compared with the present situation. As regards traditional food from third countries, one respondent stated that no 'monopoly' should be given, since this kind of food does not belong to any specific company. In general, for newly developed food, a temporary 'monopoly' could be accepted in view of the high innovation costs. The impact is, however, viewed by one organisation as limited, and other legal measures, e.g. patents, are likely to be just as effective. Some form of protection could be provided to the first petitioner. Generic authorisation and data protection might be a faster route to the market, at the same time protecting innovation and R&D investments in newly developed novel foods. 1-7 years of data protection is suggested by the food industry.

Impact on innovation and research

The present Novel Food Regulation does not, according to the results of the consultation, have a very beneficial impact on innovation and research. Somewhat surprisingly, even a generic authorisation decision, combined where appropriate with data protection for the applicant, would increase food industry's enthusiasm for innovation and research. Changing the authorisation decision to allow different kinds of authorisations is expected to have a significant beneficial impact on innovation and research in the novel food area. A certain protection period is considered to be necessary by a number of respondents.

Environmental impact (EU and third countries)

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Socio-economic impact (third countries in particular) (in particular local communities and indigenous groups)

According to the consultation results the socio-economic impact is expected to be positive if generic authorisation and different types of authorisations were introduced in the new legislation. This might be due to the positive impact on innovation, research and trade.

Conclusion:

The applicant-linked authorisation needs to be replaced and the present simplified procedure abolished by granting generic authorisations as a general rule. In order to support innovation and to ensure food safety, consideration could be given, in justified cases, to an applicant-linked authorisation for newly developed food for a certain period of time. Data protection could be a further consideration.

Policy action 4: Submission of application for several food uses

Current Problems:

At present separate applications needs to be made within the respective legal frameworks for a substance with different food uses (e.g. additives, flavourings, extraction solvents or novel foods). The regulation, assessment and authorisation of one and the same substance under different sectoral legislation leads to repetitive work and an additional administrative burden. Industry is too seeking the simplest possible regulatory framework.

Policy Options:

- Option 1: No change: Separate applications for different food uses.
- Option 2: One application for all new foods for different uses.

Analysis of impacts:

Impact on public health and food safety and consumer rights

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Impact on employment and jobs

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Impact on the administrative burden

A single application for different food uses is expected to do away with parallel risk assessments and lead to shorter processing times, thus reducing the administrative burden, especially for SMEs.

Impact on competitiveness, markets, trade and invest flows (including third countries)

The present situation, requiring separate applications under different legislative frameworks, is viewed as not very beneficial for competitiveness, market entry, trade and investment flow reasons. Simplifying the procedures, significantly improves the present situation and reduces costs, as they are incurred only once.

Impact on innovation and research

Innovation and research could benefit from simplification as the administrative burden for new product development and market access is reduced and the overall efficiency of the safety assessment procedure increases.

Environmental impact (EU and third countries)

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Socio-economic impact (third countries in particular) (in particular local communities and indigenous groups)

According to the consultation results, for traditional food from third countries there could be easier access to the European market. Increased trade could have a positive social impact in some third countries but no significant effects are expected.

Conclusion:

The present system should be simplified and applicants should be able to apply for an approval by a single application covering novel food and food uses regulated under various regulatory frameworks.

5. MONITORING AND EVALUATION

The following indicators are proposed for monitoring and evaluating the future authorisation procedure: Number of traditional food applications from third countries, number of novel foods approved and average time taken for authorisation of novel food.