COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.1.2008
SEC(2008) 12

COMMISSION STAFF WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

Draft report on

IMPACT ASSESSMENT

for a REGULATION REPLACING REGULATION (EC) No 258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS

[COM(2007) 872 final]
[SEC(2008) 13]

Lead DG: SANCO

Other involved services (Members of the Inter-Services Steering Group): SG, ENTR, TRADE, DEV, RTD, ENV

Agenda planning reference: 2007/SANCO/006

TABLE OF CONTENTS

1. Executive summary 3
2. Section 1: Procedural issues and consultation of interested parties 5
3. Section 2: Problem identification 6
4. Section 3: Objectives 13
5. Section 4: Major policy actions 15
6. Section 5: Analysis of impacts 19
7. Section 6: Comparing the options 26
8. SECTION 7: Monitoring and evaluation 35
9. Annexes 1-6

   Annex 1: Novel food applications and notifications

   Annex 2: Procedural times of novel food applications

   Annex 3: IPM online consultation explanatory note

   Annex 4: IPM online consultation questionnaire

   Annex 5: Central impact assessment results in graphics

   Annex 6: Results of Interactive Policy Making (IMP) online consultation on Revision of Regulation EC N° 258/97 on Novel Foods and Novel Foods Ingredients, 2.6. - 1.8.2006

ANNEX 36

1. EXECUTIVE SUMMARY

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. Since 2004 GM foods are separately regulated by Regulation (EC) No 1829/2003. The EU has since 1997 received 71 applications for approval from some 46 companies (as at 7 July 2006, GM foods included). Over recent years, 7-10 applications per year have been submitted.

Stakeholder consultations in 2002 on a Commission discussion paper and subsequent evaluation have underlined the importance of and the need to develop and update the Regulation.

Main objectives of the proposal are the following:

- At present traditional food which was not on the EU market before 1997, but for which there is information on safe use outside the EU, is subject to the same rigorous safety assessment procedure as any newly developed innovative food. This is perceived, especially by third countries, as an unjustified barrier to trade for their traditional foods.

- The safety assessment and product authorisation procedure takes too long. The lengthy decentralised procedure duplicates the work and often generates unnecessary delays in the authorisation process.

- The authorisation decision is presently only addressed to the applicant, so that others only after notifying the Commission through an additional administrative procedure are able to market the same food.

- Assessing and authorising the same substances within different legal frameworks causes repetition and creates an additional administrative burden.

- The general implementation of the Novel Food Regulation needs to be improved.

Furthermore, there is a need for legal clarifications and updating because:

1. There have been some misinterpretations about the definition of novel food and about the scope of the Regulations;

2. It should also be ensured in the future that there is a horizontal approach to new technologies in breeding and food production processes with an impact on food safety;

3. There is a need to update the legal text of the Regulation and to develop the provisions concerning the determination of the novelty of a food (e.g. collecting information to what extent a food was used before 15 May 1997) and concerning confidentiality and public consultation;

4. The labelling provisions could be simplified now that GM food is regulated separately.

The Commission's legislative activities are linked to the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration.

The measures to achieve these objectives can be divided into two categories:

1. Major policy actions, which are subject to an impact assessment;

2. Policy actions which constitute a refinement of existing policies (i.e. clarifying and updating the present Regulation). In this case no separate impact assessment is required.

From 2 June to 1 August 2006 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 major policy actions considered for the revision of the Regulation.

The major policy actions covered by the impact assessment were:

1. Adjusted safety assessment and management for traditional food from third countries

The results of the impact assessment support the introduction for traditional food from third countries, of 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.

2. Safety assessment and authorisation procedure

The results of the impact assessment point towards the option of replacing the decentralised procedure by a centralised procedure at EU level. The safety assessment would be carried out by EFSA, and the authorisation decision taken by comitology procedure. The procedure needs to be combined with time limits to be respected.

3. Authorisation decision

The results of the impact assessment indicate the need to replace the applicant-linked authorisation and to abolish the present simplified procedure 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.

4. Submission of application for several food uses

The results of the impact assessment favour the option of simplifying the present system and enabling applicants to apply for an approval by a single application covering novel food and food uses regulated under various regulatory frameworks. Consideration should be given to this in the context of possible a future proposal on a common authorisation procedure for foods.

2. SECTION 1: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The Commission prepared a discussion paper on the implementation of the Novel Food Regulation (EC) N° 258/97 which was published on the DG Health and Consumer Protection website in July 2002[1]. Some 40 stakeholders sent in theirs comments, which were later published on the website. In addition, the Commission organised a stakeholder meeting on 13 January 2003. All comments were summarized by an external consultant in 'A Summary Report - Stakeholder Submissions of 14 July 2003'[1]. This formed the basis for an evaluation in 2003 (Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients of 22 January 2004)[1]. The stakeholder consultations and evaluation underlined the importance of developing and updating the Regulation and made a number of recommendations (see executive summary[1]).

A Commission Inter-Service group on the Impact assessment was set up, with the participation of the following Directorates-Generals: SG, ENTR, TRADE, DEV, RTD and ENV. The group started its work on 14 March 2006 and met three times.

Member State authorities were consulted in the course of several Novel Food working group meetings in 2005-2006. The initiatives were in general well received. Informal discussions and presentations have been held with various stakeholders groups, e.g. representatives of the food industry and UNCTAD, representing some third countries.

[1] http://ec.europa.eu/food/food/biotechnology/novelfood/iniatives_en.htm

From 2 June to 1 August 2006 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 (see Annex 3-4). More than sixty responses to the questionnaire were received. The detailed outcome of the consultation is reported in Annex 6. In addition, stakeholder consultations were held on the Impact Assessment report with the Member States in the novel food working group in September 2006 and with other stakeholders in December 2006.

The European Commission Impact Assessment Board (IAB) examined the draft report on impact assessment for a Regulation replacing Regulation (EC) No 258/97 on novel food and novel food ingredients in its board meeting on 7 February 2007 and gave its opinion on 16 February 2007. The recommendations were taken on board. The report was further developed and improved, in particular, by making reference to background documents explaining in more detail the policy choices made in the process, by explaining the reasons for absence of readily available quantitative data and consequences for the impact assessment as well as by validating the consultation results, where possible, by information from other sources.

3. SECTION 2: PROBLEM IDENTIFICATION

Novel foods

Novel foods are foods that were not used for human consumption to a significant degree in the EU before 15 May 1997 and thus do not have a history of food use in the EU before that date. As a result, pre-market safety assessment and authorisation are required. In practice, novel foods can be divided into three categories: innovative food (e.g. phystosterols, salatrim reduced-energy fat, DHA-rich oil, coagulated potato protein, bacterial dextran, threhalose, phospholipids isolated from egg yellow, D-tagatose), traditional food from third countries (e.g. noni juice) and food produced by new production techniques with an possible impact on food (e.g. high-pressure fruit juice).

The authorisation decision is presently addressed to the applicant, so that others do not have the right to market the same food. However, the Regulation provides for the others to market the same food via separate simplified procedure. If a food is recognised as substancially equivalent to an existing food on the basis of scientific evidence assessed by a Member State's competent authority, it can be marketed after the Commission has been notified.

Since 1997 the EU has received 71 applications from some 46 companies (situation as at 7.7.2006, Annex 1, gm foods included). In recent years, the number of applications has been 7-10 per year. 63 notifications concerning foods substantially equivalent to foods already existing on the market have been made (Annex 1).

Some other countries in the world like Canada[2], Australia and New Zealand[3] have similar legislation on novel foods. In the USA, a substance that will be added to food is subject to a pre-market safety assessment unless its use is generally recognized as safe (GRAS) by qualified experts. The latter is done via the GRAS notification system[4].

Potential for novel foods

The European market potential for novel foods is significant. Today, some 30 food plants supply 95 % of the daily human intake of plant food calories on a worldwide basis[5]. In Europe, the remaining five percentage points come from some 300 other plant species[6]. These plants have the potential to deliver novel food from parts of plants which have not so far been used. However, the major potential source for novel foods are the close-on 7000 other plant species traditionally used as an human food source in other parts of the world[7,8,9]. According to the information provided by Colombia, Ecuador and Peru, some 60 potential novel foods have been identified. However, it would be necessary to determine if these foods where truly novel foods, e.g. not used for human consumption to a significant degree in the EU before 1997.

The Novel Food Regulation also covers newly developed foods and food derived from new production processes and technologies (now excluding gene technology) with a possible impact on food. At present, most of the applications fell under these categories. However, in the light of the high level of innovation in the food industry as presented by Confederation of the Food and Drink Industries of the EU (CIAA)[10] the number of novel food applications has to be considered very low.

Novel Food markets, imports, employment and innovation

It is very difficult produce data on the size and extent of the novel food market. It is not a single, uniform market, but rather a multitude of diverse markets covering many different products (e.g. yellow fat spreads with phytosterols, fruit juices, oils etc.) and operating in many different countries. These individual markets can be 'hidden', not least as there are often confidentiality and IPR issues. Further, even if information is available on certain products it would be difficult to extrapolate this to obtain an overall picture as there is such variation in terms of the products on the market.

---

2 http://www.hc-sc.gc.ca/fn-an/gmf-agm/index_e.html

3 http://www.foodstandards.gov.au/foodmatters/novelfoods/

4 http://www.cfsan.fda.gov/~dms/opa-noti.html

5 FAO (1996): Report on the State of the World's Plant Genetic Resources for the Food and Agriculture, prepared for the International Technical conference on Plant Genetic Resources, Leipzig, Germany, 17-23 June 1996. Food and Agriculture Organisation of the United Nations, Rome.

6 NETTOX (1997): Nettox List of Food Plants. Information on inherent food plant toxicants, report 2. Danish Vet. Food Adm., Soborg, Denmark.

7 Wilson E.O. (1992): Diversity of Life. Penguin, London.

8 IPGRI (International Plant Genetic Resources Institute). URL: http:// ww.ciat.cgiar.org/ipgri/fruits.

9 Traditional food from third countries is understood as food with a history of use meaning that there is documented data for the food as an ongoing food part of the diet for number of generations in a large population.

10 CIAA (2006): Data and trends of the European food and drink industry 2006, Brussels, Belgium.

Data on novel foods and the novel food market are consequently not readily available through normal sources such as Eurostat, European organisations or market research institutes. Therefore, it was not possible to quantify costs of the various aspects of the legislation that are being considered for change. Although were possible some data is provided to give an indication of the market and how the proposed changes would impact on this.

According to the IPM online consultation, the estimated total size and value of the novel food market in the different organisations in relation to their total sales, is seen as fairly significant in 2000-2005 (Annex 6). This holds true for both traditional food from third countries and newly developed novel foods. However, one organisation stated that 'from former experience of some member companies with novel food it can be assumed that novel food ingredients and novel foods play only a minor role in the daily diet'.

The total value of novel food imports into the EU was not significant (Annex 6). In terms of import values by product categories, traditional foods were estimated to be slightly more significant than newly developed novel foods. One organisation stated that traditional food from third countries had not been a central concern for food ingredient manufacturers. Hardly any information on exports on traditional food from third countries was obtained. Traditional food exports in 2005 from Peru were: maca 2,28, camu camu 0,7, yacon 0,63, sacha inchi 0,17, maize moraco 0,35, tara 12, 3 and hercampuri 0,11 million euro (IPM online consultation).

Nine organisations employed 1-50 persons in the novel food sector in 2000-2005. Four organisations provided information on their innovation expenditure in relation to novel foods, ranging from 85 000 to 10 000 000 euro in 2000-2005.

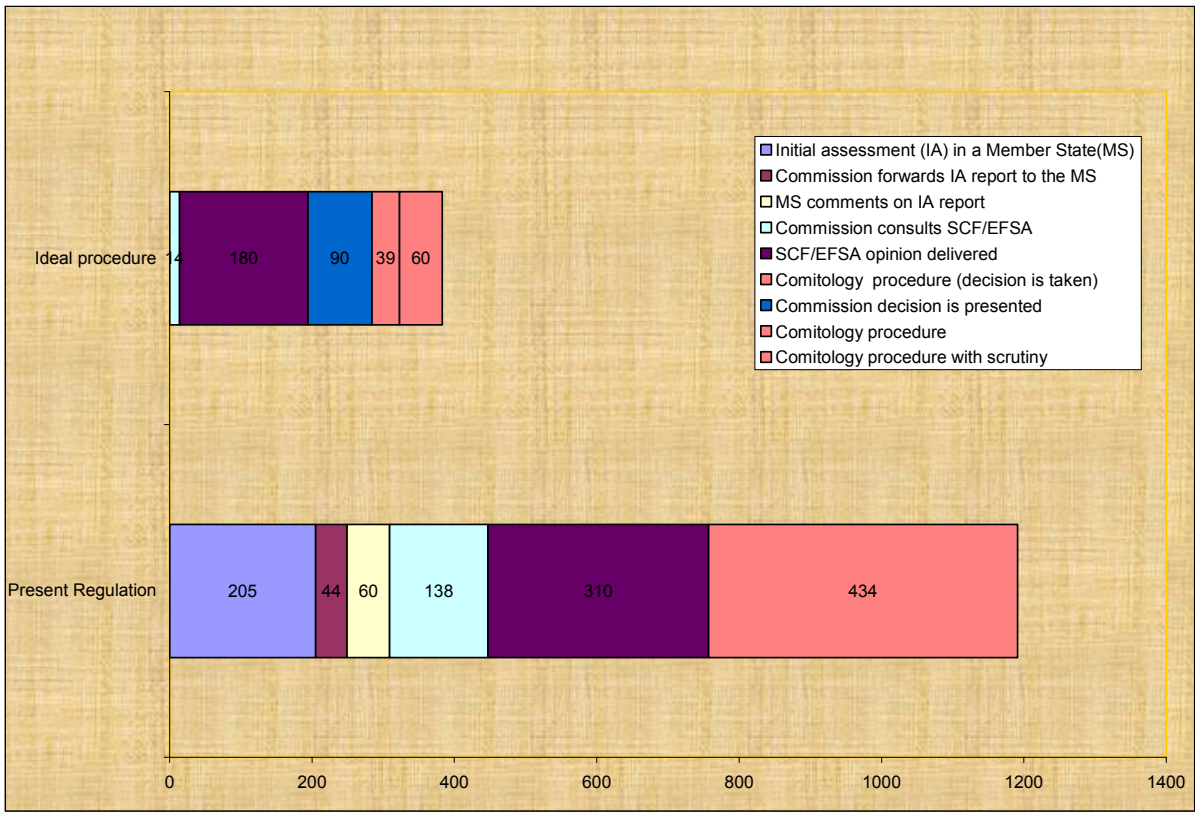
Administrative costs

The administrative costs per novel food application (e.g. upfront administrative burden costs) were viewed as significant during 2000-2005 (see Annex 6). This was the case for traditional food from third countries as well as for newly developed novel food. One consultancy company from Spain stated that 'the cost of novel food application is so high that none were submitted from this organisation. Potential applicants were discouraged by high costs and long time scale.'

The upfront administrative burden costs, e.g. the costs related to the application including the dossier, largely depend on the scientific guidelines for preparing and assessing a novel food application. These guidelines are usually prepared by European Food Safety Authority and they contain the necessary information to carry out a safety assessment on a case by case basis. However, during the novel food Revision process a possibility to simplify the authorisation procedure was identified allowing to decrease some of the related administrative burden costs (see graphic 1) while maintaining safety standards.

At present the applications for authorisation are submitted to the Member States authorities, which carry out the safety assessment. The results of this initial assessment are distributed to the other Member States and the Commission. If no objections are raised, the Member State, to which the application was submitted, informs the applicant that he may place the food on the market. If objections are raised (as in most cases), a community decision is required. In such case the safety assessment is frequently duplicated by EFSA. Therefore, as outlined in graphic 1, the decentralised authorisation system could be switched to a centralised one.

Graphic 1: Possible changes in procedural times for novel food authorisation (in average number of days)[11]



Because of the limited scope of the Regulation and the absence of readily available data it was decided not to use the EU Standard Cost Model to calculate the administrative burden costs.

Main issues

On the strength of experience gained since 1997 and the consultations and evaluation carried out[12], the main issues with potential economic and social impacts were as follows.

– At present traditional food which was not on the EU market before 1997, but for which there is information on safe use outside the EU, is subject to the same rigorous safety assessment procedure as any newly developed innovative food. This is perceived, especially by third countries, as an unjustified barrier to trade for their traditional foods.

---

11 There is only one case where a novel food authorisation procedure was finalised and an approval given at the Member State level (http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm).

12 Evaluation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and food ingredients, executive summary; http://ec.europa.eu/food/food/biotechnology/novelfood/iniatives_en.htm.

– The safety assessment and product authorisation procedure takes too long. The lengthy decentralised procedure duplicates the work and often generates unnecessary delays in the authorisation process.

– The authorisation decision is presently only addressed to the applicant, so that others only after notifying the Commission through an additional administrative procedure are able to market the same food.

– Assessing and authorising the same substances within different legal frameworks causes repetition and creates an additional administrative burden.

– The general implementation of the Novel Food Regulation needs to be improved.

Furthermore, there is a need for legal clarifications and updating because:

– There have been some misinterpretations about the definition of novel food and about the scope of the Regulation.

– It should also be ensured in the future that there is a horizontal approach to new technologies in breeding and food production processes with an impact on food and food safety.

– There is a need to update the legal text of the Regulation and to develop the provisions concerning the determination of the novelty of a food (e.g. collecting information to what extent a food has been used for human consumption within the Community before 15 May 1997) and concerning confidentiality and public consultation.

– The labelling provisions could be simplified now that GM food is regulated separately.

The regulatory action concerns a number of stakeholders: the food industry, consumers, EU (e.g. European Food Safety Authority) and national authorities, the general public and third countries.

Without taking action to revise he Regulation (i.e. leaving the situation as it is) we would miss the opportunity to clarify the scope of the Regulation and its application, to reduce authorisation time and the associated administrative burden, to support innovation in food production by creating a clearer legal framework, to facilitate trade in safe food from third countries, and to improve the general implementation of the Regulation.

In addition to ensuring food safety, having harmonised food safety regulations plays a part in the proper functioning of the internal EU market. The Novel Food Regulation adopted in 1997 harmonised the rules and contributed to free circulation of food in the EU. Repealing the Novel Food Regulation could endanger this and encourage the Member States to introduce different national authorisation procedures like those that were in place in some Member States before 1997. This could lead to different safety levels in the Member States and create obstacles for the free movement of food products in the EU. Authorisations for novel foods have been refused because of safety concerns[13].

Non-legislative action based, for example, on a code of good practice or guidelines could not give sufficient protection and would lack legal certainty. The General Food Law (Regulation 178/2002), which lays down general food safety provisions, was adopted in 2002. It lays down general principles and requirements regarding food safety but it does not address specific issues such as the pre-market safety assessment of food which is covered by sectoral legislation.

Therefore, there is a need for regulatory action to be taken. Otherwise the known problems would get worse and jeopardize the underlying aims of the Regulation.

The Commission is acting on the basis of the powers conferred on it by the Treaty establishing the European Community, in particular Articles 95.

The action is not in conflict with the basic principles that should guide the EU intervention, especially:

– the subsidiarity principle, since the individual action by Member States could only lead to differing levels of food safety and protection of human health. Repealing the Novel Food Regulation would do away with harmonised food safety rules and would endanger the free movement of (novel) food in the EU.

– the proportionality principle, since the proposal harmonises the regulatory framework for novel food approval and thus contributes to the functioning of the (novel) food market in the EU. The proposed measures are sufficient in terms of reaching the objectives of ensuring food safety and securing the functioning of the internal market for food. At the same time they do not impose an excessive or unjustified burden. The absence of harmonisation could result in the appearance of individual national approval systems, resulting in multiple authorisation work and increased administrative burden in the EU.

[13] http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

4. SECTION 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 and

- Achieve legal clarity by making any necessary changes and updating the legislation.

These objectives are linked to the Commission's strategic objectives and principles of Better Regulation, improving the implementation of regulations, facilitating innovation, especially in biotechnology, fostering entrepreneurship and investments (especially in relation to SMEs) and enhancing risk management and taking into account economic prosperity, social equity, environmental protection and international responsibilities while ensuring the safety of food and maintaining high level of public health protection (e.g. EU's Sustainable Development Strategy) as well as to EU's development policy (e.g. the 'European consensus').[14,15,16,17,18]

With a view to achieving these objectives a number of measures have been considered. These have been divided into two categories.

1. Measures that during the consultations were identified as having a major impact, e.g. major policy actions with potential economic, social or environmental impact. For these a more detailed analysis has been carried out.

---

14 http://ec.europa.eu/sustainable/welcome/index_en.htm

15 First progress report on the strategy for the simplification of the regulatory environment; COM(2006) 690 final.

16 Strategic objectives 2005-2009, Europe 2010: A Partnership for European Renewal; Prosperity, Solidarity and Security; Communication from the President in agreement with Vice-President Wallström; COM(2005) 12 final.

17 Communication to the Spring European Council: Working together for growth and jobs - A new start for the Lisbon Strategy; Communication from President Barroso in agreement with Vice-President Verheugen; COM(2005) 24 final.

18 Communication from the Commission to the Council, the European Parliament, the European Economic and Social committee and the Committee of the Regions - Proposal for a joint declaration by the Council, the European Parliament and the Commission on the European Union Development Policy - "The European Consensus"; COM/2005/0311 final */.

2. Measures that are required to bring the legal text into line with other EU policies and legislation. Experiences so far have shown that some of the measures were not capable of delivering the set objectives. The impacts of these measures are considered minor and not requiring detailed analysis as they mostly relate to legal updating and clarification.

Below is a list of measures that will be taken on board and that fall under the second category. The aim of the measures is given in brackets.

- Making use of the food definition in the General Food Law (Regulation N° 178/2002) and abandoning the categories describing foods (taking into account legal developments, avoiding problems associated with the categories and clarifying the scope).

- Maintaining a horizontal approach to new technologies with impact on food (rapid delivery of safe food using new technologies).

- Setting out definitions for traditional food from third countries and history of safe use (giving clearer guidance).

- Developing current practice on collecting information on novelty of a food and publishing the results (creating an open and transparent procedure and criteria, improving information flow).

- Introducing deadlines (increasing the efficiency of the system).

- Defining the role of EFSA (clearer procedures).

- Updating and formulating provisions on confidentiality and public consultation (consistency with general EU policy).

- Simplifying labelling provisions now that GM food is regulated separately (in addition following general EU policy on food labelling).

- Updating rules for issuing guidance documents (increased level of harmonisation).

- Creating a list of authorised novel foods (improving information flow and transparency).

EU legislation that has been taken into consideration in revising the Novel Food Regulation includes:

- Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents.

- Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods.

5. SECTION 4: MAJOR POLICY ACTIONS

The proposal for the new Regulation on Novel Foods is intended to amend and replace provisions already in place under Regulation N° 258/97. This means that for some of the problems, there is a need to develop a new policy. For other issues, corrective measures including updating and clarifying the legal text, are introduced.

The major policy actions that have been identified[19] and were the subject of an impact assessment are as follows:

1. Adjusted safety assessment and management for traditional food from third countries.

2. Safety assessment and authorisation procedure.

3. Authorisation decision.

4. Submission of application for several food uses.

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

Current problems

At present, uniform criteria and guidelines apply for the safety assessment of all kinds of food, including traditional food from third countries and newly developed innovative food. The present system is simple and straightforward to administrate. However, the requirements are not always proportional to the potential risks, which mean that the cost of application could be considered disproportionate (i.e. applicants can face what could be considered an unnecessary administrative burden). This is perceived, for example, by third countries as unjustified barriers to trade in their traditional food.

[19] Evaluation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel food and food ingredients, executive summary; http://ec.europa.eu/food/food/biotechnology/novelfood/iniatives_en.htm.

Options

Option 1: *No change 'One size fits all'*

No change to the present regulation would mean keeping the present system of uniform criteria and guidelines for the safety assessment of all kinds of food, e.g. traditional food from third countries and newly developed innovative food.

Option 2: *Adjusted safety assessment for traditional food from third countries*

Creating criteria and guidelines for different kinds of food by maintaining the safety level through an adjusted safety assessment could lead to a more proportional and rational system of food safety assessments. Data on safe food use outside the EU could better be taken into account.

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

To further adjust the authorisation procedure for traditional food from third 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 safety assessment, the Commission could consult Member States and ask then if they have objections to the authorisation. If no objection is raised, the applicant would be informed by the Commission of the positive outcome. In case of objections the general authorisation procedure could apply (comitology procedure).

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

The repeal of the pre-market safety assessment and authorisation for traditional foods entering the market after 15 May 1997 would be the target of a major simplification. 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 potentially unsafe food around the world. Without a pre-market safety assessment for novel food, the general safety level of food would decrease. The internal market for food could be affected by measures that might be taken by e.g. Member States.

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.

Options

Option 1: *No change (Decentralised assessment and authorisation procedure)*

If no changes are made to the Regulation the present decentralised assessment and authorisation procedure would continue.

Option 2: *Centralised risk assessment and authorisation procedure*

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 food.

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 common horizontal legal act which will seek to 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 harmonising of the authorisation procedures, including the authorisation decision and the submission of one application (points 3 and 4).

Policy action 3: Authorisation decision

Current problems

At present the authorisation decision is, in practice, linked to the applicant, thus allowing initially only this applicant to market the novel food in the EU. Other who wish to also market the food have to make additional administrative notification (simplified procedure). This allows food to be marketed in the EU which is substantially equivalent to food already authorised in the EU. This system causes multiple work for a food that has already been authorised.

Options

Option 1: *No change: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)*

In the case of no changes are made to present Regulation the authorisation continues to be linked to the applicant. Other parties interested in marketing the same product would have to make a notification of substantial equivalence using the simplified procedure.

Option 2: *Generic authorisation (all companies able to market in the EU and abolishment of the simplified procedure)*

A generic authorisation addressed to the EU would allow the whole food industry to market the authorised novel food. The present simplified procedure would no longer be needed and could be abolished.

Option 3: *Generic authorisation + data protection for certain foods (abolishment of simplified procedure)*

In this case only a generic authorisation would be given. Research invested in the innovative food could be covered by protecting the data presented in the application. At the same time, the present simplified procedure would no longer be needed and could be abolished.

Option 4: *Different types of authorisations (generic and for certain foods applicant-linked, abolishment of simplified procedure)*

Different types of authorisation decisions would in this case be given: generic and applicant-linked. At the same time, the present simplified procedure would no longer be needed and could be abolished. Innovative novel foods based on considerable product development could be protected by an authorisation linked to the applicant ('brand specific authorisation'). Certain criteria for this would have to be developed.

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 sectorial legislation leads to repetitive work and an additional administrative burden. Industry is too seeking the simplest possible regulatory framework.

Options

Option 1: *No change: Separate applications for different food uses*

At present, separate applications have to be made for a substance for different food uses, e.g. additives, flavourings, extraction solvents or novel foods, within the respective legal frameworks.

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

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

6. SECTION 5: ANALYSIS OF IMPACTS

The analysis of impacts takes account of the results of the IMP online consultation carried out between 2 June and 1 August 2006 on the four major policy actions and their alternatives (Annex 3-4). 65 responses were received. 76% of the responses came from the EU (50% from the Netherlands, Belgium, France and Germany, see Annex 6). The majority of the third-country responses came from Ecuador (4), Colombia (3) and Peru (2) and mostly from their competent authorities. Most of the responses were from the food industry (41%) followed by competent authorities (26%) and international organisations (12%). Only two consumers and one SME responded to the questionnaire.

In addition, many other sources of information were used as a means of validating the responses from the on-line consultation. For example, in-house data on applications and procedural times (see Annex 1-2) or information from UNCTAD Biotrade Initiative[20] and Nordic Project on risk assessment and risk management of novel plant foods[21]. Further, the impact assessment results were scrutinised by the Member States experts, experts from different Commission Directorate-Generals' represented in the Inter-Service Group on Impact Assessment on Novel Food Revision and experts from other relevant stakeholder groups in the working group of the DGSANCO Advisory Group on the Food Chain and Animal and Plant Health.

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

Impact on public health and food safety and consumer rights

Developing an adjusted safety assessment (option 2) or management procedure (option 3) for traditional food from third countries is seen as having a beneficial impact on public health and food safety. However, the neutral impact expected by a number of respondants shows that most likely options 2 and 3 will not have impact on public health and food safety. The responses underline the importance of a documented history of safe use, ascertaining possible undesirable effects. One consumer organisation stressed the need for uniform criteria and clear guidelines for the safety assessment of novel foods. In addition, it expressed concern that any different approach to traditional food from third countries might result in a relaxation of safety assessments, leading to a loss of trust in novel food ingredients on the part of European consumers.

---

20 http://www.biotrade.org/Intro/bti.htm

21 Risk assessment and risk management of novel plant foods – concepts and principles; TemaNord 2005:588.

A majority of respondents expressed the view, that the omission of a pre-market safety assessment and authorisation for traditional food from third countries (option 4) would have an adverse impact on public health and food safety. Potentially unsafe food, with no recorded history of safe use, could under this option enter the EU market. It is well established that many foods contain natural toxicants, allergens or anti-nutrients that can cause problems if they were present above accepted levels. This is phenomenon is also observed in pharmacovigilance as there have been regular reports of problems concerning plants with traditional uses in third countries. Concerns were also expressed by some respondents about whether the EU population would be able to 'tolerate' some novel foods, especially that which is only used in exceptional cases and for medical purposes in the country of origin. It is possible that the food could be used differently by consumers in the EU. Therefore, in some cases it is essential to inform the consumers about preparation methods and use. The third countries, however, frequently comment that 'the safety of foods has been tested by traditional regular consumption over many years in the country of origin'.

As regards impact on consumer rights, the options concerning an adjusted safety management procedure (option 3) and abolishing the requirements for third countries (option 4) were viewed as beneficial. One consumer made the point that food choice would increase. One consumer organisation stressed the need to develop transparent procedures.

Impact on employment and jobs

According to the consultation results any changes to the present situation (options 2-4, especially option 4) could to lead to some increased employment due to a number of positive economic impacts, however no significant impacts are expected. For the developing countries, easier market access facilitating trade could have a positive social impact.

Impact on administrative requirements imposed on business

A better adjusted safety assessment (option 2) or management system (option 3) would lead to a decrease in the administrative burden imposed on business. It is clear that removing the requirement for a pre-market safety assessment and authorisation for traditional food (option 4) would eliminate the present administrative burden concerning traditional foods from third countries, including for the competent authorities.

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

Developing a better adjusted safety assessment (option 2) or management system (option 3) 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[22]. Abolishing the requirements for traditional food from third countries (option 4) would also 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 (option 2) or management system (option 3) 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 (option 4) 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)

The environmental impact is mostly viewed as positive or as 'neutral/not relevant/don't know'. This is the case in relation to changing to a more adjusted safety assessment or management procedures or simply abandoning the pre-market safety assessment requirements for traditional food from third countries. The importance of trade as a positive incentive measure for biodiversity conservation is increasingly recognised at national and international levels[22]. Increased trade in traditional food might lead to higher production of different food plants and thus greater biodiversity in the country of origin, if this is in conjunction withsustainable development. Efforts are underway to promote trade that takes into account ecological and social issues[20].Socio-economic impact (third countries in particular) (in particular local communities and indigenous groups)

[22] BioTrade Initiative Implementation Strategy, Elaborated by UNCTAD BioTrade Initiative Geneva, March 2005, biotrade@unctad.org.

The most significant impact of developing a better adjusted safety assessment (option 2) or management system (option 3) is expected in the socio-economic field. Abolishing the requirements for traditional food from third countries (option 4) would further improve the situation. Traditional food is often produced by farmers in poor rural areas. The social impact of increased trade on these products is regarded as high, with reduced poverty being one possible outcome. For example, in one of the Andean countries many of these new products form part of the national export portfolio and are linked to policies promoting green markets, organic production, replacement of illegal crops and agricultural sustainability in conflict zones. The social impacts could include increased employment, recovery of farmland and improvements to the quality of life of the rural population.

Policy action 2: Safety assessment and authorisation procedure

Impact on public health and food safety and consumer rights

The switch from a decentralised (option 1) to a centralised assessment and authorisation procedure (option 2) 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. Until now, only in one case (Tagatose) was the initial safety assessment on the national level satisfactory allowing the product to be marketed in the EU. Some Member States and a consumer organisation underline the importance of the Member States (scientific bodies) and stakeholders commenting on the applications.

Impact on employment and jobs

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 timeframe of the present authorisation procedure for novel foods is considered to be too long. Abolishing the initial safety assessment at Member State level would, by introducing a centralised procedure (option 2), do away with the duplication of administrative burden for both industry and Member States' competent authorities. The present time-consuming system of initial assessment of 90 days at national level and subsequent commenting period of 60 days, not to mention the associated exchange of information, could be avoided (see Procedural times, Annex 2). This was also reflected in the IMP online consultation results. The switch to a centralised procedure (option 2) 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. One smaller Member State indicated that currently a Member State with limited resources would find it difficult to meet the requirements of the decentralised procedure at national level.

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

A centralised authorisation procedure, incorporating deadlines (option 2) and a reduced administrative burden, is expected to work in favour of new product development. More new novel food products could enter the market more rapidly. Enhanced competitiveness and higher investments would 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 (option 2). 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. Food ingredient manufacturers are constantly seeking to improve existing ingredients and to develop new ones. In practice, customers of food ingredient suppliers are increasingly demanding confirmation of official approval before purchasing ingredients. Hence, the greater the novelty of the food ingredient, the more official approval becomes a commercial necessity.

Environmental impact (EU and third countries)

No impact is expected under the different options, but the consultation responses give a fairly positive - or at least neutral picture - of the centralised risk assessment and authorisation procedure in terms of its impact on the environment.

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

Creating a centralised assessment and authorisation procedure (option 2) for novel food is viewed to have a positive socio-economic impact due to the more general positive economic impacts, and this goes for third countries too.

Policy Action 3: Authorisation decision

Impact on public health and food safety and consumer rights

Changing the authorisation decision, under the various options, has a mostly 'neutral/don't know/ not relevant' impact on public health and food safety. The impact of the option on the different types of authorisations (option 4) was somewhat surprisingly seen as fairly positive. One reason might be that applicant-linked authorisation could allow post-market monitoring which could better ensure consumer protection with regard to newly developed food products. The consumer organisation underlined the importance of making sure that all foods placed on the market under the same generic authorisation are equivalent.

Changing the authorisation decision into a generic one (option 2) or having different types of authorisation (option 4, also board neutral impact) is expected to have a positive impact on consumer rights compared to the 'no change' alternative. The data protection (option 3) aspect is viewed as 'neutral/don't know/not relevant'.

Impact on employment and jobs

According to the consultation results changing the authorisation decision to generic (option 2) or to different types of authorisations (options 4) could create new jobs, however no significant impact is expected. Adding data protection to generic approval (option 3) would not change the present situation.

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)

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. A food should not be privatised, if it has been in the public domain in the country of origin. Most food and original ingredients are generic and should remain so. Food should not be patentable (a view expressed by a food producer). Some respondents consider a generic authorisation decision for SMEs as a good alternative. 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 (option 3) 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 IPM consultation, have a very beneficial impact on innovation and research. Somewhat surprisingly, even a generic authorisation decision (option 2), combined where appropriate with data protection for the applicant (option 3), would increase food industry's enthusiasm for innovation and research. Changing the authorisation decision to allow different kinds of authorisations (option 4) 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)

No environmental impact is expected under the various options. However, the generic authorisation (option 2) and generic authorisation including data protection (option 3) are considered to have a moderate beneficial impact on the environment. This might be due to some the respondents expecting a positive on biodiversity in third countries as a result of increased trade and production of traditional food plants.

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

The socio-economic impact is expected to be positive if generic authorisation (option 2) and different types of authorisations (option 4) were introduced in the new legislation. This is due to the positive impact on innovation, research and trade.

Policy Action 4: Submission of application for several food uses

Impact on public health and food safety and consumer rights

The introduction of a single application for all novel foods for different uses (e.g. additives, flavourings, extraction solvents or novel foods, option 2) is expected by some respondents to have a beneficial impact on public health and food safety compared with separate applications for different food uses (option 1). As explained by one respondent, this might be due to a broader view being taken of overall exposure for a new substance. At any rate, more account is taken of all aspects and uses of a substance. However, it is well established that the food safety assessment procedures in the EU have resulted in a high level of food safety. It follows, then, that a neutral impact, as viewed by a number of respondents, is more likely to be the case. Similarly, switching to a single application for multiple food uses (option 2) is expected to improve consumer rights or have a neutral impact.

Impact on employment and jobs

The simplification through introducing the possibility for one single application (option 2) is viewed to increase employment and number of jobs. This is probably due to the general positive economic impacts of the option but no significant impact is expected.

Impact on the administrative burden

A single application for different food uses (option 2) 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, as presented in option 2, significantly improves the present situation and reduces costs, as they are incurred only once.

Impact on innovation and research

Innovation and research would benefit from simplification (option 2) 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)

The consultation results supported option 2 by expecting beneficial or neutral impacts.

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

The simplification set out in option 2 would lead to a significant positive socio-economic impact. 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 the impact is not expected to be significant.

7. SECTION 6: COMPARING THE OPTIONS

This section sets out how the current situation can be improved through a legal proposal reflecting the most favourable policy option.

Legal act

The results of the IPM online consultation are summarised in Table 1. Judging by the impact assessment, the revision of the Novel Food Regulation is generally expected to have a beneficial impact on competitiveness, market access, trade flows, administrative burden imposed on business, innovation and research. Public health and food safety, employment, socio-economy and environment are thought likely to improve to a certain degree (see also Annex 5, Fig 1).

Table 1: Impacts of the revision of the Novel Food Regulation N° 258/97 based on responses from the online consultation

Type of impact	Revision of Regulation N° 258/97
Social impacts	
Impact on public health and food safety	++
Impact on consumer rights	++
Impact on employment and jobs	++
Economic impacts	
Impact on the administrative burden imposed on business	++
Impact on competitiveness, markets and trade (including third countries)	++
Impact on innovation and research	++
Environmental impact	+
Socio-economic impact (third countries in particular)	++

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/don't know.
- Not very beneficial impact
-- Not at all beneficial impact

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

The results of the impact assessment are summarised in Table 2.

Table 2: Summary of impacts of different options for adjusted safety assessment and management for traditional food from third countries based on responses from the online consultation

Type of impact	Option 1	Option 2	Option 3	Option 4
Description of option	No change 'One size fits all'	Adjusted safety assessment for traditional food from third countries	Adjusted safety assessment and management for traditional food from third countries	No pre-market safety assessment and authorisation for traditional food from third countries
Social impacts				
Impact on public health and food safety	--	+	++	-
Impact on consumer rights	--	0	+	+
Impact on employment and jobs	--	+	+	++
Economic impacts				
Impact on the administrative burden imposed on business	--	++	+	++
Impact on competitiveness, markets and trade (including third countries)	--	++	+	+
Impact on innovation and research	--	+	+	+
Environmental impact	-	+	++	+
Socio-economic impact **(third countries in particular)**	**--**	++	++	++

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/don't know
- Not very beneficial impact
-- Not at all beneficial impact

Potential for optimising options

As indicated by some respondents, any changes in the safety assessment procedure need to be supported by transparent and clear criteria and scientific guidelines for conducting the safety assessment.

Analysis of current situation and justification of the proposal

The current situation provides for food, which was not on the EU market before 1997 but where there is information on safe use outside the EU, to be regulated by the same rigorous safety assessment as any newly developed innovative food. This is perceived, especially by third countries, as unjustified barriers to trade for their traditional food.

The impact assessment (see table 2) confirms that a system with a better adjusted safety assessment and management for different types of food (e.g. traditional food from third countries vs. newly developed food) could be established. The same level of safety would be achieved. The preferred system is an adjusted safety assessment and management (option 3), followed by option 4, where no pre-market safety assessment is required. The latter option would not be acceptable for public health and food safety reasons, concerns having been expressed by various stakeholders in the EU. Adjusting the procedures could thus facilitate imports of exotic food with a history of safe use outside the EU, while keeping in place the safety measures needed to ensure food safety in the EU.

Proposal

The results of the impact assessment support the introduction for traditional food from third countries, of 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.

Policy Action 2: Safety assessment and authorisation procedure

The results of the impact assessment are summarised in Table 3.

Table 3: Summary of impacts of different options for safety assessment and authorisation procedure for novel foods based on responses from the online consultation

Type of impact	Option 1	Option 2
Description of option	No change: Decentralised assessment and authorisation procedure	Centralised risk assessment and authorisation procedure
Social impacts		
Impact on public health and food safety	--	++
Impact on consumer rights	--	++
Impact on employment and jobs	--	++
Economic impacts		
Impact on the administrative burden imposed on business	--	+
Impact on competitiveness, markets and trade (including third countries)	--	++
Impact on innovation and research	--	++
Environmental impact	-	+
Socio-economic impact (third countries in particular)	-	++

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/don't know
- Not very beneficial impact
-- Not at all beneficial impact

Potential for optimising options

The action needs to be combined with time limits for the procedure and a possibility for Member States (scientific bodies) and stakeholders to comment on the applications.

Analysis of current situation and justification of the proposal

The present safety assessment and authorisation procedure takes too long, according to 82% of the respondents (see Annex 6). It is also, in some cases, unpredictable for the applicants due to the lengthy decentralised authorisation procedure. In most cases, the national initial assessment has been duplicated at EU level (see Annex 2). As a result, the present system is time-consuming with a heavy administrative burden. A centralised safety assessment and authorisation procedure (option 2) is preferred by the majority of respondents.

Proposal

The results of the impact assessment point towards the option of replacing the decentralised procedure by a centralised procedure at EU level. The safety assessment would be carried out by EFSA, and the authorisation decision taken by comitology procedure. The procedure needs to be combined with time limits to be respected.

Policy Action 3: Authorisation decision

The results of the impact assessment are summarised in Table 4.

Table 4: Summary of impacts of different options for authorisation decision on novel food based on responses from the online consultation

Type of impact	Option 1	Option 2	Option 3	Option 4
Description of option	No change: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	Generic authorisation (all companies able to market in the EU and abolishment of the simplified procedure	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	Different types of authorisations (generic and for certain foods applicant-linked, abolishment of simplified procedure)
Social impacts				
Impact on public health and food safety	0	0	0	+
Impact on consumer rights	0	+	0	+
Impact on employment and jobs	-	+	0	++
Economic impacts				
Impact on the administrative burden imposed on business	-	+	+	+
Impact on competitiveness, markets and trade (including third countries)	-	+	+	+
Impact on innovation and research	-	+	+	++
Environmental impact	0	+	+	0
Socio-economic impact (third countries in particular)	0	++	0	+

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/don't know
- Not very beneficial impact
-- Not at all beneficial impact

Potential for optimising options

When assessing the potential for optimising the different options, consideration could be given to the question of data protection, as its impacts were in general viewed as beneficial. Thought could be given, to granting an applicant-linked authorisation for a newly developed for example upon request (as suggested by one respondent) subject to good justification or in the event of an established need for post-market monitoring.

Analysis of current situation and justification of the proposal

The authorisation decision is at present only addressed to the applicant, so that others do not have the right to market the authorised food. It follows that an additional separate administrative procedure (simplified procedure) is needed for others to market the same novel food. Simplification could be achieved by abolishing this procedure and allowing generic authorisations (authorisation for the EU) as a general rule. On the other hand, the results indicate that innovation and research in the food industry could be supported by granting, for the newly developed foods, in justified cases, an authorisation linked to the applicant. The applicant-linked authorisation would allow, if deemed necessary, a post-market monitoring in the interests of public health and food safety. Generic authorisation was supported by 42% (20% with or 22% without data protection) and differentiated authorisation (generic and applicant-linked) by 44% of the responses.

Proposal

The results of the impact assessment indicate the need to replace the applicant-linked authorisation and to abolish the present simplified procedure 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

The results of the impact assessment are summarised in Table 5.

Table 5: Summary of impacts of different options for submission of application for several food uses based on responses from the online consultation

Type of impact	Option 1	Option 2
Description of option	No change: separate applications for different food uses	One application for all new foods for different uses
Social impacts		
Impact on public health and food safety	0	++
Impact on consumer rights	-	++
Impact on employment and jobs	-	++
Economic impacts		
Impact on the administrative burden imposed on business	-	++
Impact on competitiveness, markets and trade (including third countries)	--	++
Impact on innovation and research	--	++
Environmental impact	-	+
Socio-economic impact (third countries in particular)	-	++

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/don't know
- Not very beneficial impact
-- Not at all beneficial impact

Potential for optimising options

-

Analysis of current situation and justification of the proposal

Duplication of work and a heavy administrative burden are caused by assessing and authorising the same substances within different legal frameworks. The preferred option was to have a single application for all new food uses regulated under different legislative frameworks (option 2). This was supported by the majority of the respondents.

Proposal

The results of the impact assessment favour the option of simplifying the present system and enabling applicants to apply for an approval by a single application covering novel food and food uses regulated under various regulatory frameworks. Consideration could be given to this in the context of possible future proposal on a common authorisation procedure for foods.

8. SECTION 7: MONITORING AND EVALUATION

Monitoring of implementation

The effective monitoring of the new Regulation on novel food requires evaluations at regular intervals. For this purpose, it is necessary to put a system in place. The following indicators are proposed for monitoring and evaluating the future authorisation procedure of novel foods.

Problem	Potential Indicator	Data Source	Rationale
Claims on trade barrier against third countries	Number of traditional food applications from third countries.	European Commission	With a better adjusted safety assessment and management procedure the number of applications should increase.
Duration of authorisation procedure and administrative burden	Average time taken for authorisation of novel food.	European Commission	Authorisation should speed up with new legislation. Binding deadlines need to be monitored.
Influence on competition and innovation	Number of novel foods approved.	European Commission	Aims to review innovation in the EU by monitoring the introduction of new provisions on authorisation decision and data protection.

ANNEX

Working document

Does not necessarily represent the views of the Commission

Draft report on

IMPACT ASSESSMENT FOR A REGULATION REPLACING REGULATION (EC) NO 258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS

Annexes 1 - 6

Lead DG: Health and Consumer Protection (SANCO)

Other involved services: SG, ENTR, TRADE, DEV, RTD, ENV.

Agenda planning reference: 2007/SANCO/006

Annex 1: Novel food applications and notifications

Annex 2: Procedural times of novel food applications

Annex 3: IPM online consultation explanatory note

Annex 4: IPM online consultation questionnaire

Annex 5: Central impact assessment results in graphics

Annex 6: Results of Interactive Policy Making (IMP) online consultation on Revision of Regulation EC N° 258/97 on Novel Foods and Novel Foods Ingredients, 2.6. - 1.8.2006

Annex 1: Novel food applications and notifications

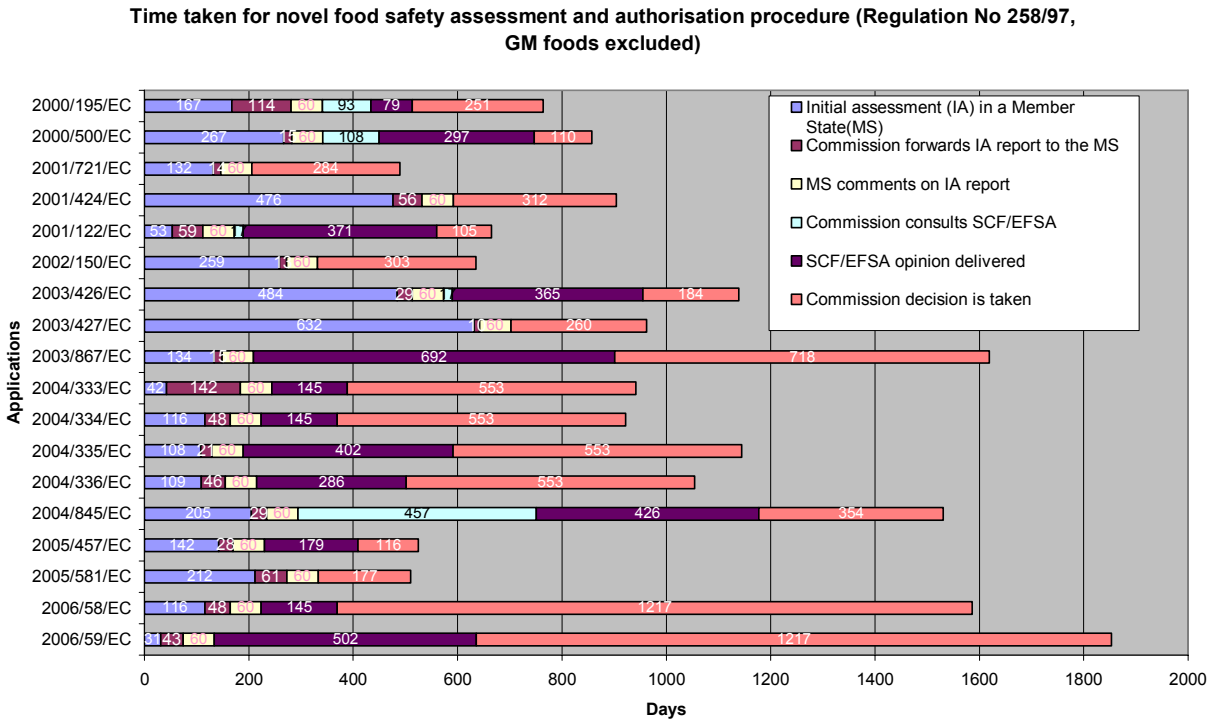
Applications under the Regulation (EC) N° 258/97 on novel foods and novel food ingredients (7.7.2006)

Progress of applications under the Novel Food Regulation (including GM foods)	
Total Number of Applications Accepted by Member States	71
Applications Withdrawn	12
Erroneous application	1
Initial assessment report pending	12
SCF/EFSA opinion requested	17
Authorised on national level	1
EFSA opinion delivered but no decision (July 2006)	7
Authorised	22
Refused	3

Notifications under the Regulation (EC) N° 258/97 on novel foods and novel food ingredients (7.7.2006)

Number of notifications	68

Annex 2: Procedural times of novel food applications



Annex 3: IPM on line consultation explanatory note

31/5/06

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.

Annex 4: IPM online questionnaire

IMPACT ASSESSMENT

REVISION OF REGULATION 258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS

DG Health and Consumer Protection

European Commission

Brussels

NAME OF THE ORGANISATION	
STAKEHOLDER GROUP	☐ **Competent Authority (CA)** ☐ **Food ingredient producer** ☐ **Food ingredient importer** ☐ **Food producer (food ingredient user, final food producer)** ☐ **Consumer** ☐ **Other, please specify:** **----------** ☐ **SME company** ☐ **Company operating on national level** ☐ **International company** **----------** ☐ **Organisation operating on national level** ☐ **International organisation**
COUNTRY	
ADDRESS: (postal, e-mail address, telephone, fax and web page if available)	

INSTRUCTIONS, necessary? **Only one cross/line**

1. General questions

European market, imports and employment

1. What was the estimated market size and value of novel foods as a total, or by product categories, in your organisation in 2000-2005 in relation to your total sales?

Item	Not applicable	Very significant	Significant	Not significant
Novel foods as total	☐	☐	☐	☐
Traditional food from 3rd countries (outside the EU)	☐	☐	☐	☐
R & D based novel foods	☐	☐	☐	☐

Please specify main products, market shares and values in 2000-2005 (in euro)

2. What was the value of novel food imports as a total, or by product categories, in your organisation 2000-2005?

Item	Not applicable	Very significant	Significant	Not significant
Novel foods as total	☐	☐	☐	☐
Traditional food from 3rd countries (outside the EU)	☐	☐	☐	☐
R & D based novel foods	☐	☐	☐	☐

Please specify main products, exporting countries, market shares and values in 2000-2005 (in euro)

3. How many persons were employed in your organisation in the novel food sector in 2000-2005?

Please specify

Innovation costs

How high were the R & D costs (innovation costs) related to novel foods in the period of 2000-2005 for your organisation (in euro)?

Please specify

Authorisation time and application costs

How do you consider the time that is taken for the authorisation procedure of novel foods?

Item	Short	About right	Long	Don't know
Safety assessment of novel foods	☐	☐	☐	☐
Authorisation decision on novel foods	☐	☐	☐	☐
Authorisation procedure as a whole	☐	☐	☐	☐

What were the administrative burden costs per novel application as total, or by product categories, in the period of 2000-2005 for your organisation?

Item	Not applicable	Very significant	Significant	Not significant
Novel foods as total	☐	☐	☐	☐
Traditional food from 3rd countries (outside the EU)	☐	☐	☐	☐
R & D based novel foods	☐	☐	☐	☐

Please specify which administrative burden costs are directly related to novel food applications as a total, or by product categories (traditional food from 3rd countries, R & D based novel foods, in euro)

2. Questions to assess the possible impact on your organisation of the main options for the revision of the Novel Food Regulation

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

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Choose your preferred option

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

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

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

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

Detailed explanation of the reasons for or against the above-mentioned options:

Please specify

2. Safety assessment and authorisation procedure?

Option 1 ***No changes (decentralised assessment and authorisation procedure)***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Option 2 ***Centralised risk assessment and authorisation procedure***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Choose your preferred option

☐ Option 1: *No changes (decentralised assessment and authorisation procedure)*

☐ Option 2: *Centralised risk assessment and authorisation procedure*

Detailed explanation of the reasons for or against the above-mentioned options:

Please specify

3. Authorisation decision?

Option 1 ***No changes: Authorisation linked to the applicant (only applicant able to market)***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Option 2 ***Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Option 3 ***Generic authorisation + data protection for certain foods***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Option 4 ***Different types of authorisations (generic and for certain foods, applicant linked)***

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Choose your preferred option

☐ Option 1: *No changes*: *Authorisation linked to the applicant (only applicant able to market)*

☐ Option 2: *Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)*

☐ Option 3: *Generic authorisation + data protection for certain foods*

☐ Option 4: *Different types of authorisations (generic and for certain foods, applicant linked)*

Detailed explanation of the reasons for or against the above-mentioned options:

Please specify

4. Submission of application for several food uses

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

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

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

☐ Option 1: *No changes*: *Separate applications for different food uses*

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

Detailed explanation of the reasons for or against the above-mentioned options:

Please specify

5. Legal Act

What would be the impact of the revision for your organisation?

Type of impact	Not relevant	Very beneficial	Fairly beneficial	Neutral	Not very beneficial	Not at all beneficial	Don't know
Impact on public health and food safety	☐	☐	☐	☐	☐	☐	☐
Impact on consumer rights	☐	☐	☐	☐	☐	☐	☐
Impact on competitiveness, markets and trade (including third countries)	☐	☐	☐	☐	☐	☐	☐
Impact on the administrative burden imposed on business	☐	☐	☐	☐	☐	☐	☐
Impact on innovation and research	☐	☐	☐	☐	☐	☐	☐
Impact on employment and jobs	☐	☐	☐	☐	☐	☐	☐
Environmental impact (EU and 3rd countries)	☐	☐	☐	☐	☐	☐	☐
Socio-economic impact (3rd countries in particular)	☐	☐	☐	☐	☐	☐	☐

Detailed explanation of the reasons for or against the above-mentioned option:

Please specify

Please make reference here to any available data/documents that support your answers, or indicate sources where such data/documents can be found.

Please specify

Annex 5: Central impact assessment results in graphics

Figure 1 :

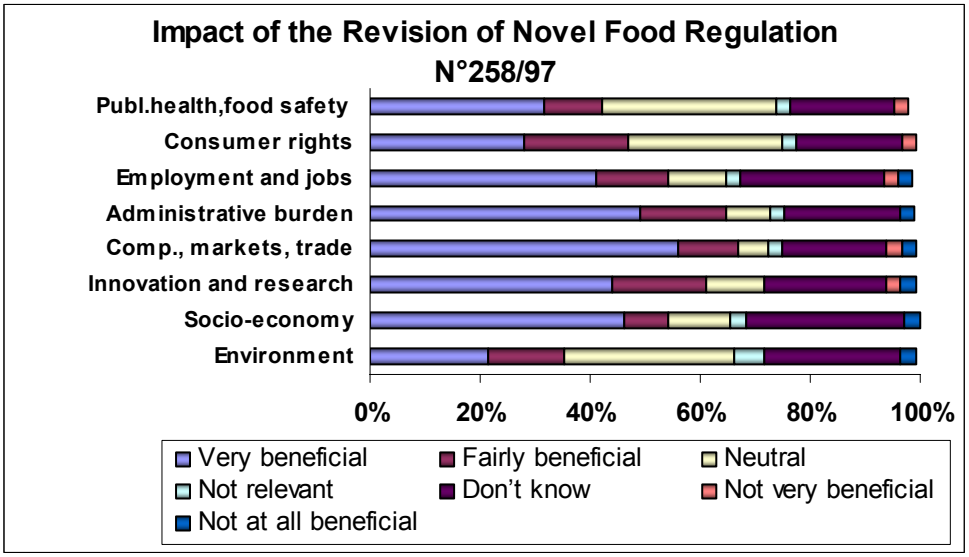


Figure 2:

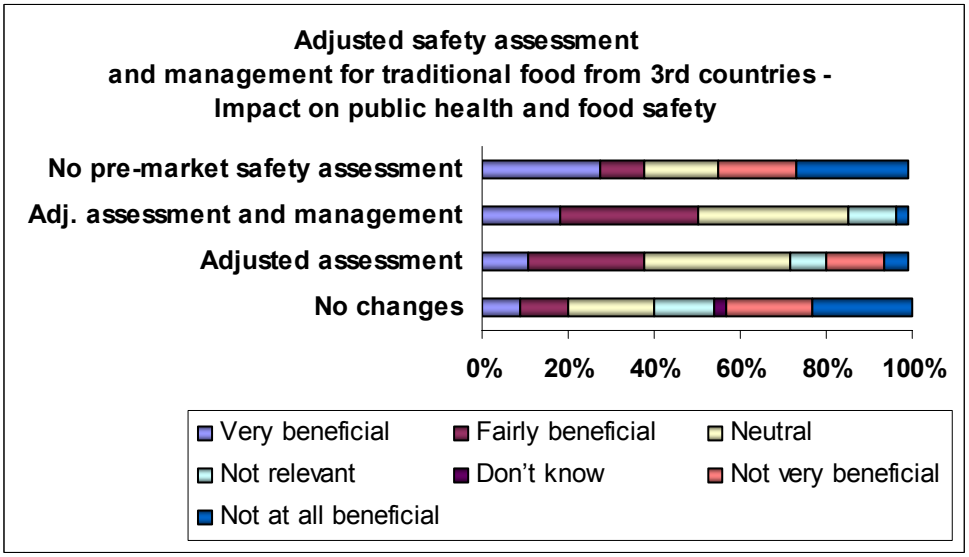


Figure 3:

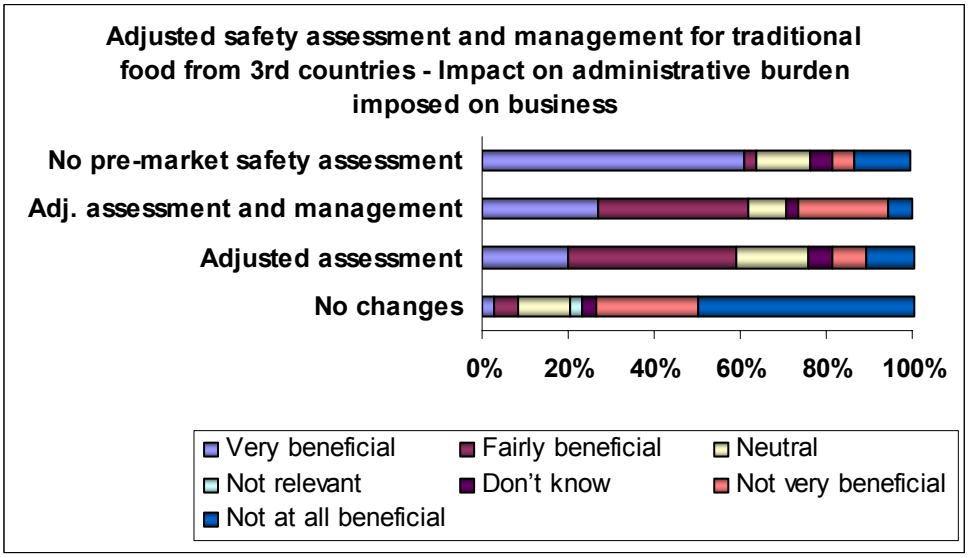


Figure 4:

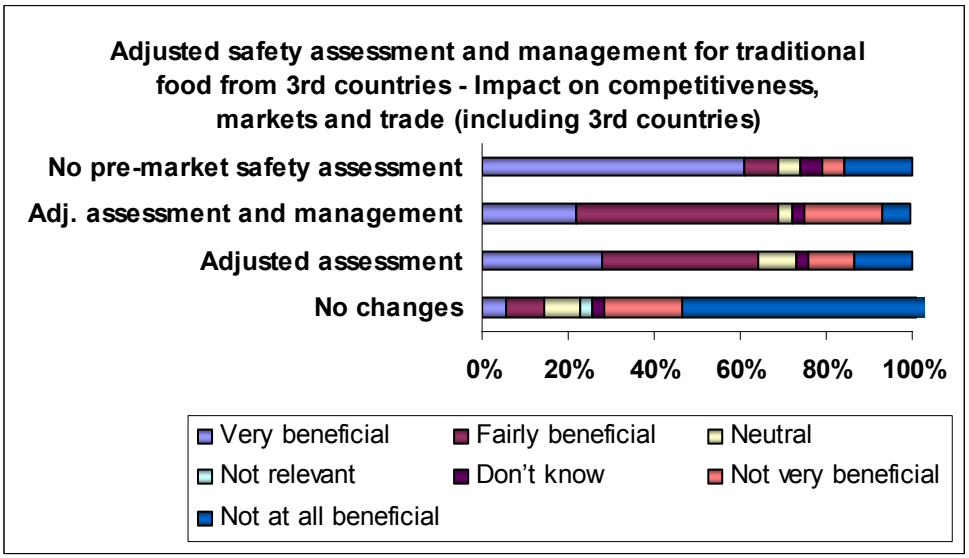


Figure 5:

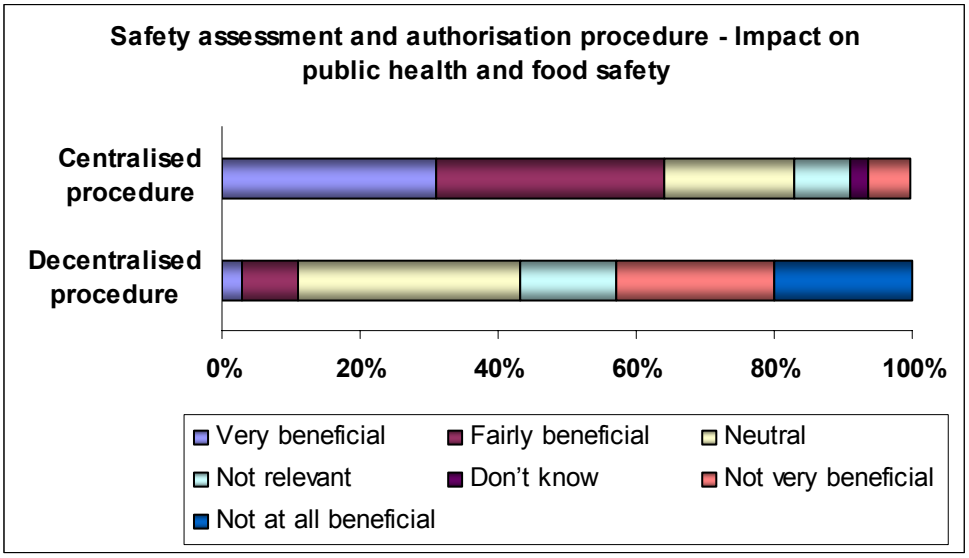


Figure 6:

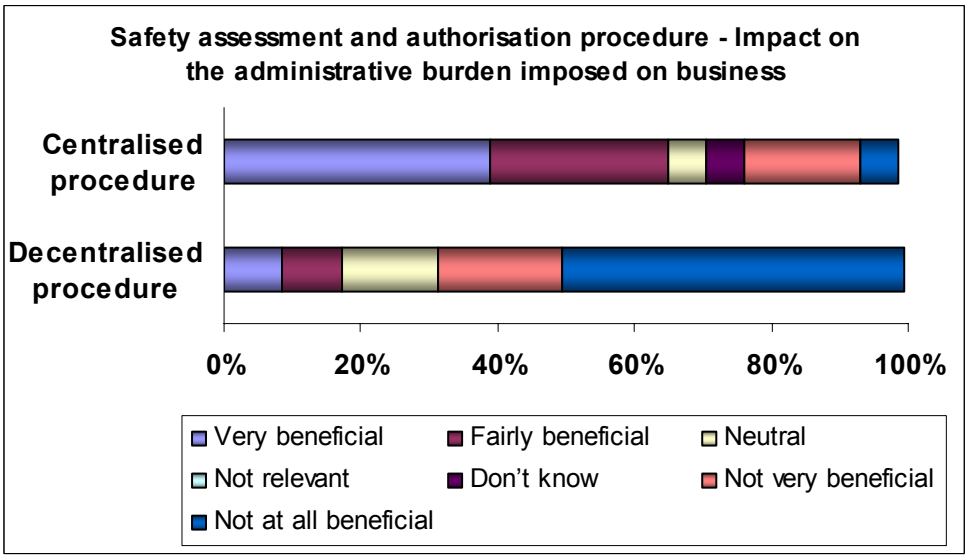


Figure 7:

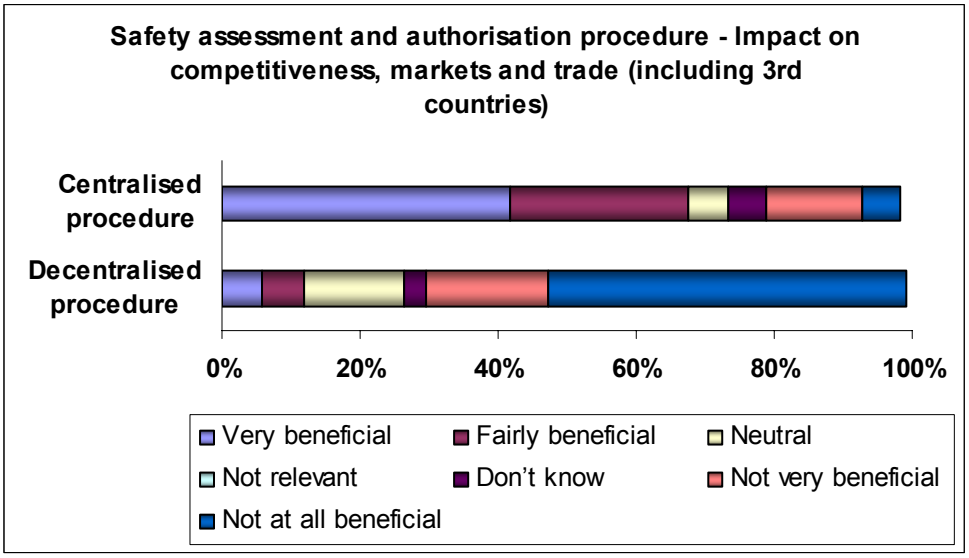


Figure 8:

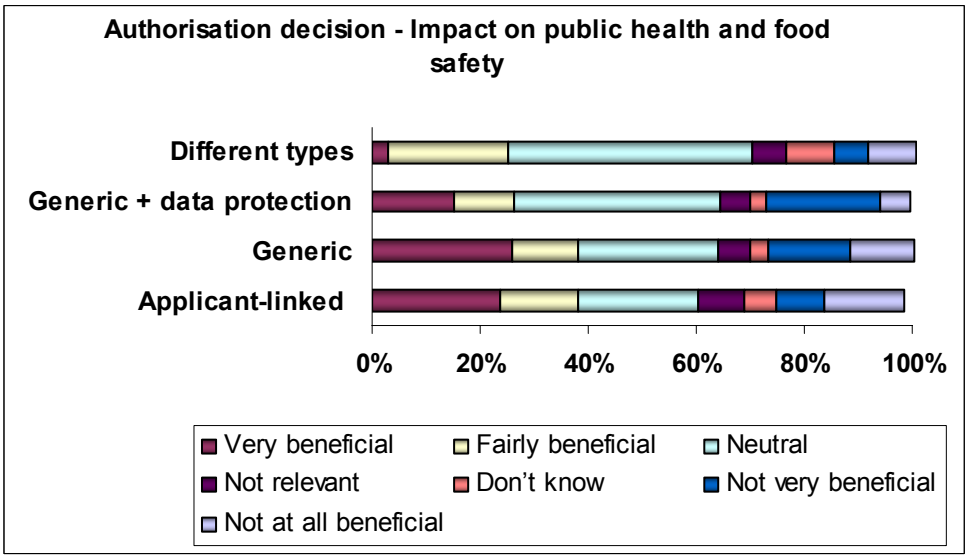


Figure 9:

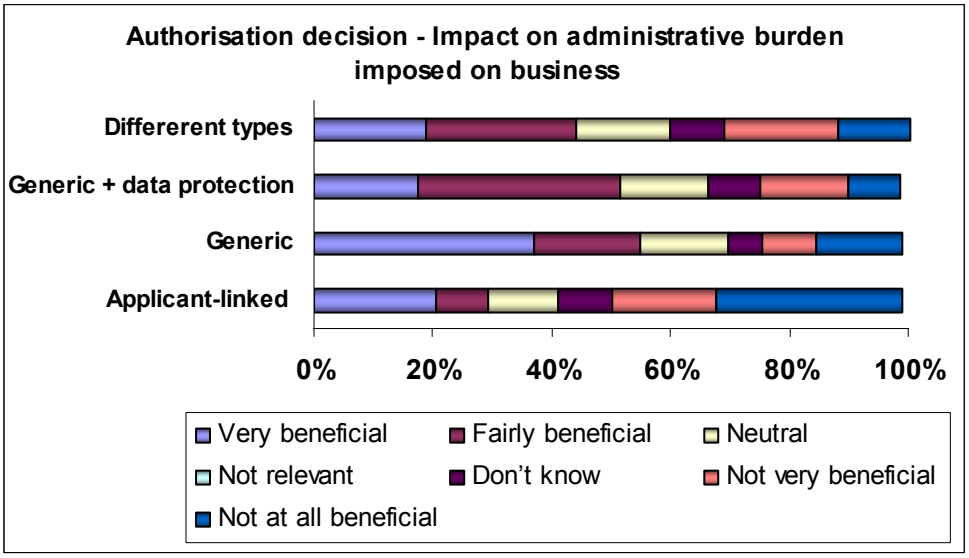


Figure 10:

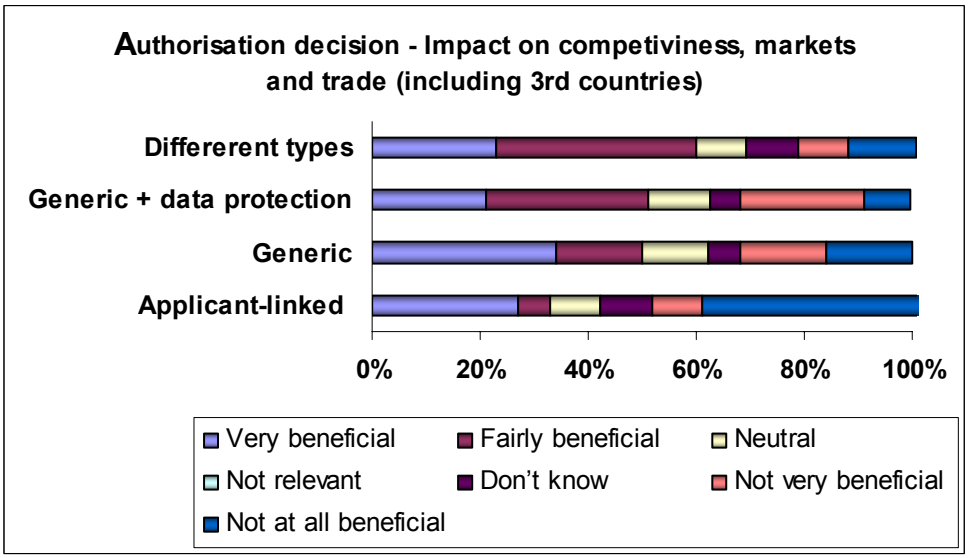


Figure 11:

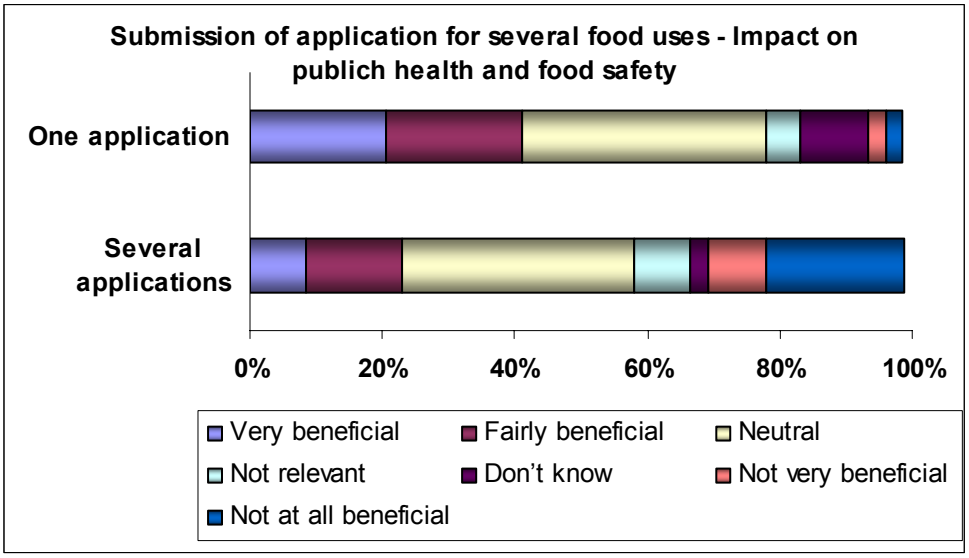


Figure 12:

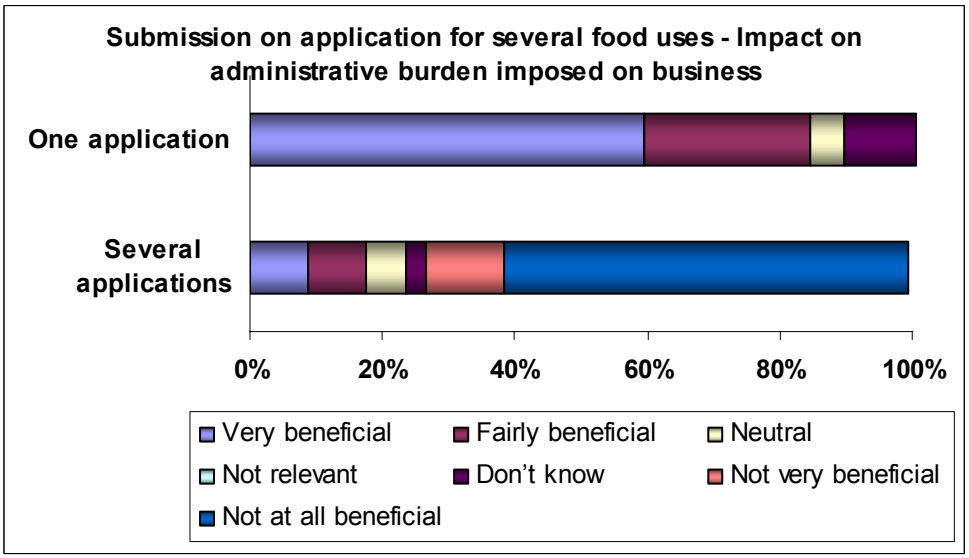
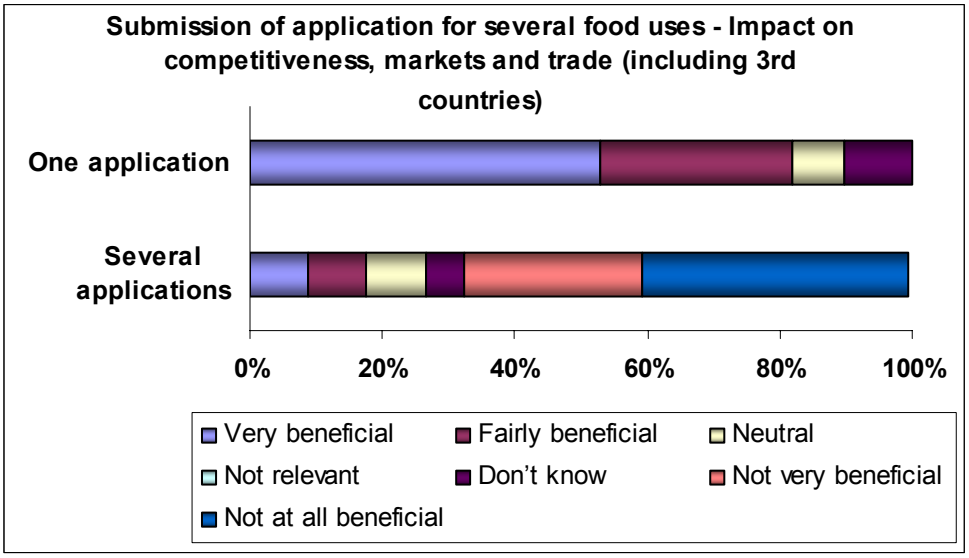


Figure 13:


Submission of application for several food uses - Impact on competitiveness, markets and trade (including 3rd countries)
One application
Several applications
0%
20%
40%
60%
80%
100%
Very beneficial
Fairly beneficial
Neutral
Not relevant
Don't know
Not very beneficial
Not at all beneficial

Annex 6: Results of Interactive Policy Making (IMP) online consultation on revision of Regulation EC N° 258/97 on Novel Foods and Novel Foods Ingredients, 2.6. - 1.8.2006

(in relation to number of responses given for a specific question)

Total number of responses 65[23]

Stakeholder group	**Number of responses**	**In % of total number of responses**	
Competent Authority (CA)	17	26%	
Other	8	12%	
International organisation	8	12%	
International company	7	11%	Food industry:
Food ingredient producer	7	11%	41%
Food producer	6	9%	
National organisation	4	6%	Organisations:
Food ingredient importer	3	5%	18 %
SME company	1	2%	
National company	2	3%	
Consumer	2	3%	
	65	100%	

Country

Netherlands	11	18%	EU:
Belgium	8	13%	75.8%
France	7	11%	Third countries:
Germany	5	8%	24.2%
Ecuador	4	6%	
Spain	4	6%	
Italy	4	6%	
Colombia	3	5%	
Denmark	2	3%	

[23] Four responses were disqualified: empty or double responses or only a name given.

Finland	2	3%
Peru	2	3%
Argentina	1	2%
Chile	1	2%
China	1	2%
Guatemala	1	2%
Ireland	1	2%
Latvia	1	2%
Norway	1	2%
New Zealand	1	2%
Poland	1	2%
United Kingdom	1	2%
Sum	62	

I. General questions

European market, imports and employment

1. What was the estimated market size and value of novel foods as a total, or by product categories, in your organisation in 2000-2005 in relation to your total sales ?

Novel foods as total	Number of responses	In % of number of responses
Not significant	9	20%
Significant	13	29%
Very significant	4	9%
Not applicable	19	42%
	45	

Traditional food from 3rd countries (outside the EU)

Not significant	10	22%
Significant	8	18%
Very significant	9	20%
Not applicable	18	40%
	45	

R & D based novel foods

Not significant	8	19%
Significant	11	25%
Very significant	7	16%
Not applicable	17	40%
	43	

2. What was the value of novel food imports as a total, or by product categories, in your organisation 2000-2005?

Novel foods as total

Not significant	11	27%
Significant	4	10%

Very significant	2	5%
Not applicable	24	58%
	41	

Traditional food from 3rd countries (outside the EU)

Not significant	9	22%
Very significant	5	13%
Significant	5	13%
Not applicable	21	52%
	40	

R & D based novel foods

Not significant	10	27%
Significant	5	13%
Very significant	2	5%
Not applicable	21	55%
	38	

Authorisation time and application costs

1. How do you consider the time that is taken for the authorisation procedure of novel foods?

Safety assessment of novel foods

Long	29	66%
About right	9	20%
Short	2	5%
Don’t know	4	9%
	44	

Authorisation decision on novel foods

Long	34	79%
About right	6	15%
Short	1	2%
Don’t know	2	5%
	43	

Authorisation procedure as a whole

Long	38	82%
About right	5	12%
Short	0	0%
Don't know	3	6%
	46	

2. What were the administrative burden costs per novel application as total, or by product categories, in the period of 2000 - 2005 for your organisation?

Novel foods as total

Significant	8	21%
Not significant	6	15%
Very significant	6	15%
Not applicable	19	49%
	39	

Traditional food from 3rd countries (outside the EU)

Significant	9	22%
Not significant	7	17%
Very significant	4	10%
Not applicable	21	51%
	41	

R & D based novel foods

Significant	8	21%
Very significant	7	19%
Not significant	4	10%
Not applicable	20	51%
	39	

II. Questions to assess the possible impact on your organisation of the main options for the revision of the Novel Food Regulation

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

Option 1: No changes 'One size fits all'	Number of responses	In % of number of responses
Impact on public health and food safety		
1 Very beneficial	3	9%
2 Fairly beneficial	4	11%
3 Neutral	7	20%
4 Not relevant	5	14%
5 Not Very beneficial	7	20%
6 Not at all beneficial	8	23%
7 Don't know	1	3%
	35	
Impact on consumer rights		
1 Very beneficial	2	6%
2 Fairly beneficial	4	11%
3 Neutral	5	15%
4 Not relevant	4	11%
5 Not Very beneficial	6	17%
6 Not at all beneficial	10	29%
7 Don't know	4	11%
	35	
Impact on competitiveness, markets and trade (including third countries)		
1 Very beneficial	2	6%
2 Fairly beneficial	3	9%
3 Neutral	3	9%
4 Not relevant	1	3%
5 Not Very beneficial	6	18%

6 Not at all beneficial	19	56%
7 Don’t know	0	0%
	34	

Impact on the administrative burden imposed on business

1 Very beneficial	1	3%
2 Fairly beneficial	2	6%
3 Neutral	4	12%
4 Not relevant	1	3%
5 Not Very beneficial	8	24%
6 Not at all beneficial	17	50%
7 Don’t know	1	3%
	34	

Impact on innovation and research

1 Very beneficial	4	11%
2 Fairly beneficial	0	0%
3 Neutral	6	17%
4 Not relevant	1	3%
5 Not Very beneficial	4	11%
6 Not at all beneficial	20	58%
7 Don’t know	0	0%
	35	

Impact on employment and jobs

1 Very beneficial	2	6%
2 Fairly beneficial	1	3%
3 Neutral	8	24%
4 Not relevant	1	3%
5 Not Very beneficial	8	24%
6 Not at all beneficial	12	35%
7 Don’t know	2	6%
	34	

Environmental impact (EU and 3rd countries)

1 Very beneficial	2	6%
2 Fairly beneficial	3	9%
3 Neutral	9	27%
4 Not relevant	4	12%
5 Not Very beneficial	2	6%
6 Not at all beneficial	9	27%
7 Don't know	5	14%
	34	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	2	6%
2 Fairly beneficial	3	9%
3 Neutral	5	14%
4 Not relevant	3	9%
5 Not Very beneficial	6	17%
6 Not at all beneficial	15	43%
7 Don't know	1	3%
	35	

Option 2: Adjusted safety assessment for traditional foods from 3rd countries

Impact on public health and food safety

1 Very beneficial	4	11%
2 Fairly beneficial	10	28%
3 Neutral	12	34%
4 Not relevant	3	8%
5 Not Very beneficial	5	14%
6 Not at all beneficial	2	5%
7 Don't know	0	0%
	36	

Impact on consumer rights

1 Very beneficial	4	11%
2 Fairly beneficial	9	25%
3 Neutral	9	25%
4 Not relevant	1	3%
5 Not Very beneficial	5	14%
6 Not at all beneficial	5	14%
7 Don’t know	3	8%
	36	

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

1 Very beneficial	10	28%
2 Fairly beneficial	13	36%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	4	11%
6 Not at all beneficial	5	14%
7 Don’t know	1	3%
	36	

Impact on the administrative burden imposed on business

1 Very beneficial	7	20%
2 Fairly beneficial	14	39%
3 Neutral	6	17%
4 Not relevant	0	0%
5 Not Very beneficial	3	8%
6 Not at all beneficial	4	11%
7 Don’t know	2	5%
	36	

Impact on innovation and research

1 Very beneficial	8	22%
2 Fairly beneficial	12	33%
3 Neutral	4	11%

4 Not relevant	0	0%
5 Not Very beneficial	4	11%
6 Not at all beneficial	6	17%
7 Don’t know	2	5%
	36	

Impact on employment and jobs

1 Very beneficial	6	17%
2 Fairly beneficial	10	29%
3 Neutral	6	17%
4 Not relevant	0	0%
5 Not Very beneficial	7	20%
6 Not at all beneficial	2	6%
7 Don’t know	4	11%
	35	

Environmental impact (EU and 3rd countries)

1 Very beneficial	3	8%
2 Fairly beneficial	7	20%
3 Neutral	10	29%
4 Not relevant	2	6%
5 Not Very beneficial	4	11%
6 Not at all beneficial	1	3%
7 Don’t know	8	22%
	35	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	8	22%
2 Fairly beneficial	9	25%
3 Neutral	7	20%
4 Not relevant	1	3%
5 Not Very beneficial	5	14%
6 Not at all beneficial	1	3%
7 Don’t know	5	14%
	36	

Option 3: Adjusted safety assessment and management for traditional foods from 3rd countries

Impact on public health and food safety

1 Very beneficial	6	18%
2 Fairly beneficial	11	32%
3 Neutral	12	35%
4 Not relevant	4	11%
5 Not Very beneficial	0	0%
6 Not at all beneficial	1	3%
7 Don't know	0	0%
	34	

Impact on consumer rights

1 Very beneficial	5	15%
2 Fairly beneficial	11	32%
3 Neutral	9	26%
4 Not relevant	1	3%
5 Not Very beneficial	5	15%
6 Not at all beneficial	2	6%
7 Don't know	1	3%
	34	

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

1 Very beneficial	7	22%
2 Fairly beneficial	15	47%
3 Neutral	1	3%
4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	2	6%
7 Don't know	1	3%
	32	

Impact on the administrative burden imposed on business

1 Very beneficial	9	27%
2 Fairly beneficial	12	35%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	7	21%
6 Not at all beneficial	2	6%
7 Don't know	1	3%
	34	

Impact on innovation and research

1 Very beneficial	7	21%
2 Fairly beneficial	14	42%
3 Neutral	2	6%
4 Not relevant	0	0%
5 Not Very beneficial	4	12%
6 Not at all beneficial	5	16%
7 Don't know	1	3%
	33	

Impact on employment and jobs

1 Very beneficial	5	15%
2 Fairly beneficial	13	41%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	4	13%
6 Not at all beneficial	4	13%
7 Don't know	3	9%
	32	

Environmental impact (EU and 3rd countries)

1 Very beneficial	3	9%
2 Fairly beneficial	11	33%
3 Neutral	7	22%

4 Not relevant	2	6%
5 Not Very beneficial	3	9%
6 Not at all beneficial	1	3%
7 Don't know	6	18%
	33	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	7	22%
2 Fairly beneficial	10	31%
3 Neutral	4	12%
4 Not relevant	2	6%
5 Not Very beneficial	3	9%
6 Not at all beneficial	2	6%
7 Don't know	5	15%
	33	

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

Impact on public health and food safety

1 Very beneficial	11	28%
2 Fairly beneficial	4	10%
3 Neutral	7	18%
4 Not relevant	0	0%
5 Not Very beneficial	7	18%
6 Not at all beneficial	10	26%
7 Don't know	0	0%
	39	

Impact on consumer rights

1 Very beneficial	15	40%
2 Fairly beneficial	5	13%
3 Neutral	4	10%
4 Not relevant	1	3%
5 Not Very beneficial	4	10%

6 Not at all beneficial	8	21%
7 Don’t know	1	3%
	38	

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

1 Very beneficial	23	61%
2 Fairly beneficial	3	8%
3 Neutral	2	5%
4 Not relevant	0	0%
5 Not Very beneficial	2	5%
6 Not at all beneficial	6	16%
7 Don’t know	2	5%
	38	

Impact on the administrative burden imposed on business

1 Very beneficial	23	61%
2 Fairly beneficial	1	3%
3 Neutral	5	13%
4 Not relevant	0	0%
5 Not Very beneficial	2	5%
6 Not at all beneficial	5	13%
7 Don’t know	2	5%
	38	

Impact on innovation and research

1 Very beneficial	21	54%
2 Fairly beneficial	0	0%
3 Neutral	3	8%
4 Not relevant	0	0%
5 Not Very beneficial	4	11%
6 Not at all beneficial	6	16%
7 Don’t know	4	11%
	38	

Impact on employment and jobs

1 Very beneficial	17	45%
2 Fairly beneficial	5	13%
3 Neutral	6	16%
4 Not relevant	0	0%
5 Not Very beneficial	1	3%
6 Not at all beneficial	4	10%
7 Don’t know	5	13%
	38	

Environmental impact (EU and 3rd countries)

1 Very beneficial	13	34%
2 Fairly beneficial	0	0%
3 Neutral	10	26%
4 Not relevant	1	3%
5 Not Very beneficial	3	8%
6 Not at all beneficial	4	10%
7 Don’t know	7	19%
	38	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	20	53%
2 Fairly beneficial	4	10%
3 Neutral	5	13%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	3	8%
7 Don’t know	4	10%
	38	

Preferred option

Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	26	47%

Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	15	27%
Option 2: Adjusted safety assessment for traditional food from 3rd countries	10	18%
Option 1: No changes 'One size fits all'	4	8%
	55	

2. Safety assessment and authorisation procedure

Option 1: No changes (decentralised assessment and authorisation procedure)

Impact on public health and food safety

1 Very beneficial	1	3%
2 Fairly beneficial	3	8%
3 Neutral	11	32%
4 Not relevant	5	14%
5 Not Very beneficial	8	23%
6 Not at all beneficial	7	20%
7 Don't know	0	0%
	35	

Impact on consumer rights

1 Very beneficial	2	6%
2 Fairly beneficial	2	6%
3 Neutral	9	28%
4 Not relevant	3	9%
5 Not Very beneficial	7	21%
6 Not at all beneficial	8	24%
7 Don't know	2	6%
	33	

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

1 Very beneficial	2	6%
2 Fairly beneficial	2	6%
3 Neutral	5	15%
4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	17	52%
7 Don't know	2	3%
	33	

Impact on the administrative burden imposed on business

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	5	14%
4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	17	50%
7 Don't know	0	0%
	34	

Impact on innovation and research

1 Very beneficial	2	6%
2 Fairly beneficial	4	12%
3 Neutral	6	18%
4 Not relevant	0	0%
5 Not Very beneficial	7	21%
6 Not at all beneficial	14	43%
7 Don't know	0	0%
	33	

Impact on employment and jobs

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	5	14%

4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	14	41%
7 Don't know	3	9%
	34	

Environmental impact (EU and 3rd countries)

1 Very beneficial	1	3%
2 Fairly beneficial	2	6%
3 Neutral	10	32%
4 Not relevant	2	6%
5 Not Very beneficial	7	22%
6 Not at all beneficial	3	9%
7 Don't know	7	22%
	32	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	3	9%
2 Fairly beneficial	5	16%
3 Neutral	5	16%
4 Not relevant	1	3%
5 Not Very beneficial	7	22%
6 Not at all beneficial	8	25%
7 Don't know	3	9%
	32	

Option 2: Centralised risk assessment and authorisation procedure

Impact on public health and food safety

1 Very beneficial	11	31%
2 Fairly beneficial	12	33%
3 Neutral	7	19%
4 Not relevant	3	8%
5 Not Very beneficial	2	6%

6 Not at all beneficial	0	0%
7 Don’t know	1	3%
	36	

Impact on consumer rights

1 Very beneficial	9	26%
2 Fairly beneficial	11	32%
3 Neutral	8	22%
4 Not relevant	1	3%
5 Not Very beneficial	4	11%
6 Not at all beneficial	0	0%
7 Don’t know	2	6%
	35	

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

1 Very beneficial	15	42%
2 Fairly beneficial	9	26%
3 Neutral	2	6%
4 Not relevant	0	0%
5 Not Very beneficial	5	14%
6 Not at all beneficial	2	6%
7 Don’t know	2	6%
	35	

Impact on the administrative burden imposed on business

1 Very beneficial	14	39%
2 Fairly beneficial	9	26%
3 Neutral	2	6%
4 Not relevant	0	0%
5 Not Very beneficial	6	17%
6 Not at all beneficial	2	6%
7 Don’t know	2	6%
	35	

Impact on innovation and research

1 Very beneficial	10	29%
2 Fairly beneficial	11	31%
3 Neutral	5	14%
4 Not relevant	0	0%
5 Not Very beneficial	5	14%
6 Not at all beneficial	2	6%
7 Don’t know	2	6%
	35	

Impact on employment and jobs

1 Very beneficial	9	26%
2 Fairly beneficial	7	21%
3 Neutral	5	15%
4 Not relevant	0	0%
5 Not Very beneficial	2	6%
6 Not at all beneficial	3	9%
7 Don’t know	8	23%
	34	

Environmental impact (EU and 3rd countries)

1 Very beneficial	5	14%
2 Fairly beneficial	8	23%
3 Neutral	9	26%
4 Not relevant	2	6%
5 Not Very beneficial	2	6%
6 Not at all beneficial	0	0%
7 Don’t know	9	25%
	35	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	10	29%
2 Fairly beneficial	8	23%
3 Neutral	6	17%

4 Not relevant	1	3%
5 Not Very beneficial	4	11%
6 Not at all beneficial	0	0%
7 Don't know	6	17%
	35	

Preferred option

Option 2: Centralised risk assessment and authorisation procedure	45	94%
Option 1: No changes (decentralised assessment and authorisation procedure)	3	6%
	48	

3. Authorisation decision

Option 1: No changes : Authorisation linked to the applicant (only applicant able to market)

Impact on public health and food safety

1 Very beneficial	8	24%
2 Fairly beneficial	5	15%
3 Neutral	7	22%
4 Not relevant	3	9%
5 Not Very beneficial	3	9%
6 Not at all beneficial	5	15%
7 Don't know	2	6%
	33	

Impact on consumer rights

1 Very beneficial	7	22%
2 Fairly beneficial	4	12%
3 Neutral	4	12%
4 Not relevant	3	9%
5 Not Very beneficial	4	12%

6 Not at all beneficial	8	24%
7 Don’t know	3	9%
	33	

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

1 Very beneficial	8	27%
2 Fairly beneficial	2	6%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	3	9%
6 Not at all beneficial	12	40%
7 Don’t know	3	9%
	31	

Impact on the administrative burden imposed on business

1 Very beneficial	7	21%
2 Fairly beneficial	3	9%
3 Neutral	4	12%
4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	10	31%
7 Don’t know	3	9%
	33	

Impact on innovation and research

1 Very beneficial	8	24%
2 Fairly beneficial	2	9%
3 Neutral	4	12%
4 Not relevant	0	0%
5 Not Very beneficial	8	24%
6 Not at all beneficial	8	24%
7 Don’t know	3	9%
	33	

Impact on employment and jobs

1 Very beneficial	7	22%
2 Fairly beneficial	3	10%
3 Neutral	4	12%
4 Not relevant	0	0%
5 Not Very beneficial	7	22%
6 Not at all beneficial	6	18%
7 Don't know	5	16%
	32	

Environmental impact (EU and 3rd countries)

1 Very beneficial	5	15%
2 Fairly beneficial	2	6%
3 Neutral	8	24%
4 Not relevant	2	6%
5 Not Very beneficial	3	10%
6 Not at all beneficial	5	15%
7 Don't know	8	24%
	33	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	6	18%
2 Fairly beneficial	2	7%
3 Neutral	6	18%
4 Not relevant	1	3%
5 Not Very beneficial	6	18%
6 Not at all beneficial	6	18%
7 Don't know	6	18%
	33	

Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)

Impact on public health and food safety

1 Very beneficial	8	26%
2 Fairly beneficial	4	12%
3 Neutral	8	26%
4 Not relevant	2	6%
5 Not Very beneficial	5	15%
6 Not at all beneficial	4	12%
7 Don't know	1	3%
	32	

Impact on consumer rights

1 Very beneficial	7	22%
2 Fairly beneficial	7	22%
3 Neutral	6	19%
4 Not relevant	1	3%
²5 Not Very beneficial	5	16%
6 Not at all beneficial	4	12%
7 Don't know	2	6%
	32	

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

1 Very beneficial	11	34%
2 Fairly beneficial	5	16%
3 Neutral	4	12%
4 Not relevant	0	0%
5 Not Very beneficial	5	16%
6 Not at all beneficial	5	16%
7 Don't know	2	6%
	32	

Impact on the administrative burden imposed on business

1 Very beneficial	12	37%
2 Fairly beneficial	6	18%
3 Neutral	5	15%
4 Not relevant	0	0%
5 Not Very beneficial	3	9%
6 Not at all beneficial	5	15%
7 Don't know	2	6%
	33	

Impact on innovation and research

1 Very beneficial	8	25%
2 Fairly beneficial	7	22%
3 Neutral	4	12%
4 Not relevant	0	0%
5 Not Very beneficial	4	12%
6 Not at all beneficial	7	22%
7 Don't know	2	7%
	32	

Impact on employment and jobs

1 Very beneficial	8	25%
2 Fairly beneficial	6	19%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	4	13%
6 Not at all beneficial	5	15%
7 Don't know	6	19%
	32	

Environmental impact (EU and 3rd countries)

1 Very beneficial	5	15%
2 Fairly beneficial	4	13%
3 Neutral	8	25%

4 Not relevant	2	6%
5 Not Very beneficial	2	6%
6 Not at all beneficial	3	10%
7 Don't know	8	25%
	32	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	6	19%
2 Fairly beneficial	9	28%
3 Neutral	5	16%
4 Not relevant	1	3%
5 Not Very beneficial	3	9%
6 Not at all beneficial	3	9%
7 Don't know	5	16%
	32	

Option 3: Generic authorisation + data protection for certain foods

Impact on public health and food safety

1 Very beneficial	5	15%
2 Fairly beneficial	4	11%
3 Neutral	13	38%
4 Not relevant	2	6%
5 Not Very beneficial	7	21%
6 Not at all beneficial	2	6%
7 Don't know	1	3%
	34	

Impact on consumer rights

1 Very beneficial	6	18%
2 Fairly beneficial	5	14%
3 Neutral	10	29%
4 Not relevant	1	3%
5 Not Very beneficial	8	24%

6 Not at all beneficial	2	6%
7 Don’t know	2	6%
	34	

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

1 Very beneficial	7	21%
2 Fairly beneficial	10	30%
3 Neutral	4	11%
4 Not relevant	0	0%
5 Not Very beneficial	8	23%
6 Not at all beneficial	3	9%
7 Don’t know	2	6%
	34	

Impact on the administrative burden imposed on business

1 Very beneficial	6	18%
2 Fairly beneficial	11	34%
3 Neutral	5	15%
4 Not relevant	0	0%
5 Not Very beneficial	5	15%
6 Not at all beneficial	3	9%
7 Don’t know	3	9%
	33	

Impact on innovation and research

1 Very beneficial	4	11%
2 Fairly beneficial	12	35%
3 Neutral	7	21%
4 Not relevant	0	0%
5 Not Very beneficial	7	21%
6 Not at all beneficial	2	6%
7 Don’t know	2	6%
	34	

Impact on employment and jobs

1 Very beneficial	3	9%
2 Fairly beneficial	9	26%
3 Neutral	6	18%
4 Not relevant	0	0%
5 Not Very beneficial	6	18%
6 Not at all beneficial	3	9%
7 Don't know	7	20%
	34	

Environmental impact (EU and 3rd countries)

1 Very beneficial	3	9%
2 Fairly beneficial	4	11%
3 Neutral	12	35%
4 Not relevant	2	6%
5 Not Very beneficial	3	9%
6 Not at all beneficial	2	6%
7 Don't know	8	24%
	34	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	5	14%
2 Fairly beneficial	7	21%
3 Neutral	9	28%
4 Not relevant	1	3%
5 Not Very beneficial	5	14%
6 Not at all beneficial	2	6%
7 Don't know	5	14%
	34	

Option 4: Different types of authorisations (generic and for certain foods, applicant linked)

Impact on public health and food safety

1 Very beneficial	1	3%
2 Fairly beneficial	7	22%
3 Neutral	14	45%
4 Not relevant	2	6%
5 Not Very beneficial	2	6%
6 Not at all beneficial	3	9%
7 Don't know	3	9%
	32	

Impact on consumer rights

1 Very beneficial	2	6%
2 Fairly beneficial	6	19%
3 Neutral	13	41%
4 Not relevant	1	3%
5 Not Very beneficial	3	9%
6 Not at all beneficial	3	9%
7 Don't know	4	13%
	32	

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

1 Very beneficial	7	23%
2 Fairly beneficial	11	37%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	3	9%
6 Not at all beneficial	4	13%
7 Don't know	3	9%
	31	

Impact on the administrative burden imposed on business

1 Very beneficial	6	19%
2 Fairly beneficial	8	25%
3 Neutral	5	16%
4 Not relevant	0	0%
5 Not Very beneficial	6	19%
6 Not at all beneficial	4	12%
7 Don't know	3	9%
	32	

Impact on innovation and research

1 Very beneficial	5	16%
2 Fairly beneficial	12	38%
3 Neutral	7	22%
4 Not relevant	0	0%
5 Not Very beneficial	2	6%
6 Not at all beneficial	3	9%
7 Don't know	3	9%
	32	

Impact on employment and jobs

1 Very beneficial	4	13%
2 Fairly beneficial	9	28%
3 Neutral	9	28%
4 Not relevant	0	0%
5 Not Very beneficial	1	3%
6 Not at all beneficial	3	9%
7 Don't know	6	19%
	32	

Environmental impact (EU and 3rd countries)

1 Very beneficial	1	3%
2 Fairly beneficial	2	6%
3 Neutral	12	38%

4 Not relevant	2	6%
5 Not Very beneficial	2	6%
6 Not at all beneficial	3	10%
7 Don't know	10	31%
	32	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	4	13%
2 Fairly beneficial	7	22%
3 Neutral	7	22%
4 Not relevant	1	3%
5 Not Very beneficial	3	9%
6 Not at all beneficial	2	6%
7 Don't know	8	25%
	32	

Preferred option

Option 4: Different types of authorisations (generic and for certain foods, applicant linked)	24	44%
Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	12	22%
Option 3: Generic authorisation + data protection for certain foods	11	20%
Option 1: No changes: Authorisation linked to the applicant (only applicant able to market)	8	14%
	55	

4. Submission of application for several food uses

Option 1: No changes : Separate applications for different food uses

Impact on public health and food safety

1 Very beneficial	3	9%
2 Fairly beneficial	5	14%
3 Neutral	12	35%

4 Not relevant	3	9%
5 Not Very beneficial	3	9%
6 Not at all beneficial	7	21%
7 Don’t know	1	3%
	34	

Impact on consumer rights

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	12	38%
4 Not relevant	3	9%
5 Not Very beneficial	3	9%
6 Not at all beneficial	6	20%
7 Don’t know	2	6%
	32	

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

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	3	9%
4 Not relevant	0	0%
5 Not Very beneficial	9	27%
6 Not at all beneficial	13	40%
7 Don’t know	2	6%
	33	

Impact on the administrative burden imposed on business

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	2	6%
4 Not relevant	0	0%
5 Not Very beneficial	4	12%
6 Not at all beneficial	20	61%
7 Don’t know	1	3%
	33	

Impact on innovation and research

1 Very beneficial	2	6%
2 Fairly beneficial	4	12%
3 Neutral	5	15%
4 Not relevant	1	3%
5 Not Very beneficial	8	24%
6 Not at all beneficial	11	34%
7 Don't know	2	6%
	33	

Impact on employment and jobs

1 Very beneficial	3	9%
2 Fairly beneficial	4	12%
3 Neutral	6	19%
4 Not relevant	1	3%
5 Not Very beneficial	5	16%
6 Not at all beneficial	8	25%
7 Don't know	5	16%
	32	

Environmental impact (EU and 3rd countries)

1 Very beneficial	1	3%
2 Fairly beneficial	2	6%
3 Neutral	10	34%
4 Not relevant	3	10%
5 Not Very beneficial	3	10%
6 Not at all beneficial	5	17%
7 Don't know	6	20%
	30	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	3	9%
2 Fairly beneficial	3	9%
3 Neutral	3	9%

4 Not relevant	2	6%
5 Not Very beneficial	10	32%
6 Not at all beneficial	6	19%
7 Don't know	5	16%
	32	

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

Impact on public health and food safety

1 Very beneficial	8	21%
2 Fairly beneficial	8	21%
3 Neutral	14	37%
4 Not relevant	2	5%
5 Not Very beneficial	1	3%
6 Not at all beneficial	1	3%
7 Don't know	4	10%
	38	

Impact on consumer rights

1 Very beneficial	9	24%
2 Fairly beneficial	9	24%
3 Neutral	11	29%
4 Not relevant	3	8%
5 Not Very beneficial	2	5%
6 Not at all beneficial	0	0%
7 Don't know	4	10%
	38	

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

1 Very beneficial	20	53%
2 Fairly beneficial	11	29%
3 Neutral	3	8%
4 Not relevant	0	0%
5 Not Very beneficial	0	0%

6 Not at all beneficial	0	0%
7 Don’t know	4	10%
	38	

Impact on the administrative burden imposed on business

1 Very beneficial	21	59%
2 Fairly beneficial	9	25%
3 Neutral	2	5%
4 Not relevant	0	0%
5 Not Very beneficial	0	0%
6 Not at all beneficial	0	0%
7 Don’t know	4	11%
	36	

Impact on innovation and research

1 Very beneficial	14	37%
2 Fairly beneficial	12	31%
3 Neutral	7	18%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	0	0%
7 Don’t know	3	8%
	38	

Impact on employment and jobs

1 Very beneficial	15	39%
2 Fairly beneficial	8	21%
3 Neutral	6	16%
4 Not relevant	1	3%
5 Not Very beneficial	2	5%
6 Not at all beneficial	0	0%
7 Don’t know	6	16%
	38	

Environmental impact (EU and 3rd countries)

1 Very beneficial	6	15%
2 Fairly beneficial	6	15%
3 Neutral	14	38%
4 Not relevant	3	8%
5 Not Very beneficial	0	0%
6 Not at all beneficial	0	0%
7 Don't know	9	24%
	38	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	12	32%
2 Fairly beneficial	9	24%
3 Neutral	6	16%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	0	0%
7 Don't know	8	22%
	37	

Preferred option

Option 2: One application for all new foods for different uses	41	87%
Option 1: No changes: Separate applications for different food uses	6	13%
	47	

5. Legal Act

What would be the impact of the revision for your organisation?

Impact on public health and food safety

1 Very beneficial	12	32%
2 Fairly beneficial	4	11%
3 Neutral	12	32%
4 Not relevant	1	3%

5 Not Very beneficial	1	3%
6 Not at all beneficial	0	0%
7 Don’t know	7	19%
	37	

Impact on consumer rights

1 Very beneficial	10	28%
2 Fairly beneficial	7	19%
3 Neutral	10	28%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	0	0%
7 Don’t know	7	19%
	36	

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

1 Very beneficial	20	56%
2 Fairly beneficial	4	11%
3 Neutral	2	5%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	1	3%
7 Don’t know	7	19%
	36	

Impact on the administrative burden imposed on business

1 Very beneficial	18	49%
2 Fairly beneficial	6	16%
3 Neutral	3	8%
4 Not relevant	1	3%
5 Not Very beneficial	0	0%
6 Not at all beneficial	1	3%
7 Don’t know	8	21%
	37	

Impact on innovation and research

1 Very beneficial	16	44%
2 Fairly beneficial	6	17%
3 Neutral	4	11%
4 Not relevant	0	0%
5 Not Very beneficial	1	3%
6 Not at all beneficial	1	3%
7 Don’t know	8	22%
	36	

Impact on employment and jobs

1 Very beneficial	15	41%
2 Fairly beneficial	5	13%
3 Neutral	4	11%
4 Not relevant	1	3%
5 Not Very beneficial	1	3%
6 Not at all beneficial	1	3%
7 Don’t know	10	26%
	37	

Environmental impact (EU and 3rd countries)

1 Very beneficial	8	22%
2 Fairly beneficial	5	14%
3 Neutral	11	31%
4 Not relevant	2	5%
5 Not Very beneficial	0	0%
6 Not at all beneficial	1	3%
7 Don’t know	9	25%
	36	

Socio-economic impact (3rd countries in particular)

1 Very beneficial	16	46%
2 Fairly beneficial	3	8%
3 Neutral	4	11%
4 Not relevant	1	3%

5 Not Very beneficial	0	0%
6 Not at all beneficial	1	3%
7 Don’t know	10	29%
	35	

Analysis of the preferred option by stakeholder subgroups

1.	**Adjusted safety assessment and management for traditional food from 3rd countries**		
	Preferred option	Number of responses	In % of number of responses
	Option 1: No changes 'One size fits all'	4	7%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	10	18%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	26	47%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	15	28%
	Preferred option by subgroup		
	Competent Authority (CA), in total	17	100%
	Option 1: No changes 'One size fits all'	1	6%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	3	18%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	9	52%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	3	18%
	No answer	1	6%
	CA EU	11	100%
	Option 1: No changes 'One size fits all'	0	0%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	2	18%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	8	73%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	0	0%
	No answer	1	9%
	CA 3rd countries	6	100%
	Option 1: No changes 'One size fits all'	1	17%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	1	17%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	1	17%

Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	3	50%
Organisation operating on national level		4	100%
Option 1:	No changes 'One size fits all'	0	0%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	1	25%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	0	0%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	1	25%
No answer		2	50%
International organisation		8	100%
Option 1:	No changes 'One size fits all'	0	0%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	2	25%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	3	37%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	1	13%
No answer		2	25%
Consumer		2	100%
Option 1:	No changes 'One size fits all'	1	50%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	0	0%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	1	50%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	0	0%
Food industry, total		27	100%
Option 1:	No changes 'One size fits all'	2	7%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	2	7%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	10	37%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	8	30%
No answer		5	19%

Food ingredient producer		7	100%
Option 1:	No changes ‘One size fits all’	0	0%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	0	0%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	4	57%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	1	14%
No answer		2	29%
Food ingredient importer		3	100%
Option 1:	No changes ‘One size fits all’	0	0%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	0	0%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	1	33%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	1	33%
No answer		1	33%
Food producer (food ingredient user, final food producer)		6	100%
Option 1:	No changes ‘One size fits all’	2	33%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	1	17%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	1	17%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	2	33%
SME company		1	100%
Option 1:	No changes ‘One size fits all’	0	0%
Option 2:	Adjusted safety assessment for traditional food from 3rd countries	0	0%
Option 3:	Adjusted safety assessment and management for traditional food from 3rd countries	0	0%
Option 4:	No pre-market safety assessment and authorisation for traditional food from 3rd countries	1	100%

	Company operating on national level	2	100%
	Option 1: No changes 'One size fits all'	0	0%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	0	0%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	1	50%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	0	0%
	No answer	1	50%
	International company	7	100%
	Option 1: No changes 'One size fits all'	0	0%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	1	14%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	3	43%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	3	43%
	Other	7	100%
	Option 1: No changes 'One size fits all'	0	0%
	Option 2: Adjusted safety assessment for traditional food from 3rd countries	2	29%
	Option 3: Adjusted safety assessment and management for traditional food from 3rd countries	3	42%
	Option 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries	2	29%
2.	**Safety assessment and authorisation procedure**		
	Preferred option		
	Option 2: Centralised risk assessment and authorisation procedure	45	94%
	Option 1: No changes (decentralised assessment and authorisation procedure)	3	6%
		48	
	Preferred option by subgroup		
	Competent Authority (CA), in total	17	100%
	Option 1: No changes (decentralised assessment and authorisation procedure)	1	6%
	Option 2: Centralised risk assessment and authorisation procedure	11	65%
	No answer	5	29%

CA EU	11	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	7	64%
No answer	4	37%
CA 3rd countries	6	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	1	17%
Option 2: Centralised risk assessment and authorisation procedure	4	67%
No answer	1	17%
Organisation operating on national level	4	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	2	50%
No answer	2	50%
International organisation	8	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	1	12%
Option 2: Centralised risk assessment and authorisation procedure	6	76%
No answer	1	12%
Consumer	2	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	1	50%
No answer	1	50%
Food industry, total	27	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	1	4%
Option 2: Centralised risk assessment and authorisation procedure	19	70%
No answer	7	26%
Food ingredient producer		
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%

Option 2: Centralised risk assessment and authorisation procedure	5	72%
No answer	1	14%
Food ingredient importer	3	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	1	33%
No answer	2	67%
Food producer (food ingredient user, final food producer)	6	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	1	17%
Option 2: Centralised risk assessment and authorisation procedure	4	66%
No answer	1	17%
SME company	1	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	1	100%
Company operating on national level	2	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	1	50%
No answer	1	50%
International company	7	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	7	100%
Other	7	100%
Option 1: No changes (decentralised assessment and authorisation procedure)	0	0%
Option 2: Centralised risk assessment and authorisation procedure	5	71%
No answer	2	29%

3.	**Authorisation decision**		
	Preferred option		
	Option 1: No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	8	14%
	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	12	22%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	11	20%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	24	44%
		55	
	Preferred option by subgroup		
	Competent Authority (CA), in total	17	100%
	Option 1: No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	6%
	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	3	18%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	5	29%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	7	42%
	No answer	1	6%
	CA EU	11	100%
	Option 1: No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%
	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	0	0%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	3	27%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	7	64%
	No answer	1	9%

CA 3rd countries		6	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	17%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	3	50%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	2	33%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
Organisation operating at national level		4	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	1	25%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	2	50%
No answer		1	25%
International organisation		7	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	14%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	2	29%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	4	57%
Consumer		2	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	50%

Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	0	0%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
No answer		1	50%
Food industry, total		27	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	2	7%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	7	26%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	6	22%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	7	26%
No answer		5	19%
Food ingredient producer		7	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	14%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	0	0%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	5	72%
No answer		1	14%
Food ingredient importer		3	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%

Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	0	0%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	1	33%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
No answer		2	66%
Food producer (food ingredient user, final food producer)		6	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	17%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	2	33%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	2	33%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
No answer		1	17%
SME company		1	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%
Option 2:	Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	1	100%
Option 3:	Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
Option 4:	Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
Company operating on national level		2	100%
Option 1:	No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%

	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	2	100%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
	International company	7	100%
	Option 1: No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	0	0%
	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	2	29%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	3	42%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	2	29%
	Other	7	100%
	Option 1: No changes: Authorisation linked to the applicant (only applicant able to market, others by simplified procedure)	1	14%
	Option 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)	3	43%
	Option 3: Generic authorisation + data protection for certain foods (abolishment of simplified procedure)	0	0%
	Option 4: Different types of authorisations (generic and for certain foods, applicant linked, abolishment of simplified procedure)	0	0%
	No answer	3	43%
4.	**Submission of application for several food uses**		
	Preferred option		
	Option 1: No changes: Separate applications for different food uses	6	13%
	Option 2: One application for all new foods for different uses	41	87%
		47	

Preferred option by subgroup		
Competent Authority (CA), in total	17	100%
Option 1: No changes: Separate applications for different food uses	3	18%
Option 2: One application for all new foods for different uses	11	65%
No answer	3	18%
CA EU	11	100%
Option 1: No changes: Separate applications for different food uses	2	18%
Option 2: One application for all new foods for different uses	6	55%
No answer	3	27%
CA 3rd countries	6	100%
Option 1: No changes: Separate applications for different food uses	1	17%
Option 2: One application for all new foods for different uses	5	83%
No answer		
Organisation operating on national level	4	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	3	75%
No answer	1	25%
International organisation	8	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	7	88%
No answer	1	12%
Consumer	2	100%
Option 1: No changes: Separate applications for different food uses	1	50%
Option 2: One application for all new foods for different uses	0	0%
No answer	1	50%

Food industry, total	27	100%
Option 1: No changes: Separate applications for different food uses	2	7%
Option 2: One application for all new foods for different uses	17	63%
No answer	8	30%
Food ingredient producer	7	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	3	43%
No answer	4	57%
Food ingredient importer	3	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	1	33%
No answer	2	66%
Food producer (food ingredient user, final food producer)	6	100%
Option 1: No changes: Separate applications for different food uses	2	33%
Option 2: One application for all new foods for different uses	3	50%
No answer	1	17%
SME company	1	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	1	100%
No answer	0	0%
Company operating on national level	2	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	2	100%
International company	7	100%
Option 1: No changes: Separate applications for different food uses	0	0%
Option 2: One application for all new foods for different uses	7	100%

Other		7	100%
Option 1:	No changes: Separate applications for different food uses	1	14%
Option 2:	One application for all new foods for different uses	3	43%
No answer		3	43%