



Novel foods

Complementary Impact
Assessment reviewing and
updating the European
Commission's 2008 Impact
Assessment for a Regulation
on Novel Foods

STUDY

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**Complementary Impact Assessment
reviewing and updating the European Commission's 2008
Impact Assessment for a Regulation on Novel Foods**

Novel foods

Commission proposal for a Regulation of the European Parliament
and of the Council on Novel Foods (COM(2013)894 final)

**Study by
the Centre for Strategy & Evaluation Services
and ADAS**

Abstract

This research paper was undertaken at the request of the European Parliament's Committee on Environment, Public Health and Food Safety. It provides a complementary impact assessment, reviewing and updating the 2008 European Commission Impact Assessment of a proposal for a Regulation replacing Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients. In particular, it assesses the impacts of the Commission's 2013 proposal on the various parties concerned, i.e., EU-level and Member State-level decision-makers, European consumers, and the food industry.

This complementary impact assessment focuses on key aspects of the 2013 proposal, namely: the scope of its 'Novel Foods' definition; the efficiency and the impact of the centralised authorisation procedures on the various parties concerned; the role of national authorities and agencies in the centralised system, and the proposed Regulation's coherence with other EU regulatory requirements.

AUTHORS

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Executive summary

The purpose of this assignment was to review and update the 2008 Commission Impact Assessment of a Regulation replacing Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients, by assessing the impacts of the Commission's proposal of 2013¹ on the various parties concerned, i.e. EU-level and Member State-level decision-makers, European consumers, and the food industry.

This assignment takes the form of a research paper examining five main research questions. The study involved a combination of desk research to review relevant material (position papers, scientific studies, etc.), and an interview programme with key decision-makers and stakeholders at the EU and Member State levels. Key findings were presented at a meeting of the European Parliament's Environment Committee on 23 July 2014. The main conclusions of the research and recommendations are summarized below.

1. Scope and definition

Research found that the use of a 'cut-off' date is the simplest and clearest way to define Novel Foods from those that are not novel, i.e. have been used in the diet before. The date of 15 May 1997 was based on the date of entry into force of Regulation 258/97, rather than any scientific rationale. Choosing another date based on the entry into force of the new regulation would also be just as arbitrary. In light of these considerations, there would appear to be little value in changing the date of 15 May 1997 under the 2013 proposal.

The removal of the categories in the new definition may result in a situation whereby products already on the market that were not previously considered to be 'novel' may be legally challenged, and whereby a greater number of products would require authorisation as 'novel' foods, where this was not required before. As a result, this could have negative impacts on innovation and competition in the EU food sector and could also increase the administrative burden placed on EU bodies and Member States. If the new definition means that certain products may be withdrawn from the market to undergo an authorisation procedure as novel foods, this may impact on the confidence of consumers that food is safe. Furthermore, the broadening of the definition should not impact on its clarity and thus create legislative loopholes that the industry could exploit by bypassing safety assessments.

On the basis of these findings, the following recommendations were made:

- Further dialogue is needed between European institutions and stakeholders to understand more fully the concerns that the new definition of Novel Foods introduces legal uncertainties for operators and potential legislative loopholes.
- The definition of Novel Foods given in the 2013 proposal should be amended to clarify the scope of what is included.

¹ COM(2013) 894 final

2. Impact of the centralised procedures for authorisation

There was agreement amongst the organisations and institutions consulted that centralised procedures would certainly speed up the process of reaching an initial opinion because only the EFSA will have full responsibility for assessing applications. Furthermore, for Novel Food applications (other than traditional foods from third countries), Member States would no longer be empowered to raise reasoned objections to safety, which, under the current decentralised system, can mean multiple clarifications being asked of the applicant.

Based on interview feedback, it seems that the effectiveness of the centralised system may be challenged as regards the approval of traditional foods from third countries. As the notion of 'history of safe consumption' still remains relatively loosely defined in the proposal, there is a risk that reasoned safety objections will be made by Member States. These findings led to the following recommendations:

- More consideration should be given to the exact requirements for a 'notification' of a traditional food, particularly given the discourse surrounding the concept of 'history of safe use' to ensure that reasoned safety objections by Member States and EFSA are minimised and that consumer safety is not compromised.
- Consideration should be given to whether deadlines should be introduced at more stages in the Novel Foods authorisation procedure, if the desire is to speed up the application process.

3. Effectiveness of the centralised system and its tools

In accordance with the rationale of the proposal, the new centralised system is expected to result in shorter approval times and reduced administrative burdens. However, research found that the costs and resources to submit a Novel Foods application will depend on the clarity of EFSA's initial guidance on data requirements, and by extension on the complexity of the application.

The data protection regime is expected to stimulate innovation within the food industry, despite the fact that it remains difficult to ascertain whether the five year protection period will generate the expected returns on investment from the perspective of applicants. In light of these findings, the recommended actions to be taken are as follows:

- EFSA should issue updated guidance for applicants in light of the changes to the 'Novel Food' definition and the changes brought about by the centralised system.
- Whilst the five year data protection period is a positive development, the notion of 'right of reference' should be further examined as it may discourage innovation within the EU food industry.

4. Role of national agencies and authorities in the centralised system

In accordance with the aims of the proposed regulation, the centralised system is thought likely to be more effective in terms of issuing decisions on Novel Food applications. Member State authorities will use their decision making powers differently in the centralised system as their role will be limited to voting in the Standing Committee. It can be expected that EFSA will go through a period of adjustment or adaptation after the switch from a decentralised, to a centralised system, therefore Member States' assistance with safety assessments during that period may be critical.

On traditional foods from third countries, however, it is difficult to predict how Member State authorities will consider applications given the novelty of the notification procedures. If reasoned objections are often raised, this would seriously call into question the efficiency of the special procedure for traditional foods from third countries.

These findings have led to the formulation of the following recommendations:

- Member States should be involved in the safety assessment procedures as far as their expertise allows them to do so, to improve the effectiveness and efficiency of the centralised system and scientific robustness of EFSA's safety assessments.
- Member State authorities' support will be critical to assist in the switch from a decentralised system of authorisation to a centralised system.
- The risk of Member States raising reasoned objections to traditional foods from third countries on a frequent basis needs to be mitigated by putting in place clear guidance and rigorous quality standards for the collection of data on history of safe consumption.

5. Inter-relationship with other EU regulatory requirements

The research found no overlaps between the new Novel Foods Regulation and Regulation 1925/2006 on the addition of vitamins, minerals and other substances to food. This is because the Novel Foods Regulation requires the performance of comprehensive safety assessments. Any potentially harmful substance would thus be identified, tested for and flagged up by EFSA.

With regards the relationship between the Novel Foods Regulation and Regulation 1924/2006 on nutrition and health claims, the industry and EFSA expressed the view that problems would arise if a Novel Food authorisation and a health claim authorisation are not issued on the same date. It was argued anything other than this would imply that the respective data protection periods (both lasting five years) will end on different dates. In such cases, the five-year data protection period following a Novel Food authorisation would lose much of its value from an applicant company's perspective.

It was understood that there would be a risk of duplication of efforts as regards the assessment of Novel Foods containing nutritional or dietary substances, namely food supplements and food for specific medical purposes. Given the similarities between the respective safety assessment procedures, research found that there is a strong argument for combining both procedures into one, or at least ensuring that both procedures run in parallel to avoid unnecessary duplication.

In relation to the possibility of a regulation on the use of botanicals in food, there is currently no harmonisation at EU-level in relation to the status of botanical ingredients or substances. In other words, it is possible for the same botanical product to be classified as a foodstuff in one Member State and as a medicinal product in another. A number of stakeholders, including the industry and consumer associations pointed out that this could cause problems in a centralised system as to whether all Member States would all agree on certain botanical ingredients to be authorised in food.

The following recommendations have been put forward based on the findings above:

- If possible, the safety assessment and health and nutrition claims assessments of a Novel Food should be carried out simultaneously to alleviate problems with data protection periods.
- Updated EFSA guidance may be needed so that Novel Foods which contain nutritional or dietary substances do not undergo two separate, but similar safety assessments.
- The lack of harmonisation in terms of the status of certain botanical substances and ingredients in Novel Foods needs to be carefully considered, to ensure that this will not affect the effectiveness of the new centralised authorisation procedures.

Chapter 1: Introduction

I – Assignment aims

On 26 March 2014, in the context of its consideration of the 2013 proposal on novel foods, the European Parliament's Committee on Environment, Public Health and Food Safety requested a complementary impact assessment reviewing and updating the Commission's 2008 impact assessment, for a Proposal, for a Regulation replacing Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients (SEC(2008) 13).

The findings of the 2008 Impact Assessment served as the basis for the Commission's proposal of 18 December 2013 for a Regulation on Novel Foods. This complementary and updated impact assessment looks at how the findings of the 2008 Impact Assessment have been translated into proposed regulatory provisions, whilst attempting to measure the impact of those provisions on EU bodies, Member State relevant authorities, the wider food industry and European consumers.

Hence, the purpose of this assignment is to carry out this complementary impact assessment, which as requested, will take the form of a research paper examining five main research questions, and whenever possible, quantifying the economic and social added value for; citizens, relevant stakeholders and society at large.

The five research questions are listed below:

- The impact of the removal of the categories and widening of the definition to all foods that were not used to a significant degree before 15 May 1997.
- The requirements, process and impact of the new procedures, including the impact of generic authorisations and the process for data protection (both for Novel Foods and for traditional foods from third countries).
- The effectiveness of the tools proposed to reduce administrative burden and increase competitiveness and innovation.
- The role of national agencies and authorities – particularly focusing on their role in support of reasoned objections.
- The inter-relationship with other food regulatory requirements.

II – Methodological Approach

The study involved a combination of desk research to review relevant material, and an interview programme with key decision-makers and stakeholders at the EU and Member State levels.

1. Literature review

We have reviewed key literature, in particular documents related to the proposal that include the evidence used in the 2008 impact assessment and evidence published since this date, to provide a more up to date assessment. Where relevant, peer-reviewed scientific journals have also been analysed. It is important to highlight here that very little scientific literature has been published on the subject of Novel Foods since 2008.

Other sources included position papers from the food industry to illustrate the views of industry stakeholders on the proposed changes to the Novel Food Regulations. Some of these position papers were published after 2008, but make reference to the previous Commission proposal of 14 January 2008. These position papers were useful in informing our research when the points under discussion related to certain provisions which are still present in the 2013 proposal. Finally, in carrying out the interview programme (see below), we also used the content of some of these position papers as a basis for engaging in discussions with the associations who had published them, as well as for substantiating the information gathered during the interviews.

2. Interview programme

In order to accurately assess the impact of the proposals on relevant stakeholders, including applicants, consumers and public authorities, a number of representative consultations were carried out.

Table 1 lists the types of organisations consulted. The study team consulted a mix of stakeholder types to get the broadest possible view on the impacts of the proposed regulation. These included both public and private stakeholders to get the views of regulators, authorities, consumers and applicants who will be affected by the Regulation. Within the time frame available for this assessment it was not practical to interview all Member States' competent authorities. As such, the Member States initially targeted, were those who have the most experience in dealing with applications under the current system. For the industry member bodies interviewed, this included large organisations and SMEs (one member body had 22% of its industry members being SMEs, two in which SME membership was 70-80%, and one in which SME membership was over 90%). The European umbrella organisation for consumer associations (BEUC) was interviewed and one of its member associations also provided additional feedback.

Table 1.1: Organisations interviewed

Type of interviewee	No. of interviews
Member state competent authorities currently responsible for Novel Food authorisations	6
EU body responsible for risk assessment under the new proposals (EFSA)	1
EU Membership bodies representing applicants in different food sectors	3
European and national consumer associations	2
Representative from a third country	1
Relevant EU Commission DGs	2
Total	15

The interview checklist we used was structured around the key issues outlined in the European Parliament's terms of reference for the assignment. The checklist was sent to respondents prior to interview so they could prepare. A copy of the interview checklist is provided in Appendix B. The interviews were conducted by telephone in a semi-structured manner in order to elicit the greatest amount of detail from respondents. Each interview typically lasted between 60-90 minutes.

3. Reporting

The findings from the assessment have been written up in way that reflects the principles in the European Commission's Impact Assessment Guidelines of 2009². The analysis consisted of presenting all evidence gathered from literature and interviews with organisations under each of the five key research questions outlined above. The viewpoints of different organisations interviewed (consumers, industry and regulatory) were summarized for each research question and a conclusion reached on the impact of the proposal for a new Regulation on novel foods. Recommendations were based on the conclusions reached in each section and aimed to outline further actions which might be needed on the proposal to address the concerns identified.

² SEC(2009) 92

Chapter 2: Background – Novel Foods & the 2008 Impact Assessment

I – Background and policy context

Novel Foods – as defined in Article 1 of Regulation (EC) 258/97 – are foods which were not consumed in the EU to a significant degree before 15 May 1997, i.e. before Regulation (EC) 258/97 entered into force. This is in particular relation to food produced using new techniques and technologies, such as nanomaterials. Currently, foods falling under the scope of Regulation (EC) 258/97 are subject to pre-market approval, based on a safety assessment. In other words, to market a Novel Food or ingredient, companies must apply to an EU Member State authority for authorisation, presenting the scientific information and safety assessment report.

Under the existing assessment procedure, the competent body of the Member State which receives an application, must make an initial assessment and determine whether or not an additional assessment is required. If neither the Commission nor the Member States raise an objection, and if no additional assessment is required, the Member State informs the applicant that they may place the product on the market. In other cases an authorisation decision is required. This decision is adopted in accordance with the measures proposed by the Commission within the Committee on Food Safety and Animal Health. The decision defines the scope of the authorisation and specifies, as appropriate, the conditions of use, the designation of the food or food ingredient, its specification and the specific labelling requirements. Finally, any decision or provision concerning a Novel Food or food ingredient which is likely to have an effect on public health must be referred to the Scientific Committee for Food. The safety assessment and product authorisation procedure for Novel Foods is currently described as very lengthy, by both the food industry and relevant Member State authorities. The decentralised procedure (i.e. on a Member State basis) duplicates the work and often generates unnecessary delays in the authorisation process.

A first proposal streamlining the approval process of the 1997 Novel Food Regulation was issued by the Commission on 14 January 2008³. Inter-institutional negotiations on the content of this proposal started in 2009. The legislative discussions on that proposal mainly focused on the provisions applicable to nanomaterials and traditional foods from third countries, but also the cloning of animals for food production. Further discussions concentrated on the criteria to be examined for the risk assessment and risk management, and the procedure for the authorisation of Novel Foods in accordance with the Lisbon Treaty⁴.

³ COM(2007) 872 final

⁴ Treaty on the Functioning of the European Union (TFEU)

However, the discussions reached a stalemate on a number of issues. More specifically, no agreement could be reached between the Council and the European Parliament on any of the issues linked to cloning. The Conciliation Committee did not reach a final agreement at its last meeting on 28 March 2011, and the proposal was not therefore adopted. Following this failure, the Commission undertook to present a separate proposal on cloning based on an impact assessment.

Thus, the proposal of December 2013 on Novel Foods⁵ (the '2013 proposal') is limited to the safety of Novel Foods and is said, by the Commission, to be based on the overall agreement, which had been achieved in Conciliation in that area. It aims to streamline the authorisation procedure and to improve its efficiency and transparency, whilst maintaining a high level of public health protection. Under the proposed Regulation, Novel Food would be subject to a simpler, clearer and more efficient authorisation procedure, fully centralised at EU level, which should enable safe and innovative food to be placed on the EU market faster, without compromising a high level of public health.

The proposal also clarifies the definition of a Novel Food, including new technologies which have an impact on food, by replacing existing categories of Novel Food laid down in Article 1 of Regulation (EC) No 258/97, with reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002⁶. Special provisions are also made for food which has not been marketed in the EU, but which has a history of safe use in non-EU countries. The aim here is to create a more balanced system and a positive environment for trade.

Protecting and stimulating innovation, so as to improve the competitiveness of the European food industry, is also a feature of the proposal. Under the new approval system put forward in the proposal, in case of innovation supported by new scientific developments, the food company which submitted the application may be given the authorisation to market the food for five years before it can be produced and marketed by others.

II – Key points in the 2008 Impact Assessment

The Impact Assessment published by the Commission in 2008 presented four key measures that were identified during the consultations as having a major impact, and in this regard, recommended four key policy actions intended to amend and replace provisions already covered under Regulation (EC) No. 258/97. These are presented below:

⁵ COM(2013) 894 final

⁶ Regulation (EC) No 178/2002 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

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

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

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

Policy Action 2: Safety assessment and authorisation procedure

Current problems: at present the initial risk assessment is carried out by a Member State's competent assessment body within three months of receiving the application. The initial assessment report is circulated to the other Member States. If no objections are presented within the 60 days' commenting period, the Member State's competent authority informs the applicant that it may place the Novel Food product in question on the market. An application is only assessed and authorised at EU level if member state 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.

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

Policy action 3: Authorisation decision

Current problems: at present the authorisation decision is linked to the applicant, thus only initially allowing this applicant to market the Novel Food in the EU, and making it necessary to have an additional administrative notification procedure (simplified procedure). This allows food to be marketed in the EU which is substantially equivalent to food already authorised in the EU. This system is held in high regard by industry, but causes duplication of work for food that has already been authorised and is regarded as safe.

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

Policy action 4: Submission of application for several food uses

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

Conclusions: the present system should be simplified and applicants should be able to apply for an approval by a single application covering Novel Food and food uses regulated under various regulatory frameworks.

In addition, the Commission Impact Assessment of 2008 explored possibilities for bringing the revised Novel Foods Regulation into line with other EU food safety policies.

Amongst the possibilities that were explored were the following:

- Making use of the food definition in the General Food Law and abandoning the categories of describing foods;
- Setting out definitions or criteria for significant human consumption as food, traditional food from third countries and history of safe use;
- Defining the role of EFSA and introducing deadlines for its opinions;
- Updating and formulating provisions on confidentiality and data protection;
- Creating a register of Novel Foods.

The findings of the 2008 Impact Assessment served as the basis for the Commission's proposal of 18 December 2013 for a Novel Food Regulation.

III – Developments since 2008

As discussed previously, very little research relating to the EU Novel Foods Regulation has been published since 2008. A number of position papers were published after 2008, but these relate to the previous proposal of January 2008. Most of these position papers were thus published prior to the failure of the Conciliation procedure in March 2011.

EFSA and the Member State authorities interviewed reported that no change has been observed since 2008 as regards the volume of Novel Food applications submitted. Similarly, the Commission has not observed any particular changes since 2008 in terms of Member States' voting patterns in the context of the decentralised system and whether, as a consequence, the decentralised system has become even more burdensome since 2008.

As mentioned earlier, the failure of the conciliation procedure in March 2011 was mainly due to disagreements over food produced from cloning. As such, cloning has been

excluded from the scope of the 2013 proposal. The second major disagreement was over the notion of 'delegated acts'⁷ for the procedure of authorisation of Novel Foods. Delegated acts allow the European Parliament and Council to delegate, to the European Commission, the power to adopt non-legislative acts of general application and to supplement or amend non-essential regulatory requirements. In this case, the Council would not agree to delegated acts in relation to the authorisation procedure, as it may mean that Member States national experts are unable to vote on the authorisation of particular Novel Foods.

Delegated acts can be vetoed by either the European Parliament or the Council. In this regard, it is worth pointing out that in February 2014 the European Parliament rejected the Commission's proposal for a delegated act⁸ amending the definition of nano-materials contained in Regulation 1169/2011 on the Provision of Food Information to Consumers, as its views were that this could lead to existing nano-materials not being labelled.

In summary, very little research has been published on the topic of novel foods and no changes to the volume of applications or Member States' voting patterns have been reported since 2008. Since the failure of the Conciliation procedure in March 2011, the use of Delegated Acts by the Commission, as a legal instrument, has remained a rather sensitive issue for both the European Parliament and the Council. This particular issue is likely to be further debated in inter-institutional negotiations on the 2013 Novel Foods proposal.

⁷ Introduced by the Lisbon Treaty (Article 290 of the TFEU)

⁸ Commission Delegated Regulation 1363/2013 to adapt the definition of 'engineered nanomaterials' by excluding natural and incidental nanomaterials from the definition.

Chapter 3: Assessment of Key Issues

In this section we examine the key issues at stake regarding the 2013 Novel Foods proposal. The aim is to identify and understand the impacts of the proposal's provisions for the various parties concerned, i.e. EU-level and Member State-level decision-makers, European consumers and the food industry.

I – Scope and definition

We start by examining the impact of the removal of the categories and the widening of the definition to all foods that were not used to a significant degree before 15 May 1997.

Background and rationale

Under the current system, the Novel Foods regulations are limited to food and food ingredients not used for human consumption before 1997, and with features such as, a novel production process or with intentionally modified molecular structures. The proposal to widen the definition to all foods not used to a significant degree before 1997, may serve to require more products to undergo a safety assessment. The research team will make an assessment of; the types of products that will be covered by the new definition, the impact of requiring a pre-market authorisation for all these products for companies, consumers and authorities.

1. Appropriateness and relevance of retaining the date of 15 May 1997 as part of the Novel Food definition

Recital (6) of the 2013 proposal states that:

"In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997, should be maintained as a criterion for a food to be considered as a Novel Food. A use within the Union should also refer to a use in the Member States irrespective of the date of accession of the various Member States to the Union".

Our research suggests that very few alternatives have been put forward in this regard and that this has resulted in the 15 May 1997 date being kept in the 2013 Commission proposal. More particularly, the majority of the interviewees in Member States concurred with the idea of retaining the date of 15 May 1997 as a threshold in order to determine whether a product can be considered a Novel Food, for the sake of consistency and continuity, i.e. giving legal certainty to companies submitting Novel Food applications. Last but not least, the research also found that consumer associations in Europe are in favour of retaining the date for consistency reasons.

However, not all those we consulted agreed with this approach and some of the interviewees expressed concerns as regards the 15 May 1997 date. For three of the membership organisations, representing applicants, that we spoke to, their concerns relate to the fact that retaining the date, whilst also making changes to the definition of

Novel Food (by removing the categories of foods that should be considered 'novel' (see sections below), could lead to some products already on the market and considered 'safe', to retrospectively apply for approval. This is seen as introducing serious legal uncertainty for business operators, who need predictability regarding the legal environment in which they operate. Removal of the categories may serve to widen the amount of products which may be considered to be Novel Foods. At the same time retaining the original date means that some products already on the EU market, because they are not currently classed as 'novel', may have to gain approval retrospectively under the Novel Foods Regulations. The idea of retrospectively requiring a Novel Food submission for products that have been legally placed on the market was not seen as acceptable for industry, especially in the absence of a well-defined and targeted food safety need.

In addition, one of the national authorities commented that this date might in future appear to be arbitrary and that it will become more and more difficult to provide consumption data predating 1997. Criticism of the choice to retain the 15 May 1997 date in this respect is understandable. For this Member State, an alternative would be to remove a fixed date, and use a period of time of safe consumption to determine whether a food is 'novel' (i.e. a 25 year period of history of safe use as is the case with traditional foods). However, whilst in principle this idea is valid, in practice it is hard to understand how the definition would apply to foods other than those from third countries, given that 'novel' foods are principally those that have not been consumed to a significant degree in the EU before.

An industry association expressed the view that the date of 15 May 1997 poses problems for other reasons. Given that the guidance on establishing whether a food has been used for human consumption to a significant degree before 15 May 1997, was only released in October 2012⁹, this association pointed out that various interpretation issues have arisen that make it difficult for many companies to provide the required evidence. For example, before October 2012 it has not been clear whether sales through pharmacies or health stores constitute human consumption to a significant degree, even though many countries have traditionally limited distribution of food supplements through these channels. This association further added that in record-keeping terms, the 15 May 1997 date precedes the widespread use of electronic records. When combining this with the gap between May 1997 and October 2012, it is evident that the existing system poses practical problems.

An example was given related to botanical extracts. When Regulation 258/97 came into force, it initially covered plants and their parts (e.g. stevia leaves) and plants that had been genetically modified. However, Regulation 258/97 was not able to fully identify the impact on botanical extracts. Questions about how plant extracts should be considered arose much later (e.g. if the plant and its parts are present in a list of the plants allowed for food supplements and a traditional manufacturing process for extraction is used, the

⁹http://ec.europa.eu/food/food/biotechnology/novelfood/documents/substantial_equivalenc_en.pdf

product can still be considered new). Companies, did not therefore have the awareness of need to preserve the evidence of use until several years after the entry into force of the regulation. This view was shared by a representative from a third country, who stated that providing proof that a product had been consumed to a significant degree before 15 May 1997 is difficult as most companies do not keep records that far back.

This again raises the issue of the gap between the guidance document of 2012 and the adoption of the Regulation in 1997. This particular example shows that companies can have great difficulty in demonstrating that an extract already on the market has been produced before 1997, because the fiscal and technical documentation may not have been preserved, since there were no such requirements in the 1997 Regulation. An industry association concluded that to consider the date of the new regulation as part of the new Novel Food definition would allow companies to begin to collect proper information on human consumption as food. The date of 15 May 1997 has no scientific basis and was chosen by virtue of the entry into force of the relevant Regulation.

A Commission representative stated that if the date was to be changed, this would have no effect on Novel Foods developed in recent years (i.e. post-1997) because it would not be possible to fulfil data requirements on significant consumption as the food was not on the market prior to 1997. To change the date would affect the status of those Novel Foods which have been authorised between 15 May 1997 and the application date of the new Regulation. If these Novel Foods have been consumed to a significant degree since their authorisation (e.g. chia seeds and phytosterols, which are popular Novel Foods) they would no longer fall under the definition of Novel Food.

For those Novel Foods authorised between 15 May 1997 and the application date of the new Regulation which do not fulfil the criterion of having been consumed to a significant degree, they would remain classified as Novel Foods under the new Regulation. Nevertheless, this scenario may require that the criterion of a food that has been consumed to a significant degree be further clarified. This may imply the inclusion of additional data requirements covering a specific period of time and create additional administrative burdens.

Based on evidence from interviews it can be concluded that despite a few concerns, most interviewees from EU bodies and Member States agreed that keeping the date of 15 May 1997 is still appropriate. A change would create confusion. However, this view was not shared by those organisations interviewed that represented applicants and a third country which consider that retaining the date, whilst simultaneously removing the categories, would lead to legal uncertainty for operators and potentially mean that foods that are currently on the market require approval retrospectively. All of the organisations interviewed which took this view stated that they did not think it was the Commission's intention to create this environment for operators, or cause legal uncertainty, but that the definition needed to be amended to reinstate the categories along with the date (see below).

Summary – Scope and definition

- For a food to be considered 'novel', i.e. something not used before, clearly the use of a date is the simplest way to define these foods from those that are not novel, i.e. have been used in the diet before.
- The only alternative put forward is to place greater emphasis on a period which constitutes a history of safe use, rather than a date fixed in time.
- The date of 15 May 1997 was based on the date of entry into force of Regulation 258/97, rather than any scientific rationale. Similarly, if a new date was used in the 2013 proposal it would also be likely that this would be an arbitrary selection, rather than one based on a scientific rationale.
- Whilst there would appear to be little value in changing the date of 15 May 1997 under the 2013 proposal, the impact of retention is dependent upon whether categories are used or not.

2. Impact of the definition of Novel Food in the 2013 proposal on the types of product that would require authorisation

Under the current Novel Foods authorisation process, when an applicant first contacts a Member State as part of the authorisation process, an assessment is made as to whether the food in question is classed as 'novel' under Regulation (EC) 258/97, and should therefore undergo an authorisation procedure. In the 2013 proposal for a Regulation on Novel Foods, the definition of Novel Food is said to be 'clarified and updated', and is defined as:

"All food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

(ii) food containing or consisting of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;

(iii) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

– A new production process has been applied as referred to in point (i) of this paragraph;
or

– such substances contain or consist of "engineered nanomaterials" as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;

(iv) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC¹⁰."

¹⁰ Article 2 (a), COM(2013) 894 final

In this new definition, the wording reads that all food (where food is defined in Regulation (EC) No 178/2002) not used to a significant degree in the EU before 15 May 1997, is defined as a 'Novel Food', and would require authorisation. The proposal then makes reference to cases where food would classify as novel, in particular where the definition applies (points i - iv above), however this is not an exhaustive list.

This is in contrast to the definition of Novel Food given in Regulation (EC) No 258/97 which applies to foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories. The categories listed include food or food ingredients with a new or intentionally modified primary molecular structure, and those isolated from micro-organisms, fungi or algae, amongst others.

In its 2008 Impact Assessment, the European Commission stated that the new definition is:

"Making use of the food definition in the General Food Law (Regulation No 178/2002) and abandoning the categories describing foods, and the aim takes into account legal developments, avoiding problems associated with the categories and clarifying the scope"¹¹.

The Commission proposal is seen by one Member State to follow a much more product-based approach compared to the definition under 258/97 and gives more flexibility (in view of future product developments/scientific progress) by using examples, instead of a fixed list of categories.

As part of this assessment, respondents were asked whether 'the new definition of Novel Food in the 2013 proposal would change the types of product that would require authorisation?' A mixed response was given. Two Member State authorities, and a consultant who prepares dossiers on Novel Foods, stated that the new definition did not change the scope of what should be authorised as a Novel Food, and just clarified it further. However, two membership-based organisations which represented companies (both large and SMEs) who have submitted, or would be likely to submit Novel Food applications, and a representative from a third country stated that, under the new definition, the date of 15 May 1997 had now become more important than the categories of food deemed to be 'novel' (such as those under Regulation 258/97). Whilst the respondents thought that this definition was not intended to change the amount of foods requiring authorisation, from a market competition perspective this was problematic, as organisations could challenge existing products on the market claiming that they would need a safety assessment. One consumer association further argued that if new definition means that certain products may be withdrawn from the market to undergo an authorisation procedure as novel foods, this may impact on the confidence of consumers that food is safe.

¹¹ European Commission (2008) Impact assessment for a regulation replacing regulation (EC) no 258/97 on Novel Foods and Novel Food ingredients, p14.

The respondent used the example of pangasius freshwater fish (imported from Asian countries), which currently does not need an authorisation, as freshwater fish are deemed to have a history of safe use and consumption in European countries. As the fish was imported from the early 2000s, other rival companies could claim that under the new definition of Novel Food (i.e. not consumed to a significant degree before 15 May 1997) the fish should be classed as a Novel Food, be given an authorisation, and ultimately withdrawn from the market until any authorisation is granted. This interpretation of the definition is also conveyed in other industry-facing publications. 'EU Food Law Weekly', for example, carried an article reporting on a meeting hosted by the U.S Mission to the EU in which the definition was interpreted as meaning 'thousands of new products could be covered'¹².

Another example is a background note produced by the Federation of European Speciality Food Ingredients Industries (ELC) which cited the following consequences:¹³

- Foods legally placed on the market after 15 May 1997 not falling within the categories identified in Regulation 258/97/EC have an uncertain legal status.
- Food ingredients produced by a new process after 15 May 1997 but not significantly changing the structure, nutritional value and safety of the ingredient (currently excluded from the scope of Regulation 258/97/EC) likewise have an uncertain legal status.
- A wide range of new foods resulting from traditional breeding (e.g. fruit/vegetables) and processing innovations (e.g. cheeses, beers, dairy products) would be captured by the new definition.

One of the interviewees described above thought that the new definition in legal terms covered all foodstuffs, all different preparations, all new varieties and composite foods not consumed to a significant degree before 15 May 1997.

Given the evidence gathered from interviews, and from the existing literature, it can therefore be concluded that currently there are mixed interpretations of the definition put forward in the 2013 proposal on what should be considered 'novel'. The purpose of the new definition was to achieve greater clarity. However, by removing the categories present in the definition under Regulation 258/97 this has caused confusion and uncertainty amongst some stakeholders, particularly within the industry.

¹² EU Food Law Weekly (2014) *Warning new Novel Foods definition too broad*. Number 623. 2 April 2014.

¹³ ELC (2014) *Novel Food Proposal: Impact of new definition of Novel Food, background note*. Unpublished. April 2014.

Summary – Impact of the definition

- Clearly it was not the intention of the Commission to introduce a system of legal uncertainty, especially as the rationale behind the definition was to 'clarify and update', rather than introduce uncertainty.
- Whilst the changes to the definition may be seen as a clarification to the Commission, Member States and other regulatory stakeholders, this view is not shared by industry.
- The potential issues arising from the current proposal for changes to the definition could therefore be numerous:
 - (1) Significant legal challenges to products already on the market that were not considered to be 'novel' before but may be under the new definition.
 - (2) As a result of (1), the withdrawal of certain foods from the market, and resulting impacts on competition.
 - (3) As a result of (1), a negative impact from consumer opinion in terms of food safety of already authorised products.
 - (4) A greater number of products requiring authorisation as 'novel' foods, where this was not required before.
 - (5) As a result of (4), resulting negative impacts on innovation and competition in the EU food sector.
 - (6) As a result of (1) and (4), considerable administrative burden placed on EU bodies and Member States.

3. Consequences of removing the Novel Food categories¹⁴ and the necessity/proportionality of applying a pre-market authorisation for all new foods and food ingredients, irrespective of their risk profile

Article 2 of the 2013 Commission proposal makes use of the food definition in the General Food Law (Articles 2 and 3 of Regulation N° 178/2002), thus abandoning the Novel Food categories as set out in Regulation 258/97.

From the Commission's point of view, the removal of categories is designed to take into account recent legal developments with other authorised products (e.g. GMOs, cloned animals), with the aim of clarifying the scope and avoiding problems associated with the categorisation of Novel Foods.

The current categories already cover all sources from which food can be made, with the exception of Novel Foods produced from whole animals (i.e. not cloned). For whatever food is novel, an authorisation is required on the basis of a safety assessment, with the exception of traditional food from third countries where the risk is considered lower (i.e.

¹⁴ Defined in Reg. 258/97 as foods and ingredients which: present a new or modified primary molecular structure; consist of micro-organisms, fungi or algae; consist of or are isolated from plants and ingredients isolated from animals; whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.

the only criterion for authorisation is data evidence of safe consumption for 25 years if no reasoned safety objections are presented). The removal of the categories means, in principle, that the new definition is broader in scope than that of Regulation (EC) No 258/97, and therefore would potentially cover many more products or ingredients (as discussed above).

The intention of the 2013 proposal is not to change the field of application by removing the categories, but rather to eliminate some uncertainties, particularly regarding Novel Foods produced from animals. Indeed, as mentioned earlier, Novel Food produced exclusively from cloned animals and their offspring is excluded from the 2013 proposal. On the other hand, Article 1.e. of Regulation 258/97 categorises food and food ingredients isolated from animals as novel, with the exception of those foods obtained by traditional breeding.

Feedback from the research suggests that under Regulation 258/97, there can be uncertainties as to under which specific category a particular ingredient would fall. On the other hand, the removal of the categories implies that there would need to be a case-by-case approach to determining whether a type of food would qualify as 'novel'. Two Member State authorities suggested that, if categories were removed, consultations between the applicant company and the relevant EU and national authorities would need to be held more frequently to determine whether a new (or newly consumed) product¹⁵ could be defined as a 'Novel Food'. Under the current system, companies already have the possibility to seek Member State authorities' advice before submitting an application.

In light of the points raised in the previous subsection, it seems that the industry is in favour of retaining categories. However, given that innovation is fast-moving, some of the Member State authorities we interviewed pointed out that it is important to have a flexible definition of the categories if these were to be reinstated.

All the Member State authorities that were interviewed thus agreed on the need for broader categories. A recurrent suggestion was that categories would need to be updated and broadened to reflect developments in the food industry (e.g. the inclusion of minerals). However, one member organisation representing applicants commented that if the categories were to be re-instated, these would need to be sufficiently specific to avoid any legal uncertainty.

The European umbrella organisation for consumer associations (BEUC) was found to be in support of having a broader definition to capture all relevant products, but made it clear that the broadening of the definition should not damage its clarity, as this could create a number of loopholes that the industry could exploit. This association, thus expressed the view that the Novel Foods Regulation should have its own definition rather than referring to the definition of the General Food Law Regulation.

¹⁵ e.g. pangasius freshwater fish

Another issue raised by the European umbrella organisation for consumer associations was the fact that the Novel Foods Regulation refers to the definition of 'engineered nano-materials' laid down in Regulation 1169/2011 on Food Information to Consumers, which was only formulated for labelling purposes¹⁶. In particular, the 50% nanoparticles threshold for a food ingredient to qualify as 'nano', which has been put forward for labelling purposes, would not be appropriate for safety risk assessment in light of EFSA's recommendation of a 10% cut-off value. As such, the association would like the Novel Foods Regulation to contain a specific definition of nano-materials for assessment purposes.

From the research, it can be concluded that, with regard to changes under the 2013 proposal to the definition and scope of Novel Food, there are very different views. On one hand, Member States and the European Commission see the new definition as a clarification of scope, and a means of keeping pace with the high rate of new products coming to market that could be considered novel. On the other hand, industry stakeholders have serious concerns that the new definition will introduce legal uncertainty to food business operators, potentially meaning numerous products legally already placed on the market could be subject to authorisation. This, they say, will create competition issues for the EU food industry, which could delay the introduction on the market of new products, and create a risk that competitors in the EU and third countries may become aware of a new product launch which is under preparation. In addition, it is thought by these industry stakeholders that, due to uncertainty as to what can be classed as a Novel Food, the amount of queries competent authorities will receive will be unmanageable.

Summary – Removing the Novel Food categories

- The diverging views on the impacts of the new scope and definition of the 2013 proposal between public and industry sectors resulting from the removal of the categories has the potential to be damaging if the legislation enters into force as proposed.
- Even if, in reality, the new scope and definition does not widen the scope of products that may require authorisation, the administrative burden for industry of dealing with challenges and queries from the European Commission and Member States authorities, could be vast.
- In addition, if the new scope and definition are enough to discourage food business operators from seeking approval for new products, and subsequently delay authorisations, this has the potential to cause huge ramifications for innovation and competition in the food sector in the EU.
- There is a risk that broadening the definition – also by referring to definitions in other Regulations – could impact on its clarity and create a number of legal uncertainties or legislative loopholes.

¹⁶ The Commission recently proposed to amend this definition via a delegated act which was rejected by the European Parliament (see Chapter 2, Section III).

II – Impact of the centralised procedures for authorisation

We now examine the requirements, process and impact of the new procedures, including the impact of generic authorisations and the process for data protection (both for Novel Foods and for traditional foods from third countries).

Background and rationale

Under the 2013 proposal¹⁷, all applications will now be submitted to the European Commission, rather than individual Member States. The European Commission may then request a scientific opinion from the European Food Safety Authority (EFSA) to help determine whether a Novel Food should be included in the Union list. For traditional foods from third countries, a safety assessment and risk assessment based on a demonstration of ‘history of safe use’ is introduced. If it can be demonstrated that the food in question has a history of safe food use in a third country for at least 25 years, and no reasoned safety objections are presented by EFSA or Member States, the food may be included in the Union list.

1. Extent to which the centralised authorisation procedures may be quicker

The current system for Novel Foods approval under Regulation 258/97 requires an applicant first to submit an application dossier to a Member State competent authority, who then produces an opinion, which then is circulated to all Member States for comment. If objections by Member States cannot be satisfied, the Commission may request a further assessment from EFSA. Given these multiple stages, this means that for any one Novel Food application, dossiers are scrutinised by a large number of scientists.

An impact assessment, conducted by an independent consultant for the food industry in 2007 stated that over the last 10 years the average time to authorisation of a Novel Food in the EU was 35 months, with a range of 16-60 months¹⁸.

With a centralised procedure, the application is sent directly to the Commission which checks its validity, i.e. ensuring that all the elements required for the authorisation and evaluation are contained in the application. The Commission then sends the application to EFSA, which must deliver its opinion within nine months of receiving it. Once the opinion is adopted, the Commission has a maximum time of nine months to present a measure to the regulatory committee to authorise the Novel Food in question.

The 2008 Commission impact assessment states that an ideal procedure could take as little as 400 days¹⁹. Interviews with four respondents indicated that, in theory, the

¹⁷ COM (2013) 894

¹⁸ Brookes, G. (2007) Economic impact assessment of the way in which the EU Novel Food regulatory approval procedures affect the EU food sector.
<http://www.pgeconomics.co.uk/archive.php>

¹⁹ European Commission (2008) *Impact assessment for a regulation replacing regulation (EC) no 258/97 on Novel Foods and Novel Food ingredients*, p.10

authorisation process should be quicker under a centralised procedure, as the process removes duplication, and means less scientists review the document. However, whilst these respondents welcomed the changes, in reality they stated that it is hard to assess whether the new procedures will actually be quicker as there are still many opportunities for the process to be delayed (i.e. in the standing committee where there are no fixed deadlines).

An advantage of the centralised authorisation procedure is the harmonization of safety assessment criteria. According to one Member State authority, about half the applications are currently approved on the basis of an EFSA opinion – the other half on consensus by the Member States (within that, half are approved after explanation by the applicant in relation to an objection). Another Member States authority stated that it may be that EFSA will require more time at the beginning to deliver opinions – there will probably be a period of adaptation. It is also likely that during the nine month period, EFSA will ‘stop the clock’ to require additional data from the applicant.

EFSA will produce guidance for applicants, which details the type of information needed in an application dossier to make an opinion. Two respondents stated that the comitology procedure involving the Standing Committee is still in place, and that this process has no deadlines and can take one to two years of discussion before a final decision is taken.

Summary – Centralised authorisation procedures

- The new centralised procedures will ensure that only one body (EFSA) now reviews dossiers, which will certainly make the time taken to come to an initial opinion quicker.
- Furthermore, for applications (other than traditional foods) there will be no facility to raise reasoned objections to safety, which under the current system can mean multiple clarifications being asked of the applicant.
- Whilst, in theory, a centralised procedure for risk assessment may reduce time whilst an opinion on an application is produced by EFSA, the comitology procedure in place will still take time, and in industry's view this is the main time period where applications can be held up.

2. Data requirements for the submission of applications under the new extended definition (i.e. with no specific data requirements depending on the category)

Under the 2013 proposals, data requirements for Novel Food applications will be detailed in guidance documents produced by EFSA. As such, at the time of writing it is not possible to make an accurate assessment of what these data requirements will be.

However, the broad data requirements for applications for Novel Foods under the 2013 Regulation proposal include²⁰:

- The name and description of the Novel Food;
- The composition of the Novel Food;
- Scientific evidence demonstrating that the Novel Food does not pose a safety risk to human health;
- Where applicable, a proposal for the conditions of use and a proposal for specific labelling requirements which do not mislead the consumer.

After the publication of Regulation 258/97 a Commission Recommendation 97/618/EC was published. This detailed the scientific aspects and the presentation of information necessary to support applications for the placing on the market of Novel Foods and Novel Food ingredients and the preparation of initial assessment reports. As this recommendation was released at the time when genetically modified organisms (GMOs) were part of the Novel Foods regulations, some of the information contained in this document was out of date after the GMO specific legislation (Regulation EC 1829/2003) came into force in 2003. The Recommendation uses concepts that are used in the assessment of other food products such as 'substantial equivalence'²¹. Importantly, the types of data presented in an application are on a 'case by case basis' to ensure that risks are adequately addressed by appreciating the differing risks presented by different foods²². Whilst no similar Commission Recommendation has yet been published for the 2013 proposal, there is no evidence to suggest that data requirements will change significantly for Novel Foods, regardless of type.

In a position paper published by the European umbrella organisation for consumer associations (BEUC), emphasis is placed on ensuring dietary exposure is thoroughly considered, especially in terms of recommendations on daily intake²³. BEUC also states that Post Market Monitoring (PMM) should be a long term requirement for all Novel Foods, to take into account food safety, environmental impact and animal health and welfare.

Currently, exposure assessments are predicted based on the consumption of similar foods that are already on the market, and inform the recommendations on the daily intake of the Novel Food. Under Regulation 258/97, PMM is a possibility for any Novel Food as a condition of authorisation, and is typically used as a mechanism to qualify consumption of the Novel Food once authorised. If requirements for PMM were in place for all Novel Foods, regardless of risk profile, clearly this would mean that the data

²⁰ COM (2013) 894 Article 9 (1)

²¹ If the new food that is modified can be demonstrated to be substantially equivalent to an existing food then further safety or nutritional concerns are expected to be insignificant (OECD, 1993).

²² Commission Recommendation 97/618/EC part 3.

²³ BEUC (2010) *Novel Foods Regulation Proposal, BEUC Position*.

<http://www.beuc.org/publications/2010-00064-01-e.pdf>

requirements on applicants would be greatly increased. In some cases it may be beneficial to consumers to conduct PMM, for example to check consumers are following dietary guidelines. However, this is only likely to be for a limited number of cases, and the routine application of PMM may give rise to uncertainty amongst consumers about the safety of novel foods given that safety is supposed to be ensured.

The Commission will issue implementing guidelines in accordance with Article 9 of the 2013 proposal. Furthermore, Article 12 of the proposal establishes the implementing power concerning administrative and scientific requirements for applications. Point c) states that the Commission shall adopt implementing acts concerning the type of information required to be included in the opinion of EFSA.

EFSA is thus due to update its guidance on the information needed depending on the type or origin of food in question (e.g. plant- or animal derived Novel Foods, Novel Foods of microbial origin, polymers used as Novel Foods, Novel Foods consisting of or containing "engineered nano-materials", single substances and simple mixtures, complex mixtures or whole foods etc.). This is necessary and totally independent of whether or not the categories are explicitly stated. The Commission has already requested EFSA to revise the existing scientific guidance on Novel Foods, which dates back from 1997. Interview respondents suggested that the data requirements for novel food applications would be completely dependent on this guidance document.

On this basis, it is expected that EFSA will produce guidance for applicants for data to be presented to make a safety assessment of a Novel Food, as the body does for other authorised products.

Summary – Data requirements for the submission of applications

- The basic data requirements for the submission of applications on Novel Foods will be completely dependent on 'guidance for applicants' created by EFSA, which is yet to be finalised.
- It is expected that this guidance will follow the same basic principles as other authorised products, using terms such as 'substantial equivalence'.
- Whilst EFSA will produce guidance for applicants, it is expected that the data requirements for each Novel Food application will continue to be on a 'case by case' basis to take into account the varied nature of the products seeking authorisation.

3. Impact on competition of the introduction of generic authorisations, and the new data protection regime²⁴

In the 2013 proposal the current system of addressing a Novel Food authorisation to the specific applicant will be replaced by a system of generic authorisations, so that once authorised, the food can be marketed by any company. To support innovation in the EU food industry, and only in 'duly justified' cases, individual authorisations can be granted for a maximum period of five years.

Two respondents stated that the introduction of generic authorisations is positive in the sense that it removes the need for another applicant to seek to verify that another product is substantially equivalent to the Novel Food authorised. However, the majority of respondents representing applicants had concerns with generic approvals.

One member based organisation stated that generic approvals mean that one applicant does all the work for the application and all competitors will be able to use the substance after approval. This means that companies will reflect carefully on whether, they want to do all the work for an application in the first place, what the requirement for proprietary data protection will be, and if there is any other form of protection (e.g. patenting or exclusive licences). However, the respondent also stated that on the other hand generic approvals may be advantageous to SMEs, who may not have the resources to compile an application.

Another respondent (a consultant for applicants) stated that generic authorisations will greatly disadvantage companies who diligently follow the regulatory procedures for approval. This will be the case if other manufacturers use the generic approval to market a product that is the 'same', but of a lower quality. The respondent commented that if he were advising a Novel Food applicant, he would ensure that the specification of the Novel Food (which is published at the end of the authorisation) was as complex as possible, to deter competitors.

Generic authorisations for traditional food from third countries were, however, generally viewed as beneficial, compared with the present situation. This echoes the findings of the 2008 Impact Assessment in which one respondent stated that no 'monopoly' should be given, since traditional foods do 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."

In conclusion, it is uncertain whether generic approvals and the provision for data protection will have an impact on competition and innovation in the EU food sector. Whilst generic approvals may discourage companies from channelling resources into authorising Novel Foods, measures under Article 24 of the proposal (data protection) are

²⁴ Generic authorisation will avoid the resubmission of new applications by other companies for the same Novel Food

intended to alleviate this. As such, the effectiveness of data protection measures will be fundamental to ensure no detrimental impacts on competition and innovation in the EU food sector.

Based on responses from this assessment, member bodies representing the food industry have concerns over the length of time data protection can be awarded (five years), compared with other regulated products, and the conditions for data protection in relation to 'rights of reference' (Article 24; 2(C)).

Summary – Impact on competition of the introduction of generic authorisations

- Under the current Novel Foods system, applicants, to whom the original authorisation was not addressed, must submit a dossier to prove that the food they wish to market is substantially equivalent to that which has already been authorised.
- In principle, the fact that generic authorisations avoid this situation is good for those businesses (especially SMEs) that do not have the resources to compile applications, but have a product that is the same as one already authorised.
- Generic authorisations therefore are beneficial to those who may be wishing to market a similar product to one already authorised, but disadvantageous for those who commit resources to authorising the product initially.

4. Impact of the distinct authorisation procedure for traditional foods from third countries

Under the 2013 proposal traditional foods from third countries may use a different procedure of 'notification' in order to obtain authorisation if the applicant can demonstrate that the product has a history of safe use as food in a third country.

'History of safe use' means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a large population of a third country²⁵. Under the procedure for traditional foods from third countries, a company must first notify the Commission in order to introduce a product on the EU market. Within four months of the notification, Member States or EFSA may raise 'reasoned safety objections' in which case the company may be required to submit an application to the Commission with data relating to the safety objections raised²⁶. The requirements for demonstrating the safety of traditional

²⁵ COM (2013) 894 Article 2.2 (c)

²⁶ COM (2013) 894 Article 14.5

foods (i.e. data on the history of safe consumption) are however different from those for demonstrating the safety of a Novel Food (i.e. safety assessment).

If no reasoned objections are raised within four months, the traditional food may be placed on the EU market by the Commission without having to consult a regulatory committee (i.e. accelerated procedure).

The Commission representatives we interviewed stated that this procedure is expected to facilitate the placing on the market of traditional foods from third countries which currently require full application and authorisation. They also expressed the view that this new procedure for traditional foods is fairer and more proportionate because it is based on a history of consumption. There is no evidence to suggest the extent to which Member States or EFSA would be likely to raise 'reasoned safety objections', however clearly this is a determinant of how effective a simplified procedure for traditional food from third countries works in practice. Two respondents stated that past experience suggested that Member States would be likely to raise objections, and that it only takes one Member State out of 28 to do this, and thus require more data from an applicant.

For an applicant to prove that their product has a history of safe use as food in a third country, can be problematic. After the 2008 proposal for a revised regulation on Novel Foods²⁷, an EFSA Scientific Colloquium entitled 'What's New on Novel Foods'²⁸ discussed this issue. In particular, the following two questions were posed:

- Which data should be requested for the history of safe use (including possible adverse effects)?
- What is the relevant information on the "experience of use and continued use in the normal diet of a large part of the population of a country", which should be provided by an applicant?

In particular, the definition refers to a 'large part of the population of a country', however a product could be regionally specific, and be consumed by more people in that region, than the totality of a population in a smaller country. Various other publications have discussed the data needs for proving the concept.^{29,30} In particular, it is noted that the

²⁷ COM (2007) 872

²⁸ EFSA (2009) *What's new on Novel Foods*. EFSA Scientific Colloquium Summary Report. 19-20 November 2009, Amsterdam, The Netherlands.

²⁹ Constable A, Jonas D, Cockburn A, Davi A, Edwards G, Hepburn P, Herouet-Guichenev C, Knowles M, Moseley B, Oberdörfer R, Samuels F, 2007. History of safe use as applied to the safety assessment of Novel Foods and foods derived from genetically modified organisms. *Food Chem Toxicol.* 2007 Dec;45(12):2513-25. Epub 2007 Jun 21. http://www.ilsa.org/Europe/Publications/2007Hist_Safe.pdf

³⁰ Jones, A and Craddock, N, 2009. Definitions, Concepts and History of Safe Use Assessment. Issue Paper Prepared for UNCTAD BioTrade Initiative concerning the proposed amendment to the European Novel Foods Regulation with particular reference to Traditional Foods from Third Countries, UNCTAD and GTZ. <http://www.biobio.org/BTFP/BTFP-docs/novelfoods-issue.pdf>

concept of 'history of safe use' is hard to define as it relates to an existing body of information which describes a safety profile of the food, rather than an exact checklist.

In EFSA discussions, the example of baobab fruit pulp, a previously authorised Novel Food, was used to illustrate the types of data use to determine history of safe use, namely sales figures by companies and information from Government organisations, ethnobotanists, peer-reviewed publications or patent applications. It is therefore reasonable to assume that proving history of safe use is very much done on a case by case basis, utilising a number of different data sources that may vary in their methodological quality.

The European umbrella organisation for consumer associations stated in its position paper that clearer criteria for what constitutes a 'history of safe use' should be put forward, and current requirements fall short of providing adequate protection to consumers³¹. It was argued that the fact that a product has been consumed for many years in a country does not necessarily mean that it is safe. It may be just that there has not been any monitoring carried out that would determine whether there have been any adverse effects. Among the suggestions made by this consumer association as regards criteria for determining a history of safe use were, the collection of data to establish relationships between consumption patterns and health status, or the collection of medical cases that may be relevant in the case of a particular traditional food. The position paper adds that EFSA should issue guidelines that describe the information which must be provided by the operators looking to place their product on the EU market.

A membership-based organisation commented that it would be a challenge to prove a history of safe use of traditional foods since there are no guidelines indicating the type of information operators are required to provide. A consultant compiling applications on Novel Foods expressed a desire for more specific criteria for the notification of traditional foods, as in absence of this it is likely that more Member States will provide reasoned safety objections at an early stage in the process, diverting most 'notifications' to require a full application. A member organisation also commented that the benefit of having a simplified procedure for traditional foods would only be of little benefit, as it would not apply to primary products that have not undergone processing, such as fruit or vegetables. This view was shared by a representative from a third country, who thought that as most primary products are processed in some way, the impact of a different, more simple procedure would be negligible.

Overall it can be concluded that, whilst the 2013 proposal intends to provide a proportionate risk assessment and management procedure for traditional foods, allowing for quicker placing on the market without compromising food safety, the ability to do this will be completely dependent on the level of reasoned safety objections presented by Member States and EFSA. If the criteria for proving a 'history of safe use' are more descriptive, and hard to substantiate with rigorous scientific data, then it may be more

³¹ BEUC (2010) Novel Foods Regulation Proposal, BEUC Position.

likely that reasoned safety objections will be made, and traditional foods will still be required to submit applications, which must then be reviewed by EFSA, and submitted to the comitology procedure. Additionally, the value of such a procedure has to be questioned if it only applies to a very narrow range of products (i.e. only primary products that have not undergone any processing).

Summary – Impact of the distinct authorisation procedure for traditional foods from third countries

- The value of a simplified procedure for traditional foods is questionable if it only affects a very narrow range of products (i.e. only primary products that have not undergone any processing).
- Given the current discourse over what constitutes a ‘history of safe use’, it may seem inevitable that reasoned safety objections will be made.
- Clearly, the data to prove a ‘history of safe use’ will range from application to application, depending on what information is available. Given the range in data submitted, it may therefore be ‘easy’ for Member States or EFSA to raise a safety objection, based on a lack of evidence of safe use of the product.
- Proving a ‘history of safe use’ may also be problematic if the food in question has been prepared in a specific way by the population that has consumed it. An applicant would need to prove that adequate provision had been given to ensure that when a product is marketed in the EU, consumers are aware of how to prepare it safely.
- All these factors mean that a traditional food notification will vary markedly from applicant to applicant, and ultimately unless rigorous data is presented it will be open to interpretation from Member States and EFSA.

Introducing more rigorous guidelines to applicants may be a solution to the issue; however it is questionable whether this could be done whilst still keeping the procedure of a system of ‘notification’, rather than ‘application’.

III – Effectiveness of the centralised system and its tools

This section looks at the effectiveness of the tools proposed in order to reduce administrative burden and their impact on competitiveness and innovation.

Background and rationale

Under the current authorisation procedures, applicant companies first submit their application to a Member State authority which carries out an assessment, in some cases via a national independent scientific body. The assessment is then sent to the Commission, which forwards it to the other Member States. Member States have 60 days

to respond, with the possibility to raise 'reasoned safety objections'. Under the new centralised system, applications are made directly to the Commission and are then transmitted to EFSA for risk assessment. According to the Explanatory Memorandum of the 2013 proposal, the authorisation procedure is streamlined and fully centralised with deadlines for each step of the procedure: the administrative burden is less (removal of current double risk assessment), and time and related costs for obtaining a Novel Food authorisation are reduced.

1. Impact of the centralised authorisation procedure on the costs and resources needed to compile and submit an application

The costs and resources needed to complete a Novel Food application under the current decentralised system vary considerably, and depend on factors such as the level of data required to support the application initially, the applicant fees charged by the Member State authorities, and whether further data is required as a result of 'reasoned scientific objections' raised by Member States. An impact assessment on the current EU Novel Foods authorisation process, completed in 2007, estimated the cost associated with meeting regulatory requirements (for studies that are fairly common to most markets) of Novel Food applications at a global level is between €0.3 million and €4 million. The report estimated that the longer authorisation times for Novel Foods in the EU add a further €0.3 million and €0.75 million per Novel Food application³².

A further estimate, provided by a multinational company suggested that their costs of bringing to market plant stanols in yellow fat spreads was €19-24 million³³. As such, whilst that impact assessment demonstrates that the cost of making a Novel Food application may be similar on a global level (as data requirements are largely similar), any extra cost in making an EU Novel Foods application, is largely due to the time taken to complete the authorisation process. It must also be pointed out that for the example above, Post-Market Monitoring of the novel food was required, which added to the costs of application. Therefore, the level of costs required to bring a Novel Food to market can be highly dependent on the length of the application procedure. Indeed, if the centralised process is quicker, this logically implies shorter delays for placing Novel Foods on the EU market and thus improved cost-effectiveness from the perspective of applicant companies. The extent to which a centralised authorisation process will be quicker is evaluated elsewhere in this report (See Section II.1).

However, according to the experience of one Member State authority, it is not so much the length of time of the process that matters, as the predictability of the process. Uncertainty as to the successful outcome of the process is more of a problem for smaller

³² Brookes, G. (2007) Economic impact assessment of the way in which the EU Novel Food regulatory approval procedures affect the EU food sector.
<http://www.pgeconomics.co.uk/archive.php>

³³ Unilever (undated) *Consultation Response to Commission's Discussion Paper on the Evaluation of Regulation EC258/97. Bringing Novel Foods to Market - Unilever's Experience.*
http://ec.europa.eu/food/food/biotechnology/novelfood/unilever_en.pdf

companies who can only rely on a small range of products, as opposed to larger companies that have the capacity to absorb these uncertainties. This view was shared by a representative from a third country who stated that a longer, and less dependable authorisation process would have a more negative impact for SMEs, who may not be able to afford an investment if it took a longer time to pay off. In this context, applicants' experience in assembling Novel Food applications is relevant here.

Under Regulation 258/97 applicants may receive guidance from individual Member States in terms of data requirements, and how to submit an application. It is uncertain how the support from EFSA in this area will compare. EFSA currently does not charge an application fee to conduct additional risk assessments following a reasoned objection. The 2013 proposal makes no mention of whether EFSA will charge any fees, but in any case these fees would be harmonised across the EU depending on the complexity of the application. However, if support from EFSA is less than that provided by Member States, this may increase the need to hire external consultants to support an application submission, which will increase the costs of application (feedback from a Member State competent authority).

In the Commission's Staff Working Document on impact assessment for the establishment of fees for EFSA³⁴, it is estimated that average cost for an applicant producing a Novel Foods dossier would be €20,000/45,000 (see ANNEX II Processed data from association's consultation questionnaire). This cost would also apply to other types of market authorisation, not just Novel Food. The document goes on to say: "A dossier submitted for an authorisation has to respect a set of requirements". Specific legal acts (usually implementing rules), complemented by EFSA's guidance, indicate the type and quality of information required. The costs may differ significantly from sector to sector and by type of application. In some cases the cost of preparing an application for authorisation can cost a few hundred Euros, whereas in most cases the cost will be around EUR 350,000 with costs of EUR 1 Million for complex applications. The costs are linked in particular to the complexity of the scientific evidence required."

For SMEs, the costs of submitting a Novel Food application, whilst not different from those for large companies, will be higher in comparison with the overall budget or revenue of the organisation. However, as pointed out by a Commission DG, the 2013 proposal gives SMEs the possibility of submitting joint applications. Indeed, joint applications under Regulation 258/97 are currently not submitted, as Article 4 of the Regulation refers to the applicant as the "*person responsible for placing on the Community market the Novel Food*". As such, under Regulation 97/258, applications are in practice submitted by single companies, who then become the sole authorisation-holders (an authorisation is delivered to the 'applicant' as defined under 97/258).

³⁴ Impact Assessment on the Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA, SWD(2013) 45 final.

Conversely, the provisions of the 2013 proposal define the applicant as “*the Member State, the third country or the interested party*”. This can therefore be interpreted as removing the restriction that the applicant should be one single food business operator. This can be seen as a positive development as far as SMEs are concerned.

Summary – Impact on application costs

- The costs and resources required to submit an application will depend on the clarity, and what requirements are included in EFSA’s initial guidance on data requirements, and by extension on the complexity of the application, whilst the centralised procedure will imply harmonised fees across the EU for the submission of applications.
- Different estimates are given of the costs of submitting an application and this ranges from €20,000 to submit a dossier, to €4 Million.
- Experience in submitting Novel Food applications has also been identified as a factor impacting on the level of costs and resources required.
- A longer and less dependable authorisation process is thought to impact SMEs more negatively, given that their business may depend more on a narrower suite of products, and the investment in the authorisation process is likely to be a relatively greater cost to the business than larger companies.
- As a general rule, the faster or the more predictable the process is, the lower the cost of an application will be for a company.

2. Impact of the length of the current pre-market authorisation procedure on competition on a global level

It was acknowledged by those we consulted that, under the current Novel Foods system, any Member State can raise objections and cause huge delays in the decentralised authorisation process, which can have considerable negative implications for applicant companies in the EU.

According to feedback from the industry associations, this decentralised procedure has failed to establish the mutual recognition principle which was originally intended. The current decentralised system has somewhat resulted in a relatively low level of successful applications and this is clearly hampering innovation and competitiveness in the European Union.

There is no doubt that the current length of the pre-market authorisation process is an administrative burden for economic operators, not least because transaction costs go up as a result. On the other hand, the Commission representatives we spoke to argued that authorisations are valuable to companies keen to maintain a certain reputation on the market as they help them in substantiating the safety of their products and give them an

official status or 'seal of approval'. In addition to confirming the safety of the Novel Food, pre-market authorisation could also be a way for industry to gain consumer acceptance (e.g. insects as food). An impact assessment conducted for the food industry in 2007 estimated that the longer authorisation times for Novel Foods in the EU add a further €0.3 million and €0.75 million per Novel Food application (when compared to third countries such as Japan and the US)³⁵. It is uncertain as to what these costs are borne from.

However, according to feedback from a Member State authority, the length of the current decentralised Novel Food authorisation procedures in the EU is not really a barrier to global competition. Companies can still market Novel Foods outside the EU - they simply do not have access to the European market if they do not have an EU marketing authorisation. There are several examples of products which must undergo a pre-market authorisation in the EU as a Novel Food which, for example, already have a GRAS (Generally Recognized As Safe) authorisation in the United States and vice-versa. Applicants can first put together an EU application and later or simultaneously fill a GRAS petition. There is also a similar procedure in Australia and New Zealand (FSANZ³⁶).

To conclude, interview feedback generally suggests that the length of EU authorisation procedures equally penalises all applicant companies looking to market their Novel Food products in Europe.

Summary – Pre-market authorisation procedure

- Whilst the length of authorisation procedures in the decentralised system equally penalises all companies looking to market their products in the EU, this is logically even more problematic for those companies whose main market is Europe.
- One impact assessment stated that the longer authorisation process in the EU approval process added between €0.3 - €0.75 million to regulatory compliance costs (when compared to the US and Japan). However, it is uncertain what these costs are borne from.
- From the perspective of companies whose main market is the EU, the length of the authorisation procedures in the decentralised system is clearly a barrier to innovation and competitiveness.
- From a global perspective, the length of the procedures can only be seen as a barrier to market the products in the EU.

³⁵ Brookes, G. (2007) Economic impact assessment of the way in which the EU Novel Food regulatory approval procedures affect the EU food sector.

<http://www.pgeconomics.co.uk/archive.php>

³⁶ FSANZ: Food Standards Australia New Zealand

3. Impacts of the new data protection regime on innovation in the industry

It was acknowledged by all of the interviewees that data protection can be seen as incentivising investment in innovation, or research and development (as has been witnessed with pharmaceutical products).

According to the impact assessment carried out by the Commission in 2008, it was estimated that the impact of a data protection regime would be fairly beneficial to the companies concerned as it would enhance their motivation to develop new products. Similarly, the data protection regime now proposed for Novel Foods introduces the notion of intellectual property rights and therefore has the potential to curb unfair competition. Patents can in addition be requested by the applicants pursuant to national and EU laws³⁷.

In the present situation, depending on whether the product in question is patented or not, competitors can present data which proves a similar product is 'substantially equivalent' to the authorised product, and simply market their own 'equivalent'. Under the proposal, the applicant company has a five-year exclusivity if data protection is granted, which means that other companies cannot refer to the original applicant company's data to have their equivalent product authorised. In other words, companies looking to place equivalents on the market would have to produce new data.

There have been some discussions about extending the data protection period from 5 to 10 years, but the Commission decided on five years as it is the data protection period that applies to nutrition and health claims in food products once they have been approved after assessment³⁸. However, two industry associations pointed out that aligning the data protection period for Novel Foods, with that for nutrition and health claims could be problematic if the two respective assessments do not run in parallel (see Section V.2 for further information). Their point was that the five-year period for proprietary data protection as regards Novel Foods is not sufficiently long in cases where further separate applications are required (e.g. for nutritional substances and for health claims). A period of 10 years would be more appropriate and act as a better incentive for companies to undertake the research to compile an application in view of return on their investment.

However, developing Novel Foods requires substantial investment to undertake research to compile an application and, in this context, all the industry representatives that were interviewed indicated that they would like the period to be extended to 10 years in view of a better return on their investment. This time period would be in line with legislation concerning GMOs and Plant Protection Products, and would be logical given the level of investment into an application is similar.

Under the 2013 proposals there are three conditions for data protection³⁹, namely:

³⁷ Cf. European Patent Convention (EPC) 15th Edition (2013), Chapter V

³⁸ Regulation (EC) No. 1924/2006

³⁹ COM (2013) 894 Article 24

- the newly developed scientific evidence or scientific data was designated as proprietary by the prior applicant at the time the first application was made;
- the prior applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made, and
- the Novel Food could not have been authorised without the submission of the proprietary scientific evidence or scientific data by the prior applicant.

Two respondents from membership-based organisations oppose the use of ‘right of reference’, as this phrase limits the data that can be used to grant a data protection licence. The respondents used the example of a business working with an academic organisation, which ultimately is public/state funded. If the University has presented data in a scientific publication which is then used for a Novel Foods application, the applicant may not be granted a data protection licence. This issue is expanded upon in a briefing note issued by one member organisation, in which a call for ownership of data, rather than ‘right of reference’ is made.⁴⁰

One industry association identified a further potential weakness in relation to the proposed data protection regime, pointing out that it is in practice difficult to consider as proprietary, data that has been shared with another party even when these data are the property of the applicant. This could prompt companies in the industry to avoid undertaking research with institutions such as universities who customarily require research to be published. Furthermore, this could potentially have a negative effect on innovation activities in the food sector more generally.

In summary, whilst all those we consulted welcome the introduction of a data protection regime as a way to counterbalance the effects of the introduction of generic authorisations for Novel Foods, the industry has raised a number of issues in relation to the length of the data protection period, with regard to the confidentiality of proprietary data.

Summary – Impacts of the new data protection regime on innovation

- The data protection regime is a new measure which is expected to stimulate innovation within the food industry.
- This regime should effectively prevent competitors from marketing equivalents using data from the authorisation holder.
- It is however difficult to ascertain at this stage whether the five year protection period will generate the expected returns on investment for businesses.
- Furthermore, the ‘right of reference’ may act as a disincentive for companies to innovate

⁴⁰ Federation of European Speciality Food Ingredients Industries (ELC) (2013) *Novel Food Review, Data Protection in the Novel Foods Regulation: Time for a Rethink*. July 2013.

4. Issues regarding confidentiality and innovation

Article 22 of the 2013 proposal refers to the confidentiality of the application. Paragraph 4 refers to which information may not be considered confidential. Paragraph 4(e) mentions "*where applicable, the analysis methods*". It is thus not a systematic requirement to provide analysis methods in a Novel Food application. In case these are provided they may not be treated as confidential information.

In other words, whilst analytical information as well as the methods applied regarding standardisation and quality is considered an important part of an application, applicants have no obligation to provide such information according to the 2013 proposal. It is up to the applicant ultimately to provide the right information and data. In the current applications, however, especially in case of chemically defined substances, test methods are already provided by the applicant in accordance with the 1997 Commission recommendations regarding information to be included in Novel Food applications⁴¹.

The logic here is that given that applications already contain information on the properties of a product (e.g. toxicity/health effects according to levels of intake) this implies that the applicant used methods to analyse them before submitting the application. Considering this point, the Member State authorities interviewed pointed out that providing a description of the methods used for analysing the property of a product would come at no extra cost for the applicant. Conversely, if no such information is provided by the applicant, Member State authorities would have to develop for themselves analytical methods to test a product's properties which would result in resources being inefficiently used and longer delays for completing an assessment.

The Member State authorities interviewed were thus in support of the idea that Novel Food applications have to include information on methods of analysis '*where applicable*' or appropriate in a centralised procedure. While being in favour of this rule as well, a consumer association has also made it clear that there needs to be a balance between confidentiality and consumer information, whilst stressing that the detailed outcomes of safety assessments should be made available to consumers.

Whereas the requirement as regards information on methods of analysis may not be as clearly stated in Regulation 258/97, it is already common practice for EFSA to ask for such information in order to perform its complementary safety assessments of Novel Food products or ingredients, the initial assessment of which was objected to by Member States.

In summary, feedback gathered from the interviews reveal that companies are already advised to include, in their application, information on the methods used for analysing the safety of a product or ingredient, so that Member State assessment bodies and EFSA can perform safety assessments. This is the case especially with Novel Food applications

⁴¹ Commission Recommendation 97/618/EC concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of Novel Foods and Novel Food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council

for chemicals and nano-materials. If no such information is provided in novel applications in the context of the centralised procedure, interview feedback suggests that safety assessments could not be as thoroughly performed, with the likelihood that EFSA would have to refer back to the applicant to ask for the information.

One respondent further highlighted that, as far as confidentiality is concerned, it is important not to confuse information relating to methods of analysis with information relating to production processes. Companies are usually reluctant to disclose information on their production or manufacturing process when submitting applications. This information is of a more confidential nature. In cases where a production process results in a food product's properties being significantly changed, this product would be considered as novel and would have to undergo a safety assessment before being authorised under the 2013 proposal⁴². However, there is no reference in the proposal to any requirement for the applicant to provide information on the production process in such cases.

Summary – Issues regarding confidentiality and innovation

- The five year data protection period can only realise its full potential in terms of enhancing competitiveness and generating innovations in the EU market if applicants understand the provisions relating to the confidentiality of application data.
- Whilst there is no obligation for applicants to provide information on the methods of analysis they used to produce data relating to the safety of the product, it is understandable that providing such data where appropriate will facilitate the work of EFSA when carrying out safety assessments.
- There needs to be a balance between confidentiality and consumer information. Detailed outcomes of safety assessments should be made available to consumers.

IV – Role of national agencies and authorities

This section looks at the role of Member State food safety agencies and authorities under the proposed centralised system, particularly with regard to reasoned objections, and seeks to identify the likely impact of the procedure on the internal market.

Background and rationale

Under the current authorisation system, an application for Novel Foods approval is first submitted to a Member State competent authority for an initial assessment. Once this is complete, Member States are entitled to object to an assessment carried out by another

⁴² Article 2.2.(a), COM(2013) 894 final

Member State. If one or several Member States raise an objection, the applicant has the right to respond to the objection. Member States can withdraw their objection on the basis of the applicant's response. In cases where an objection stands, the dossier is referred to EFSA for a complementary assessment. Following EFSA assessment, the matter is decided by Qualified Majority Voting amongst the Member States.

Member State authorities can have slightly different food safety concerns which often results in objections when an assessment has been carried out by another Member State. Objections to applications for authorisation of Novel Foods can be costly to address, both in terms of additional data that may be required and the additional delay that may be incurred for the applicant in reaching an authorisation decision.

1. The role of national authorities and agencies in the context of the new centralised authorisation procedure

In theory, the centralised system implies that the Member States' role would be significantly reduced, in that they would mainly be involved in votes in the Standing Committee on the authorisation or approval of specific Novel Foods. At the same time, Member State authorities will thus continue to play the critical role of authorising a Novel Food in the regulatory committee in the context of the centralised procedure. They will receive all the information related to the applications, as they will have to consider the Commission's proposal to authorise (or not) the Novel Food based on the application and on EFSA's opinion in the regulatory committee. In addition, they may evaluate/submit a reasoned safety objection to the notification of a traditional food from third country.

In relation to the safety assessment procedures, however, it is not clear at this point what Member State authorities' precise role would be. This has not been formalised in the 2013 proposal and still has to be discussed. The Member State competent authorities that were interviewed all expressed the view that they should try to provide knowledge, experience and advice to EFSA to guarantee that its safety assessments are robust and to speed up the authorisation procedure. One Member State authority, further pointed out that EFSA may need the knowledge and expertise of the national assessment bodies to deal with an increase in the number of applications resulting from the centralised procedure. In this context, EFSA may experience a period of adaptation where Member State authorities should fulfil a support role on the basis of their experience in the decentralised system. One respondent suggested that individual Member State authorities might, for instance, take the lead on a specific topic in order to provide additional capacity to that of EFSA.

Other public sector representatives pointed out that national food safety authorities could continue to advise applicants before they submit their application, particularly on the type of data they need to provide to make sure that the safety assessment can be swiftly completed. In this context, Member State authorities would be able to guide applicant companies in the authorisation process without imposing any financial or administrative burdens on them.

Interview feedback from EFSA has revealed that a considerable number of Member State authorities have been shown to have a good capacity for conducting safety assessments (in the current decentralised procedure, these can be performed either 'in-house' or outsourced to a third-party national body, depending on the Member State). Once the new centralised procedure is established, EFSA is willing to make use of the capacity of Member State authorities (and their subcontractors, where relevant) by involving them in consultations on specific Novel Food applications, or by asking them to produce data summary sheets (i.e. scientific pre-assessment of existing studies contained in the applications).

According to recent internal discussions, EFSA intends to launch a framework contract for Member State authorities to perform support activities in the context of the centralised Novel Food authorisation procedure. Other options have also been envisaged by EFSA such as creating a consultative platform involving Member State authorities, whereby information and views on applications could be exchanged more effectively.

According to interview feedback, Member State authorities still wish to play a role in the assessment procedure in the context of a centralised system. Amongst other things, they could still act as Novel Food advisers nationally and could be involved in EU-wide advisory committees and working groups. However it should be noted that one industry association pointed out that care must be taken not to duplicate efforts and potentially undermine the role of EFSA.

Regardless of the involvement of Member State authorities in the centralised system, one consumer association interviewed believes that the main challenge for EFSA will be to find the right balance between, ensuring the impartiality and independence of experts involved in its work and the need to secure the best possible expertise to deliver top-quality scientific assessments. EFSA opinions should be challenged only on their merits and on scientific grounds – and in the interest of consumers' health – thus, they should be robust from a procedural point of view.

Summary – Role of national authorities and agencies

- Member State authorities will be considerably less involved as a whole in the centralised system.
- As far as their expertise will allow them to do so, Member States will be given the opportunity to support EFSA, as it can be expected that the Authority will go through a period of adaptation after the switch to the centralised system.
- At this stage it is not possible to know how collaboration between Member State authorities and EFSA will take place, but it is important to make sure that any such collaboration does not lead to a duplication of efforts.
- From an industry perspective, Member State authorities' involvement in the centralised system should not potentially undermine the role of EFSA and result in longer authorisation procedures.

2. Member State authorities' consideration of new applications in a centralised procedure

The centralised procedure means that Member States will only have a consultative role and will no longer be directly or formally involved in performing safety assessments. On occasion, as discussed earlier, they may have the possibility of assisting EFSA in the authorisation process on the basis of their knowledge or expertise.

Whilst their workload would be drastically reduced, the way Member State authorities consider applications may not change significantly as they would be fully informed of all the steps in the centralised procedure. The change in terms of duties or responsibilities, however, means that Member State authorities may decide to re-allocate their resources to other areas than Novel Foods.

In the decentralised system, the establishment of whether a food was novel or not, or how the proof of significant use was assessed were points that were discussed amongst, and decided upon by the Member States. In the centralised system, these points will be dealt with by the Commission, which will be responsible for making decisions relating to the novel status of food products and ingredients. According to feedback from Commission services, this change in responsibility should accelerate the process for deciding on the 'novel' status of foods or ingredients. Additionally, this is expected to result in positive effects on the EU internal market.

However, according to Article 4(2) of the 2013 proposal:

"Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of [the Novel Foods] Regulation"

This provision thus confers a new advisory role on Member State authorities. One industry association pointed out that this could lead to problems in cases where a company is convinced its product is not a Novel Food, but the Member State authority insists that it is. This association indicated that, in these instances, the company should have some form of appeal process available to them before being forced to submit a Novel Food application.

All of the Member States interviewed expressed the view that, in the centralised procedure, it can be expected that Member State authorities will assist EFSA in issuing well-founded and robust opinions in relation to non-traditional Novel Foods. No such assistance from the Member States would be needed as regards traditional Novel Foods from third countries, as the assessment procedure is different (i.e. no safety assessment is required; only data showing history of safe consumption is required). On the other hand, Member State authorities cannot object to the authorisation of a non-traditional Novel Food before EFSA issues its opinion in the centralised procedure. Interview feedback suggested that if Member State authorities assist EFSA closely, it may be less likely that they would oppose an EFSA opinion on the introduction of a non-traditional Novel Food on the EU market.

Summary – Member State authorities' consideration of new applications

- While Member States would still have voting powers in the centralised system and could also provide comments whenever the Standing Committee is consulted, the responsibility for issuing opinions on Novel Foods after assessment, shifts to the European Commission and EFSA.
- If Member States assist EFSA in carrying out safety assessments, it is unlikely that they will raise reasoned objections in relation to the safety of Novel Foods.
- It is however difficult to predict at this stage how Member State authorities will consider applications relating to traditional foods from third countries since they will not undergo a safety assessment.

3. Likelihood of Member States' reasoned objections in a centralised procedure, particularly in relation to traditional foods

As mentioned above, Member States cannot object to the application or to EFSA opinion, in the context of a centralised procedure. Instead they may disagree with the Commission's proposal to authorise the Novel Food (voting in the regulatory committee). The likelihood to agree or not depends on the conditions under which the authorisation is proposed. The Commission services interviewed indicated, however, that, in this context, objections from the Member States will not be very likely if they assist EFSA in performing safety assessments.

However, a Member State authority and an industry association pointed out that it could be likely that Member States raised objections in cases where they consider a proposed Novel Food to be a drug. Recital 14 of the 2013 proposal indeed refers to the fact that:

"Where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law."

As there is no harmonisation among the Member States as to which products are considered as medicinal products, this particular scenario could cause a number of difficulties in the centralised system. It was suggested by the industry association that the proposal should guard against situations where, for example, a botanical food supplement is authorised as a Novel Food, but a Member State can still decide to classify the same product (with the same dosage level) as a medicine.

Arguing in favour of harmonisation at EU level on the status of certain types of Novel Food, a consumer association expressed the view that it is essential to maintain a clear distinction between medicines and 'novel' foods. The EMEA (European Medicines Agency) should ultimately be responsible for determining whether or not a Novel Food that may have effects comparable to a medicine should be considered a medicine. If the

EMEA decides that a particular 'Novel Food' product is in fact a medicine, then a full application to EMEA would be required.

According to the 2013 proposal, regarding notifications to the Commission of the introduction of traditional foods from third countries on the EU market, Member States may issue reasoned objections against their introduction (within four months of the notification).

There were mixed views as regards the likelihood of Member States raising objections to the authorisation of traditional foods from third countries. Feedback from interviews with the Commission DGs revealed that it is not possible to estimate the outcome of Member States views at this juncture. Two of the Member State authorities interviewed expressed the view that the likelihood of Member States having reasoned objections to applications for traditional foods from third countries to be marketed in the EU will be low, because applicants will simply have to provide data on safe consumption. On the other hand, the European umbrella organisation for consumer associations stated that clear guidance and criteria are needed for defining what constitutes safe consumption or else this could lead to a situation where products that have been consumed for many years in any third-country would be assumed to be safe.

EFSA holds the view that it may however be difficult to obtain available data on the safe consumption of a traditional third-country food, or data which meet specific EU quality standards. Similarly, as food safety standards differ between the EU and other parts of the world (with EU standards known for being higher than anywhere else in the world) there is no guarantee that assessments can be thoroughly performed by EFSA on data obtained from third countries with different food safety standards (e.g. information on allergens). In this case, the risk is that Member States will raise reasoned objections to some applications for traditional foods originating from third countries.

Furthermore, compositional data, and data that could be used to prove a history of safe consumption of a traditional food from a third country might not be easily available. Given EFSA will have a 4-month time limit to assess the application this could prove challenging. EFSA is thus not convinced that the procedure for third-country traditional foods means that their authorisation will be fast-tracked. As a result, there is a risk that many of these applications may undergo the traditional Novel Food safety assessment. If one or several Member States still object to the Commission's decision to authorise the product in question after a full safety assessment, it is likely that the whole authorisation procedure could take a considerable time.

Summary – Member States’ reasoned objections

- Whilst it remains difficult to predict how Member States will react to traditional third country foods application, it is possible to assume that the likelihood of a reasoned objection will depend on several factors, including the availability or quality of the data on history of safe consumption, but also the status of the food in question (i.e. when the Novel Food in question may be considered as a drug in some Member States).
- More generally, differences in food safety standards between the EU and third countries may also have an impact on Member States’ decision patterns.
- To avoid a situation where Member States would be likely to block marketing authorisations as regards traditional foods from third countries, it is important to establish clear guidance and high quality standards for the submission and collection of data on history of safe consumption.

V – Inter-relationship with other regulatory requirements

In this section we examine the extent to which the new Novel Foods proposals interact with other similar EU legislation, and where there are overlaps that may cause confusion, or unnecessary regulatory burden.

Background and rationale

Whilst authorisation procedures for food additives, flavourings, extraction solvents and GMOs are outside the scope of authorisation procedures for Novel Foods, a number of other authorisation procedures can apply to a Novel Food or to ingredients contained in a Novel Food. These include:

- Safety procedure of article 8 of Regulation 1925/2006;
- Claims approval procedure under Regulation 1924/2006;
- Legislation surrounding vitamins and minerals as nutritional substances/supplements (i.e. Regulation 1924/2006, Directive 2002/46/EC and Regulation 609/2013) .

It is therefore essential to examine whether these complementary authorisation procedures do not create additional burdens both from the point of view of applicant companies and EFSA.

1. Relationship between the Novel Foods procedure and the safety procedure defined under Article 8 of Regulation 1925/2006⁴³

According to the Commission services consulted, the procedure under Article 8 of Regulation (EC) No 1925/2006 may apply to substances other than vitamins and minerals that are already added to foods that are marketed in one or more EU Member States and for which potentially harmful effects on health have been identified because of their intake. As such, this procedure could not, in theory, be applied 'retrospectively' to an approved Novel Food, given that for a Novel Food to be approved, its safety has to be assessed.

Thus, Commission officials we spoke to hold the view that there would not be any overlaps between these two pieces of legislation. The aim of the Novel Foods Regulation is to assess the safety of those substances/products that have never been consumed as food in European Union, while Article 8 of Regulation 1925/2006 is applied where a substance other than a vitamin or mineral, or an ingredient containing a substance other than a vitamin or mineral, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

Finally, for Novel Foods that are or have an ingredient which constitutes a new source of nutrients under Regulation 1925/2006, this would not create any particular duplication of efforts as far as EFSA is concerned. The Commission, usually already informs EFSA if a Novel Food application that has to undergo assessment contains an aspect which would require a risk additional assessment under Regulation 1925/2006. In such cases, EFSA ensures that its safety assessment covers both the Novel Food aspect and the 'new source of nutrient' aspect of the application. Technically, this would make no difference to EFSA.

Summary – Relationship with Regulation 1925/2006

- It is difficult to see how an approved Novel Food could become subject to an Article 8 procedure given that for it to be approved as a Novel Food its safety will already have been assessed.
- There is however a potential risk that certain Member States with historic concerns on specific substances will initiate an Article 8 procedure.

⁴³ Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

2. Relationship between the Novel Foods procedure and the nutrition and health claim approval under Regulation 1924/2006⁴⁴

Here, the aim here was to look at whether the procedure for authorising a Novel Food and the procedure for validating the nutrition and health claim of that same food could run in parallel or would have to be applied consecutively, leading to a longer decision-making time and non-alignment of the protection of proprietary data periods.

Whilst the Novel Food procedure looks into the safety of the product and requires an application to be submitted to the Commission, the procedure under the Claims Regulation 1924/2006 assesses the efficacy of a food in relation to the claimed effect. Health claim applications are submitted directly to the European Food Safety Authority, via a Member State. In practice, a Novel Food safety assessment and a health claim assessment may run in parallel or consecutively. This all depends on the moment when the respective Novel Food and health claim applications are submitted.

As far as EFSA is concerned, whilst a Novel Food can be authorised irrespective of whether the health claim has been validated, Novel Food applications that contain a health claim aspect can cause a number of problems. The assessment of a health claim is based on a different set of data than the safety assessment of a Novel Food. A Novel Food safety assessment and a health claim assessment can run either in parallel or consecutively, depending on whether the two separate sets of data are submitted together or not – for instance, whether or not the applicant has done the efficacy study as well as the safety study before submitting the application.

According to EFSA, for assessments running in parallel, if the health claim is validated after assessment, but the Novel Food is not authorised on the market following a safety assessment, this would be a waste of resources and efforts for EFSA. Indeed, EFSA is quite reluctant to take the risk of carrying out these assessments in parallel if the Novel Food is not finally authorised.

For assessments running consecutively, as the data protection period for both health claims and novel foods is five years, if a Novel Food authorisation and a health claim authorisation are not issued on the same date, this would imply that the respective data protection periods will end on different dates. It would be necessary to ensure that either these separate authorisations are issued on the same date, or that one authorisation date takes precedence over the other (i.e. in relation to the start of the five-year data protection period). As regards the latter option, EFSA considers that the Novel Food authorisation date should take precedence over the health claim validation date for determining the start of the five-year data protection period.

Most Member State authorities hold the view that the safety of the Novel Food should remain the priority. A health claim for a Novel Food should not be validated unless the safety of that substance has been proved, because otherwise this could potentially create confusion as to the overall safety of the Novel Food.

⁴⁴ Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

However, interview feedback reveals that Member State authorities have different views as to whether Novel Food and health claims applications should run in parallel or consecutively. Some Member State authorities would advise companies to submit their Novel Food application and the attached health claim application at the same time so that the assessments will run in parallel. In such cases, the health claim could not be validated if the safety assessment of the Novel Food yields a negative result. Other Member State authorities, taking into account the differences in the nature of the data sets in Novel Food applications and health claim applications, admitted that the two respective assessments would have to be performed consecutively. In this respect, the Novel Food safety assessment would have to be performed before the health claim assessment. Companies should be advised to submit their Novel Food application data before their health claim application data. The logic would be to avoid any waste of resources on the part of EFSA in cases where a health claim was to be validated but a Novel Food was not finally authorised.

One industry association raised the point that there may be a practical problem with applications for foods that are novel and that present a nutrition or health claim. Whilst the Novel Foods Regulation requires authorisation to be secured before the food can be marketed for human consumption, the Nutrition and Health Claims Regulation implies that the application submitted by a company shall contain data obtained from clinical studies on humans. In practice, the health claims application would have to follow the Novel Food approval. However, given the length of time required to carry out a clinical trial before submitting a health claim application, the five-year data protection period following a Novel Food authorisation would lose much of its value from an applicant company's perspective. This industry association expressed the view that extending the data protection period for those Novel Foods that present a nutrition or health claim may be a solution to take into account the practical reality of health claims applications.

Summary – Relationship with Regulation 1924/2006

- There are a number of technical difficulties faced by applicants looking to market a Novel Food with health or nutrition claims linked to the synchronised submission of the relevant data. This determines the extent to which the safety assessment and health and nutrition claims assessments of a Novel Food can be carried out simultaneously.
- Ideally, Novel Foods safety assessments and nutrition and health claim should be carried out so that that the respective data protection periods start and end on the same dates.
- If these assessments run consecutively, appropriate measures should be taken to make sure that the respective data protection periods are synchronised.
- Finally, there is a risk that health and nutrition claims assessments could be carried out to no avail, in cases where the Novel Food in question does not receive a marketing authorisation.

3. Procedures for new sources of vitamins and minerals first needing an assessment as Novel Foods and then needing an additional assessment as nutritional substances.

This issue mainly concerns concentrated novel sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet (i.e. food supplements and food for specific medical purposes). These products fall within the scope of Regulation 1924/2006, Directive 2002/46/EC⁴⁵ and Regulation 609/2013⁴⁶. They also fall within the scope of the 2013 proposal under Article 2.a (iii).

Interview feedback suggests that there is a risk of duplication as regards novel nutritional/dietary substances which would mainly be in terms of timing and uncertainty. The industry associations that were interviewed view data requirements for the nutritional substance assessment as very similar to those for the Novel Food assessment, i.e. information mainly relating to nutritional needs. However, according to one industry association, the average time needed to get such a substance on the list after a positive EFSA opinion is about 18 months, which is seen as a major inefficiency.

The industry associations that were interviewed believe that there is a strong argument for combining both procedures into one, or at least ensuring the both procedures run in parallel to avoid unnecessary duplication. They also pointed out that there are currently two different Commission guidance documents in place for new sources of vitamins and minerals as (a) Novel Foods and (b) nutritional substances, which can potentially give rise to a duplication of efforts. Feedback reveals that, according to the industry, a common authorisation procedure in this respect should be put in place that is consistent with the procedures created by the Food Improvement Agents Package (FIAP).

Summary – Coherence with assessment procedures for nutritional substances

- Combining the Novel Food safety assessment and the nutritional substance safety assessment appears to be the most sensible measure.
- This however requires comprehensive and updated EFSA guidance for applicants looking to market Novel Foods which are entirely made of, or contain, nutritional substances.
- Further streamlining in this respect will be beneficial as much from a business perspective as from the perspective of EFSA.

⁴⁵ Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements

⁴⁶ Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

4. Relationship between the new Novel Foods authorisation procedures and a possible future regulation of botanicals

The EU legal system does not currently set out any kind of centralised EU authorisation procedure for the use of botanicals and derived preparations in food. Nonetheless, the use of botanicals and derived preparations in food has to comply with the general requirements set out in Regulation (EC) No 178/2002 laying down general principles and requirements of food law and creating the European Food Safety Authority. This *inter alia* assigns primary legal responsibility for the safety of the products placed on the market to business operators.

According to interview feedback from industry associations, it is difficult to foresee at this point what would happen exactly in relation to the interplay between the Novel Foods regulation and a possible regulation on health claim procedures for botanicals, as the latter has been put on hold by the Commission. At this point there is a lack of clarity and a number of uncertainties arising from EU legislation covering botanicals. There is currently no EU harmonisation principle in relation to the use of botanicals in food. In other words, it is possible for the same botanical product to be classified as a foodstuff in one Member State and as a medicinal product in another. A representative of a third country stated that the fact that botanicals are regulated at a Member State level means that, if these products are assessed under the novel food regulation, it creates an additional layer of complexity for exporters, who have to spend considerable time working out under what legislation their product should be authorised.

Botanical food supplements in many EU Member States require only notifying a Member State's food authority before entering the market, whereas herbal medicinal products must often be premarket-authorised first. Furthermore, a large proportion of herbal product health claims in the EU are based on the historic and traditional use of a botanical.

In order to assess how botanical health claim assessments should be handled, the Commission issued a discussion paper in December 2012. As the Commission states in its discussion paper, regulators could either allow data on traditional-use to serve as substantiation for health claims of botanicals, or, alternatively, regulators could handle botanical health claims with the same requirements they have applied to other health claim submissions—that is, EFSA has required clinical trial data to demonstrate health benefits. If EFSA does not permit the use of traditional-use data in botanical assessments, it would mean that most health claims would be disallowed because they are not substantiated by human intervention study data (i.e. clinical trial data).

Whilst data proving a traditional-use (or history of safe use) would be preferred by the industry as a way to assess botanicals, there is a risk that the approach to the assessment will differ on the basis of the availability of data to prove a history of safe use, and thus ultimately on the basis of the origin of the botanical product or ingredient. In practice, botanicals originating from within the EU could undergo an assessment based on a

history of safe use, given the ready availability of the data, whereas assessments of botanicals originating from outside the EU would have to be carried out much more thoroughly due to a lack of safe-use data. This could give rise to unequal treatment in assessments between EU and non-EU botanicals. It could also potentially contradict the procedure set out in the 2013 proposal as regards traditional foods from third countries in cases where these involve a botanical or a botanical ingredient.

Summary – Relationship with a possible regulation on botanicals

- In cases where a Novel Food is, or contains a botanical substance which is considered as medicinal in certain Member States but not in others, the effectiveness of the centralised system may be challenged.
- A regulation harmonising the status of botanical substances across the EU would be welcome by the industry, but it is clear that further discussions are needed in order to establish effective procedures for the assessment of such substances.
- Whilst consumer safety remains of primary importance, a regulation on botanical substances should not lead to substantial increases in administrative burdens for applicants and should not have any adverse effects on the effectiveness of the centralised system for Novel Food assessments.

Chapter 4: Conclusions and recommendations

This section presents a summary of the overall findings and conclusions from the interviews conducted with the key stakeholders and Commission services, and from relevant secondary sources. These main findings are formulated as conclusions and structured around the five key issues investigated in this impact assessment.

I – Scope and definition

Overall, evidence gathered from telephone interviews, and wider literature collated for this assessment indicate that there are diverging views between public and private stakeholders on the impact of changing the definition of ‘Novel Food’ under the 2013 proposal.

On the one hand, Member States and Commission services interviewed believed that the new definition, with a removal of categories and retention of the date of 15 May 1997, would not widen the scope of foods covered under the Regulation, and allow it to keep pace with new types of product seeking market authorisation.

On the other hand, organisations representing industry believe that removing the categories, whilst retaining the date of 15 May 1997, would potentially widen the scope of the definition to cover thousands more products. These stakeholders believed the new definition would create legal uncertainty for food business operators, be detrimental for innovation and competitiveness in the EU food industry, and put unnecessary administrative burden on the European Commission and Member States.

These diverging views on the impacts of the new scope and definition of the 2013 proposal, between public and industry sectors, has the potential to be damaging if the legislation enters into force as proposed. Even if, in reality, the new scope and definition does not widen the scope of products that may require authorisation, the administrative burden for industry of dealing with challenges and queries by the European Commission and Member States could be vast. In addition, if the new scope and definition are enough to discourage food business operators from seeking approval for new products, and subsequently delay authorisations, this has the potential to cause huge ramifications for innovation and competition in the food sector in the EU. From a consumer perspective, it is seen as important that the broadening of the definition should not impact on its clarity and thus create legislative loopholes that the industry could exploit by, by-passing safety assessments. Clearly, more dialogue is needed between public and private stakeholders to resolve issues with the definition and scope of the 2013 proposal and to inform the political debate.

The use of a ‘cut-off’ date is the simplest and clearest way to define Novel Foods from those that are not novel, i.e. have been used in the diet before. Whilst the date of 15 May 1997 was based on the date of entry into force of Regulation 258/97, rather than any scientific rationale, choosing another date based on the entry into force of the new

regulation would also be just as arbitrary. In light of these considerations, there would appear to be little value in changing the date of 15 May 1997 under the 2013 proposal.

As regards the definition of Novel Food itself, the aim of the proposal is to clarify and update it. However the removal of the categories in the new definition may result in a situation whereby products already on the market that were not previously considered to be 'novel' may be legally challenged, and whereby a greater number of products would require authorisation as 'novel' foods, where this was not required before. As a result, this could have negative impacts on innovation and competition in the EU food sector and could also increase the administrative burden placed on EU bodies and Member States. Food products are not positively labelled to indicate that they 'contain a novel food ingredient', and as such it is unlikely that a change in definition, and thus the amount of products to be authorised, would have an impact in terms of confusion to consumers. However, if the new definition meant that products previously regarded as safe were withdrawn from the market to undergo a pre-market authorisation procedure, it may impact on the confidence of consumers that food is safe.

Recommendations

Recommendation 1: The definition of Novel Foods given in the 2013 proposal should be amended to clarify the scope of what is intended to be included.

Recommendation 2: Further dialogue is needed between European institutions and stakeholders to understand more fully the concerns that the new definition of Novel Foods introduces legal uncertainties for operators and potential legislative loopholes.

II – Impact of the centralised procedures for authorisation

Introducing a centralised procedure for risk assessment of Novel Foods was seen as positive by the majority of stakeholders interviewed. This procedure is likely to reduce the time scientists need to review an application, as the initial assessment by the Member State competent authority is bypassed. Industry representatives nevertheless remained sceptical as to whether the centralised procedure will be much quicker than the current system in Regulation 258/97, given that the comitology procedure, and the Standing Committee are still in place. Indeed, these steps in the authorisation process have no deadline, and can often be the stage where many applications are held up in the regulatory system.

Whilst it is expected that the new data requirements to be met by applicants will not be vastly different to those required under Regulation 258/97 for Novel Foods, an EU-level consumer organisation has asked for dietary exposure to be thoroughly considered in the assessment process, especially in terms of recommendations on daily intake. This

association is also in favour of Post Market Monitoring (PMM) for all Novel Foods to observe the long term impacts of a Novel Food on consumer health, animal health and the environment. However, if requirements for PMM were in place for all Novel Foods, regardless of risk profile, this would clearly mean that the data requirements on applicants would be greatly increased, with a consequent increase in administrative burden.

For traditional foods, the extent to which the measures in place can provide a quicker authorisation process will be completely dependent on the level of reasoned safety objections presented by Member States and EFSA. If the criteria for proving a 'history of safe use' are more descriptive, and difficult to substantiate with rigorous scientific data, then it may be more likely that reasoned safety objections will be made, and that applications will still be required for traditional foods, which must then be reviewed by EFSA, and submitted through the comitology procedure. The data required by EFSA, from applicants, to compile an application will be completely dependent on the guidance for applicants, which will probably be produced after the revised Regulation comes into force. Hence, it is currently uncertain what the data requirements for a traditional foods application will be.

Consumer organisations are, however, calling for guidelines to be set out by EFSA addressing operators intending to market traditional third country foods in the EU. These guidelines should aim to ensure that the data provided by operators enable EFSA to establish clear relationships between consumption and health when performing assessments.

It is also uncertain whether generic authorisations and the provision for data protection will have an impact on innovation in the EU food sector. Whilst generic approvals may discourage companies from channelling resources into authorising Novel Foods, measures under Article 24 (data protection) are intended to alleviate this. As such, the effectiveness of data protection measures will be fundamental to ensure no detrimental impacts on innovation in the EU food sector.

In summary, the centralised procedures will certainly accelerate the reaching of an initial opinion, given that only EFSA will have full responsibility for assessing applications. Furthermore, for Novel Food applications (other than traditional foods from third countries), Member States will no longer be empowered to raise reasoned objections to safety, which under the current decentralised system can mean multiple clarifications being asked of the applicant.

The effectiveness of the centralised system may however be challenged as regards the approval of traditional foods from third countries. As the notion of 'history of safe consumption' still remains relatively loosely defined in the proposal, there is a risk that reasoned safety objections will be made by the Member States. As such, the quality of data to prove a 'history of safe consumption' may differ from application to application, depending on what information is available. In this context, it is likely that safety

objections can be raised based on a lack of (satisfactory) evidence of safe use of the product. Proving a 'history of safe consumption' may also be problematic if the food in question has been prepared in a specific way by the population that has consumed it, or more generally when considering the fact that food safety standards in certain parts of the world may not offer the same level of protection to consumers' health as in the European Union.

Recommendations

Recommendation 3: Whilst the move to a centralised authorisation procedure is seen as positive, with deadlines imposed on certain stages, (such as production of an opinion by EFSA) there are still many stages with no deadlines in which there is potential for an authorisation decision to be delayed. Consideration should be given as to whether deadlines should be introduced at more stages in the Novel Foods authorisation procedure, if the desire is to speed up the application process.

Recommendation 4: The efficiency of the simplified procedure for traditional foods is completely dependent upon whether reasoned safety objections are raised by Member States or EFSA. More consideration should be given to the exact requirements for a 'notification' of a traditional food, particularly given the discourse surrounding the concept of 'history of safe use', to ensure that reasoned safety objections by Member States and EFSA are minimised and that consumer safety is not compromised.

III – Effectiveness of the centralised system and its tools

Research found that the length of EU authorisation procedures under the current system equally penalises all applicant companies looking to market their Novel Food products in Europe. This is more problematic for those companies whose main market is Europe. The length of the procedures, when compared to the quicker process for other third countries (e.g. US, Canada) can only be seen as a barrier to market products in the EU.

The new centralised system is expected to improve the situation. However, the costs and resources to submit a Novel Foods application will depend on the clarity of EFSA's initial guidance on data requirements, and by extension on the complexity of the application, whilst the centralised procedure will imply harmonised fees across the EU for the submission of applications. Experience in submitting Novel Food applications has also been identified as a factor impacting on the level of costs and resources required. As a general rule, the faster or the more predictable the process is, the lower the cost an application will be for a company.

The introduction of a data protection period was identified as a way of incentivising innovation in the food industry and of curbing unfair competition. The Commission and

Member State authorities see the introduction of the five-year protection period as a measure which effectively counterbalances the introduction of generic authorisations. An important point that was raised, is that this provision would prevent competitors from referring to data from another company (i.e. a Novel Food authorisation holder) to market products equivalent to the original authorised Novel Food.

Although those we consulted welcome the provision on the protection of proprietary data, the industry expressed concerns in relation to the length of the protection period, in particular as regards the fact that it is aligned with the data protection period for nutrition and health claims. The industry's main concern is that the five-year period for data protection, as regards Novel Foods, is not sufficiently long in cases where further separate applications are required for nutritional substances and for health claims. More generally, for the industry, the longer the data protection period is, the higher the return on investment will be.

The industry has raised a number of issues around the confidentiality of proprietary data which potentially can exclude an applicant from gaining a data protection licence. This issue, which relates to the notion of 'right of reference', could be a large barrier to companies requesting Novel Food approval, if they have no ability to get exclusivity on the resulting products. Concerns were also raised by some industry representatives as regards the extent to which proprietary data can actually be kept confidential when shared with third parties. A potentially negative impact would be that companies investing in research to develop Novel Foods would avoid undertaking research with other institutions such as universities. On the other hand, from a consumer association's perspective it is important to ensure a balance between confidentiality and consumer information.

As regards the economic impact of provisions on confidentiality, the main point that was raised related to the inclusion of analysis methods in Novel Food applications. If such information is to be provided by the applicant, it would not be treated as confidential according to Article 22.4(e). Feedback revealed that applicant companies are often advised by Member State authorities and EFSA to provide this information to explain how the data on a product's properties was obtained. This is seen as facilitating the work of national assessment bodies and EFSA in the current system.

In summary, the data protection regime is expected to stimulate innovation within the food industry despite the fact that it remains difficult to ascertain whether the five year protection period will generate the expected returns on investment from the perspective of applicants. This regime should however effectively prevent competitors from marketing equivalents using data from the authorisation holder; hence competition will be further driven by innovation within the sector. There are however outstanding issues around the 'right of reference' and its implications on data protection and confidentiality, which may act as a disincentive to innovate.

Recommendations

Recommendation 5: EFSA should issue updated guidance for applicants in light of the changes to the 'Novel Food' definition and the changes which would be brought about by the centralised system.

Recommendation 6: Whilst the five year data protection period is a positive development, the notion of 'right of reference' should be further examined as it may discourage innovation within the EU food industry.

IV – Role of national agencies and authorities in the centralised system

It was acknowledged by the interviewees that Member States' role would be significantly reduced in the centralised authorisation procedure, as they would mainly be involved in votes in the Standing Committee to authorise or reject authorisations. However, it has emerged that many Member State authorities still wish to retain a role in the assessment procedure. What such a role would involve and how it would work in practice still needs to be clarified.

Suggestions made by the Member State authorities interviewed were that they could assist EFSA in dealing with applications by providing their own knowledge and expertise, at least so as to ensure a smooth transition to a fully centralised system. Some of the Member State authorities interviewed also mentioned that they could hold discussions with companies, giving them advice as to the type of data they would need to include before they submit an application to EFSA. Feedback has revealed that this is already common practice in the decentralised system. Last but not least, EFSA mentioned that it has already held internal discussions about different possibilities to make use of Member State authorities' expertise for conducting safety assessments in the centralised system.

From a consumer perspective, it will be important that EFSA can find the right balance between ensuring the impartiality and independence of experts involved in its work, and the need to secure the best possible expertise to deliver top-quality scientific assessments.

The centralised system is seen by the Commission as an effective and speedier way of determining which products or ingredients need to undergo a Novel Food safety assessment procedure. In the decentralised system, such matters are discussed among and decided upon by the Member States. The Commission has pointed out that this particular aspect of the decentralised system causes long delays before decisions can be taken. However, the industry pointed out that the fact that applicants may still consult with Member State authorities to determine whether the product or ingredient they want to market should have a 'novel' status (in accordance with Article 4(2) of the 2013

proposal) could potentially lead to contradicting views and opinions between the Member State authority and an applicant as to whether the latter needs to submit a Novel Food application.

The Commission expects that Member States will be less inclined to issue reasoned objections to its decisions to authorise Novel Foods on the market in the context of a centralised system. This is because decisions will now be made on the basis of EFSA's safety assessment opinions. Member States will be less inclined to raise reasoned objections if they assist EFSA in the safety assessment procedure by providing advice, knowledge and expertise. However, research found that the most likely reasoned objection would be if one or several Member States consider a proposed Novel Food to be a drug. Recital 14 of the 2013 proposal indeed refers to this scenario, which could prove to be problematic. In this respect, consumer associations are calling for the harmonisation at EU level of the status of certain products or ingredients as food or medicine.

As regards traditional foods from third countries, the Commission expressed the view that it is not possible to predict the extent to which Member States will raise reasoned objections. Whilst some of the Member State authorities interviewed said that the likelihood of Member States raising objections to the introduction of traditional third country foods on the EU market would be low, the views of EFSA were rather more pessimistic. EFSA holds the view that given differences in food safety standards in other parts of the world – with Europe's standards being the highest – there could be many reasoned objections to the introduction of various traditional third country foods on the EU market. Conversely, one Member State authority and one third country stakeholder noted that the effectiveness of the simplified procedures for traditional foods would be negligible as they only apply to primary products which have not undergone any processing.

Another difficulty identified is that if a reasoned objection is raised, EFSA would have four months to examine data on history of safe consumption. EFSA anticipates that there may be problems in obtaining satisfactory data in this regard, i.e. data meeting its quality standards. As a result, it could be that without a thorough assessment of data on safe consumption, these traditional foods would possibly have to undergo a full 'Novel Food' safety assessment procedure. In such cases, this means that it could, in practice, take considerably longer to authorise traditional foods from third countries, than (non-traditional) Novel Foods and food ingredients (e.g. chemicals).

In summary, the centralised system should indeed be more effective in terms of issuing decisions on Novel Food applications. Member State authorities will use their decision making powers differently in the centralised system. If they assist EFSA in the safety assessment procedures, this is likely to result in consensual views amongst the parties concerned on the authorisation of Novel Foods. On traditional foods from third countries, however, it is difficult to predict how Member State authorities will consider applications. If reasoned objections are often raised, this would seriously call into question the efficiency of the special procedure for traditional foods from third countries.

Recommendations

Recommendation 7: Member States should be involved in the safety assessment procedures as far as their expertise allows them to do so. Member States' assistance to EFSA in this respect should further improve the effectiveness and efficiency of the centralised system, and the scientific robustness of the Agency's safety assessments.

Recommendation 8: It can be expected that EFSA will go through a period of adjustment or adaptation after the switch from the decentralised to the centralised system. Member State authorities' support will be critical in this respect and should be provided.

Recommendation 9: The risk of Member States raising reasoned objections to applications for traditional foods from third countries on a frequent basis needs to be mitigated by putting in place precise and rigorous quality standards for the collection of data on history of safe consumption.

V – Inter-relationship with other EU regulatory requirements

The Commission does not consider that there would be any overlap between the new Novel Foods Regulation and Regulation 1925/2006 on the addition of vitamins, minerals and other substances to food. This is because the Novel Foods Regulation requires the performance of comprehensive safety assessments. Any potentially harmful substance would thus be identified, tested for and flagged up by EFSA. EFSA has further pointed out that the Commission would usually inform the Agency when an additional safety assessment on a particular aspect of the product is needed.

A number of problems were however identified as regards the relationship between the Novel Foods Regulation and Regulation 1924/2006 on nutrition and health claims. EFSA pointed out that if the two respective assessment procedures run in parallel, but that the Novel Food fails to obtain a marketing authorisation, whilst its health claim is validated, this would be a waste of resources. If the two procedures run consecutively, problems would arise if a Novel Food authorisation and a health claim authorisation are not issued on the same date, as this would imply that the respective data protection periods (both lasting five years) will end on different dates.

Industry is concerned that there may be a practical problem with applications for foods that are novel, and that present nutrition or health claims, particularly if the respective assessment procedures run consecutively. This is due to the length of time required to carry out a clinical trial before submitting a health claim application. In such cases, the five-year data protection period following a Novel Food authorisation would lose much of its value from an applicant company's perspective. One industry association expressed the view that extending the data protection period for those Novel Foods that present a nutrition or health claim may be a solution to take into account the practical reality of health claims applications.

Research found that there is a risk of duplication of efforts as regards the assessment of Novel Foods containing nutritional or dietary substances, namely food supplements and food for specific medical purposes. The risk is that two separate but similar safety assessments would have to be conducted (by virtue of Regulations 609/2013 and 1924/2006). The industry associations that were interviewed pointed out that there are currently two different Commission guidance documents in place for assessing new sources of vitamins and minerals as, (a) Novel Foods and (b) nutritional substances. They hold the view that there is a strong argument for combining both procedures into one, or at least ensuring the both procedures run in parallel, to avoid unnecessary duplication.

Finally, as regards the possibility of a regulation on the use of botanicals in food products, whilst discussions have been put on hold by the Commission, the industry favours assessments of botanicals being based on, data on, history of safe use as opposed to clinical trials. At this point there is a lack of clarity and a number of uncertainties arising from EU legislation covering botanicals. There is currently no EU harmonisation principle in relation to the use of botanicals in food. In other words, it is possible for the same botanical product to be classified as a foodstuff in one Member State and as a medicinal product in another. This again could cause problems in a centralised system as to whether all Member States would all agree for certain botanical ingredients to be authorised in food.

Recommendations

Recommendation 10: The safety assessment and health and nutrition claims assessments of a Novel Food, where relevant or appropriate, should be carried out simultaneously if possible so that the respective data protection periods start and end on the same dates. If these assessments run consecutively, special arrangements need to be considered to achieve coherence between the respective data protection periods.

Recommendation 11: More comprehensive and updated EFSA guidance is needed so that Novel Foods which contain nutritional or dietary substances do not undergo two separate but similar safety assessments. Special arrangements need to be put in place for those Novel Foods containing nutritional or dietary substances as per Regulations 609/2013 and 1924/2006.

Recommendation 12: The lack of harmonisation in terms of the status of certain botanical substances and ingredients may be an obstacle to the effectiveness of the centralised system: e.g. problems may emerge in cases where a Novel Food is or contains a botanical substance which is considered as medicinal in certain Member States but not in others. This particular issue needs to be carefully considered to ensure that this will not impact on the effectiveness of the new centralised authorisation procedures.

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Appendix A: Organisations consulted

European regulatory bodies and agencies:

- DG SANCO, European Commission
- DG AGRI, European Commission
- European Food Safety Authority (EFSA)

Member State competent authorities:

- Austria: Bundesministerium für Gesundheit – Besondere Waren, neue Technologien und internationale Lebensmittelangelegenheiten
- Finland: Maa- ja metsätalousministeriö (Agriculture and Forestry)
- Italy: Ministero della Salute – Dipartimento Sanità pubblica veterinaria, Sicurezza alimentare
- Netherlands: Ministerie van Volksgezondheid, Welzijn en Sport
- Spain: Agencia Española de Consumo, Seguridad Alimentaria y Nutrición
- UK: Food Standards Agency

Third country representatives:

- The United States Department of Agriculture (USDA)

Consumer organisations:

- BEUC – Bureau Européen des Unions de Consommateurs
- Forbrugerrådet (BEUC Danish member association)

Industry associations:

- European Federation of Associations of Health Product Manufacturers (EHPM)
- Food Additive and Ingredients Association (FAIA)
- Food Supplements Europe

Appendix B: Interview checklist

The interview checklist below covers the key evaluation issues we have been asked to examine for this assignment.

Section 1: Scope and definition

1. To what extent is it still appropriate and relevant to retain the date of 15 May 1997 as part of the Novel Food definition? If this date is no longer relevant, please explain why.
2. Under the definition of Novel Food in the new proposal, would this change the types of product that would require authorisation?
3. What would be the consequences of removing the Novel Food categories⁴⁷ and the necessity/proportionality of applying a pre-market authorisation for all new foods and food ingredients, irrespective of their risk profile (for companies, consumers, and authorities)?

Section 2: New procedures for approval

4. Will the new centralised authorisation procedures really be quicker? Please explain why
5. What will be the data requirements for the submission of applications if many different categories of food fall under the new extended definition and there are no specific data requirements depending on the category?
6. What will the impact be on competition of the introduction of generic authorisations⁴⁸?
7. What is the impact of having a different procedure for traditional foods?

Section 3: Efficiency of the new tools

8. What will be the level of costs and resources needed to compile and submit an application? Would there be any differences for small and large companies?
9. Is the length of the current pre-market authorisation process a barrier to competition on a global level for applicants?
10. What would be the impact of the new data protection regime on innovation for companies?
11. If Novel Food applications have to include methods of analysis as per Article 22 paragraph 4.e of the proposal, what impacts would this have for the applicants?

⁴⁷ Defined in Reg. 258/97 as foods and ingredients which: present a new or modified primary molecular structure; consist of micro-organisms, fungi or algae; consist of or are isolated from plants and ingredients isolated from animals; whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.

⁴⁸ Generic authorisation will avoid the resubmission of new applications by other companies for the same Novel Food

Section 4: National food safety authorities and agencies

12. What would their new role be in the context of the new centralised authorisation process?
13. Will this new role have any impacts on the way national authorities consider new applications?
14. What is the likelihood of Member States having a reasoned objection to an application in a centralised procedure, particularly in relation to traditional foods?

Section 5: Relationship with other food regulatory requirements

15. Will there be any overlaps between the Novel Foods procedure, applying retrospectively to all foods marketed since 1997, and the safety procedure of article 8 of Regulation 1925/2006, which is intended to cover safety issues with products that are already on the market?
16. Can both the Novel Foods procedure and the claims approval procedure under Regulation 1924/2006 for the same food run in parallel or will they be applied consecutively, leading to a longer decision-making time and non-alignment of the protection of proprietary data periods?
17. What would be the impact on businesses of the risk of duplication arising from procedures for new sources of vitamins and minerals that will first need an assessment as Novel Foods and, after Novel Food approval, would then need an additional assessment as nutritional substances?
18. What would be the relationship between the new Novel Foods authorisation procedures and the general pre-market authorisation imposed on all foods and policy areas under consideration (e.g. possible future regulation of botanicals)?

This study was undertaken at the request of the European Parliament's Committee on Environment, Public Health and Food Safety. It provides a complementary impact assessment, reviewing and updating the 2008 European Commission Impact Assessment of a proposal for a Regulation replacing Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients. In particular, it assesses the impacts of the Commission's 2013 proposal on the various parties concerned: EU and Member State decision-makers, European consumers and the food industry.

This complementary impact assessment focuses on key aspects of the 2013 proposal, namely: the scope of its 'Novel Foods' definition; the efficiency and the impact of the centralised authorisation procedures on the various parties concerned; the role of national authorities and agencies in the centralised system, and the proposed Regulation's coherence with other EU regulatory requirements

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