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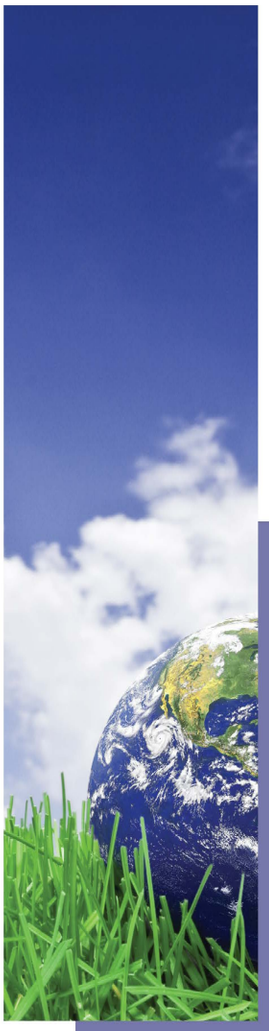

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Novel Foods

Study for the ENVI Committee

EN

2015

Novel Foods

EUROPEAN PARLIAMENT

DIRECTORATE GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

Proceedings of the Workshop on Novel Foods

Brussels, 7 October 2014

STUDY

Abstract

This report summarises the presentations and discussions during the Workshop on Novel Foods, held on 7 October 2014. The aim of the workshop was to allow an exchange of views between MEPs, the European Commission, stakeholders of the novel foods industry, NGOs, public administration and academia.

There is general agreement that amendment to the Novel Foods Regulation is required to reflect scientific and technological advances. Following an outline of the current state of play, presentations focussed on certain aspects of the Novel Foods Regulation and in particular innovation, the importance of novel foods from the industry and consumer perspectives and whether the draft Regulation solves existing problems. The requirement for further amendments was also considered. The Workshop was chaired by MEP James Nicholson, ENVI Rapporteur for the Commission proposal for Novel Foods Regulation.

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AUTHORS

Mrs Sue Keenan, Campden BRI
Dr Alan Alldrick, Campden BRI
Mr Steven Tompkins, ADAS

RESPONSIBLE ADMINISTRATOR

Ms Dagmara Steorring
Policy Department Economic and Scientific Policy
European Parliament
B-1047 Brussels
E-mail: Poldep-Economy-Science@ep.europa.eu

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To contact Policy Department A or to subscribe to its newsletter please write to:
Poldep-Economy-Science@ep.europa.eu

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LIST OF ABBREVIATIONS

ACSNP	Advisory Committee on the Safety of Novel Foods and Processes
CA	Competent authority
CUDN	Commissione Unica Dietetica e Nutrizione (CUDN)
EFSA	European Food Safety Authority
EC	European Commission
EP	European Parliament
EU	European Union
FBOs	Food Business Operators
FSAI	Food Safety Authority of Ireland
FSG	Food for Specific Groups
MS	Member State
MEPs	Members of the European Parliament
NGO	Non-governmental organisation
PARNUTS	Foods for particular nutritional uses
SMEs	Small and medium enterprises
TTIP	Transatlantic Trade and Investment Partnership

EXECUTIVE SUMMARY

The workshop was held on 7 October 2014 at the European Parliament in Brussels to discuss European Commission proposal for a Regulation on novel foods (COM (2013) 894 final of 18.12.2013) to amend Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients in the European Union.

Currently (October 2014) the ENVI Committee is preparing its mandate for negotiations with the Council (Rapporteur: MEP James Nicholson, Shadow Rapporteurs: MEP Pilar Ayuso, MEP Pavel Poc, MEP Marit Paulsen, MEP Lynn Boylan, MEP Bart Staes, MEP Eleonora EVI).

The workshop was organised to provide Members of Parliament (MEPs) and their political collaborators with expertise in the area of novel foods through receiving presentations from representatives of the member states, EFSA, industry and consumers in relation to the issues related to novel foods and Commission's proposal, and allowing an exchange of views between MEPs and invited speakers.

The workshop began with a welcome and background introduction by the Chair (Mr James Nicholson, ENVI Rapporteur). This was followed by presentations providing a general introduction to the current status of novel foods within the EU, the status of proposed new regulations as proposed by the Commission, and the experiences of Member States and EFSA concerning implementation of current EU novel foods legislation. Following discussion further presentations were received from various stakeholders, including industry and consumers on current issues in the area of novel foods, their opinion of the Commission's proposal and what improvements might be made to them. This was followed by another round of discussion.

There was general agreement that the current regulation needs to be amended; both to reflect scientific and technological advances since the original regulation came into force as well as to address the failure to meet an agreement to update the regulation proposed by the Commission in 2008. Agreement could not be reached at that time due to the inclusion of cloned animals and food from cloned animals. These issues are now the subject of a separate proposal. A revised proposal on Novel Foods was issued by the Commission in December 2013.

During the Workshop the invited speakers raised concerns about a number of issues.

The need for clarification about the definition of novel food was highlighted. The categories of novel foods have been removed in the proposal. The intention of the Commission proposal was reported to be to clarify the novel food definition not to broaden it. Generally however the categorisation of novel foods is considered unclear and the need for the reintroduction of the previous product categories and the removal of a reference to food already covered by other legislation was expressed. Clarification concerning the implication of the date of 15 May 1997 is also required. The need for clear guidance documents on the definition of novel foods and the data required for scientific evaluation was also emphasised. Similar guidance is also particularly required in the area of traditional foods from third countries in relation to how these and history of their safe use are defined. These guidance documents are currently in the process of being compiled by EFSA.

The streamlined application procedure, whereby all applications are processed by EFSA, rather than by individual member states, was generally welcomed. Questions were raised about the capability and resource of EFSA to cope with this increased workload. EFSA intend to utilise member states' expertise and to issue a series of four year framework contracts to assist with the workload. At present most applications are processed by a small number of member states (predominately the UK and Ireland). The reason for this is

unclear. The need for the application process via EFSA to be open and approachable was highlighted.

The streamlined approach also includes a revised approval process. Currently an application can take on average 35 months (ranging from 16 – 60 months). The new process envisages that applications can still take 24 – 36 months. The need to introduce deadlines was highlighted. Industry, it was commented, target a rate of return of 20 to 25% over the lifetime of a product to justify research and development. Delays therefore reduce the potential returns, hence the attractiveness of investment and also of innovation.

A generic approval process is proposed however the need for adequate data protection provisions were discussed.

The proposed regulation does not resolve the potential for overlap and duplication with other legislation, in particular that for new vitamins and minerals, which it was suggested should be removed from the novel food regulation. The potential for conflict with the separate proposed regulation on cloned animals and their offspring was also raised.

Benefits were envisaged for small and medium enterprises by the removal of fees and by generic applications. Member States also envisage benefits in the reduction in administrative burden.

In addition consumer acceptability and the demonstration of clear benefits for the consumer also need to be considered.

Thus, whilst the need to amend the novel food regulation was recognised and benefits of the Commission's proposal identified, a number of issues still need to be resolved.

WORKSHOP PROCEEDINGS

Opening remarks

MEP James Nicholson, ENVI Rapporteur

Mr Nicholson, MEP welcomed all participants and stated that the Novel Foods Regulation proposal is also the subject of discussion by the Committee on Agriculture and Rural Development which is responsible for the proposals for directives concerning cloning. There have been many developments in this area, both with respect to products requesting authorisation and methods. The original regulation is therefore in need of updating. The European Commission first put forward a proposal to amend the existing Regulation in 2008. In 2011 however agreement could not be reached due to the inclusion of cloned animals and offspring from cloned animals. These issues are now the subject of a separate proposal. A revised proposal on Novel Foods was issued by the Commission in December 2013.

Mr Nicholson in his draft report has put forward amendments to the revised Commission proposal in relation to the definition of novel foods, the protection of intellectual property and the streamlining of the process. These aspects are considered to be the main focus of the amendments, which are also required to stimulate innovation and ensure consumer safety.

The three main issues that need to be resolved, from Mr Nicholson's perspective, are the definitions surrounding novel foods, the deadlines of application and data protection in order to stimulate, not stifle, innovation.

1. GENERAL INTRODUCTION TO THE REGULATION OF NOVEL FOODS IN THE EU

1.1. The State of Play in Novel Foods in the EU

Kate Trollope, Editor, EU Food Policy began her presentation by providing a brief background to the current situation in relation to the Novel Foods Regulation. Although agreement between the Council and Parliament could not be reached in 2011 over the issue of cloned animals some MEPs and member states have mentioned that they still want to include cloning in the Novel Foods Regulation. Although now the subject of a separate proposal, she queried therefore whether this topic would again present a problem to the amendment of the Novel Food Regulation.

Reasons for the need to review the current Regulation, and possible remaining problems, were discussed. These included the risk assessment process; the definition of novel foods; traditional foods and evidence of safe use; health claims; the time involved in an application, EFSA's role, data protection and delay as a barrier to innovation.

Risk assessments currently involve the potential for duplication and delay since, when a member state conducts the first safety assessment and finds the novel food safe, other member states can object. This leads to the file being referred to EFSA who then produces its own opinion. In the revised proposal EFSA is responsible for the full risk assessment. Ms Trollope queried however whether EFSA has sufficient budget and resources to fulfil this role alone, and commented on the strong expertise that already exists in certain member states. The novel food application system in the UK, via the advisory committee on novel foods and processes (ACNFP), was described and it was explained how this is a very open process since the application, meeting minutes and documents and final opinion for public comment are all published. In addition the ACFNP also agrees to meet with applicants prior to submission. It is considered essential that EFSA would be equally as transparent in its proceedings.

The definition of novel foods given in the proposed Regulation is reported to be too vague. The reintroduction of the categories from the existing Regulation into the proposal would solve this problem and the Commission has recognised this. Whilst keeping the 15 May 1997 cut-off date for defining what a novel food is may seem confusing, changing it would lead to greater uncertainty. The amendments with respect to traditional foods from third countries were well intentioned but various aspects including the length of the period required to demonstrate safe use, how this is defined and how this would it be assessed by EFSA were queried. The example of the Saskatoon berry was given. This has been consumed in Canada for the last ten years but would require a full, expensive risk assessment in the EU. The Council are suggesting that third countries may be able to trigger a full assessment for traditional foods from the outset, rather than a notification, which appears sensible since member states have a long history of objecting to applications. The issue of harmonised applications and the appropriateness of novel food and health claim applications being made at the same time were also discussed. Companies can submit two applications at the same time for health claims and novel foods and the appropriateness of this was queried. As there are no fees for submission the need to ensure appropriate use of budgetary resource by EFSA was highlighted. Additionally deadlines on risk managers for authorisation decisions can be meaningless if there are no deadlines for votes to be made in the Standing Committee.

Finally the issue of nanotechnology and whether more was required on its definition and risk assessment was raised.

1.2. Introduction by the Commission

Mr Poudelet, Director of the Safety of the Food Chain, DG Sanco, European Commission provided a background to the Commission proposal and explained that the proposed revisions to the existing novel foods regulations resulted in two proposals being put forward – one on cloning and one on novel foods. In particular the Commission amendments to the Novel Foods Regulation were intended to make the application process:

- Simpler - by avoiding national assessments;
- Quicker - as a decision is required within 18 months;
- Free of charge - as an incentive to small and medium enterprises.

A deadline for a vote is not included so as not to encourage negative decisions due to short deadlines.

Criticisms concerning the definition of a novel food and the scope of the new regulation, both of which are claimed to be unclear, were acknowledged by Mr Poudelet. He explained that the Commission's responsibility is to ensure the safety of novel foods for the consumer. One issue concerning the use of nanotechnology, however, is not linked to safety but to the level of use in food ingredients and eventually food itself.

He stated that currently there is not a parallel discussion with regards to the question of cloned animals.

Mr Poudelet commented that the Commission would like to progress the novel foods regulation quickly.

1.3. Member States authorities' experiences with Novel Foods applications

1.3.1 Italian Presidency

Valeria D. Di Giorgi Gerevini, Italian Ministry of Health, Italian Presidency described Italy's experiences of novel food applications. The competent authority (CA) in Italy is the Ministry of Health and in particular the Scientific Committee: Commissione Unica Dietetica e Nutrizione (CUDN). Since the Italian industry is comprised of many small and medium enterprises (SMEs), who cannot afford to submit a full novel food application, the Italian CA has processed a very limited number (two) of full novel food applications. Italy's involvement has therefore mainly been in the assessment procedure of dossiers submitted to other Member States. They have however evaluated a lot of applications with respect to substantial equivalence. Dr Gerevini explained that their role involves guiding and assisting food business operators in the correct classification of the novel food and in dossier preparation and presentation. In addition they have arranged training courses for official control officers at central and regional level which have been found to be very beneficial in helping them understand what makes a novel food and their role in the implementation of the Regulation. They have found the central information on the guidelines on significant consumption and the novel food catalogue available online very useful.

With respect to the proposed regulation Ms Gerevini commented that increased clarity is required to enable categorisation. It was stated that the proposed regulation provides for a faster authorisation procedure and for a generic authorisation, when there is no reason for greater data protection and which is not linked to a specific food business operator. This she said would aid both SMEs and competent authorities. The removal of an application fee would also aid SMEs. It also represents an easier process for products derived from traditional foods from third countries.

The Italian CA works closely with the committee in charge of scientific evaluation and with EFSA, the working group on novel foods and with other competent authorities. Since Member States have experience in novel food applications it was hoped that their involvement would remain high, in particular with regards to participation in the novel foods working group, guidance for food business operators and in continuing to work with EFSA. As the Italian Presidency they are willing to take on the role of coordination and cooperation.

1.3.2 Food Safety Authority, Ireland

Mr O'Mahoney, Chief Specialist, Food Technology, Food Safety Authority Ireland (FSAI) discussed Ireland's experiences with Novel Food applications. The following problems with the current regulations were identified: they are complex and resource consuming for the applicant and for regulators alike, they are expensive, and the process is uncertain with regard to the time scale involved. Thus, as a small member state with limited resources that processes a number of novel food applications, he welcomed centralisation of authorisations.

From 1997 to date there have been 157 (non-GMO) novel food applications of which 6 were rejected, 13 were authorised without objection, 20 withdrawn and 64 Commission Decisions authorising novel foods. Objections were raised to 83% of authorised novel foods and therefore few applications have gone through with no objections. The number of applications shows annual variation but is generally increasing with 15 applications being made so far in 2014. Twelve member states have handled most applications, predominantly represented by the UK (45), Ireland (22), Netherlands (21), Belgium (16), Finland (15) and France (14). This pattern is again reflected in pending novel food applications. The reason the UK and Ireland have received most applications is unknown but it was suggested this may be due to the ability to submit in the English language or due to different charging structures by the different member states. With respect to substantial equivalence opinions (non GM) however in 2013 France received most applications (55), followed by Finland (33), UK (25), and Ireland (21).

Issues identified with the proposed regulation were considered.

The scope of the proposed regulation and definition of novel foods need to be flexible and adaptable. For example cloning, nanotechnologies, insects and synthetic biology were not mentioned at the time of his first involvement with the Novel Foods working group in 2006. In some cases however a novel food application may be made for an existing food as a marketing tool. Conversely others have not applied and may still be placing products on the market illegally. The need for guidance to decide whether a food is novel or not was therefore also emphasised.

Other issues highlighted included: the possibility for overlap with other regulations, such as food supplements and medicines; the requirement for member state involvement in the centralised application process and scientific input to EFSA assessments; generic authorisation – which are considered akin to the situation of substantial equivalence and thus would not be expected to prove to be a problem; traditional foods from third countries.

In conclusion Mr O'Mahoney commented that successful implementation requires: the implementation of streamlined Novel Food legislation; strong leadership as shown in the Novel Foods working group; the provision of adequate guidance for all stakeholders (which was considered very important), along with the adoption of good science and a pragmatic approach (reasoned safety objections) by both member states and by EFSA, along with the ability to adapt to new challenges.

1.3.3 EFSA's position on the Novel Foods Regulation

Mr Valeriu Curtui, **Head of Nutrition Unit, EFSA** explained that EFSA is not involved in the development of legislation. He would therefore address EFSA's involvement in the current novel food application process and in the new proposal; a consideration of novel foods vs health claims and food supplements; the preparation of guidance documents and the involvement of member states.

Currently EFSA only reviews a novel food application when there has been an objection by a Member State. Approximately two thirds of applications are currently referred to EFSA. Since the application has already been assessed by the member state where the application was made there is therefore currently a duplication of effort. Under the new proposal EFSA would receive all applications directly with no prior involvement from the Member States.

In the current system EFSA undertakes five to seven scientific assessments a year for which the deadline is negotiated. In the new proposed application process the deadline for EFSA to complete the scientific assessment is nine months which, Mr Curtui commented, is considered tight but feasible. In the case of applications concerning traditional foods the important criteria are the definition of 'traditional foods' and the evidence requirements to establish a history of safe use. EFSA wish to avoid a mass of applications for traditional foods and is therefore preparing guidance documents relating to the scientific evidence required for a traditional food application whilst the Commission is looking at the risk assessment requirement. Objections may be raised by member states or EFSA within four months.

EFSA is aware that concern has been expressed about novel foods and health claims applications. Novel food and health claim applications, Mr Curtui explained, involve two different processes with no overlap. Although they are evaluated by the same scientific panel different scientific evidence is required. Furthermore, novel food applications are submitted via the Commission and are assessed with respect to safety. Health claim applications are submitted via the Member States and assessed with respect to efficacy. In the cases of novel foods and food supplements, there is however some overlap, the assessment is similar and the submission of one dossier for both is possible.

A request was received from the Commission in May 2014 for the production of relevant guidance documents. EFSA is therefore currently working on the development of the following:

- Guidance on the preparation and presentation of applications for the authorisation of a novel food.
- Guidance on the preparation and presentation of applications for the authorisation of traditional foods from third countries.

Following a public consultation planned for June 2015 it is expected that the documents will be finalised by the end of 2015, subject to the progress of the legislation. Training for applicants would then take place in 2016.

In undertaking the requirements of the revised proposal EFSA also wish to take advantage of Member States expertise and, as such, to out-source the preparation of product datasheets by the means of four year grants. In addition they envisage a network to access expertise and are consulting with an advisory forum as to the form this should take.

In summary; EFSA agree with the centralised, streamlined procedure and that this will speed up the novel food application process. It is recognised that the provision of guidance documents and definitions are very important and this is in progress. Whilst it is known that concerns have been raised, EFSA see no overlap with the scientific assessment for novel food applications and those of health claims or with a combined assessment of novel

foods and novel nutrient sources. Finally EFSA plan to utilise member states expertise and to develop a network (particularly in the area of traditional foods) to provide assistance to them.

1.4. Questions & Answers

A query was made by Mrs Giulia Moi, MEP concerning EFSA's neutrality. The questioner commented that in the European Parliament there is a lack of awareness about how EFSA reports are drawn up, how the scientific panels work and their independent nature.

Mr Curtui, Head of Nutrition Unit, EFSA responded indicating that there are strict rules and continual checking procedures to ensure the independence of the members of the expert panels. The scientific panels are also independent of the management board.

Nigel Baldwin, Intertek commented on the complication that was created due to the existence of two sets of guidance, one for novel foods and one for vitamins and minerals, both of which, he stated, are now very old. The guidance on novel foods, he commented, was written with genetically modified food in mind however this was taken out of the regulation a number of years ago. Why, he asked, has it taken so long for there to be a request to rewrite the guidance documents?

Mr Poudelet, European Commission, responded and commented that the experience with health claims applications demonstrated the need for clear guidance. He explained that such documents are not easy to prepare since many factors need to be taken into account in their preparation. They also need to be as clear as possible so that Food Business Operators (FBOs) know what data and information is required from them and how they need to provide this to EFSA. The provision of clear guidance will avoid the introduction of delay in the application process since it will enable FBOs to provide the required information from the outset and hence will reduce the need for EFSA to revert back to the applicant requesting clarification or additional information.

Mr Curtui, Head of Nutrition Unit, EFSA added that the original regulation dated from 1997. At the time EFSA was created (2002) the current guidance documents and implementing measures already existed and there was no request for them to produce a guidance document. A request to produce guidance was received in May 2014 and is in progress.

Mr Poc, MEP queried that the proposed legislation makes reference to that on cloning which does not yet exist. Additionally he asked whether there was the potential for possible interference with possible legislation on Botanicals?

Mr Poudelet, European Commission, responded that they recognise that the issue of cloning is a controversial proposal but do not see the reference to cloning presents a problem. With respect to botanicals, he described the sector and some of the related issues. The Botanicals sector, he stated, is an active one involving many micro companies and SMEs but employing a significant number of people overall. Of 500 claims concerning botanicals considered by EFSA none were accepted with respect to scientific evidence of efficacy. Hence a particular botanical material may not be banned but the claim may not be permitted. In some member states, he commented, the same botanicals treated differently so that sometimes it is considered as a part of the product, sometimes as a novel food, or a traditional herbal product and sometimes as a supplement. The need for clarification and to define botanicals is recognised, along with the need for a decision as to what action to take.

An Italian representative in the audience referred to the Court of Justice 2012 comment concerning a possible conflict of interest in Italy if EFSA is impacted by Italian political opinion, with representatives having no scientific qualifications. She asked how can EFSA's impartiality be accepted?

Dr Gerevini, Italian Ministry of Health, Italian Presidency replied stating that she can not comment on political matters but to her knowledge EFSA's experts are appointed on the basis of their scientific knowledge.

The Rapporteur then thanked all contributors and invited the speakers for the next part of the workshop to come forward.

2. THE 2013 PROPOSAL FOR REGULATION ON NOVEL FOODS: ROOM FOR IMPROVEMENT?

2.1. Potential impact of the 2013 Regulation on innovation in the food sector

Patrick Coppens, Director International Food and Health Law and Scientific Affairs, EAS outlined the aims of the Novel Foods Proposal (COM(2013) 894 final) and then focused on the potential impact of the proposed regulation on innovation. It was important that decisions were binding and that they should be implemented in the same way in all Member States. Supporting innovation is one of the main aims of the proposed regulation and the development of novel foods is key with respect to the innovation of new foods and food based on new technologies. Mr Coppens then outlined the necessary requirements if the proposal is to promote innovation and went on to discuss each in further detail.

Firstly, a clear definition of the scope is required and since the legislation has been in existence for 17 years there is experience with this. Originally the legislation specifically aimed not to cover all foods, defining what was included and focusing on specific risks whereas the new proposal refers to the definition of food and applies to all foods put on the market since 15 May 1997, removing the categories included previously. This means that the definition has the potential to apply legally to all foods put on the market since 1997. Potentially this has a high impact on innovation, costs and administrative burden without significantly improving consumer safety. The difficulties of demonstrating significant use before 1997 were discussed as well as the need for clarification on the definition of novel foods. It is accepted that the new proposed regulation needs to be expanded to include new developments and new categories, however these need to be well defined, based on a safety perspective, assessed on impact and introduced at the same time as the new regulation. Currently the proposal appears to cover all foods however, there is already legislation for foods generally.

The centralised procedure, which is intended to reduce the time, costs and administrative burden involved, was considered. This procedure would aid innovation by the reduction of the administrative burden involved in applications; that the inclusion of generic authorisation would assist SMEs and that the data protection safeguards would maintain the incentive to develop innovative food products. The proposal also aims to reduce the time involved in the application procedure which is currently three years on average. The timelines for the current and proposed application procedures do not differ significantly and a required time scale of eighteen months was indicated. Even so these do not compare favourably with those for medicines where a decision is given in 15 days rather than months. On traditional foods from third countries, where a notification receives no reasoned objections from member states it should be assumed that the food is safe and can be placed on the market.

Suggestions for further improvements to promote innovation were put forward including: Uniform implementation (with no possibility for Member States to have national approvals (e.g. as medicines); Appropriate incentives for innovation (with respect to data protection provision); Avoidance of duplicate procedures (for example the automatic inclusion of vitamins/minerals); Notification of traditional foods from third countries (definition and guidance). He referred the attendees to the complementary impact assessment carried out and reported previously where these further improvements were also highlighted.

2.2. The importance of the novel foods market in the EU – industry perspective

Marta Baffigo, Cargill R&D Centre Europe speaking on behalf of FoodDrinkEurope began by outlining the structure of the food industry in Europe. She explained that with a turnover of €1,048 billion and employing 4.2 million people and a trade balance of €23 billion the food and drink industry is one of the most important industries in Europe. Consisting of 286,000 companies it is however a fragmented industry, made up of many SMEs who constitute 51.6% by turnover; 64.3% by employment of the industry. Such SMEs need to be incentivised with respect to innovation. R&D expenditure in Europe in the food and drink industry (0.27% of output) is not the highest of all manufacturing industries in the EU or when compared to other countries such as Japan, US and Norway. When a product is launched a manufacturer expects a return on their investment of 20-25% over the life of a product to justify R&D costs. A delay in approval of 30 months or longer can reduce return on investment by up to 30%. The average time for the approval process (2000 – 2013) to be completed is 35 months, ranging from 16 – 60 months. Any delay can lead to a reduction in profits, a loss of competitive edge and a reduction in the attractiveness of investment in Europe. There was a decrease in innovation between 2011 and 2013 and, whilst this was partly due to the economic downturn, it was also thought that the uncertainty in relation to the novel food regulation could have also played a significant role.

Innovation, including investment in R&D, is a key driver for growth. By simplifying and streamlining the current regulatory framework and facilitating market access for novel foods The Novel Foods Regulation can and should stimulate innovation. Additional key elements that FoodDrinkEurope hope will be taken into account were outlined including: re-inclusion of the categories to clarify the scope; a reduction in administrative burden (including a reduced timescale for novel food applications), data protection and the conclusion of pending dossiers.

Although the current proposal addresses certain aspects Ms Baffigo added that there is still room for improvement. The Novel Food Regulation was not intended to cover all 'new' food and food ingredients but only novel foods that fell within specific categories. The removal of these categories in the proposed regulation extends the scope and makes the date of 15 May 1997 the only criterion. The re-introduction of a category based approach is therefore considered essential to provide legal certainty. The centralised procedure should provide for a shorter, more efficient application process but from the timescales given authorisation would still last 2-3 years and hence represent no improvement on the current situation. Reassurance is required that the approval process will be quicker and FoodDrinkEurope propose six months for EFSA assessment, 3 months for the Commission and a limitation on the discussion in committee. Adequate data protection is required for companies (large or SMEs) for a certain time period otherwise she suggests innovation will stop. Currently there is overlap with other legislation (vitamin and minerals, engineered nano-materials) resulting in a duplication of effort. Industry therefore favours a 'one key one door' approach.

2.3. Does the draft regulation solve existing problems?

Nigel Baldwin, Intertek Scientific & Regulatory Consultancy and the European Federation of Associations of Health Products Manufacturers (EHPM) discussed the proposed amendments to the regulation. Issues with the draft novel food regulation were identified including: the need for additional clarity relating to the classification of what is novel / not novel and the definition of terms such as 'significant use', which would avoid borderline issues; and on what is proprietary and confidential information and what is not;

the need for setting time limits in the submission procedure and the avoidance of national provisions.

In particular the proposed regulation was discussed with reference to vitamins and minerals. The situation of vitamins and minerals was compared with the work undertaken in relation to the new food improvement aids (additives Regulation (EC) No 1333/2008; enzymes Regulation (EC) No 1332/2008 and flavourings Regulation (EC) No 1334/2008) and the common authorisation procedure Regulation (EC) No 1331 / 2008. New vitamins and minerals are classed as novel foods and two procedures currently apply whereby they require approval as a novel food and can only then apply for approval in specific food categories (food supplements, fortified foods, Food for particular nutritional uses (PARNUTS)/ Food for Specific Groups (FSG)). Both currently have their own sets of guidance and comitology and, although some steps would be simplified, these would remain in the new proposed procedure. Examples of other inconsistencies relating to enzymes and extraction solvents were also given. Many companies in this area are SMEs and, he commented, it was difficult for individual companies, especially when the approach was not harmonised, for example when legislation is implemented slightly differently in each Member State or where national rules apply e.g. medicinal decisions.

The new proposal, Mr Baldwin suggested, did not help this sector and vitamins and minerals should be taken out of the scope of Novel Foods to avoid duplication and inefficient regulation. Food supplements, fortified foods and PARNUTS/FSG should be referred to the Common Authorisation Procedure. Guidance should also be harmonised as far as possible. Significant amendments to other legislation would be involved to amend procedures but the work on Food Improvement Agents had shown that it was possible and that excessive complexity of different approval procedures is unnecessary.

2.4. The EU consumer perspective on novel foods

Camille Perrin, Senior Food Policy Officer, BEUC (the European Consumer Organisation) explained that BEUC is an umbrella organisation of forty national consumer organisations from thirty one European countries. Their mission is to promote consumer interests in EU decision making and one of their work priorities is "Safe and healthy food for informed consumers". Ms Perrin commented that BEUC has limited resources and that a robust legal framework is required for novel foods approval to ensure the compatibility of safety, consumer benefits and social/ethical/environmental concerns. Novelty / innovation, she stated, is attractive however the consumer still requires that the food is safe to eat, to know how it has been produced and what the benefits are. Benefits can range from those associated with improved nutrition to that of broader consumer choice. Innovation is only accepted if it is trusted by consumers. Concerns were raised about the scope and definition of novel foods in the proposed regulation commenting that legal certainty is in the interest of consumers and business alike. The definition of novel foods should be clarified in order to ensure the capture of all relevant products and a high level of consumer protection without creating any loopholes. In particular the retention of the cut-off date of 15 May 1997, the need for the reintroduction of categories, and clarification of the term 'significant' in relation to changes in the product and to levels of human consumption were highlighted. The proposal that all applications be processed directly by EFSA is welcomed although BEUC have concerns about how EFSA will cope with the workload. The need for additional guidance on the data required was highlighted. BEUC do not agree with substantial equivalence particularly in relation to nanotechnologies. The need for a balance between proprietary information and the availability to the public of toxicological data used for an evaluation of safety was identified. BEUC also consider that there should be post-marketing monitoring.

The required conditions for the approval of novel foods and in particular the benefit for the consumer, social/ethical concerns and the need for labelling to allow informed consumer choice were outlined. The criteria to establish a history of safe use of traditional foods from third countries was queried. BUEC consider that the history of a number of years of consumption is no guarantee of safety since apparent historical 'safe' use could depend on factors such as the reporting requirements / capability within individual countries. Clear guidance was needed of the evidence requirements for traditional foods.

With respect to nanotechnologies the definition given is for labelling not food safety purposes and therefore the threshold level should, in the opinion of BEUC, be 10% not 50% and there should be stricter definitions and guidance on their use to ensure safety. The need for the cloning and novel foods regulations to proceed in parallel was also discussed.

Ms Perrin concluded that the success of food innovation required a robust and transparent procedure for food safety risk assessment, full consideration of consumer acceptability and the demonstration of clear benefits for the consumer.

The Rapporteur then thanked the contributors and introduced the next part of the agenda which included a debate with shadow rapporteurs.

2.5. Debate with Shadow Rapporteurs and Q&As

Paul Brannen, MEP questioned Marta Baffigo concerning her comment that whilst the fall-off in novel food applications was partly due to the economic climate it might also be due to uncertainty relating to the Novel Food Regulation. He stated that he needs specific evidence and examples where a company deliberately did not do something because of the regulation.

Ms Baffigo replied that it was difficult to give specific examples and numbers. The fall-off in the number of applications can be seen from the data provided. She had no further facts than those presented. She commented however that legal uncertainty is not conducive to good business or innovation.

Mr Poc, MEP asked whether this legislation could be misused by industry or member states to influence the market somehow. If Yes – does the Commission have some measures that would be needed to tackle this?

Martha Baffigo replied that she would not use the word mis-use. She explained that a food business operator needs to decide if a food is novel and if so what are the procedures that it needs to follow. Businesses, she said, spend a lot of time doing this and are making decisions every day with respect to safety. If a product is so novel then, she added, they would be pleased to go to member states or EFSA for a third party opinion and assurance. She could not see how the legislation would be misused. She commented that clarification of the definitions and procedures is required however to assist in the initial decision – Is it a novel food?

Chantel Bruetschy, Head of Unit for Innovation and Sustainability (DG Sanco), European Commission also agreed that in the case of a novel food it is beneficial to have confirmation from EFSA with respect to safety and risk assessment and this also adds to consumer acceptability. She continued to outline the aims of the current proposal which she commented streamlines the application process and for which there has already been agreement to produce guidance and clarification of the definition of novel foods. The Commission proposal was not intended to expand the coverage of novel foods but to clarify it. There is the opportunity to speed up the procedure in relation to traditional foods from third countries but this, she stated, will not compromise safety. The intention of the proposed regulation is to increase innovation and to help SMEs. There is no intention for

this to be misused. Approval will be generic but with the potential for data protection. If a manufacturer puts 'novelty' in food it needs to be risk assessed. The proposal aims also to avoid duplication of effort and to be efficient.

Ms Ayenso, MEP commented that Ms Perrin had stated that novel foods need to be shown to be not only safe but also to provide a benefit. She asked Ms Perrin to define this benefit further.

Ms Perrin responded that the product should have some benefit to health and should not necessarily just provide the consumer with a wider choice. Their concern relates to when the product is marketed to consumers as having a benefit to those with a particular disease, which then also raises the issue of claims i.e. health claims. Primarily the consumers should not be misled. Thus she confirmed that if the food is just replacing one that already exists on the market and is using the concept of 'novel' as a marketing tool then it needs to show a benefit.

Nigel Baldwin, Intertek and EHPM commented that the standards set for establishing a health claim are similar to those for approval of a pharmaceutical. The same type of data is required with respect to novel foods but there is not the same process for risk vs. benefit.

Mrs Giulia Moi, MEP commented that, in the new proposal, traditional foods from third countries will potentially have a faster application procedure. She queried that whilst industry may be frustrated with the speed of progress of applications is it feasible to increase the speed of processing the application with respect to balancing speed and safety? She stated that she was concerned that this would give easy access for potentially unsafe or GM foods e.g. from China and US especially considering the pending Transatlantic Trade and Investment Partnership (TTIP) deal.

Chantel Bruetschy, Head of Unit for Innovation and Sustainability (DG Sanco), European Commission responded commenting that strict conditions have been added for traditional foods from third countries: They must be from primary production i.e. not new; have formed part of the main diet for a long time (>one generation, 25 years); they cannot be a food supplement; cannot form only part of the main diet. She confirmed that these traditional foods will not be GM as GM foods are covered by a different regulation, and are not novel foods. Nor can the traditional foods be from clones. The safety net of reasoned objections from Member States remains. If a business wanted to put such a food on the market it would need to go to EFSA for a full risk assessment. Such traditional foods, she stated are required to be as safe as those that originate from within the EU.

Ms Boylan, MEP queried the Commission about the evidence on which the 50% threshold re nanotechnologies was based

Chantel Bruetschy, European Commission responded that this is from the scientific evidence of the common recommendation definition of nanotechnologies where specific examples are given of particular categories e.g. food. The evidence was from various sources including EFSA.

2.6. Conclusions by Rapporteur

The Rapporteur thanked everyone who participated. He thought that it has been a very good workshop. Further discussions would now take place and he advised that the first reading agreement would hopefully take place in December.

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PARLAMENT EUROPEJSKI PARLAMENTO EUROPEU PARLAMENTUL EUROPEAN
EURÓPSKY PARLAMENT EVROPSKI PARLAMENT EUROOPAN PARLAMENTTI EUROPAPARLAMENTET

ANNEX 1: WORKSHOP AGENDA

Organised by the Policy Department A-Economy & Science Committee on the Environment, Public Health and Food Safety (ENVI)

Workshop on Novel Foods

Tuesday, 7 October 2014 -12.15 -14.30 European Parliament (Brussels), Altiero Spinelli (A1E-2)

The event is open to the public and will be web-streamed:
http://www.europarl.europa.eu/ep-live/en/schedule
Interpretation EN-ES

FINAL AGENDA

12.15-12.20 Welcome by the Chair: James NICHOLSON, ENVI Rapporteur

Part 1 General introduction of Regulation of Novel Foods in the EU

12.20-12.30 **The State of Play in Novel Foods in the EU**
Kate Trollope, Editor, EU Food Policy, Belgium

12.30-12.35 **Introduction by the Commission**

12.35-12.55 **Member States authorities' experiences with Novel Foods applications** *Valeria Di Giorgi, Italian Ministry of Health, Italian Presidency*
Pat O'Mahony, FSAI, Ireland

12.55-13.05 **EFSA's position on the Novel Foods Regulation**
Valeriu Curtui, Head of Nutrition Unit, EFSA

13.05-13.20 **Questions & Answers**
Commission (DG SANCO) representatives will be present for questions: Eric Poudelet, Director of the Safety of the Food Chain; Chantal Bruetschy, HoU, Innovation and Sustainability; Sirkku Heinimaa

Part 2 The 2013 Proposal for Regulation on Novel Foods: room for improvement?

13.20-13.30 **Potential impact of 2013 Regulation on innovation in the food sector**

Patrick Coppens, Director, International Food and Health Law and Scientific Affairs, EAS

13:30-13:40 **The importance of the novel foods market in the EU -industry perspective**

Marta Baffigo, Cargill on behalf of FoodDrinkEurope

13:40-13:50 **Does the Draft Regulation solve existing problems?**

Nigel Baldwin, CSci Director, Intertek, on behalf of EHPM

13:50-14:00 **The EU consumer perspective on novel foods**

Camille Perrin, Senior Food Policy Officer, BEUC

14:00-14:25 **Debate with Shadow Rapporteurs Questions & Answers**

14.25-14:30 Conclusions by the Rapporteur

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

KATE TROLLOPE

Editor, EU Food Policy

Kate Trollope edits EU Food Policy, the leading online news service which reports on the latest developments in the areas of food safety and nutrition from Brussels. EU Food Policy covers Commission proposals, debates and votes in the European Parliament, and the deliberations in the Council as well as votes in the Standing Committee on the Food Chain and Animal Health. The service also takes a keen interest in the risk assessments by the European Food Safety Authority (EFSA), as well as some of the activities of the national food agencies, such as the French agency, ANSES, and the German Federal Institute for Risk Assessment (BfR).

Kate reports on a wide range of topics from novel foods, food fraud and the horsemeat scandal to nutrition labelling, "growing up milks", country of origin labelling and health and nutrition claims. She has more than 20 years experience reporting on food issues and graduated from Exeter University with a degree in English literature and worked in magazines and newspapers in the UK before reporting from Brussels.
EU Food Policy is a subscription-only news service and publishes "breaking news" online on the major stories as well as a weekly newsletter.

DR PAT O'MAHONEY Chief Specialist in Food Technology, Food Safety Authority of Ireland (FSAI)

Dr. Pat O'Mahony has a B.Sc. in microbiology, a M.Sc. in biotechnology and a Ph.D. in plant molecular Biology. He has been the Chief Specialist in Food Technology with the Food Safety Authority of Ireland (FSAI) since September 2000. In his current role with the FSAI, Dr. O'Mahony has responsibility for a number of regulatory areas including novel food, GM food, nanotechnology, irradiated food, organic food, food labelling and the scientific detection of food fraud. Dr. O'Mahony represents the FSAI/Ireland on the EU Novel Food Working Group and has coordinated the assessment of more than 30 novel food applications and provided opinions on more than 40 substantial equivalence applications. Dr. O'Mahony is a member of the EFSA Expert Working Group on GMOs and the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed as well as the OECD Task Force for Novel food and Feed.

DR VALERIU CURTUI Head of Nutrition Unit, European Food Safety Authority (EFSA)

Dr Valeriu Curtui is Head of the Nutrition Unit at the European Food Safety Authority (EFSA), which provides scientific and administrative support to the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies. Prior to his appointment in February 2013, he worked, from 2008 onwards, as a scientific officer in EFSA's Dietary and Chemical Monitoring Unit on subjects such as chemical occurrence in food and dietary exposure assessments.

From 2001 to 2008, Dr Curtui was an Assistant Professor at the Institute of Veterinary Food Science of the Justus Liebig University (Giessen, Germany), and from 1991 to 2001 he was an academic member of staff in the field of toxicology and medicinal plants at the University of Agricultural Sciences and Veterinary Medicine of Timisoara (Romania). His research activity was focused on chemical food safety.

Dr Curtui was awarded a degree in Veterinary Medicine from the University of Agricultural Sciences and Veterinary Medicine of Timisoara (Romania) in 1991, and received a PhD in Toxicology from the same University in 1998. His scientific formation included scholarships at Universities in France, Germany and the UK.

PATRICK COPPENS Director, International Food and Health Law and Scientific Affairs, European Advisory Services (EAS)

Patrick Coppens has a Master's degree in nutritional sciences and has work experience in the fields of scientific coordination, medical marketing, quality assurance, regulatory affairs and crisis management. For the last 15 years he is a leading expert in international food and health law, with particular expertise in food safety, health claims and nutrition policy. He has been chairing task forces in a number of European trade federations on the subject of health claims. In January 2005 he joined Brussels-based EAS specialising in regulatory and strategic advice on nutritional products, where he is Director of International Food and Health Law and Scientific Affairs. In this capacity he advises a number of trade bodies, in particular Food Supplements Europe. He is a member of the Belgian Food and Health Plan Steering Committee. Mr Coppens has a great expertise of food law, in particular with regard to Novel Foods, Health Claims and Nutritional issues and has spoken at numerous international conferences on these topics.

DR MARTA BAFFIGO Cargill on behalf of FoodDrinkEurope

Dr Marta Baffigo is a Public and Regulatory Affairs freelancer.
Since July 2014, Marta Baffigo has been supporting Cargill R&D Centre Europe on food regulatory issues. Until May 2013 she was Director Global Public and Regulatory Affairs at Kellogg's. In her role, she was responsible for developing and leading the global external influencing strategy to support business objectives and growth. Marta was the company liaison worldwide between professional associations, government agencies and trade associations on nutrition health policy and advertising practices. Additionally, she had public affairs responsibilities for Kellogg Europe and headed the European Public Affairs office in Brussels.

Before joining the Kellogg Company in February 2004, she worked for Kraft Foods as Manager European Affairs.

She holds a doctorate in Food Science and Technology from the Università di Milano, Facoltà di Agraria, where she conducted an experimental thesis in biochemistry in the Department of Agrifood Molecular Sciences.

NIGEL BALDWIN CSci Director, Intertek, on behalf of European Federation of Associations of Health Products Manufacturers (EHPM)

Nigel Baldwin has a wealth of knowledge and experience with international food, food ingredient, and specialty chemical regulations. He is a recognized expert in the area of novel foods and food supplements in Europe with extensive practical insight into the areas of food and feed additives, food enzymes, infant formula, functional foods and health claims. Providing invaluable expertise to international companies seeking to develop and implement strategies for gaining approvals for new products and health claims in Europe. Nigel has worked on more than 30 successful regulatory approvals world-wide.

Mr. Baldwin has worked in technical and regulatory affairs for over 20 years, encompassing nutritional and chemical microbiology, analytical chemistry, food science, quality management and toxicology. Prior to joining Intertek Scientific & Regulatory Consultancy (formerly Cantox) in 2003, he was previously Corporate Regulatory Affairs Manager for a major international food ingredient company working on regulatory strategies for food additives and novel food ingredients.

He was also European Director of Technical and Regulatory Affairs for a major functional food ingredient company during its initial development and market launches working extensively on novel foods, food supplements, health claims, infant formula and feed regulatory approvals and strategies. Therefore, Nigel Baldwin has firsthand experience with the technical, time and cost pressures facing new product development. Mr. Baldwin has worked on more than 100 regulatory submissions, including more than 30 novel food applications.

Mr. Baldwin received his B.Sc. with honours in Biochemistry and Physiology in 1987 from the University of Central Lancashire, majoring in Microbial Biotechnology and Pharmacology and is a Chartered Scientist in the UK. He is also a member of the Institute of Food Science and Technology, and Society of Cosmetic Scientists.

CAMILLE PERRIN Senior Food Policy Officer, European Consumer Organisation (Bureau Européen des Unions de Consommateurs, BEUC)

Camille Perrin is Senior Food Policy Officer at BEUC, the European Consumer Organisation, where she deals with a variety of issues pertaining to EU food law, including European legislation on food hygiene and safety, labelling, etc. Before joining BEUC, she worked as Scientific & Regulatory Affairs Manager for a trade association from the agri-food sector, following EU and international (Codex Alimentarius) regulatory developments relating to food and feed law.
She holds a M.Sc. in Food Science and Technology from the National School of Agronomy of Nancy (France) and a M.Sc. in Nutrition from Montpellier University (France).

ANNEX 3: SPEAKERS' PRESENTATIONS

Part 1: The State of Play in Novel Foods in the EU Presentation Presentation by Kate Trollope

Kate Trollope, Editor

EU Food Policy –online news service
www.eufoodpolicy.com

WHY ARE WE HERE?

- The failure of the Council and Parliament to reach a deal on Novel Foods in March 2011
- This was over the labelling of food from the offspring of clones
- The Council agreed to some labelling of beef and reports on further labelling but this did not satisfy MEPs

Why do we need a review of Novel Foods?

- Duplication over risk assessments
- A member state carries out a first safety assessment
- But invariably if it concludes the novel food is safe, other member states disagree
- The file then goes to EFSA and EFSA has to produce its own Opinion
- Length of time it all takes and lack of deadlines for risk assessment and then risk management decision
- In the new proposal there will be deadlines for the risk assessment.

The definition of novel foods is too vague?

- The Commission has already acknowledged this
- The solution suggested by Council and MEPs is to reintroduce the categories in the current legislation
- Problem solved
- Date of 15 May 1997 is a bit bizarre but changing it would lead to confusion and uncertainty

Problem of imports of traditional foods – the Saskatoon berry

- Currently, the only option for imported, traditional products is a full risk assessment unless they can demonstrate they are equivalent (substantial equivalence) to an approved novel food
- Good example is the Saskatoon berry. This looks a bit like a blue berry and was eaten in Canada for at least ten years.
- But it would have needed a full, expensive risk assessment in the EU

Problems with Commission proposal on traditional products

- Lots of arguments over how long the safe history of use should be – 10 years, 15 years, 25 years (chose by the Commission) 30 years?
- How exactly, scientifically, does EFSA assess history of safe use? Data?
- A third country can only notify a traditional novel food, rather than go for a full risk assessment, if nobody objects
- The 28 member states have quite a history of objecting (over the national risk assessments) in the history of Novel Foods
- Member states have four months to issue safety objections
- EFSA also has this right to object
- Perhaps the Council idea of allowing a third country to go for a full risk assessment at the beginning could, in fact, save time in the long
- The definition of a Novel Food

Novel Foods and Health Claims

- Industry is lobbying strongly for a harmonised application so it can apply for novel food status and a health claim at the same time
- There is nothing to stop companies now from putting in two applications at the same time
- Is it sensible for EFSA to be asked to evaluate a health claim when a product is not considered safe?
- Example BASF and Lipid Nutrition
- EFSA has a limited budget

Deadline for risk managers is meaningless

- The deadline for the Commission and member states to decide (qualified majority) whether to authorise is only a deadline for the Commission to submit a draft act.
- There is no deadline for a vote.
- As we have seen on health claims, there can be a long gap between the first draft and an actual agreement when the issue is controversial

EFSA's big role

- EFSA will be responsible for the full risk assessment
- It has already said it will set up a network with member states
- Some member states have strong expertise – the Advisory Committee on Novel Foods and Processes (ACNFP) does about 40% of current initial assessment
- The ACNP is very transparent – publication of the application, publication of detailed minutes and papers of the meetings, publication of the final opinion for public comment
- Will EFSA be as transparent?
- ACNFP secretariat meets with some applicants, EFSA does not offer pre-submission meetings. Can member states do these?

Proprietary data five year exclusivity

- In practice in health claims very few firms get this exclusivity
- The NDA panel at EFSA would have to say that it could not have reached the conclusion on safety without the proprietary data

Nanotechnology

- Does more need to be said on nanotechnology, the definition, the risk assessment?

Thank you

- Any Questions?
  Kate.Trollope@eufoodpolicy.com
- www.eufoodpolicy.com

Part 1: Member States authorities' experiences with Novel Food applications
Presentation by Valeria Di Giorgi


THE ITALIAN EXPERIENCE (1)
We have been mainly involved in the assessment procedure of dossiers submitted to other MSs


THE ITALIAN EXPERIENCE (1a)
A very limited number of complete application dossiers has been submitted to IT

THE ITALIAN EXPERIENCE (2)

We directly evaluated:

A) substantial equivalence on:

- already authorised novel food
- food already existing

THE ITALIAN EXPERIENCE (3)

We directly evaluated:

B) 2 complete authorization dossier


THE ITALIAN EXPERIENCE (4)
Guidance to FBOs for a correct classification of the novel food
Guidance to FBOs for the dossier preparation and presentation
Training courses for the official control officers at central and regional level


THE ITALIAN EXPERIENCE (5)
Assistance to our Committee in charge of the scientific evaluations
Partecipation to the WG on novel food
Exchange of infos with the other CAs

WHAT NOW: REG. (CE) 258/97

- Consumer protection
- Novel foods working group: MSs involvement
- Guidelines on significant consumption
- Novel food catalogue

IMPROVEMENTS: NEW REGULATION (1)

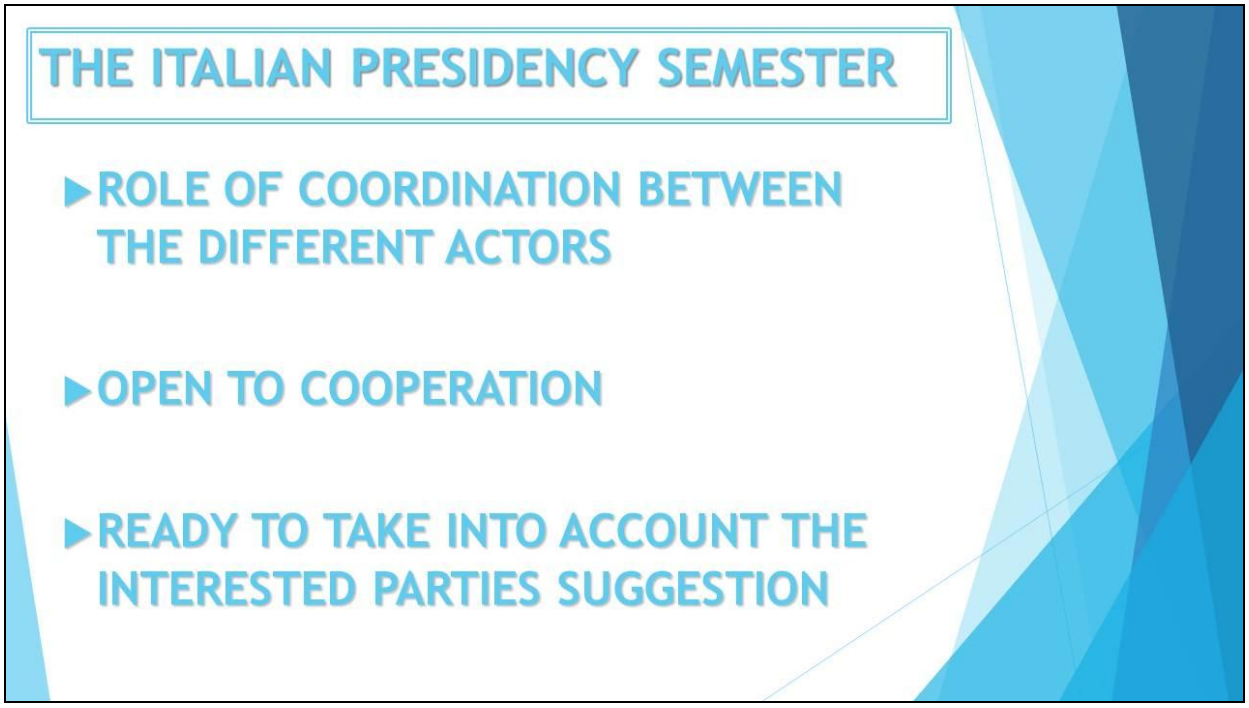
- Increased clarity on when it is applicable
- Faster authorization procedure

IMPROVEMENTS: NEW REGULATION (2)

- Generic authorization not linked to the FBO, exception: data protection
- Less burden for SME and CAs
- Easiest procedure for traditional food from third country

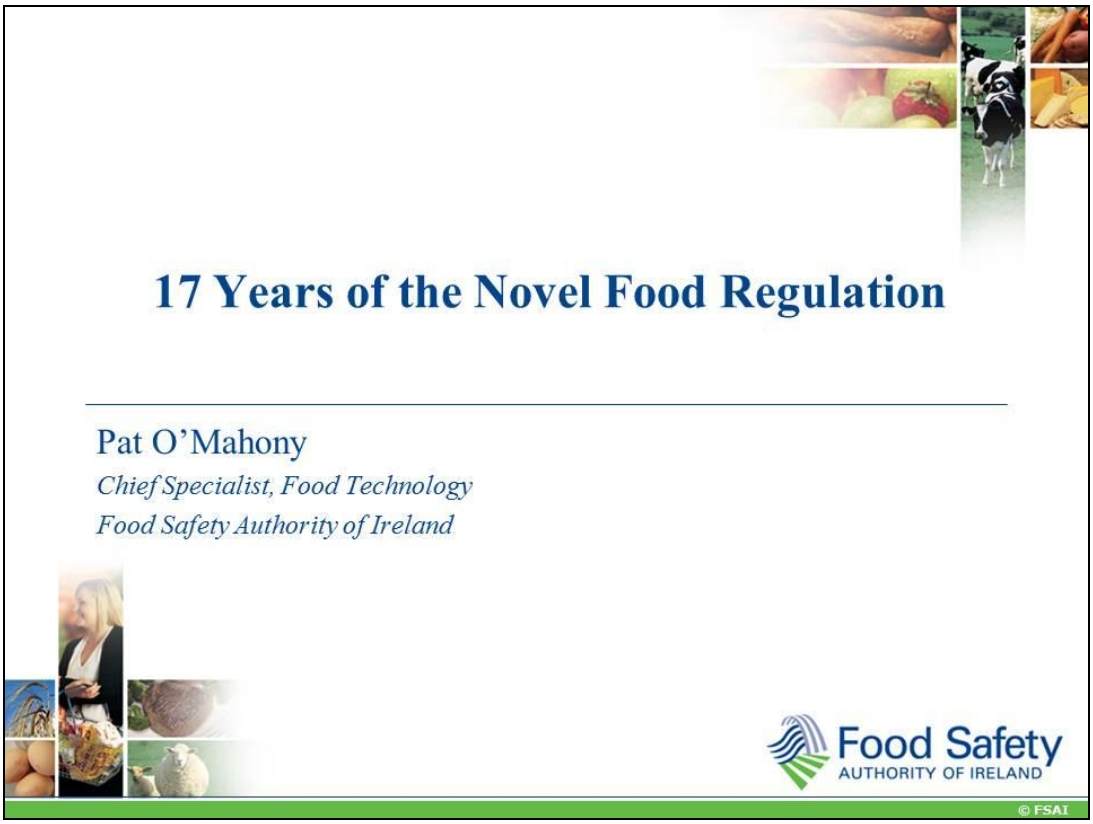
HOPE FOR THE POSSIBILE FUTURE

- Mantaining MSs involvement:
  - novel food working group
  - guidance to FBOs
  - work with EFSA
- More guidance document
- Implementation of the novel food catalogue


THE ITALIAN PRESIDENCY SEMESTER
ROLE OF COORDINATION BETWEEN THE DIFFERENT ACTORS
OPEN TO COOPERATION
READY TO TAKE INTO ACCOUNT THE INTERESTED PARTIES SUGGESTION


THANKS

Part 1: Member States authorities' experiences with Novel Food applications
Presentation by Pat O'Mahony



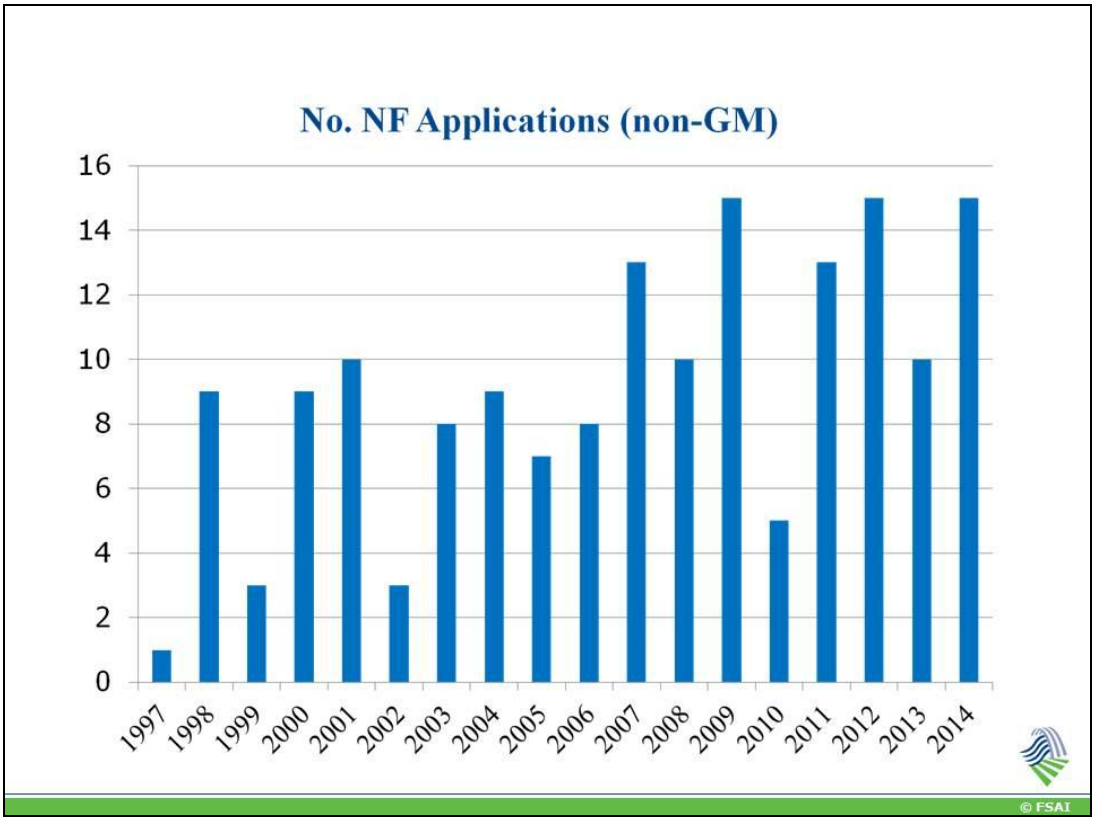
Problems with the Current Regulation

- Complex for first time or infrequent applicants
- Complex for regulators
- Expensive
- Resource consuming for applicants and regulators
- Uncertainty - *Timelines/Scope/"Reasoned objections"/Available regulators*

To Date

- 157 (non-GMO) NF Applications to date
- 6 rejections
- 13 authorised without objection
- 20 withdrawn
- 64 Commission Decisions authorising novel foods

Objections raised to **83%** of authorised novel foods


No. NF Applications (non-GM)
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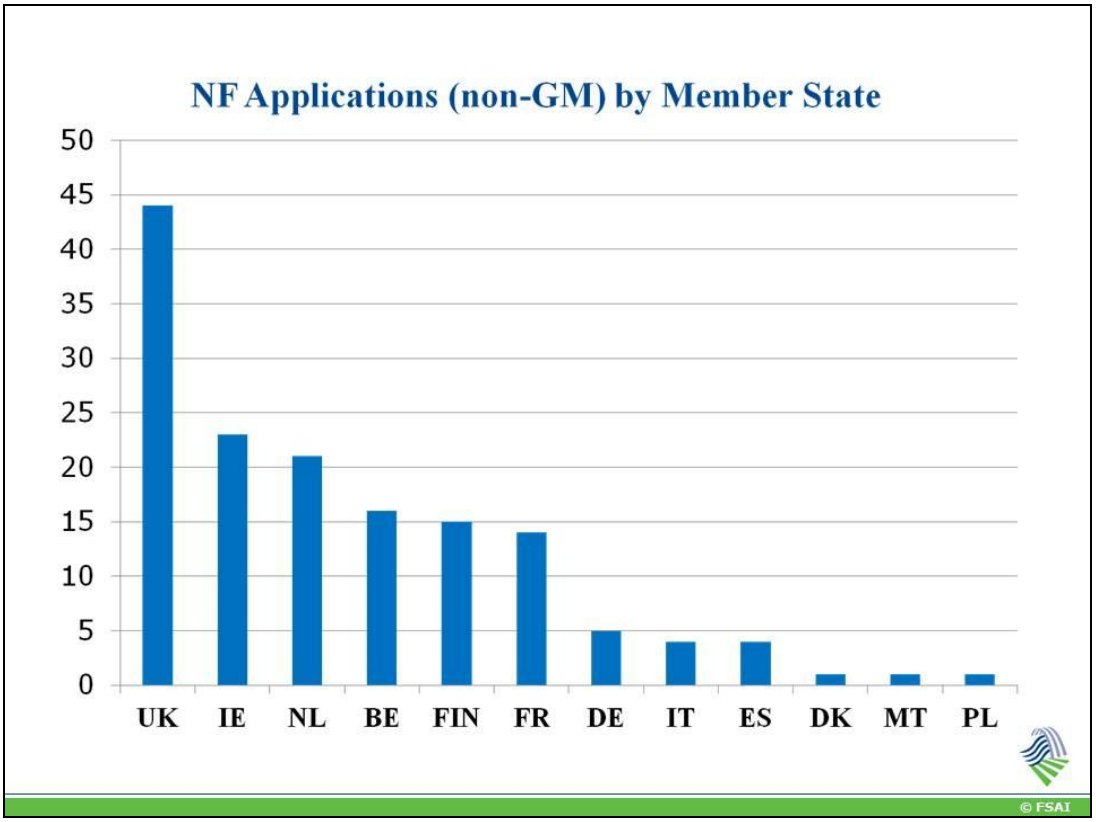
NF Applications (non-GM) by Member State
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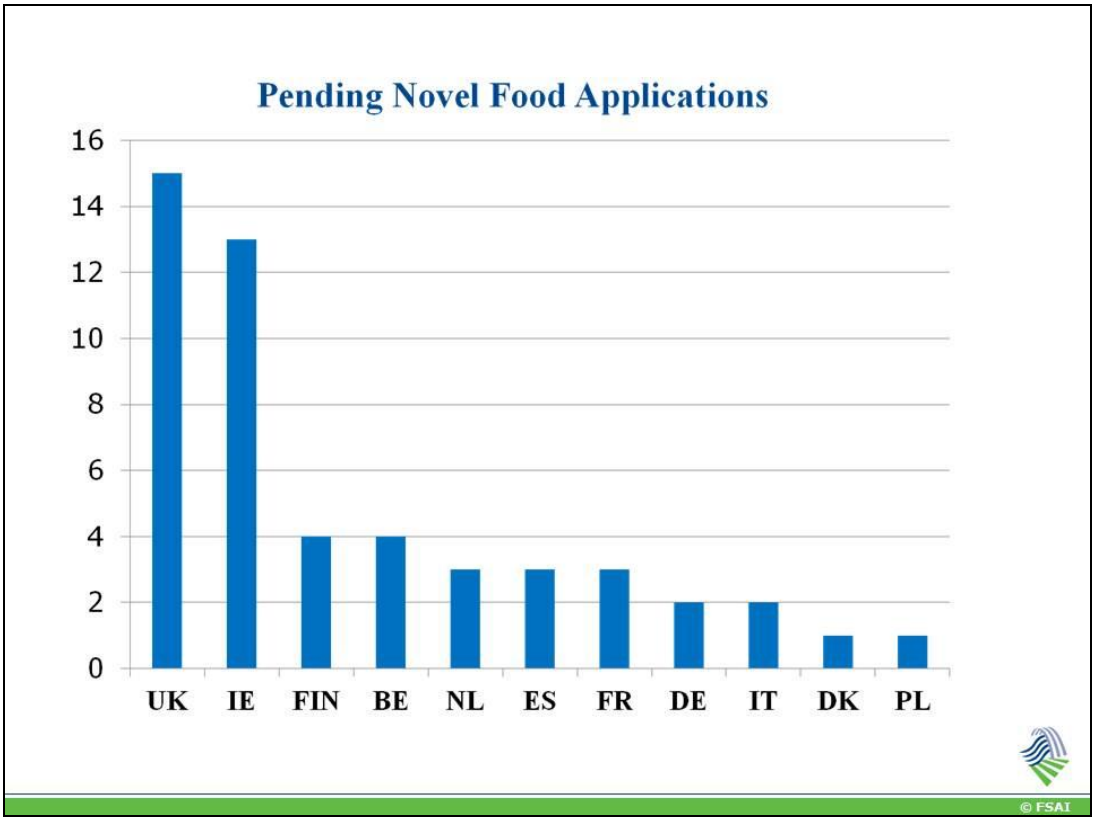
Pending Novel Food Applications
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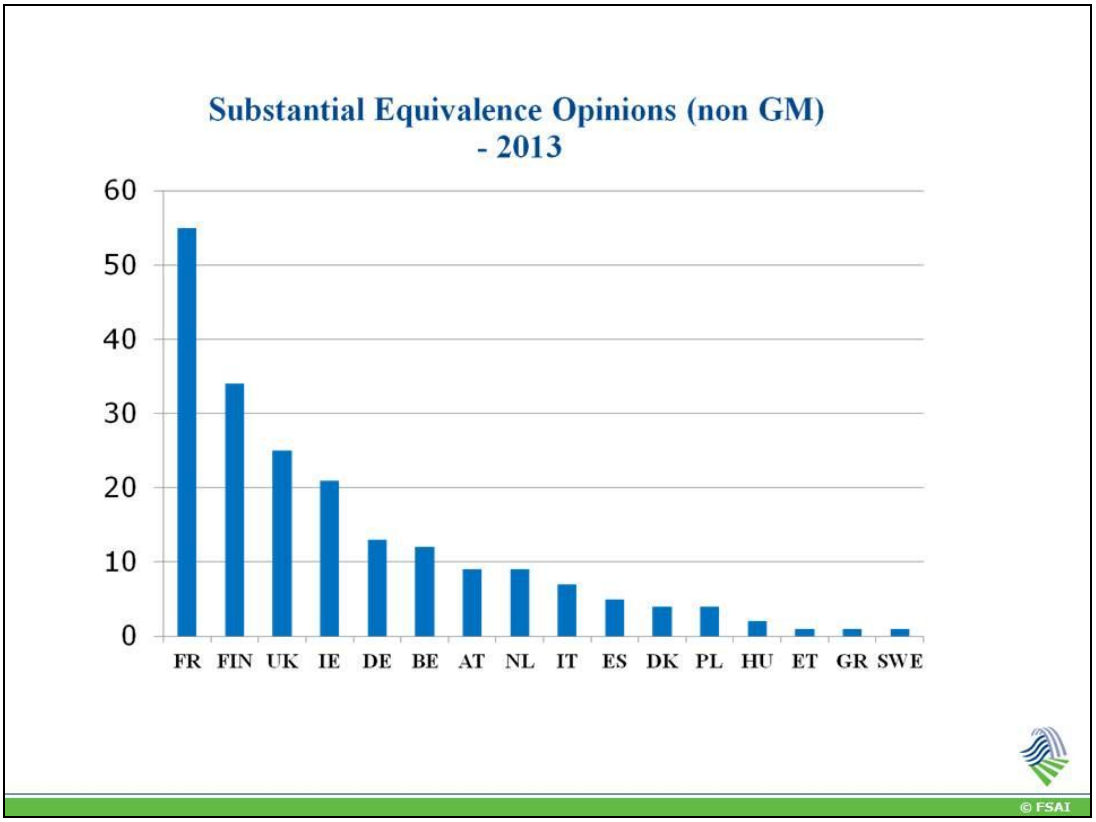
Substantial Equivalence Opinions (non GM) - 2013
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Issues with Proposed Legislation
Parliament Impact Assessment

1) Scope & Definition of novel foods

- *Categories (Cloning/Nanotechnology) (Recommendation 97/618)*
- *Food supplements/Challenge existing foods as novel/Novel ingredients illegally on the market*
- *NF as a marketing tool*
- *Guidance essential to be able to decide whether a food is novel or not*

Issues
Parliament Impact Assessment

2) Interaction with other legislation

- *Multiple authorisations (Dir 2002/46/EC, Reg EC No 1925/2006 etc)*
- *Medicines legislation*

Issues
Parliament Impact Assessment

4) Generic authorisation

- *Substantial equivalence opinions*
- *Data protection/innovation incentive*

Issues
Parliament Impact Assessment

5) Traditional foods from third countries

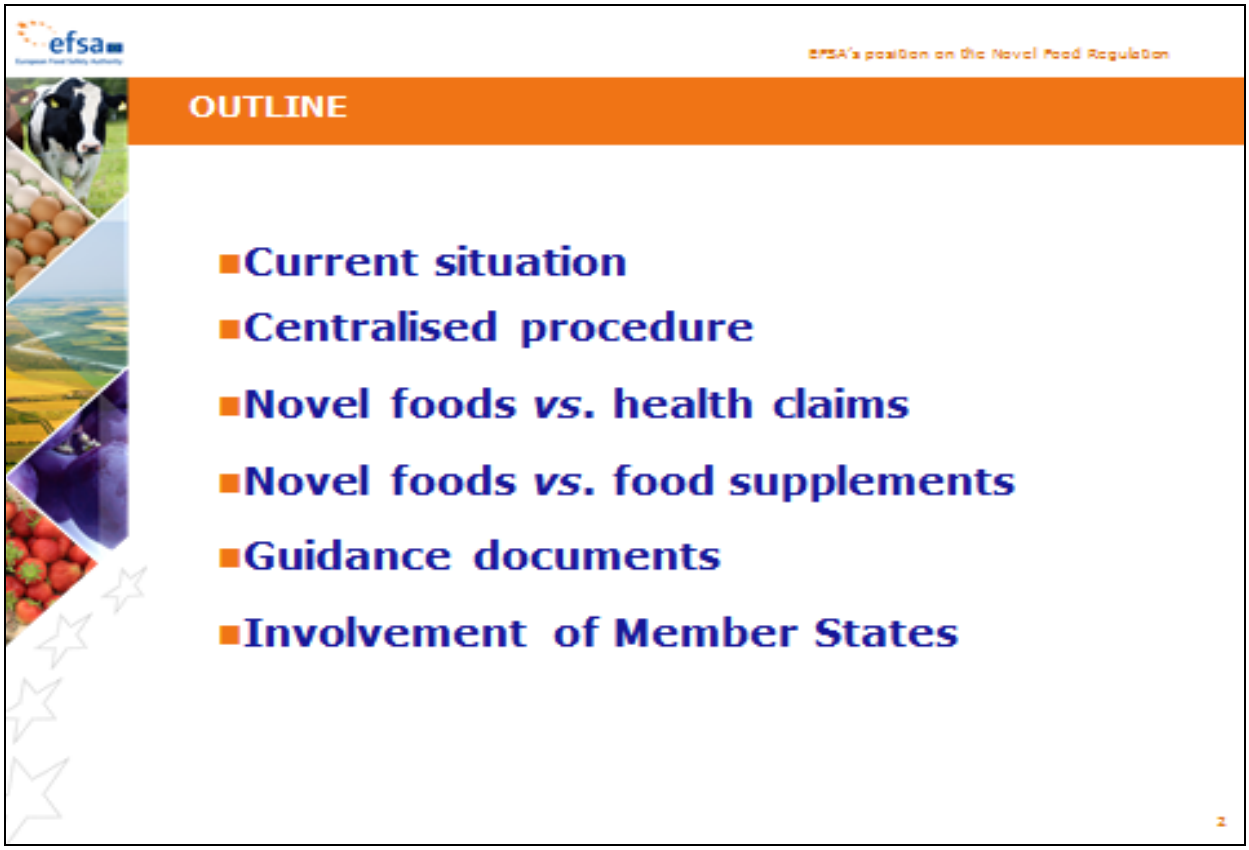
- *Proportionate*
- *"Reasoned safety objections"*
- *Data protection/innovation incentive*

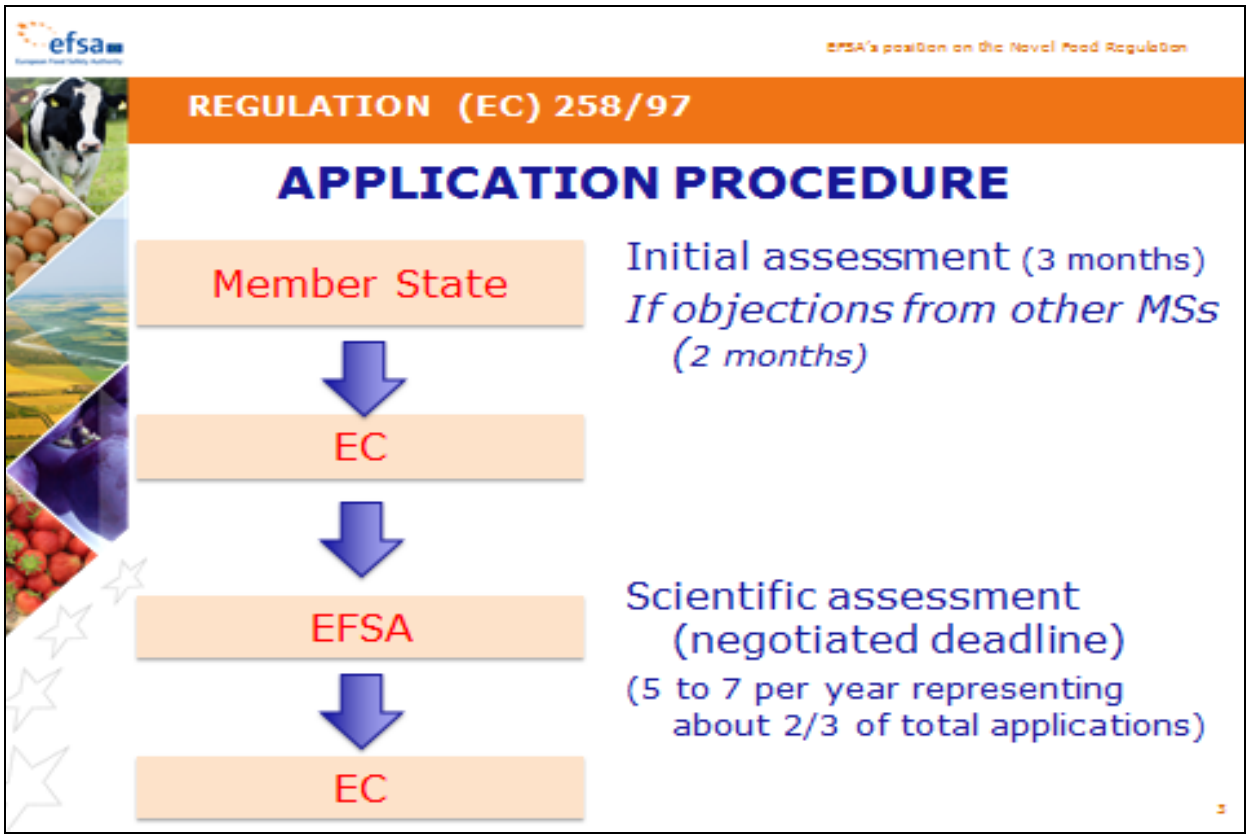
Conclusion

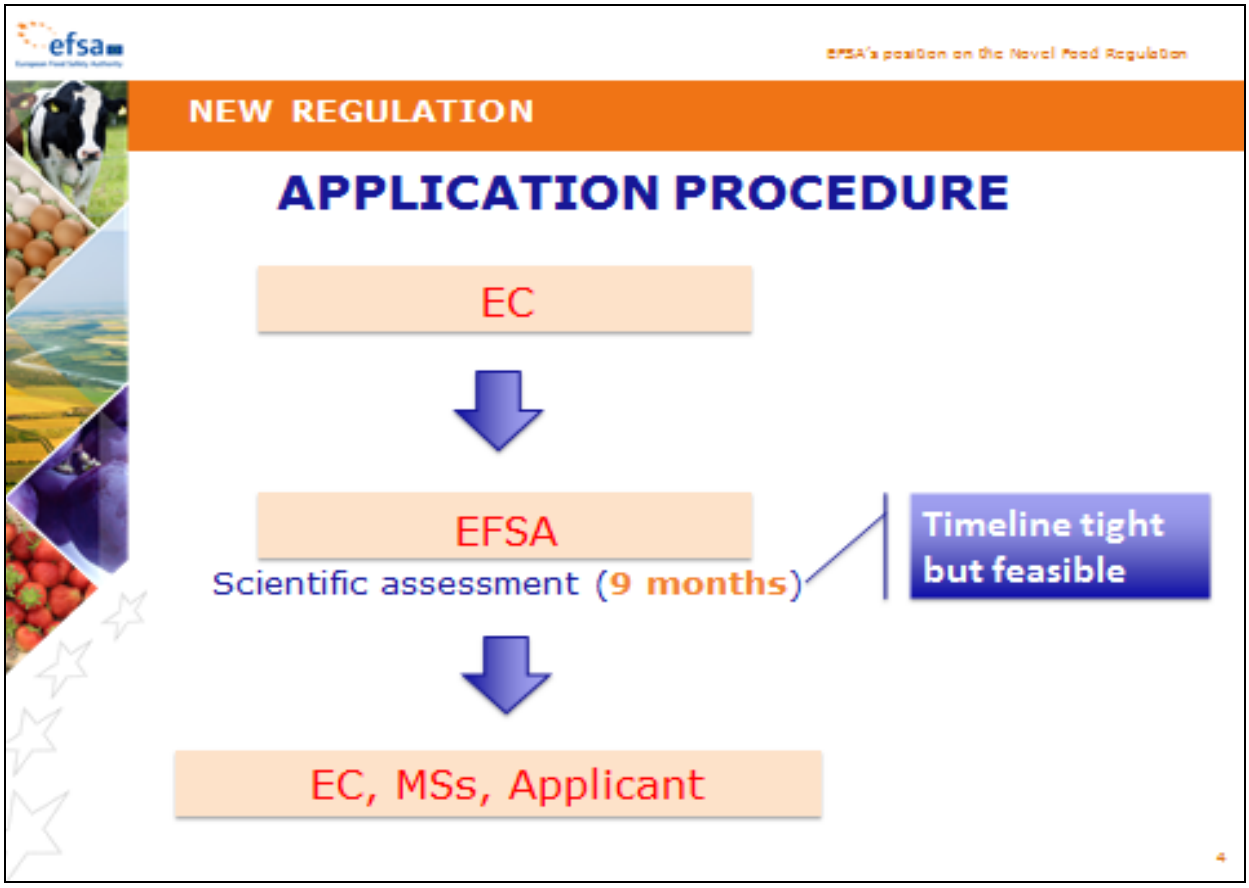
What is Required?

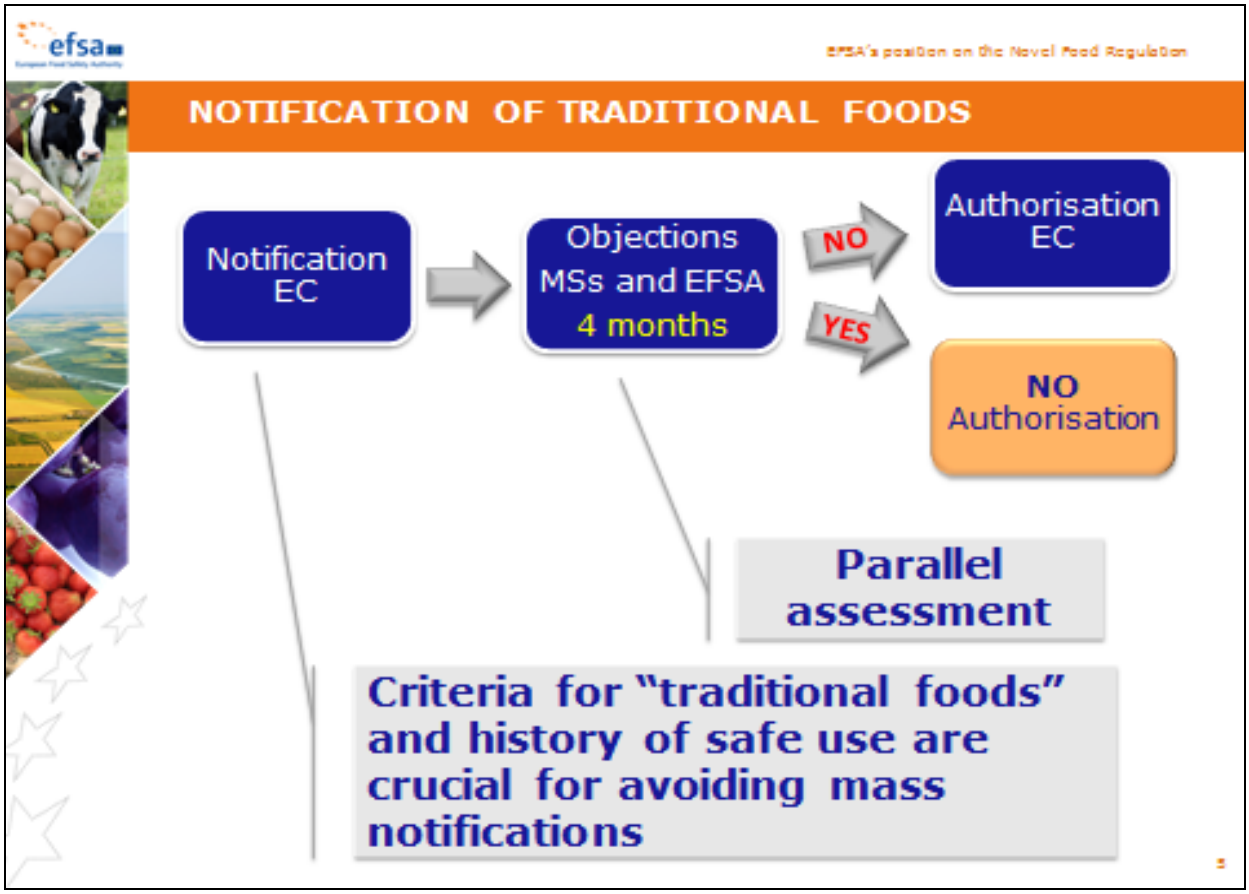
1. Streamlined Novel Food legislation
2. NF Working Group/Strong Commission leadership
3. Adequate guidance for all stakeholders
4. Good science and pragmatism (*Reasoned safety objections*)
5. Ability to adapt to new challenges

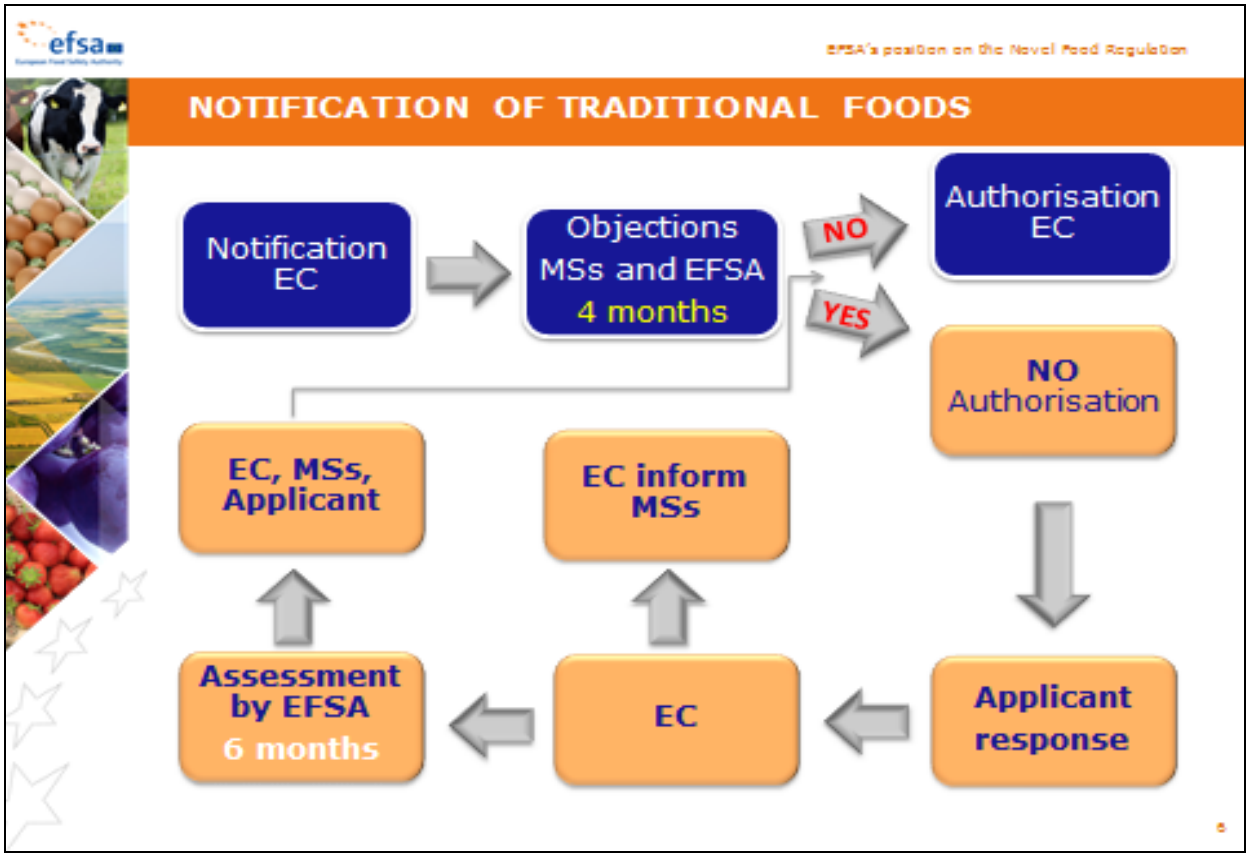
Part 1: EFSA's position on the Novel Food Regulation
Presentation by Valeriu Curtui


efsa
EFSA's position on the Novel Food Regulation
OUTLINE
Current situation
Centralised procedure
Novel foods vs. health claims
Novel foods vs. food supplements
Guidance documents
Involvement of Member States
2


efsa
EFSA's position on the Novel Food Regulation
REGULATION (EC) 258/97
APPLICATION PROCEDURE
Member State
EC
EFSA
EC
Initial assessment (3 months)
If objections from other MSs
(2 months)
Scientific assessment
(negotiated deadline)
(5 to 7 per year representing
about 2/3 of total applications)
3


efsa
EFSA's position on the Novel Food Regulation
NEW REGULATION
APPLICATION PROCEDURE
EC
EFSA
Scientific assessment (9 months)
Timeline tight but feasible
EC, MSs, Applicant
4


efsa
EFSA's position on the Novel Food Regulation
NOTIFICATION OF TRADITIONAL FOODS
Notification EC
Objections MSs and EFSA 4 months
NO
YES
Authorisation EC
NO Authorisation
Parallel assessment
Criteria for "traditional foods" and history of safe use are crucial for avoiding mass notifications
5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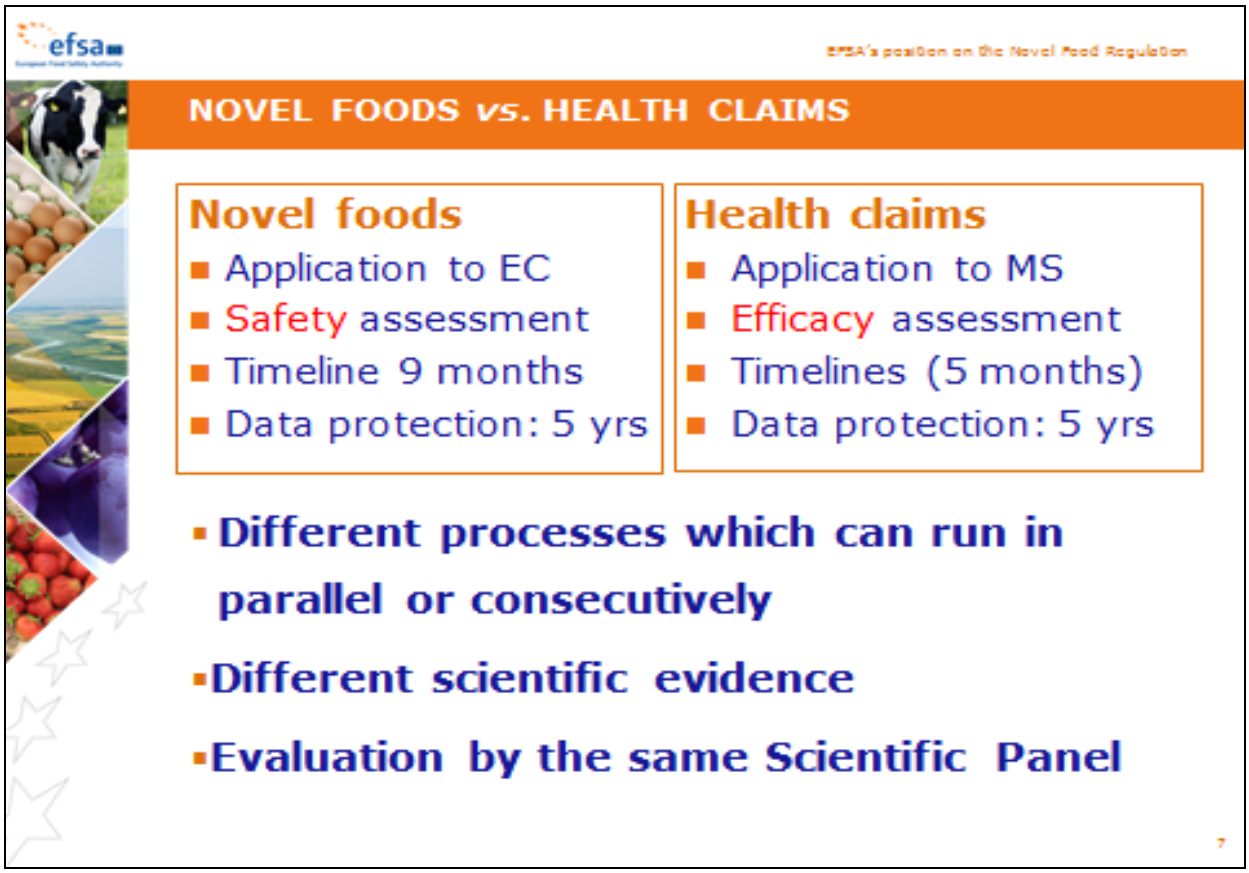
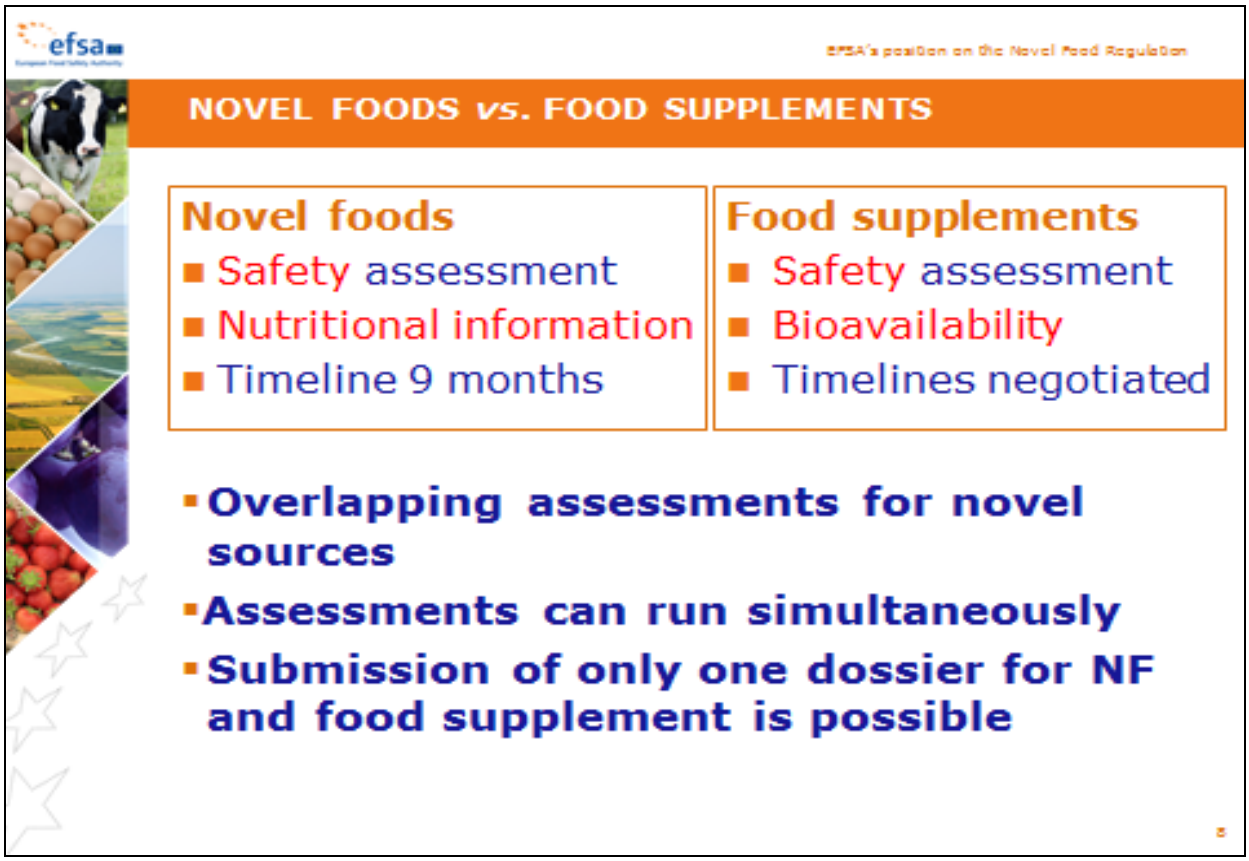
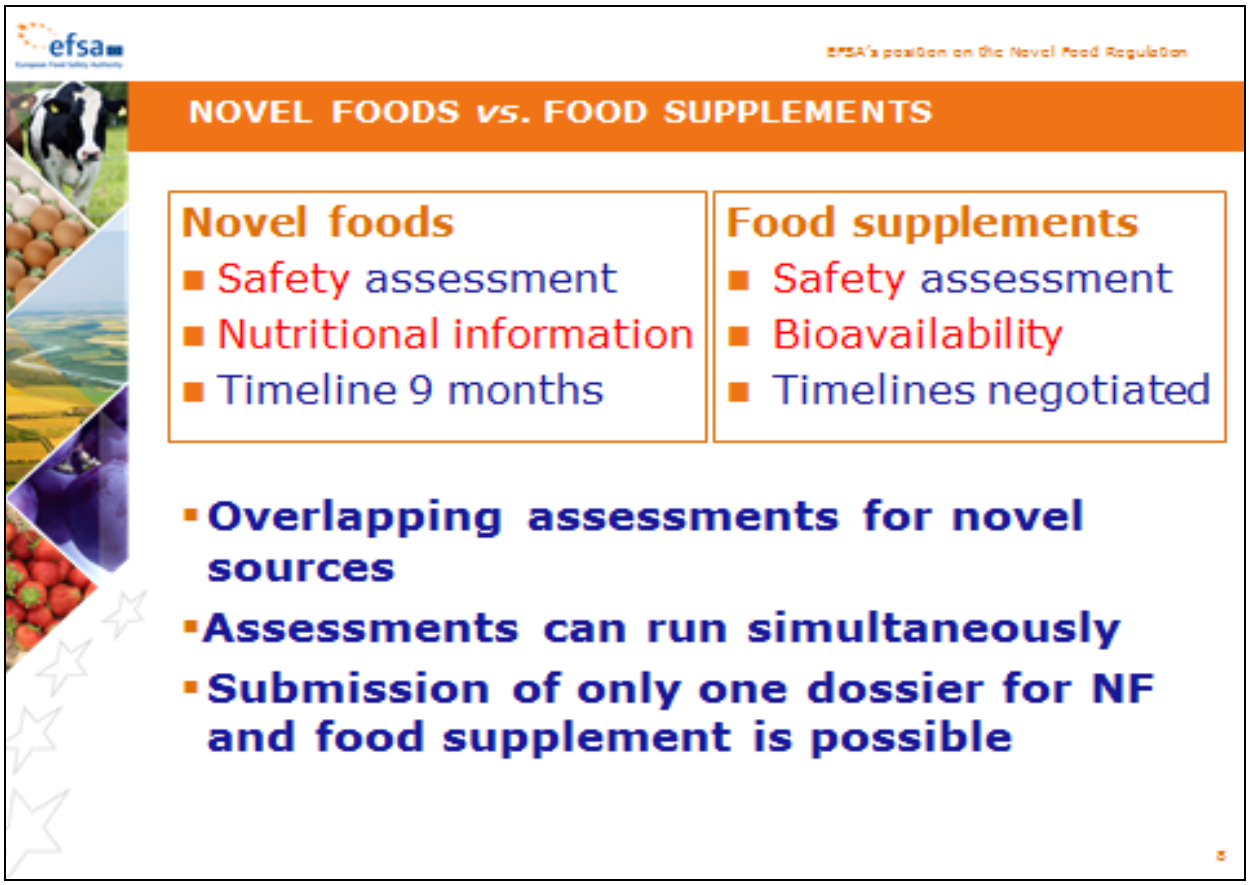
EFSA's position on the Novel Food Regulation
NOTIFICATION OF TRADITIONAL FOODS
Notification EC
Objections MSs and EFSA 4 months
NO
YES
Authorisation EC
NO Authorisation
EC, MSs, Applicant
EC inform MSs
Assessment by EFSA 6 months
EC
Applicant response
6


efsa
EFSA's position on the Novel Food Regulation
NOVEL FOODS vs. HEALTH CLAIMS
Novel foods
Application to EC
Safety assessment
Timeline 9 months
Data protection: 5 yrs
Health claims
Application to MS
Efficacy assessment
Timelines (5 months)
Data protection: 5 yrs
Different processes which can run in parallel or consecutively
Different scientific evidence
Evaluation by the same Scientific Panel
7


efsa
EFSA's position on the Novel Food Regulation
NOVEL FOODS vs. FOOD SUPPLEMENTS
Novel foods
Safety assessment
Nutritional information
Timeline 9 months
Food supplements
Safety assessment
Bioavailability
Timelines negotiated
Overlapping assessments for novel sources
Assessments can run simultaneously
Submission of only one dossier for NF and food supplement is possible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Safety assessment
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Timeline 9 months
Food supplements
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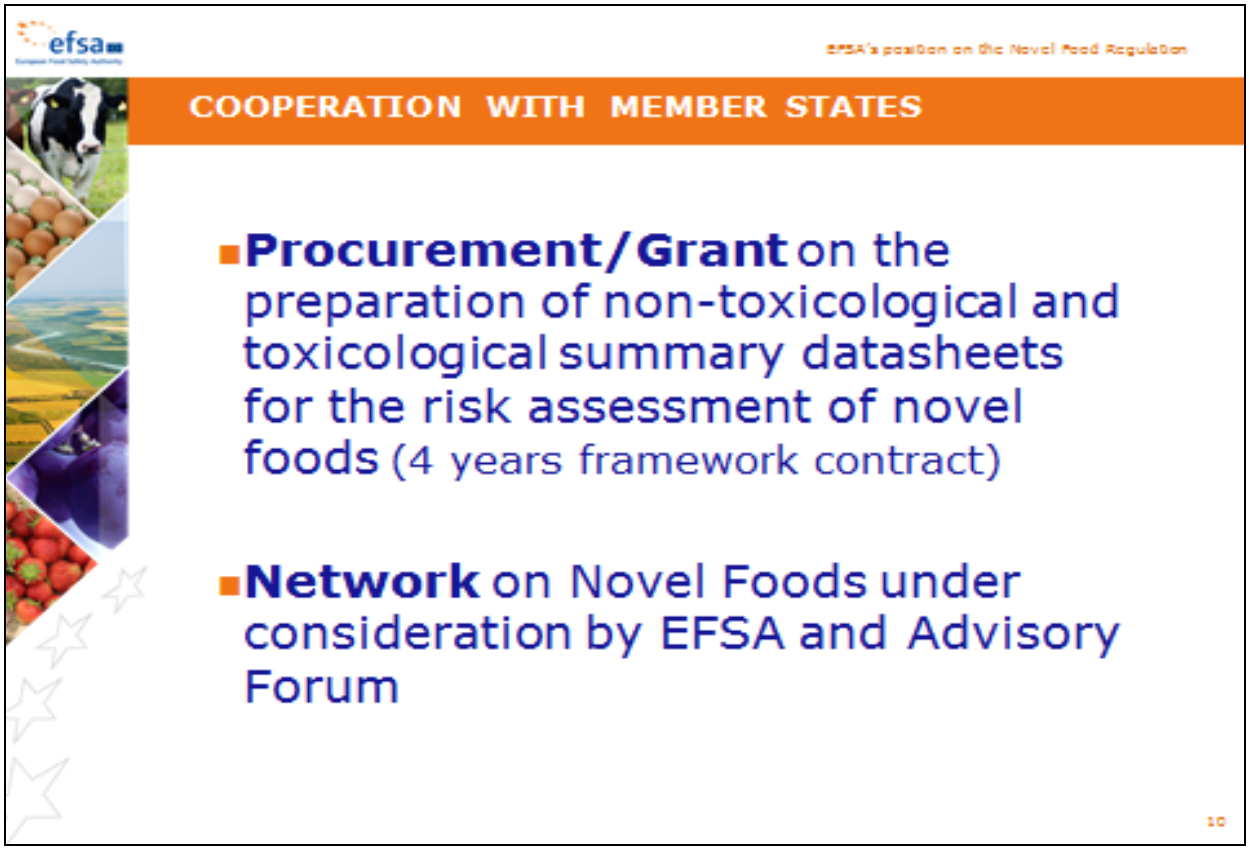
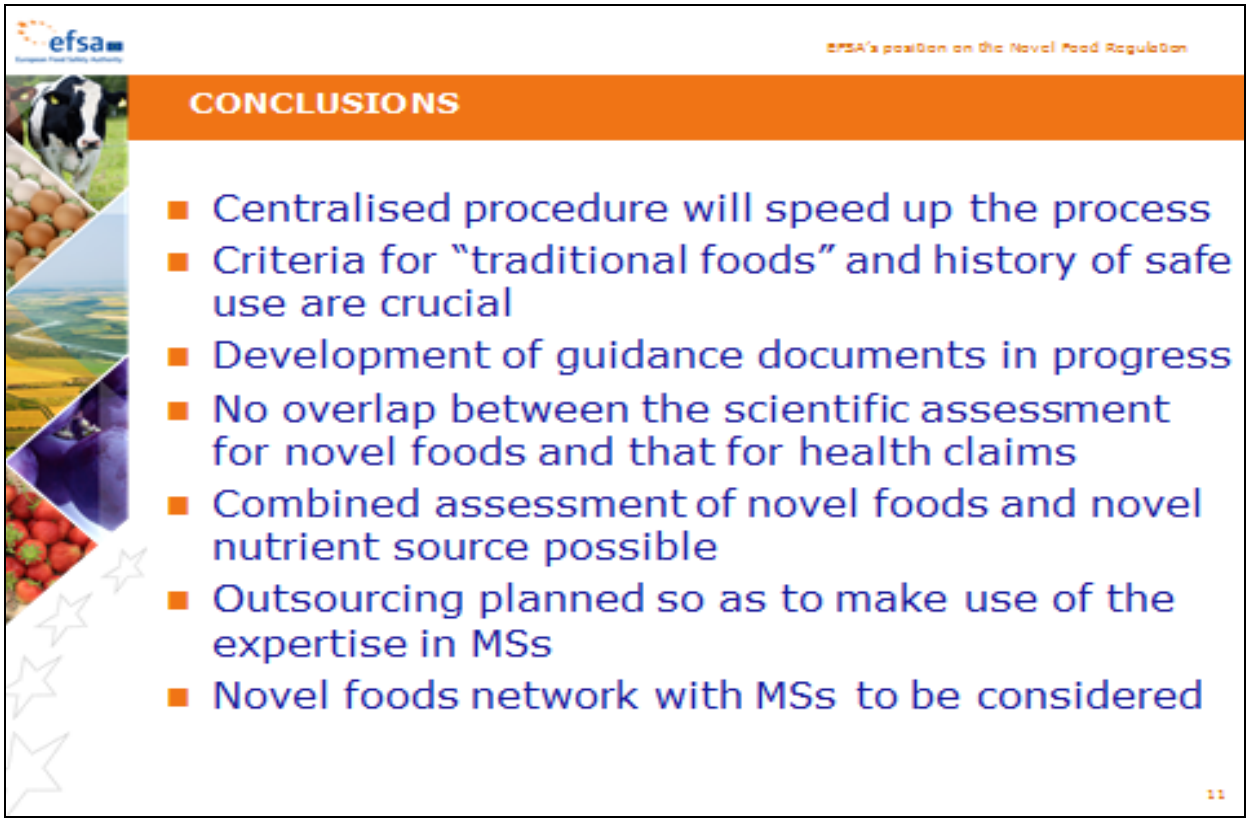
Bioavailability
Timelines negotiated
Overlapping assessments for novel sources
Assessments can run simultaneously
Submission of only one dossier for NF and food supplement is possible


efsa
EFSA's position on the Novel Food Regulation
COOPERATION WITH MEMBER STATES
Procurement/Grant on the preparation of non-toxicological and toxicological summary datasheets for the risk assessment of novel foods (4 years framework contract)
Network on Novel Foods under consideration by EFSA and Advisory Forum
10


efsa
EFSA's position on the Novel Food Regulation
CONCLUSIONS
Centralised procedure will speed up the process
Criteria for "traditional foods" and history of safe use are crucial
Development of guidance documents in progress
No overlap between the scientific assessment for novel foods and that for health claims
Combined assessment of novel foods and novel nutrient source possible
Outsourcing planned so as to make use of the expertise in MSs
Novel foods network with MSs to be considered
11

Part 2: Potential impact of the 2013 Regulation on innovation in the food sector Presentation by Patrick Coppens

EAS | Strategic advice

Potential impact of 2013 Regulation on innovation in the food sector

European Parliament
Workshop on Novel Foods

Patrick Coppens
Director International Food and Health Law and Scientific Affairs
patrickcoppens@eas.eu

EAS Strategic Advice Europe - Rue de l'Association 50 - 1000 Brussels - Belgium
Tel: (+32 2) 218 14 70 - Fax: (+32 2) 219 73 42 - Email: info@eas.eu - www.eas.eu

Novel Foods Proposal COM(2013) 894 final

AIMS

Ensure Food Safety	Protect Public Health	Secure the Internal Market	Supporting innovation

Pursues the objectives of the Communication on Smart Regulation

- Simplifying EU legislation and reducing administrative burdens
- Making legislation clearer and more accessible

Pursues the objectives of the Europe 2020 Strategy

- Developing an economy based on knowledge and innovation

European Parliament Workshop on Novel Foods – Brussels – 7 October 2014

Novel Food Proposal ➡ Key for innovation into new food and technologies

WILL PROMOTE INNOVATION IF

- Clear definition of the scope
- Quick and efficient procedure
- Binding decisions, implemented in the same way in all Member States
- Sufficient protection of investments while balancing the fact that companies that cannot invest still have the potential to innovate
- Avoid duplication of procedures

European Parliament Workshop on Novel Foods – Brussels – 7 October 2014

Current Definition	**New Definition**
Food not used before 1997 AND belonging to 4 specific categories	All food not used before 1997
–Covers only specific food groups –Focuses on specific risks –17 years experience with the scope	–Date is the only criterion –Covers all new foods –Applies retroactively since 1997

IMPACT IF NOT CORRECTED

On innovation: Huge

Economic burden: Huge

Administrative burden: Huge

Added value for safety: Minimal

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Difficulties of demonstrating significant use before 1997

- Before the electronic age
  - Documents only available on paper
- Proof of sales often not available any more
  - Longer back than the period required for keeping financial records
  - Mergers/acquisitions/changes of locations
- Sales documents mostly do not give the necessary information
  - Intended use
  - Product composition

Major hurdle for product innovation

- Particularly problematic if the definition is extended to cover products lawfully marketed since 1997
  - As such proof would not be available per definition

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If the date of 15 May 1997 is maintained

- The original categories should be reinserted unchanged

Discussions in Council

EP Amendments

- If changed or new categories are included these should be
  - Well defined
  - Justified from a safety perspective
  - Assessed on impact
  - Enter into force with the new regulation

Safety of products already on the market can be assessed by applying Article 8 of Regulation 1925/2006

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Aims of the centralised procedure

Reduce administrative burden by removing the national assessment part ✓

Reduce the length and cost of the authorisation procedure
- 18 months instead of 3 years in average now

?

Generic authorisation to avoid the resubmission of new applications
- Expected to benefit in particular SMEs.

✓

Data protection to maintain an incentive for developing really innovative food products ✓

Facilitate EU market access for traditional foods from third countries by setting up a simplified and more proportionate procedure ?

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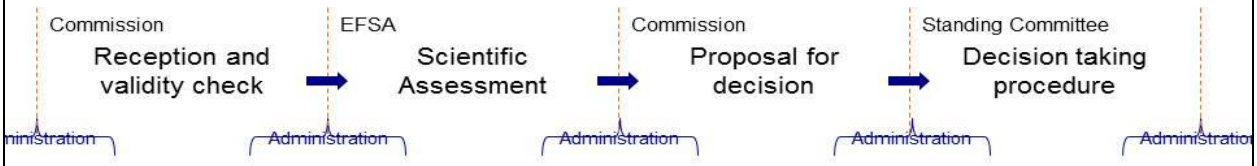
AIM: 18 months instead of 3 years in average now

4-step procedure



CURRENT

36 months

PROPOSED

Commission	EFSA	Commission	Standing Committee
No deadline	9 months With possibility to extend	9 months With possibility to extend	No deadline

34 months

REQUIRED

Commission	EFSA	Commission	Standing Committee
2 months	6 months With possibility to extend	3 months With possibility to extend	6 months

17 months

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Further possibilities for improvements to promote innovation

- Uniform implementation of a decision for legal certainty
  - No possibility to consider approved novel foods as medicinal products on national level (Recital 14), when used under the approved conditions of use.
- Appropriate incentive for innovation
  - Is 5 years proprietary data protection sufficient?
  - Should published data not also be protected
- Duplicate procedures can be avoided
  - Only one procedure for approval of vitamin/mineral sources: Automatic inclusion in the lists after Novel Food approval
  - Parallel assessment of claims applications
- Notification of traditional foods from third countries
  - Automatic inclusion in the list, when no reasoned objections

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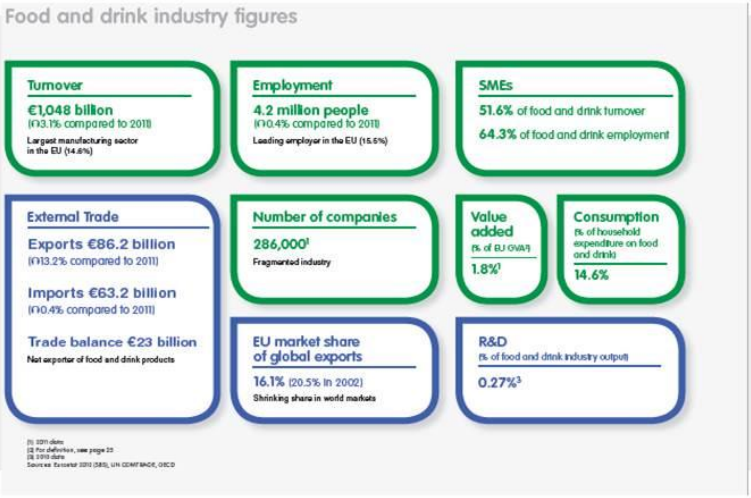
Part 2: The importance of the novel foods market in the EU – industry perspective
Presentation by Marta Baffigo

Novel Food Hearing 3

Food and drink industry figures 2013/2014



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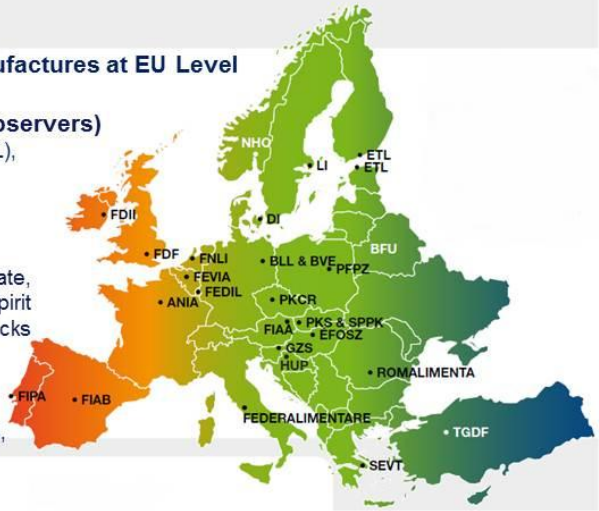
FOODDRINK EUROPE

Novel Food Hearing 4

Who we are

Role: Represent the food and drink manufactures at EU Level

- **National federations (25, including 2 observers)**
  E.g.: FDF (UK), ANIA (FR), BLL (DE), PFPZ (PL), FederAlimentare (IT), FIAB (SP), etc.
  Observers: Turkey (TGDF), Norway (NHO),)
- **European sector associations (25)**
  E.g.: Breakfast cereals (CEEREAL), Chocolate, Biscuits and Confectionary (CAOBISCO), Spirit drinks (CEPS), Diary products (EDA), Snacks (ESA), Soft drinks (UNESDA), etc.
- **Major food and drink companies (17)**
  E.g.: Coca-Cola, Cargill, Danone, Kellogg, Mars, Nestlé, PepsiCo, Ülker, Unilever, etc.



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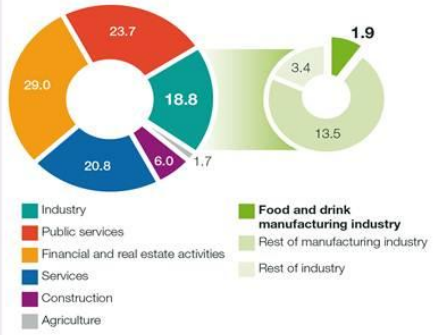
FOODDRINK EUROPE

Novel Food Hearing 5

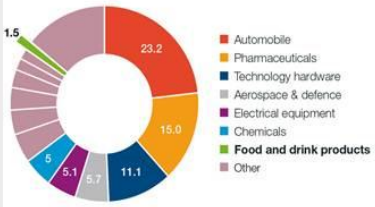
The Food Industry – Important Figures

Contribution of the EU food and drink industry to the EU economy (% of gross value added)[1]



Source: Eurostat 2010 (SBS)
(1) For definition, see page 25

R&D private investment in the EU manufacturing sector for the EU's top 1,000 companies, 2011 (%)



Source: 2012 EU Industrial R&D Investment Scoreboard, JRC and DG RTD

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Novel Food Hearing 6

Business Decisions to Innovate

- To justify research and development costs associated with new products, companies typically target a rate of return of 20 to 25% over the lifetime of the product
- A delay in approval of 30 months or longer can reduce this return by at least 30% or an average of 4 million euros per product. With delays now the norm, the attractiveness of investment in Europe is low

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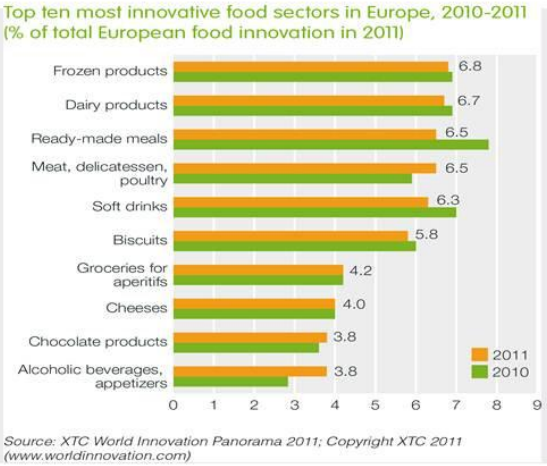
Novel Food Hearing 7

Top 10 Most Innovative Food Sectors in Europe



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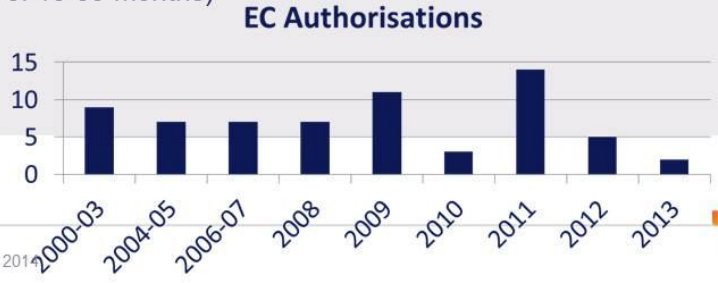
Novel Food Hearing 8

Novel Foods in Europe: status January 2014

- Status of novel food approvals, excluding withdrawn applications and GMO applications status September 2014, including foods that may be placed on the market in the EU pursuant to Regulation (EC) No. 258/97 Article 4.2 first indent
  - 77 authorisations,
  - 3 rejections
  - 2 - 9 applications per year
  - Average time for approval process to be completed: 35 months (range of 16-60 months)



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Novel Food Hearing 9

Industry Reaction on the Novel Food Proposal

- Horizon 2020, the EU Framework Programme for Research and Innovation, shows that investment in R&D is essential to increase competitiveness in Europe and can be part of the solution to exit from the economic crisis
- Innovation is invaluable to ensuring that Europe's food and drink industry will continue to provide consumers with safe, sustainable and affordable products.
- This revised Novel Foods Regulation can and should stimulate innovation in the food and drink industry by simplifying and streamlining the current regulatory framework and facilitating market access for novel foods
- In particular, FoodDrinkEurope hopes that this proposal will take into consideration key elements such as:
  - Legitimate expectations regarding stability and clarity of the scope
  - Reduction of administrative burden (including reduced timelines for novel food approvals);
  - Data protection; and,
  - Conclusion of pending dossiers.

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Novel Food Hearing 10

Does the proposed Novel food legislation respond to these expectations?

- This proposal is a major step forward as compared to the draft issued in 2010/2011
- Important amendments brought forward by the European Parliament in 2011 were introduced, for example the split between novel food and a separate legislation on cloning

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Novel Food Hearing 11

Clarification of the scope and definitions

- The Novel Foods Regulation was never intended to cover all **"new"** foods and food ingredients but only **"novel"** foods that fell within the specific categories
  - 150 applications over 15 years.
  - It did not cover foods manufactured from traditional raw materials, using conventional production technologies used in the food area and foods formulated with non-novel ingredients
- The removal of the categories would extend the scope, to include also products that have been legally marketed since 15 May 1997 since this date remains the only criterion.
- Therefore the re-introduction of a category based approach is essential to provide legal certainty.

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Novel Food Hearing 12

Centralised procedure

- A shorter and more efficient procedure is one of the key objectives on this revision.
- Deadlines for all steps in this process to ensure that this objective is met are needed.
- The current proposal foresees 9 months for EFSA and the Commission to come to their opinions and proposals, and the committee procedure not having any time limitation at all,
  - Thus authorization procedures will last 2-3 years and thereby just as long as they last now
- FoodDrinkEurope proposes
  - Six months for EFSA,
  - 3 months for the Commission and
  - limitation of the discussion in the committee

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Novel Food Hearing 13

Proprietary data protection

- Fundamental change from applicant-linked authorizations to generic authorizations needs to be accompanied by practical data protection provisions to preserve incentives for companies to invest in developments. Otherwise innovation will come to a full stop.
- The data protection provision in the Claims Regulation shows that limiting those to non-published data is not working and goes against the practicalities of undermines transparency and good scientific practice. Therefore this section needs redrafting. A pragmatic solution would be to replace it by the demonstration of the ownership of the data and/or to extend the protection period to 10 years.

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Novel Food Hearing 14

Authorisation of vitamin and mineral substances and engineered nano-materials

- New vitamin and mineral sources and engineered nano-materials need novel foods approval and an additional legislative decision to include them in the lists established under Directive 2002/46/EC, Regulation (EC) No 1925/2006 and Regulation (EU) No 609/2013.
- However, there is no need for separate categories for these products as they are covered by the categories that there are, and also, by receiving authorization via the novel foods regulation, the substances should automatically be introduced in the respective lists in the other pieces of legislation as above

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Novel Food Hearing 15

Is there still room for improvement? – Yes there is!

- Clarification of the scope
- Reintroduction of food categories
- Reassurance that approval procedures will be quicker
  - Clarity on data provisions as part of the dossier to prevent "stop the clock" effects delaying the procedure
- Need for data protection for companies having invested in innovation for a certain period of time
- Overlap with existing legislation – need to prevent duplication of efforts - industry favours a **one key one door** approach

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Novel Food Hearing 16

Conclusions

- Growth and jobs increasingly coming from innovation breakthroughs should stay Europe's strength in the world's economy

- We encourage members of the European Parliament to support a Novel Food legislation which motivates enterprises, both large companies and/or SMEs, to invest in R&D to provide European consumers with food that respond to their desires and needs

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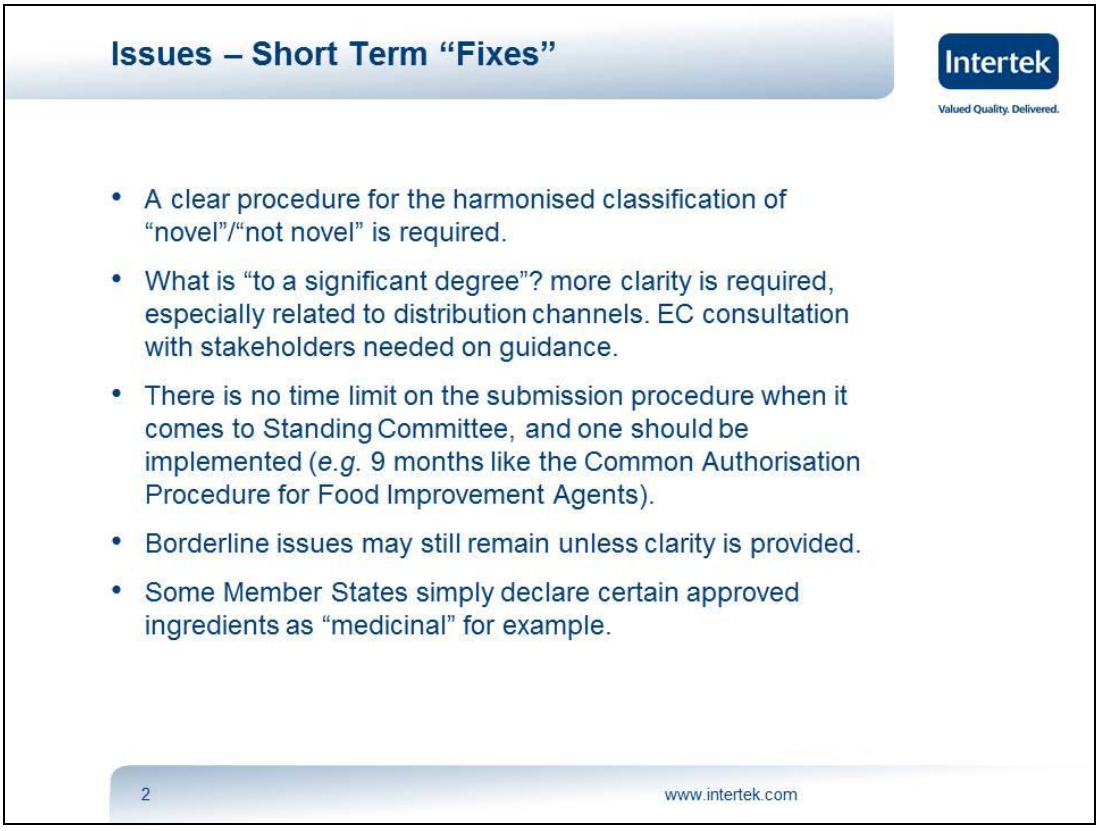
Part 2: Does the draft regulation solve existing problems
Presentation by Nigel Baldwin



Issues – Longer Term "Solutions"

Intertek
Valued Quality. Delivered.

- EU food ingredient approval legislation is not coordinated
- Approval procedures are not harmonised
- Legislative procedures are different
  - Different types of comitology (implementing acts, delegated acts, regulatory procedure with scrutiny)
    - Differing union lists

The Commission has worked hard to sort out Food Improvement Agents

Now it needs to sort out Food Nutritional Agents:

- Vitamins and minerals
- "Other ingredients"

Ingredients Added to Food

Intertek
Valued Quality. Delivered.

Food Improvement Agents - Technological

- Additives (1333/2008)
- Enzymes (1332/2008)
- Flavourings (1334/2008)

Extraction Solvents (2009/32/EC) - Technological

Novel Foods – Nutritional

Vitamins and Minerals – Nutritional

- Food Supplements (200/46)
- Addition of vitamins, minerals and certain other substances to food (1925/2006)
- PARNUTS/Foods for Specific Groups (2009/39/ 609/2003)

Approval of New Food Improvement Aids

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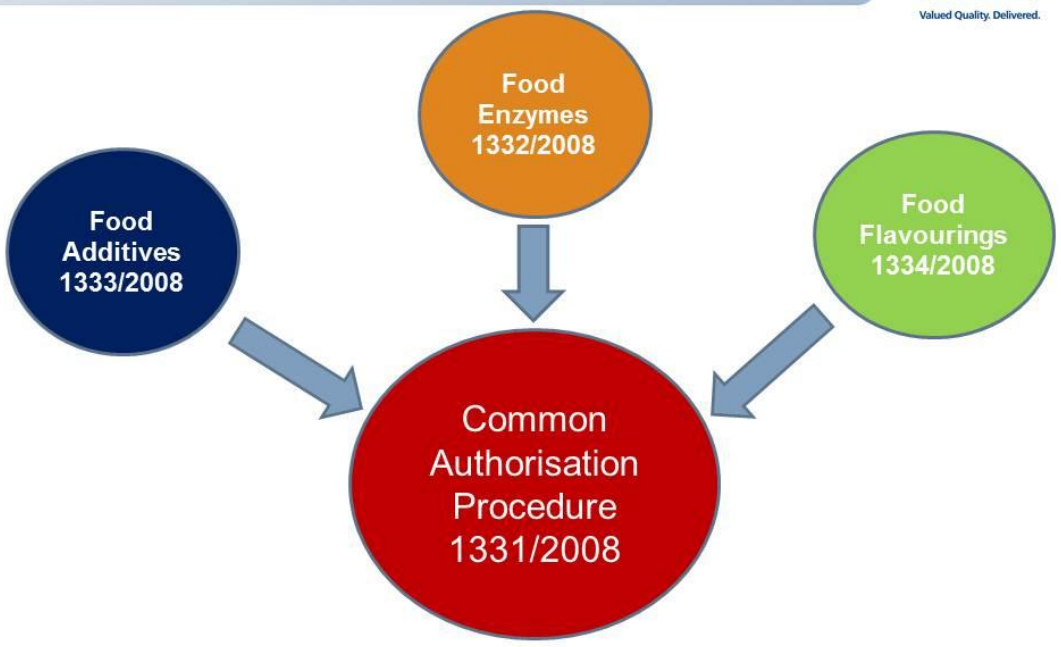

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New Vitamins and Minerals

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- All are now novel food ingredients also, so 2 procedures currently apply:
  - 1) Get approved as a novel food
  - 2) Only then can you be approved for use in specific categories of food (food supplements, fortified foods, PARNUTS/FSG)
- 2 sets of guidance
- Does the new proposal help by specifically including them in scope?

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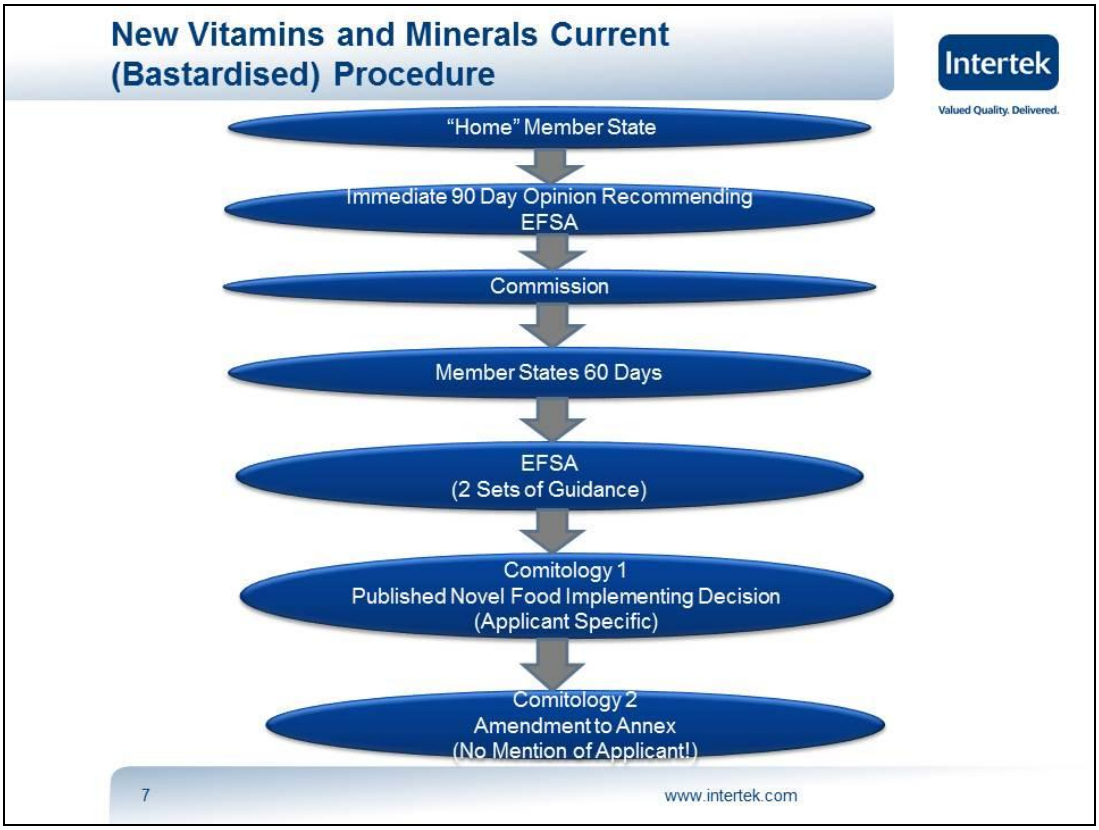
New Vitamins and Minerals Current (Bastardised) Procedure
Intertek
Valued Quality. Delivered.
"Home" Member State
Immediate 90 Day Opinion Recommending EFSA
Commission
Member States 60 Days
EFSA
(2 Sets of Guidance)
Comitology 1
Published Novel Food Implementing Decision
(Applicant Specific)
Comitology 2
Amendment to Annex
(No Mention of Applicant!)
7
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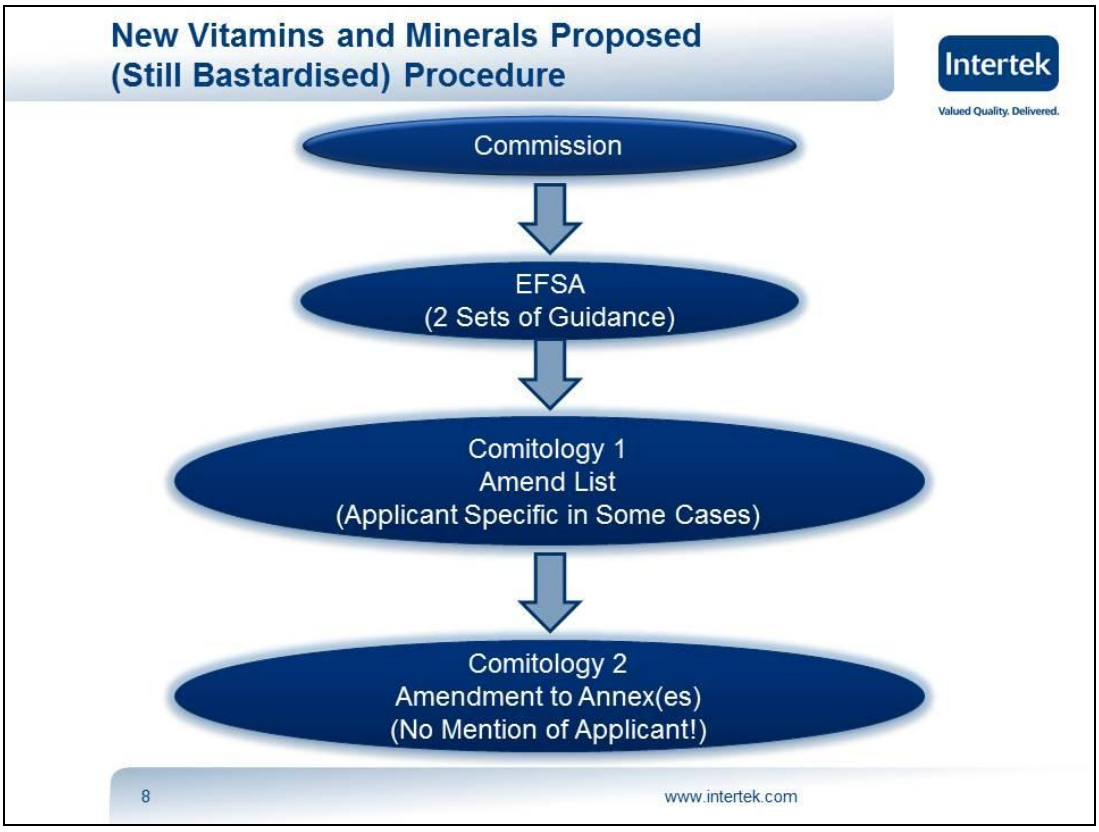
New Vitamins and Minerals Proposed (Still Bastardised) Procedure
Intertek
Valued Quality. Delivered.
Commission
EFSA
(2 Sets of Guidance)
Comitology 1
Amend List
(Applicant Specific in Some Cases)
Comitology 2
Amendment to Annex(es)
(No Mention of Applicant!)
8
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New Vitamins and Minerals

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- Still 2 sets of guidance
- Still 2 different sets of comitology in sequence
- Can add at least 6 months of administrative delay
- Currently no cross reference to the new Annex entry to cross refer to novel food approval and specification
  - Novel Food approvals are applicant specific (and some still will be)
  - Annex entries for vitamin and minerals are generic.
- Problems are not solved

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Proposal

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- Take vitamins and minerals out of scope of novel foods to avoid duplicate and inefficient regulation.
- Make Food Supplements, Fortified Foods and PARNUTS/FSG refer to Common Authorisation Procedure.
- Allow parallel comitology.
- Harmonise guidance as far as possible (specifications, production method, toxicology, *etc.*).
- Of course this will require significant amendments to other legislation to align procedures, but it has been shown to be achievable for Food Improvement Agents.
- Excessive complexity of different approval procedures is totally unnecessary.
- REFIT should focus on fixing flaws in existing system.

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Proposal

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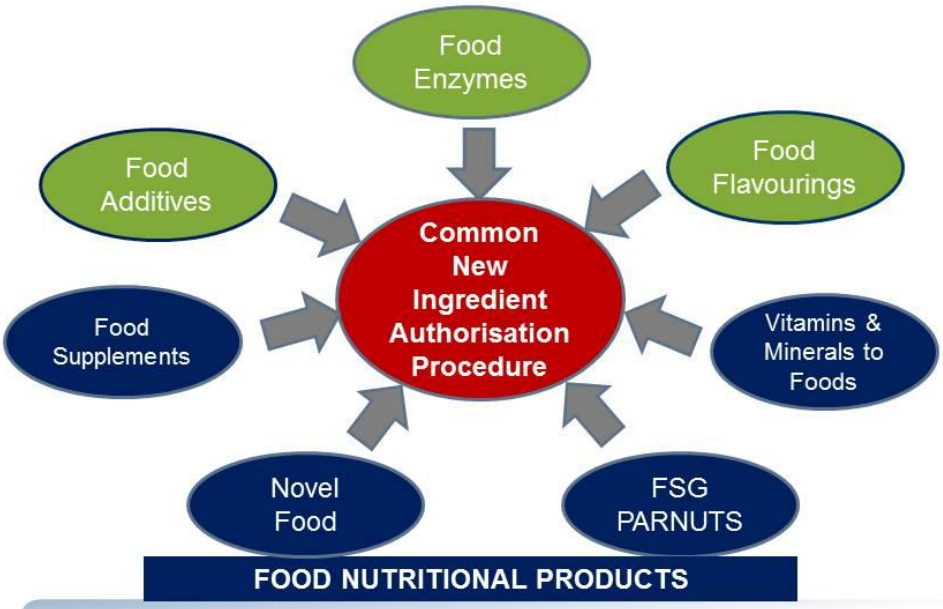

Other Issues

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- Enzymes used to make additives and flavourings do not need a separate enzymes approval (because they are assessed by EFSA during the review), but novel foods do.
- Extraction solvents used to make additives and flavourings do not need a separate extraction solvents approval (because they are assessed anyway by EFSA during the review), but novel foods do.
- These regulations should be amended to also exclude novel foods to avoid:
  - Duplicate regulation
  - Duplicate (and unnecessary) animal testing


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Part 2: The EU consumer perspective on novel foods
Presentation by Camille Perrin

BEUC in a nutshell

- The European Consumer Organisation.
- Umbrella organisation for 40 strong national consumer organisations, from 31 European countries.
- Mission = to promote consumer interests in EU decision making.
- Among our work priorities: "**Safe and healthy food for informed consumers**".

Consumers and novel foods

- Dual consumer attitude: novelty/innovation is attractive …. BUT
  - *Is it safe to eat?*
  - *How was it produced?*
  - *What are the benefits?*
- Looking at the market: a few examples

D - Tagatose | Noni juice | Phytosterol esters

- Robust legal framework needed for novel foods approval:

safety + consumer benefits + social/ethical/environmental concerns

→ Consumer trust and acceptance is key to successful food innovation!

Novel food – Scope and definition

- Legal certainty is in interest of consumers and businesses alike.
- Novel food definition must be broad enough to **capture all relevant products** and ensure **high level of consumer protection** while at the same time **not creating loopholes**.
- "*15 May 1997*" to be retained as the cut-off date for novel food status determination.
- Definition should be clarified by reintroducing the **novel food categories** while keeping the list **open** in order to keep pace with scientific progress and new products development.
- Foods for which "*production process gives rise to significant changes*" in composition/structure: can only be determined ***after*** full risk assessment.
- "*not used for human consumption to a significant degree*": current wording leaves room for interpretation and should be clarified.

A centralised and transparent safety risk assessment

- Centralised EU-level risk assessment by EFSA is welcomed. But European Commission ***may*** request EFSA advice: criteria?
- Data requirements for evaluation by EFSA need to be **clearly defined** (guidance).
- Any novel characteristic that may have an impact on health should be assessed **on an individual basis** (e.g. "*substantial equivalence*" concept not appropriate for food derived from nanotechnologies).
- Need to strike the right balance between the confidential treatment of certain proprietary data and the availability to the public of the toxicological data used for the safety evaluation.
- **Post-market monitoring** (e.g. phytosterols and recent Anses opinion).

Conditions of approval of novel foods

- **Precautionary principle** must be applied.
- Elements to be considered for novel food approval:
  - Safety risk (taking account of vulnerable consumers or particular groups of consumers);
  - Potential to mislead consumers;
  - Should offer **advantages/benefits** to the consumer;
  - "**Other legitimate factors**" such as social and ethical concerns, including any relevant opinions from the European Group on Ethics in Science and New Technologies.
- **Labelling** to allow for informed choices:
  - Characteristics: composition, nutritional value, intended use;
  - Materials which may affect the **health** of some individuals;
  - Materials that give rise to **ethical concerns** (as in current Regulation (EC) No 258/97)

Traditional foods from third countries

- Simple notification procedure provides **insufficient safety guarantees**.
- "*History of safe use*": the fact that a product has been consumed for many years in a country **should not be assumed to mean it is safe** (e.g. if inadequate monitoring has failed to record any adverse effect).
- **Clear guidance and criteria** are needed as to the type of data and evidence that are necessary to demonstrate the history of safe use.
- "Other legitimate factors" (and corresponding labelling requirements, as appropriate) should also be considered for traditional foods regardless of any safety concerns being raised.

Nanotechnologies

- Cross-reference with definition of "*engineered nanomaterials*" in the Food Information Regulation (EU) No 1169/2011 raises concerns:
  - 50% nanoparticles threshold for a food ingredient to qualify as nano is **too high** and disregards EFSA's advice to the European Commission of a **10% threshold** in light of ongoing **uncertainty over nano safety**;
  - "*Intentionally manufactured*" defined as "*to perform/fulfil a specific function or purpose*" creates **legal uncertainty**:
    - offers a **lee-way to manufacturers** who could pretend their product fulfil the exact same function as its non-nano sized counterpart and therefore does not fall under the scope of "novel food";
    - Would place the burden of proof on control authorities.

Cloning

- It is vital that the **cloning and novel foods proposals progress in parallel**:
  - Risk of legislative gap regarding **food from cloned animals** (so far falling under the scope of novel foods);
  - A majority of Europeans strongly **disapprove of cloning for food production** (84% have concerns over long-term effect, 58% say it is totally unjustifiable) and want **food from the offspring of clones to be labelled** (83%)

Source: Flash Eurobarometer 238 published in October 2008. Europeans' attitudes towards animal cloning.

  - Need to address the crucial issue of food from cloned animals' **offspring and descendants.**

BEUC

Conclusions

- BEUC's recipe for successful food innovation:
  - **Robust and transparent** procedure for safety risk assessment;
  - Full consideration given to **consumer acceptability** of a new food product;
  - Clear **benefits** for consumers.

BEUC The European Consumer Organisation

The Consumer Voice in Europe

www.beuc.eu

Bureau Européen des Unions de Consommateurs AISBL | Der Europäische Verbraucherverband
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90

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