FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Novel Foods (Scotland) Regulations 2017

Date:	November 2017
Stage:	Final
Source of intervention:	EU
Type of measure:	Regulation
Contact for enquiries:	Georgina Finch 01224 288371 Georgina.Finch@fss.scot

1. **Title of Proposal**

1.1. The Novel Foods (Scotland) Regulations 2017

2. **Purpose and intended effects**

Objectives

2.1. The purpose of the proposed Novel Foods (Scotland) Regulations 2017 ("the proposed Regulations") is to:

- Ensure that those businesses placing novel foods on the market within the UK and wider European Union (EU) are fully compliant with the new legislative requirements. This supports consumers accessing safe food innovation and facilitates trade in new foods by UK businesses, whilst providing a high level of protection of human health and consumer interests;
- Provide for the effective and proportionate enforcement of new Regulation (EU) 2015/2283 on novel foods through the use of improved enforcement tools that may be employed to deal with suspected non-compliances with the EU requirements;
- Specify penalties that the Courts may impose upon conviction and enable the award of compensation where enforcement authorities are found not to have taken appropriate action; and
- Revoke the Novel Foods and Novel Food Ingredients Regulations 1997/1335 (as amended) and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to Scotland.

2.2. The penalties referred to above reflect the requirement in the new EU Regulation to ensure that penalties are dissuasive as well as being effective and proportionate. Member States (MS) are required to notify the provisions to the Commission by 1 January 2018.

Penalties and powers

2.3. The Novel Food and Novel Food Ingredients Regulations 1997 (SI No. 1997/1335) provides for the execution and enforcement in Scotland of certain specified provisions of Regulation (EC) No 258/97. The current enforcement provisions provide a criminal offence for non-compliance but do not have specific provisions to remove products from sale. Reliance is placed on the Food Safety Act 1990 and related General Food law (178/2002 EC) provisions for the seizure and/or detention of unauthorised novel foods or products containing unauthorised novel food ingredients. This approach requires a risk assessment to determine if the ingredient is unsafe. In the absence of evidence of harm it is difficult to remove unauthorised products from the market despite the safety of the products in question not having been verified. Any other avenues of enforcement related to labelling or health claims are unlikely to result in the removal of non-compliant products from the market.

2.4. In light of this operational experience, the proposed approach would enable authorised officers to detain food which is suspected of not complying with the EU requirements pending futher investigation or seize the food to be dealt with by a

sheriff who may order the destruction of non-compliant novel food products where any alternative remedy is not or cannot be applied within a reasonable period to render products compliant with the EU Regulation. A modification of section 9 of the Food Safety Act 1990 (as amended) has been provided in the proposed Regulations in this regard.

2.5. The legislative response is designed to overcome the market's failure to ensure that food products placed on the market comply with the regulatory requirements for novel foods. For example, substances such as DMBA (1,3-dimethylbutylamine) have been found added to sports and weight loss supplements as a "fat burner". The US Food and Drink Administration first issued warnings about DMBA being used as a replacement for DMAA (1,3-dimethylamylamine) because it is an easily synthesised analogue. DMAA was banned by the UK Medicines and Healthcare Products Regulatory Agency in 2012, and it also appears on the World Anti-Doping Agency prohibited list. Consumption of DMAA has been linked to symptoms such as high blood pressure, nausea, cerebral haemorrhage, stroke and death. Due to its structural similarity to DMAA it is considered that consumption of DMBA could also possibly lead to similar effects. In this case, government intervention is necessary to provide enhanced enforcement powers. The provision of powers of entry, seizure and detention of non-compliant novel food products will help to ensure that where corrective action is not possible or appropriate, non-compliant products can be removed from the market. These preventative measures are taken to ensure protection of public health and consumer interests and prevent negative impacts on public health being realised.

Background

2.6. The current EU legislation, Commission Regulation (EC) No 258/97 concerning novel foods and novel food ingredients has been in force since 1997 and applies to foods and food ingredients that do not have a significant history of consumption in the European Union (EU) before 15 May 1997. That Regulation included a requirement for a review of its operation in order to identify possible improvements. In practice however, the review was delayed, to take account of other significant developments in EU food law particularly with the adoption of General Food Law[1], which provides an overall framework for food legislation and established the European Food Safety Authority (EFSA). The adoption of Commission Regulation (EC) No 1829/2003, removed genetically modified foods (GM) from the scope of regulation (EC) No 258/97.

2.7. The scope of the new EU Regulation broadly remains the same as Regulation (EC) No 258/97, however clarity has now been achieved that insects are clearly now in scope and maintains the requirement for novel foods to undergo a safety assessment before they can be marketed. The criteria for authorisation are essentially unchanged and it is therefore not expected that the new EU Regulation will impose new ongoing costs on applicants, food operators or enforcement bodies. All businesses placing

[1] Ref OJ L 31, 1.2.2002, p.g. 1: Regulation (EC) No 178/2002 of the European Parliament and of the Council, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

novel foods on the market are likely to be affected by the new EU Regulation. Micro-enterprises were not excluded from the scope of the EU Regulations as it was felt that such an exemption would be incompatible with the overall objective of ensuring the safety of novel foods placed on the market in the EU.

2.8. The new EU Regulation repeals Commission Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 as from 1 January 2018. However transitional measures in Article 35 of Regulation (EU) 2015/2283 allow that:

2.8.1. Where an application for placing a novel food on the market within the EU is submitted in accordance with Article 4 of Regulation (EC) No 258/97 but for which a final decision has not been reached by the date of entry into force of the new EU Regulation (i.e. 1 January 2018), shall be considered as an application made under the new EU Regulation.

2.8.2. Article 11 (requiring a scientific opinion from the European Food Safety Authority) will not be applied by the Commission where a risk assessment has already been provided by the Member State on the basis of Regulation (EC) No 258/97 and no other Member State has raised any reasoned objection to that assessment.

2.8.3. Foods not falling within the scope of Regulation (EC) No 258/97 which are lawfully placed on the market by 1 January 2018 and which fall within the scope of the new EU Regulation may continue to be placed on the market until a decision is taken in accordance with:

- Article 10 to 12 of the new EU Regulation following an application for authorisation of a novel food submitted by the date specified in the implementing rules adopted in accordance with Article 13 of the new Regulation , but no later than 2 January 2020; or
- Article 14 to 19 of the new EU Regulation following a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 20 of the new EU Regulation but no later than 2 January 2020.

2.8.4. The Commission may by means of implementing acts, adopt measures concerning the administrative and scientific requirements for applications and notifications referred to in Articles 13 (authorisation applications) and 20 (notifications of traditional foods from third countries) necessary for the application of paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2.9. The new EU Regulation also amends Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), adding in Article 2(1) the following:

- (h) the definition of “engineered nanomaterials” as established by point (f) of Article 3(2) of Regulation (EU) No 2015/2283 of the European parliament and of the Council

2.10. In the new EU Regulation the definition of a "novel food" has broader scope than the current legislation. It has been updated to include:

- Whole insects;
- Engineered nanomaterials (the definition is taken from the FIC Regulation and may be updated via delegated acts in light of technical progress);
- Food with intentionally modified molecular structure;
- Food from cell/tissue culture derived from plants, animals, microorganisms, fungi or algae;
- Food from microorganisms, fungi, algae or material of mineral origin;
- Food consisting of certain micelles or liposomes; and
- Food from plants obtained by non-traditional propagating techniques where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism, or level of undesirable substances.

2.11. Clarifying the definition of a novel food will help reduce uncertainty on whether some new technologies with an impact on food fall within the scope of the legislation. This will in turn help to protect consumers by ensuring that the effect of the new technology on food is evaluated prior to use on food entering the market. The current provisions have, on occasions, been found to be ambiguous in this regard. The new EU Regulation aims to provide a clearer definition than at present.

2.12. The new streamlined authorisation procedures, utilising EFSA to provide a centralised risk assessment function, is also anticipated to reduce burden on industry.

2.13. The new EU Regulation places a duty on food businesses to verify whether the food they intend to place on the market falls within the scope of the legislation. Whilst the establishment of the EU list of authorised novel foods will help in this regard, if unsure, food businesses should consult and provide all necessary information to the Member State in which they first intend to market the product to enable a determination to be made. Member States may consult each other to make such determinations within specified timescales. The wording has also been amended to reflect the introduction of general EU food law, Commission Regulation (EC) No 178/2002, providing improved clarity.

2.14. Overall, once further measures from the Commission on procedural steps for food businesses and the Union list are in place (expected in early 2018), it is anticipated that these changes will help reduce burdens on EU and third country businesses seeking to place novel food products on the market and facilitate consumer access to new food innovations which have been risk assessed and whose proposed use in considered to be safe.

Detailed provisions of the new EU Regulation

2.15. The new EU Regulation does not apply to:

a) Genetically modified foods falling within the scope of regulation (EC) No. 1829/2003;

b) Foods when and insofar as they are used as:

   i. Food enzymes falling within the scope of Regulation (EC) No 1332/2008;

   ii. Food flavourings falling within the scope of regulation (EC) No 1334/2008;

   iii. Food used solely as additives falling within the scope of Regulation (EC) No 1333/2008; and

   iv. Extraction solvents used or intended to be used in the production of foodstuffs or food ingredients falling within the scope of Directive 2009/32/EC.

2.16. Article 3 of the new EU Regulation provides for the applicable definitions and updates the definition of "novel foods" based on technological and scientific advancements.

EU List

2.17. The new EU Regulation requires that the Commission shall establish and update an EU list of novel foods authorised to be placed on the market within the EU in accordance with Articles 7, 8 and 9 ("the Union List") (Articles 6 – 12). Only novel foods authorised and included in the EU list may be placed on the market within the EU, or used in or on foods, in accordance with conditions of use and the applicable labelling requirements. In order for novel foods to be included in the EU list they are required to meet specific conditions:

a) The food does not, on the basis of scientific evidence available, pose a safety risk to human health;

b) The food's intended use does not mislead the consumer, especially if the food is intended to replace another food and there is significant change in the nutritional value;

c) Where food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous to the consumer.

2.18. The EU list is due to be established by 1 January 2018, by means of an implementing act from the Commission, and will include novel foods that are already authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any existing authorised conditions and requirements.

Centralised Risk Assessment

2.19. The current system requires Member States to carry out an initial assessment, which is then shared with all other Member States for comment – a process that takes a significant period of time, particularly as most dossiers are later referred to the European Food Safety Authority (EFSA) for advice on outstanding concerns raised by Member States. Once EFSA's opinion is available there is a further delay while

the Commission prepares a formal authorisation decision which is voted on by Member States. Centralising the authorisation procedure for novel foods means that in future EFSA will carry out an initial assessment. The new streamlined and time restricted approach to novel food authorisations should deliver consistency for food businesses and encourage innovation whilst ensuring that a high level of food safety is maintained.

Generic Authorisations

2.20. Introducing generic novel food authorisations as in other areas of food law such as food additives, the new EU regulation has removed the need for a separate application from a food business wishing to supply an already authorised novel food. Whilst in most cases this was considered under a simplified procedure based on demonstrating that both products are substantially equivalent, this has created unnecessary administrative burdens on applicants and competent national authorities. Where data protection provisions do not apply, food businesses wishing to supply already authorised novel foods will be able to proceed directly to market.

Simplified Notifications for traditional food from third countries

2.21. Introducing a simplified safety assessment procedure for traditional food from third countries will enable traditional foods to gain authorisation relatively quickly if applicant companies are able to demonstrate a history of safe use outside the EU. At present, foods made from plants, microorganisms, fungi, algae and animals (e.g. chia seeds or baobab fruit) that are widely consumed elsewhere in the world have to undergo the same detailed lengthy assessment procedures as completely innovative products. Under this new notification procedure applicants need to present evidence of safe use of the traditional food in at least one country outside of the EU for a period of at least 25 years. EFSA and Member States will assess the evidence in parallel procedures and a decision will be taken on whether a product should be allowed on the market. This simplified process should help facilitate free trade in traditional foods and broaden consumer choice whilst ensuring that high levels of food safety are maintained.

Data Protection

2.22. Where applicants request confidentiality for certain information submitted for updates to the EU list under the new EU Regulation, which, if made public, may harm their competitive position, applicants are required to indicate which parts of the information should be treated as confidential, and to provide the necessary details to substantiate their request. Verifiable justification will be required in such cases.

2.23. The new EU Regulation also introduces a maximum 5 year period (from the date of authorisation) of intellectual property protection for new scientific evidence and data produced in support of applications. Applicants who have invested in new data to demonstrate suitability of their product can seek a limited period of data protection. If the authorisation is granted it would give the applicant the sole right to market the product during this period, using this safety data. Other operators could also apply for authorisation but they would have to provide their own safety data.

Post market monitoring

2.24. For food safety reasons and taking into account the EFSA opinion, the Commission may impose post-market monitoring requirements, which may include, on a case by case basis, the identification of the relevant FBOs.

Consultation on the new EU Regulation

2.25. Prior to the adoption of the new EU Regulation, the European Commission carried out a formal consultation. This included stakeholders from the food industry, consumers, third countries and Member States and international organisations. Commission representatives also participated in several meetings/seminars organised by stakeholders committed to specific issues (e.g. traditional food from third countries, assessment and authorisation procedure, nanotechnologies) and bilateral meetings with interested groups. Stakeholders also had the opportunity to express their positions during the first and second reading and the Conciliation procedure on the 2008 legislative proposal.

2.26. Furthermore, the Commission carried out an Impact Assessment in 2007 for each of the measures in the 2008 proposal. Several options were considered in regards their economic, social and environmental impact on the various stakeholders and Member States. The published Impact Assessment is available at:

https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_impact-assessment_en.pdf

2.27. Whilst the 2008 proposal lapsed, the stakeholder consultations conducted in relation to it had identified a number of areas for improvement in the existing Regulation and the Commission used this exercise to identify the following objectives:

2.27.1. Avoid delays that are associated with the current authorisation procedure for novel foods;

2.27.2. Remove any unjustified barriers to the introduction of traditional foods from non-EU countries that have a history of safe food use in those countries;

2.27.3. Avoid unnecessary duplication due to the current requirements for different manufacturers to submit applications for the same product;

2.27.4. Remove the overlap with other EU food law, which currently leads to unnecessary duplication in assessments and authorisations; and

2.27.5. Update the legal text in order to improve its clarity and to bring it in line with developments in EU food law.

2.27.6. A further proposal was brought forward in 2013 based upon the objectives previously identified by the Commission and the final compromise text was adopted on 16 November 2015 resulting in Regulation (EU) No 2015/2283.

Simplification

2.28. The new EU Regulation provides for simplification of the legislation and administrative procedure for public authorities and businesses compared to the existing legislation:

2.28.1. There is only one centralised procedure for the assessment and authorisation of novel foods; the wording of the EU Regulation has been updated and now provides further clarity;

2.28.2. National administrative procedures and duplication of work have been removed;

2.28.3. The authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden in particular for businesses;

2.28.4. A simplified procedure for placing on the market of the traditional foods from third countries is introduced reducing barriers to trade.

Rationale for Government intervention

2.29. Failure to introduce enforcement provisions for the new EU Regulation could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU requirements can be enforced in Scotland. The proposed Novel Foods (Scotland) Regulations 2017 will enable the local authorities in Scotland to take action in the event of non-compliance with the specific authorisation and marketing requirements for the products covered by the new EU Regulation.

2.30. National intervention is also necessary to ensure that those placing novel foods on the market within the EU are fully compliant with the requirements of Commission Regulation (EU) 2015/2283, and facilitate the effective functioning of the internal market, whilst providing a high level of protection of human health and consumer interests.

3. Consultation

Within Government

3.1. The consultation package was discussed with Scottish Government (SG) officials from Public Health and Food Drink & Rural Communities.

Public Consultation

3.2. A shortened 8 week consultation was carried out in Scotland on the draft national legislation from 12th June 2017 to 6th August 2017. Similar consultations have been held in England, Wales and Northern Ireland.

Business

3.3. A selection of Scottish businesses of different sizes and from various geographical areas were approached during the public consultation period to discuss the likely impact on their business of the changes proposed in the SSI. Two responses were received.

4. Options

The options considered were:

4.1. **Option 1** – **Do nothing**. The new EU Regulation on novel foods will not be enforced. This option will not prevent the new EU Regulation applying in Scotland as it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it.

4.2. **Option 2** – **Make appropriate domestic regulations to provide for the enforcement of the new EU Regulation on novel foods.** This option will provide enforcement authorities with the necessary powers to enforce the new EU Regulation, and remove the risk of the UK incurring infraction proceedings.

This is the preferred option.

Sectors and groups affected

4.3. While these proposed regulations apply to Scotland only, separate enforcement regulations will be introduced in England, Wales and Northern Ireland; as such the impact on the UK as a whole has been assessed.

4.4. Consumers – Non-monetised benefits to consumers from the establishment, in due course, of an EU List of authorised novel foods, a simplified safety assessment procedure for traditional food from third countries and streamlined procedures for the assessment and authorisation of novel foods.

4.5. Enforcement Authorities – enforcement of the rules on novel foods is the responsibility of Local Authority Environmental Health Services. In Scotland, Enforcement Officers from Local Authority Environmental Health Departments will need to familiarise themselves with the new Regulations and ensure they are adhered to.

4.6. Businesses – Manufacturers and retailers will be the main groups affected by the Novel Foods (Scotland) Regulations 2017.

Option Appraisal: Costs and Benefits

4.7. **Option 1** – **Do nothing**. The new EU Regulation is binding in its entirety and directly applicable in all Member states. It is therefore not necessary to transpose the provisions of the new novel food Regulation into domestic law. Doing nothing would mean that the new EU Regulation will still apply but we would not have the domestic legislation to enforce it in Scotland. Under EU law, the UK is obliged to provide for the enforcement of EU legislation. Failure to do so may lead to the UK being liable to infraction proceedings and consequent fines. Scotland would be required to pay a percentage of any UK fine if the infraction related to a devolved matter. Option 1 is therefore disregarded as an option, but it is the baseline against which other options are appraised.

4.8. **Option 2 – Make appropriate domestic regulations for the execution and enforcement of the new EU regulation on novel foods.**

4.9. There will be some cost to industry and enforcement in ensuring compliance with the new EU Regulation as identified below.

Option 2 – One-off Costs to Industry

One-off familiarisation cost

4.10. This figure is calculated by firstly taking the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[2] figure "production managers and directors" £25.54 and uprating it by 20%, according to the Standard Cost model[3], to account for overheads, giving a mean[4] hourly wage rate of £30.65. It is estimated that the reading and understanding of the EU Regulation and the proposed regulations will take two and a half hours with a further two and a half hours for dissemination to key staff within each firm (a total of 5 hours). Given the number of enquiries received in the UK annually from companies concerning this area of legislation, it is estimated that approximately 1000 companies[5] will need to invest in understanding the new legislation. Thus yielding an approximate one-off familiarisation cost to firms of £153k. Scotland's food and drink industry is approximately 10% of the size of the UK industry, therefore yielding a one-off familirisation cost of £15,300 to Scottish firms.

Option 2 – Benefits to Industry

Generic Novel Food Authorisations

4.11. Under current regulatory requirements operators wishing to place novel foods on the market may either submit:

4.11.1. A full novel food application (with accompanying scientific dossier) for authorisation: or

4.11.2. An application seeking to demonstrate the substantial equivalence (SE) of their novel food product to one that is already authorised.

4.12. Under the current system novel food authorisations are issued specifically to the company that submitted the application, consequently any other company wishing to market the same novel food product must submit a separate application. In most cases this can be done via a simplified procedure that is based on demonstrating to one of the national competent authorities that the two products are substantially equivalent. This has led to a large number of SE applications, creating unnecessary administrative burdens on applicants and national Competent Authorities.

4.13. By way of illustration, Company A wishes to place chia seeds on the market and submits a full novel food application seeking authorisation. Company A's application is successful and is duly authorised to place their chia seeds on the market. Company B also wishes to place chia seeds on the market. Company B can submit a SE application, which would show the novel food or novel food ingredient may be substantially equivalent to the existing authorised food as regards to its:

- Composition (such as the source organism and preparation method);

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[2] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

[3] SCM methodology http://www.berr.gov.uk/files/file44503.pdf

[4] The median figure would have been used but only the "mean" figure was available at the time.

[5] We have made the reasonable assumption that approximately 1000 food business operators in the UK are active in considering placing novel foods on the market based on the number of enquiries received. These enquiries generally concern whether a product is novel, procedures for seeking authorisation of a novel food, and how to demonstrate that a product has a history of consumption in the EU.

- Nutritional value;
- Metabolism;
- Intended use (such as food ingredient or supplement; and the
- Level of undesirable substances (such as contaminants, mycotoxins and allergens).

4.14. The new EU Regulation has introduced a move from applicant specific authorisations to generic authorisations. Once a novel food is authorised any operator could benefit from that authorisation subject to any proprietary data restrictions that may apply. This move to generic authorisations has removed the need for SE applications.

4.15. Informal enquiries amongst industry sources in the UK suggest the administrative cost of preparing an SE application and taking it through the existing process may be in the order of £5k - £25k, this is a saving for industry. It is expected that this will benefit small and medium sized businesses in particular as it means they too could place an authorised novel food on the market even if they did not submit the initial application for authorisation.

Streamlined procedures for the assessment and authorisation of novel foods

4.16. The time taken for decisions to be made by the Commission on applications submitted under the current EU Regulation has varied between 6 months to more than 4 years. The Commission has calculated that authorisations have, on average, been issued 39 months after the application was submitted. This might be reduced to 18 months under the new EU Regulation if the authorisation process runs smoothly. Based on valid applications being forwarded for safety assessment within 1 month, 9 months for EFSA to carry out the safety assessment and deliver its opinion and 3 months thereafter to present a possible draft implementing decision for a vote by Member States.

4.17. The cost to an applicant of making a novel food application will vary from case to case depending on the complexity and the need to generate new data to demonstrate the acceptability of the product. Unilever estimated that the total cost of obtaining authorisation for their Phytosterol ingredient (used in spreads and other products under the brand name “Flora Pro-activ” range) was €25 million[6] (£19.8m), although this figure does not differentiate between costs which would have been incurred in the absence of the current Regulation (e.g. work required to satisfy general obligations under EU food law, to meet the company’s own level of corporate safety assurance or to obtain authorisation in other regions of the world).

4.18. There is no data that we are aware of, on which to base an estimate of the financial benefits of enabling a new product to be brought to the market in a shorter time after the dossier is submitted.

Ongoing (annual) benefit of savings due to lower “Administrative Costs”

[6] This figure was provided in 2000. To convert it to Sterling the Bank of England annual average Spot exchange rate, Euro into Sterling (code:XUAAERS) was used. This resulted in a figure of £19,860,184.

4.19. Informal enquiries amongst industry sources in the UK suggest that the administrative cost of preparing a full novel food application dossier and taking it through the existing process may be in order of £25k - £50k. If the applicant does not already have the data to undertake a formal risk assessment, the cost of individual studies could range from £5k - £12k (for a detailed analysis of the composition of the product) to a possible £250k (for a full Organisation for Economic Co-operation and Development 90-day feeding study in laboratory rats).

4.20. The current authorisation procedure is based on assessments carried out by the relevant authorities in one of the 28 EU Member States, which are then scrutinised by the others. In some cases, there are outstanding questions and concerns which, if they cannot be satisfied by further information from the applicant, are referred to EFSA. The new EU Regulation will replace this with a single centralised assessment by EFSA, in line with the approach used in other areas of EU food law, such as food additives. It is anticipated that whilst this will speed up the authorisation process, the financial cost of assembling data and preparing the initial dossiers would be substantially the same as at present. The centralised approach under the new EU Regulation is more supportive of a consortium of applicants than previously, providing opportunities for businesses to share the cost of preparing an application.

4.21. Reliance on a single, centralised safety assessment should not detract from the rigour of the safety assessment and it would be essential to ensure that assessments are carried out to a high standard and with the maximum degree of transparency.

4.22. Having a centralised safety assessment will however remove some of the burden placed on National Competent Authorities, with this being transferred to EFSA. However the ongoing need for expert advice on novel foods to support the effective functioning of the new EU Regulation is not yet clear, in particular in relation to assessment of traditional foods from third countries. No allowance has therefore been made for financial savings resulting from the transfer of the safety assessment from national level to EFSA.

4.23. The centralised authorisation procedure might reduce the administrative burden on the applicant as they would have to liaise with a single body rather than with individual Member States. However, it is anticipated that applicants may still wish to seek advice from competent authorities in the transitional period until understanding of the new regulatory framework is fully embedded. For the purpose of this Impact assessment, it has been assumed the current administrative costs of preparing a dossier and taking it through the authorisation process is £20k - £50k and that 50% of this might be saved on full applications and 100% on SE applications. Sensitivity analysis has been used by taking an upper bound of £50k, a lower bound of £20k and a best estimate of £35k, which is the mid point of the two bounds. Calculations have been made on the basis of 5.2 full applications and 2.4 applications seeking an opinion on substantial equivalence per year in the UK (the novel food applications that were made during 2011 – 2016 were 26 full applications and 12 applications seeking to demonstrate substantial equivalence). For full applications, the best estimate of annual savings in the UK is £91k, with a total cost savings over 10 years of £783k (present value), with an upper bound estimate of £1.1m and a lower bound

estimate of £448k (also present value figures). For opinions on substantial equivalence, the best estimate of annual savings is £36k with a total cost savings over 10 years of £310k (present value with an upper bound estimate of £516k and a lower bound estimate of £103k).

4.24. No calculation could be made for UK businesses seeking authorisation through other Member States as the number of businesses affected is unknown.

Ongoing (annual) benefit savings due to "Removal of application fees"

4.25. In addition to the potential administrative costs that operators might save, the proposed regulations provide for the removal of fees through revocation of the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997. This Regulation allows charges as follows:

- £4000 in respect of a full novel food application; and
- £1725 in respect of an opinion on substantial equivalence.

4.26. Calculations have been made on the basis of 5.2 full applications and 2.4 applications seeking an opinion on substantial equivalence per year. For full applications, the administrative cost saving of £4k per application leads to a total annual saving of £20.8k, leading to a total saving of £179k (present value) in the UK over 10 years. For opinions on substantial equivalence, the administrative cost saving of £1.7k per application leads to a total annual cost saving of £4.1k, leading to a total annual saving of £36k (present value) over 10 years.

Non-monetised benefit to industry of "the Establishment of an EU list of Authorised Novel Foods"

4.27. The establishment of a European Union list of authorised novel foods and any applicable conditions of use will benefit industry by providing greater clarity as to the novel foods that may legally be placed on the market. This will assist operators in the delivery of the obligation placed on them by Chapter I, Article 4 of Regulation (EU) No 2015/2283 which requires operators to verify whether the food they intend to place on the market falls within the scope of the legislation.

Non-monetised benefit to industry of "A simplified safety assessment procedure for traditional food from third countries"

4.28. There is increasing commercial interest in the introduction of exotic fruits and vegetables coming into the EU market from non-EU countries, which have not previously been exported to Europe. For example, a group of Andean countries (Colombia, Ecuador and Peru) have estimated that there are about 60 plant species that are traditionally consumed in their regions that could in future be exported to the EU.

4.29. Whilst the existing Novel Foods Regulation does not prevent trade in traditional foods, such products need to go through the full authorisation procedure that applies to other novel food but few applications have been received possibly because of the requirements for authorisation are seen by exporters as unduly onerous and burdensome.

4.30. The simplified traditional food from third countries notification procedure set out in the new EU Regulation requires the submission of a dossier demonstrating the safety of a traditional food. EFSA has developed a scientific and technical guidance document intended to support applications in providing the type and quality of information needed by EU Member States and EFSA to consider whether there are reasoned safety objections to the placing on the market within the EU of the traditional food with the proposed conditions of use.

4.31. Dossiers should contain specifications on the traditional food, information about the experience of continued use in a third country, and its proposed conditions of use. In addition to this, normal consumption of the traditional food should not be nutritionally disadvantageous for consumers. If the procedure were to operate smoothly (a valid dossier being forwarded to Member States and EFSA for consideration within 1 month of receipt by the Commission and the specified 4 month period permitted for Member States and EFSA to raise any reasoned safety objections) the notified traditional food could be added to the authorised EU list within 6 months.

4.32. This simplified procedure should help facilitate trade by enabling traditional foods to proceed swiftly to the market, unless a Member State or EFSA lodges a reasoned objection to the claim that the product has a history of safe use in a non-EU country.

Option 2 – Benefits to Consumers

Non-monetised benefit to consumers of "the Establishment of an EU list of Authorised Novel Foods"

4.33. The establishment of an EU list of authorised novel foods is expected to benefit consumers by providing clarity on what novel foods have been risk assessed and are considered not to present a risk to human health. The list will also provide any applicable conditions of use that should be observed in relation to the use of the novel food.

Non-monetised benefit to consumers of "A simplified safety assessment procedure for traditional food from third countries" and streamlined procedures for the assessment and authorisation of novel foods

4.34. It is expected that the simplified process for traditional food from third countries and streamlined procedures for the assessment and authorisation of novel foods is likely to result in an increase in the choice of foods available to consumers. It is also expected that consumers will benefit from products proceeding to market more swiftly and potentially at a lower cost as the commensurate costs to industry of authorisation are reduced.

Option 2 – Costs to Enforcement

One-off familiarisation cost

4.35. There are 210 enforcement officers across the 32 local authorities in Scotland. It is estimated that every officer in each of these authorities is expected to read and familiarise themselves with the EU Regulations and the proposed domestic regulations and that it may take them two and a half hours to do so.

4.36. An estimate of cost with respect to the time taken by enforcement officers at local authorities to familiarise themselves is £56.90 per officer (at 2.5 hours). this figure taken from the 2016 provisional ONS ASHE (Annual Survey of Hours and Earnings)[7], figures for an environmental health officer £18.97 per hour (median value), which, in line with the Standard Cost Model, is then uprated by 20% to account for overheads, which gives an hourly wage rate of £22.76. With 210 enforcement officers, this gives a total cost of £11949 . Compared with the current system there would be no additional or new burden on enforcement bodies, other than those identified in the costs and benefits above.

5. Scottish Firms Impact Test

5.1. Various Scottish businesses of different sizes and from various geographical areas were approached directly during the public consultation period to seek their views on the likely impact on their business of the changes proposed in the draft SSI. They were requested to consider all questions posed in the partial BRIA and assess the cost estimates.

Competition Assessment

5.2. The proposed legislation will apply to all businesses and individuals involved in the UK Novel Foods trade equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition.

5.3. The present system is regarded by many food businesses as a barrier to innovation and any improvements to the efficiency and clarity of the procedures (including allowing reasonable returns on investment by means of data protection) are expected to lead to increased innovation and potentially competition. Especially if the time from development to marketing of new novel food is reduced.

Test run of business forms

5.4. No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

6.1. During the consultation period the Justice Directorate was contacted to ascertain whether the new regulations will have any legal aid implications. The Scottish Legal Aid Board confirmed that these Regulations are unlikely to have an impact on the legal aid fund.

7. Enforcement, sanctions and monitoring

Enforcement

7.1. Enforcement of the regulations will be the responsibility of Local Authorities. In Scotland, Enforcement Officers from Local Authority Environmental Health Services will need to familiarise themselves with the new requirements and ensure they are

[7] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

adhered to. Enforcement action is only pursued where informal action has been unsuccessful.

Sanctions

7.2. Regulation 4 of the draft Novel Foods (Scotland) Regulations 2017 lays down that the penalty on summary conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale.

7.3. It is also deemed necessary for authorised officers/sheriffs to be empowered to seize, detain and or require the destruction of non-compliant novel food products where any alternative remedy is not or cannot be applied within a reasonable period to render products compliant with the EU Regulation. A modification of section 9 of The Food Safety Act 1990 (as amended) has been provided in the proposed regulations in this regard.

Monitoring

7.4. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Food Standard Scotland's' mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

8. Implementation and Delivery Plan

8.1. Post consultation, on 1 January 2018, the enforcement provisions for Regulation (EU) 2015/2283 on novel foods are due to be introduced through The Novel Foods (Scotland) Regulations 2017.

9. Post Implementation Review

9.1. A review to establish the actual costs and benefits and the achievement of the desired effects will take place 10 years from the date The Novel Foods (Scotland) Regulations 2017 come into force.

10. Summary and Recommendation – Summary Costs and Benefits Table Declaration

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy and administrative
1	Do nothing therefore no cost	Possible infraction fines
2	**Industry:** Administrative cost saving due to "Streamlined procedures for the assessment and authorisation of novel foods" per FBO ranges from £20k to £50k with a mid-point estimate of £35k **Industry:** Full application annual savings due to the "revocation of the Novel Food Ingredients (Fees) Regulations 1997". For full applications the annual saving is £91k and for	**Industry:** One-off familiarisation cost: £15,300 **Enforcement:** One-off familiarisation cost: 12k

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy and administrative
	substantial equivalence the annual saving is £36k **Industry:** The Establishment of a Union list of Authorised Novel Foods; A simplified safety assessment procedure for traditional food from third countries **Consumers:** The Establishment of a Union list of Authorised Novel Food; A simplified safety assessment procedure for traditional food from third countries" and streamlined procedures for the assessment and authorisation of novel foods No infraction fines due to introducing the new Scottish Statutory Instrument for the execution and enforcement of the new EU Regulation on novel foods	

Option 2 is considered to be the preferred option. It ensures that Scottish Ministers will meet their obligation to implement agreed EU legislation.

11. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's signature ……AILEEN CAMPBELL

Minister's title ……MINISTER FOR PUBLIC HEALTH AND SPORT

Date ……22 NOVEMBER 2017

Contact point

Georgina Finch
Regulatory Policy Branch
Food Standards Scotland
Pilgrim House
Old Ford Road
Aberdeen
AB11 5RL
Tel: 01224 288371
e-mail: Georgina.Finch@fss.scot