Title: THE NOVEL FOODS (ENGLAND) REGULATIONS 2018 **IA No:** FOOD0158 **RPC Reference No:** **Lead department or agency:** FOOD STANDARDS AGENCY **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 3 January 2018 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Colin Clifford Tel: 020 7276 8584, E-mail: colin.clifford@food.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£1.19m	£1.00m	-£0.1m	Not in scope	Non-Qualifying provision

What is the problem under consideration? Why is government intervention necessary?

The new directly applicable European Regulation (EU) 2015/2283 on novel foods came into full effect in the UK on 1 January 2018 and takes account of operational experience; technological and scientific advancement; and changes in other areas of food law. UK Government intervention is necessary to provide an enforcement framework for the new requirements; and to incentivise food businesses to ensure novel foods are risk assessed prior to placement on the market, in this way protecting consumers through proportionate management of food safety risks. Protection against unauthorised Novel Foods prevents consumers consuming potentially harmful products (de-merit goods). An enhanced enforcement framework will provide a more proportionate and effective deterrent to operators from placing unauthorised and potentially harmful novel food products such as DMBA (1,3-dimethylbutylamine) on the market.

What are the policy objectives and the intended effects?

The new EU Regulation introduces a streamlined authorisation process for novel foods; centralised risk assessment by the European Food Safety Authority (EFSA); up to 5 years protection for new scientific evidence produced to support applications; and a simpler authorisation process for traditional foods consumed to a significant degree in third countries but not in the EU prior to 1997. These changes will help reduce burdens on EU and third country businesses seeking authorisation of novel foods and facilitate consumer access to new food innovations that are risk assessed and considered safe. The domestic Statutory Instrument (SI) is necessary to provide effective and proportionate enforcement by means of civil penalties and maintain a criminal offence for failure to comply with critical provisions of Regulation (EU) 2015/2283. The SI will revoke, in England, the Novel Foods and Novel Food Ingredients Regulations 1997; and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The European Commission consulted on a range of options when it proposed to amend the pre-existing legislation, and published an Impact Assessment explaining the rationale for each major proposed change; options assessed in this IA:

Option 1 – Do Nothing – do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England, N Ireland and Wales. This option will not prevent the new EU Regulation applying in the UK as it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enforce the EU Regulations on novel foods; and so the UK would carry risk of infraction proceedings.

Option 2 – Make appropriate domestic Regulations for the effective and proportionate enforcement of the new EU Regulation on novel foods in a proportionate manner. Option 2 is the preferred option.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** January 2023

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Steve Brine Date: 6 February 2018

Summary: Analysis & Evidence

Policy Option 1

Description: Option 1 – Do Nothing: - do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England

FULL ECONOMIC ASSESSMENT

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0.0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.0		0.0	**0.0**

Description and scale of key monetised costs by 'main affected groups'

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

Other key non-monetised costs by 'main affected groups'

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.0		0.0	**0.0**

Description and scale of key monetised benefits by 'main affected groups'

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

Other key non-monetised benefits by 'main affected groups'

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There are no costs or benefits associated with this option. This is the baseline against which all other options are appraised.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: 0.0
Costs: 0.0	**Benefits:** 0.0	**Net: 0.0**	

Summary: Analysis & Evidence

Policy Option 2

Description: Option 2 (Preferred) – make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0.65	**High: 1.73**	**Best Estimate:** 1.19

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.1		0.0	**0.1**
High	0.1		0.0	**0.1**
Best Estimate	0.1		0.0	**0.1**

Description and scale of key monetised costs by 'main affected groups'

Industry: One-off familiarisation cost: £92k

Enforcement: One-off familiarisation cost: £28k

Other key non-monetised costs by 'main affected groups'

Non-monetised costs were not identified

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0.0		0.1	**0.8**
High	0.0		0.2	**1.9**
Best Estimate	0.0		0.2	**1.3**

Description and scale of key monetised benefits by 'main affected groups'

Industry: Savings due to "Streamlined procedures for the assessment and authorisation of novel foods". (i) Administrative Costs: £1.1m (PV) (£127k (EAC)). (ii) Application Fees: £0.2m (PV) (£25k (EAC)

Other key non-monetised benefits by 'main affected groups'

Industry: (i) The Establishment of a Union list of Authorised Novel Foods**;** (ii) A simplified safety assessment procedure for traditional food from third countries

Consumers: (i) The Establishment of a Union list of Authorised Novel Food; (ii) A simplified safety assessment procedure for traditional food from third countries" and streamlined procedures for the assessment and authorisation of novel foods

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

The 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.

It is assumed that the number of applications made over the last five years (using historical data) will reflect the number of applications over the next ten years.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: - 0.5
Costs: 0.0	**Benefits:** 0.1	**Net:** 0.1	

Evidence Base (for summary sheets)

Problem under Consideration

1. The previous EU legislation, Commission Regulation (EC) No. 258/97[1] concerning novel foods and novel food ingredients was in force since 1997 and applied to foods and food ingredients that did not have a significant history of consumption in the European Community before 15 May 1997. The Regulation included a requirement for a review of its operation after 5 years in order to identify possible improvements. The review, however, was delayed, to take account of other significant developments in EU food law, particularly:

    a) the adoption of General Food Law, Commission Regulation (EC) No. 178/2002[2], which provides an overall framework for food legislation and established the European Food Safety Authority;

    b) the adoption of Commission Regulation (EC) No. 1852/2001[3] laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to Commission Regulation (EC) No. 258/97; and

    c) the adoption of Commission Regulation (EC) No 1829/2003[4] on genetically modified (GM) food and feed removed GM foods from the scope of the novel foods Regulation.

    Two Statutory Instruments, the Novel Foods and Novel Food Ingredients Regulations 1997 and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997, provide for the execution and enforcement of Regulation (EC) No. 258/1997 in relation to England. Equivalent national legislation is in place in the devolved administrations.

2. Following a range of stakeholder consultation activities 2002-2007 the Commission attempted to revise the legislation on novel foods in 2008 to take account to scientific and technological advances that have taken place since the legislation was first put in place. The consultations highlighted the following areas for improvement:

    - operator specific authorisations mean that other operators need to demonstrate substantial equivalence of their product to the one authorised so that they too can place their product on the market;
    - most products are often risk assessed twice, once by the Member State (MS) competent authority and again by EFSA;
    - traditional foods from third countries (such as baobab fruit) without a demonstrable history of significant consumption within the EU are required to go through the full authorisation and risk assessment process; this was considered by stakeholders to be an unjustified barrier to trade;
    - considerable delays (occasionally several years) are associated with the authorisation process;
    - overlap with other European Community legislation results in unnecessary duplication in assessments and authorisations;
    - further clarity is required in the legal text; and to bring it in line with developments in EU food law (outlined above) and scientific/technical developments.

    However, that attempt failed because of disagreement over how to regulate products from cloned animals and their offspring and the definition of nanomaterials. A further attempt to revise the Regulation was initiated in 2013. With effective intervention and influence provided by the UK on a number of areas, that attempt culminated in the successful adoption of the new Novel Food Regulation in 2015.

---

[1] Ref OJ L 43, 14.2.97, p.g. 1

[2] Ref OJ L 31, 1.2.2002, p.g. 1, Full title: 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.

[3] Ref OJ L 251, 21.9.2001, p.g. 17, Full title: Commission Regulation (EC) No. 1852/2001, laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No. 258/97

[4] Ref OJ L261, 18.10.2003, p.g. 1-23, Full title: Commission Regulation (EC) No. 1829/2003, on genetically modified food and feed.

Rationale for Intervention

3. National intervention is necessary to ensure that those placing novel foods on the market within the European Union (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.

4. The new European Regulation, Commission Regulation (EU) 2015/2283[5] of the European Parliament and of the Council on novel foods ("the new EU Regulation") was published in the Official Journal (OJ) of the European Communities on 11 December 2015 and is directly applicable throughout the EU. The new EU Regulation came into force on 30 December 2015 with a two year transition period to the new provisions. The new rules became fully applicable from 1 January 2018 subject to a number of provisions (as discussed further in this Impact Assessment). Government intervention is required to make national Regulations that provide for the effective and proportionate enforcement of the new EU Regulation in England, Wales and Northern Ireland so that food businesses are incentivised to ensure novel foods are risk assessed prior to placement on the market, in this way protecting consumers through proportionate management of food safety risks.

5. The new EU Regulation delivers:

   a) an updated definition of what constitutes a 'Novel food' based on technological and scientific advancements;

   b) centralised risk assessments to be carried out by the European Food Safety Authority within 9 months (time may be stopped if further information is required);

   c) the establishment of a Union list of authorised novel foods (newly authorised food to be added within 6 months);

   d) generic novel food authorisations which remove the need for a separate application seeking to demonstrate substantial equivalence to an authorised novel food;

   e) 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; and

   f) a simpler notification procedure for traditional foods from third countries, facilitating free trade.

   This new streamlined, 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.

6. On the definition of engineered nanomaterials, the current definition from the Food Information for Consumers Regulation (EU) 1169/2011[6] has been retained and moved to the new Novel Food Regulation, with scope to amend the definition through the use of delegated acts to allow for technological and scientific advancements. The text also places emphasis on ensuring that methods used to assess the safety of engineered nanomaterials are appropriate and up to date. These changes should help to ensure that legislative requirements keep pace with scientific progress.

7. Agreement was reached on the use of delegated acts and implementing acts to update the Regulation. Implementing acts will be used for updates to the Union list of authorised novel foods. Cloning was a key issue discussed in the negotiation of the new EU Regulation; which retains the status quo of the 1997 legislation where the products of cloned animals, but not their descendants, will be subject to pre-market risk assessment under the new EU Regulation until such time as any changes are agreed as part of separate legislation on food from animal clones which is currently under discussion in the EU.

---

[5] Ref OJ L 327, 11.12.2015, p.g. 1 - Regulation (EU) 2015/2283 of the European Parliament and of the Council, on novel foods, amending Regulation (EC) no. 1169/2015 of the European Parliament and of the Council and repealing Regulation (EC) No.258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852

[6] Ref OJ L304, 22.11.2011, p.g. 18-63 – Regulation (EU) 1169/2011 of the European Parliament and of the Council, on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Proposed Regulations

8. The purpose of the proposed Novel Food (England) Regulations 2018 ("the proposed Regulations") is to:

   - Ensure that those 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 the new EU Regulation on novel foods through the use of improved enforcement tools that may be employed to deal with suspected non-compliances with the EU Regulation and a range of civil penalties;
   - Maintain access to a back stop criminal offence and provide for defences against prosecution and establish a right of appeal for committing an offence in particular circumstances;
   - 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 England.

9. 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.

Civil Sanctions; Compliance notices, Stop notices, fixed monetary penalties and powers

10. The Novel Food and Novel Food Ingredients Regulations 1997 (SI No. 1997/1335) provides for the execution and enforcement in England 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.

11. In the light of this operational experience, the proposed Regulations introduce the use of compliance notices, stop notices, and fixed monetary penalties (level to be determined) for minor contraventions. Use of civil sanctions will help to ensure that any minor non-compliances can be remedied quickly and that if sanctions are applied these are appropriate and proportionate. Consequently it will become possible for remedial enforcement action seeking to improve compliance and maintain high levels of public protection to take place without the need to prove that a non-compliant product is categorically unsafe. This will also mean that minor regulatory breaches may be addressed by authorised officers without recourse to the courts, by this means reducing the inherent cost, resource and time needed to carry forward prosecutions and reduce burdens on business at the same time.

12. It is also deemed necessary for authorised officers/justices of the peace 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.

13. The offences to arise as a result of the new EU Regulation on novel foods will be of strict liability. The proposed Regulations provide a mechanism for appeal of the fixed monetary penalties under Schedule 2 and of the compliance notices and stop notices under Schedule 3 of the proposed Regulation. The right to appeal is to the First-tier Tribunal and provision has been made for possible remedies such as the award of compensation in respect of stop notices and completion certificates.

14. 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. Ingredients such as DMBA (1,3-dimethylbutylamine) have been found added to sports and weight loss supplements as a 'fat burner'. The US Food & 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 & 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. This is an example of inefficient market response to food safety.

15. In this case, government intervention is necessary to provide enhanced enforcement powers that will help to ensure that minor non-compliances can be remedied quickly and efficiently through the use of compliance notices, stop notices and fixed monetary penalties. Whilst 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 to EU Regulatory changes

16. The previous EU legislation, Commission Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients was in force since 1997 and applied to foods and food ingredients that did not have a significant history of consumption in the European Union (EU) before 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[7], 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.

17. The scope of the new EU Regulation broadly remains the same as Regulation (EC) No. 258/97 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 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.

18. The new EU Regulation repealed 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) No. 2015/2283 allow that:

    i. 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.

[7] Ref OJ L 31, 1.2.2002, p.g. 1: Regulation (EC) No. 178/2002of 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.

ii. 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 a MS on the basis of Regulation (EC) No. 258/97 and no other MS has raised any reasoned objection to that assessment.

iii. Foods not falling within the scope of Regulation (EC) No 258/97, which were 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 Articles 10 to 12 (novel foods) or Articles 14 to 19 (traditional foods from third countries) of the new EU Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of the new EU Regulation respectively, but no later than 2 January 2020.

iv. The Commission may, by means of implementing acts, adopt measures concerning the requirements referred to in Articles 13 and 20 necessary for the application of the transitional requirements set out in paragraphs 1 and 2 of Article 35. Those implementing acts must be adopted in accordance with the examination procedure referred to in Article 30(3).

19. The new EU Regulation also amends Regulation (EU) No. 1169/2011, 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 (*)

Clarification of definitions and scope of the new EU Regulation

20. The new EU Regulation has a broader scope than the previous legislation; the definition of a 'novel food' has been updated (as mentioned at paragraph 5a above) to include:

    - whole insects;
    - engineered nanomaterials (the definition is taken from the Food Information for Consumers Regulation (EU) No. 1169/2011 and may be updated via delegated acts in light of technical progress);
    - food with an 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.

21. 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 previous provisions had, on occasions, been found to be ambiguous in this regard. The new EU Regulation aims to provide a clearer definition than at present.

22. 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 Union list of authorised novel foods will help in this regard, if unsure food businesses should consult and provide all necessary information to the MS in which they first intend to market the product to enable a determination to be made. MS 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.

23. The new EU Regulation intends to provide greater clarity and certainty for food operators who may otherwise be unsure whether a food they intend to market falls within the scope of the EU Regulation on novel foods and therefore, requires authorisation.

Detailed provisions of the new EU Regulation

24. 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;
25. 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.

Union List

26. The new EU Regulation requires that the Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ("the Union list") (Articles 6-12). Only novel foods authorised and included in the Union list may be placed on the market within the Union, 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 Union list they are required to meet the 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 for the consumer.

27. The Union List was established by Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 and includes novel foods that were already authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any associated authorisation conditions and requirements.

Centralised Risk assessment

28. Centralising the authorisation procedure for novel foods; the European Food Safety Authority (EFSA) will carry out an initial assessment on novel foods. The current system requires MS to carry out an initial assessment, which is then shared with all other MS for comment – a process that takes a significant period of time, particularly as most dossiers are later referred to EFSA for advice on outstanding concerns raised by MS. Once EFSA's opinion is available, there is a further delay while the Commission prepares a formal authorisation decision which is voted on by MS. The new streamlined, time restricted centralised 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. In accordance with Article 13 of the new EU Regulation, Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 lays down administrative and scientific requirements concerning novel foods applications.

Generic Authorisations

29. 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 to 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

30. Introducing a simplified safety assessment procedure for traditional food from third countries enables traditional foods to gain authorisation relatively quickly if applicant companies are able to demonstrate a history of safe use outside the EU. Under the previous legislation, foods made from plants, microorganisms, fungi, algae and animals (e.g. chia seeds or baobab fruit) that are widely consumed elsewhere in the world had to undergo the same detailed lengthy assessment procedures as completely innovative products. Under the 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 MS 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. In accordance with Article 20 of the new EU Regulation, Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 lays down administrative and scientific requirements concerning notifications and applications in respect of traditional foods from third countries.

Data Protection

31. Where applicants request confidentiality for certain information submitted for updates to the Union list under the new EU Regulation the disclosure of which 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.

32. The new EU Regulation also introduced 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 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

33. 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

34. Prior to the adoption of the new EU Regulation the European Commission carried out a formal consultation; this included stakeholders for the food industry, consumers, third countries and MS 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.

35. 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 to their economic, social and environmental impact on the various stakeholders and MS. The published Impact Assessment is available at:

    http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm.

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

    - avoid delays that are associated with the current authorisation procedure for novel foods;
    - 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;
    - avoid unnecessary duplication due to the current requirements for different manufacturers to submit applications for the same product;
    - remove the overlap with other EU food law, which currently leads to unnecessary duplication in assessments and authorisations; and
    - update the legal text in order to improve its clarity and to bring it in line with developments in EU food law.

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

Simplification

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

    - 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;
    - national administrative procedures and duplication of work have been removed;
    - the authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden in particular, for businesses;
    - A simplified procedure for the placing on the market of the traditional foods from third countries is introduced reducing barriers to trade.

Policy Options Considered

Option 1 – Do Nothing – do not make domestic Regulations to provide for the enforcement and execution of the new EU Regulation in England; Wales; and Northern Ireland.

38. This option will not prevent the new EU Regulation applying in England; Wales; and Northern Ireland 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.

Option 2 – Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.

39. 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.

40. This is the preferred option.

Option Appraisal

Costs and Benefits

Option 1: Do Nothing – do not make national Regulations to provide for the enforcement and execution of the new EU Regulation in England; Wales; and Northern Ireland.

41. There are no costs or benefits associated with this option. This is the baseline against which the policy option is appraised.

Option 2: Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation on novel foods.

42. 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

43. This figure is calculated by firstly taking the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[8] figure 'Production managers and directors' £25.54 and uprating it by 20%, according to the Standard Cost model[9], to account for overheads, giving a mean[10] hourly wage rate of £30.65. It is estimated that the reading and understanding of the EU Regulations and the proposed Regulations and will take one and half hours with a further one and a half hours more for dissemination to key staff within each firm (a total of three hours). Given the number of enquiries, the FSA receives annually from companies concerning this area of legislation, it is estimated that approximately 1,000 companies[11] will need to invest in understanding the new legislation. Thus yielding an approximate one-off familiarisation cost to firms of £92k.

44. In order for 'one-off' familiarisation costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs (EAC) using a standard formula.[12] In line with Her Majesty's Treasury (HMT) Green book guidance a discount rate of 3.5% is used. Annualising the total one off familiarisation of £92k (see previous paragraph) yields an EAC of £11k in the England, Wales and Northern Ireland over 10 years.

Option 2 – Benefits to Industry

Generic Novel Food Authorisations

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

---

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

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

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

[11] The FSA has made the reasonable assumption that approximately 1,000 food business operators are active in considering placing novel foods on the market based on the number of enquiries we receive; 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.

[12] EACB = PVCB/a_{tr}, Where a_{tr} is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

PVCB is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

- a full novel food application (with accompanying scientific dossier) for authorisation; or
- an application seeking to demonstrate the substantial equivalence (SE) of their novel food product to one that is already authorised.

46. 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.

47. 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 should show how 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);
    - nutritional value;
    - metabolism;
    - intended use (such as a food ingredient or supplement); and the
    - level of undesirable substances (such as contaminants, mycotoxins and allergens).

48. The new EU Regulation has introduced a move from applicant specific authorisations to generic authorisations (as mentioned at paragraph 5d). Once a novel food is authorised any operator could benefit from that authorisation subject to any proprietary data protection restrictions that may apply (see paragraph 5e above). This move to generic authorisations has removed the need for SE applications.

49. Informal enquiries amongst industry sources in the UK suggest the administrative cost of preparing an SE application and taking it through the previous 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

50. 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 MS.

51. The cost to an applicant of making a novel application will vary from case by case; depending on the complexity of the case 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[13] (£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).

[13] This figure was provided in 200. 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.

52. There are no data on which 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.

On-going (annual) benefit of savings due to lower 'Administrative Costs'

53. 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 previous process may be in the order of £20k-£50k. If the applicant does not already have the data to undertake a formal risk assessment, the cost of the 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).

54. The current authorisation procedure is based on assessments carried out by the relevant authorities in one of the 28 EU MS, 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 replaces this with a single centralised assessment by EFSA (as mentioned at paragraph 5b above), 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.

55. 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.

56. Having 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.

57. 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 MS. 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 (see above, para.46) 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 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 England, Wales and Northern Ireland 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 (also present value figures).

58. No calculation could be made for UK businesses seeking authorisation through other MS as the number of business affected are unknown.

On-going (annual) benefit savings due to 'Removal of application fees'

59. 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 empowers the FSA to charge:

    - £4,000 in respect of a full novel food applications; and
    - £1,725 in respect of an opinion on substantial equivalence.

60. 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 England, Wales and Northern Ireland over ten 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 ten years.

Non-monetised benefit to industry of "the Establishment of a Union list of Authorised Novel Foods"

61. The establishment of a Union list of authorised novel foods (as mentioned at paragraph 5c above) 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"

62. There is increasing 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 (Columbia, 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.

63. Whilst the previous EU novel foods legislation did not prevent trade in traditional foods, such products needed to go through the full authorisation procedure that applies to other novel food; but few applications have been received, possibly because the requirements for authorisation are seen by exporters as unduly onerous and burdensome.

64. The simplified traditional food from third countries notification procedure (as mentioned at paragraph 5f above) 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 applicants in providing the type and quality of information needed by EU MS and EFSA to consider whether there are reasoned safety objections to the placing on the market within the Union of the traditional food with the proposed conditions of use.

65. Dossiers should contain specifications on the traditional food; reliable data on the composition of the 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 MS and EFSA for consideration within 1 month of receipt by the Commission and the specified 4 month period permitted for MS and EFSA to raise any reasoned safety objections) the notified traditional food could be added to the authorised Union list within 6 months.

66. This simplified procedure should help facilitate trade by enabling traditional foods to proceed swiftly to the market, unless a MS, 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 a Union list of Authorised Novel Foods"

67. The establishment of a Union 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 Union list will also provide any applicable conditions of use that should be observed in relation 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

68. 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

69. There are approximately 386 local authorities and 36 Port Health Authorities in England, Wales and Northern Ireland. It is estimated that one officer in each of these authorities (one / Health Officer from each local authority'; and one 'Inspector of Standards' from each Port Health Authority) is expected to read and familiarise themselves with the EU Regulations and the proposed Regulations and that it may takes them one and a half hours to do so. In addition, we have estimated that a further hour and a half is required to disseminate to key staff within the organisation (three hours in total).

70. An estimate of the cost with respect to the time taken by enforcement officers at local authorities to familiarise themselves is £18.97. This figure taken from the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[14], figures for an Environmental Health Officer £18.97 per hour (median value), which, in line with the Standard Cost Model, is then up-rated by 20% to account for overheads, which gives an hourly wage rate of £22.76. With 386 local authorities, this gives a total cost of £26k. An estimate of the cost with respect to the time taken by 'Inspectors of standards' at Port Health Authorities, to familiarise themselves is £17.83. This figure taken from the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings), figures for an 'Inspector of standards' £15 per hour (median value), which, in line with the Standard Cost Model, is then up-rated by 20% to account for overheads. With 36 Port Health Authorities, this gives a total cost of £2k. This result in a total approximate one-off cost for enforcement bodies of £28k.

71. 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.

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

Data Protection

72. As mentioned earlier, under the new EU Regulation, authorisations will be issued on a generic basis, as they are in other areas of EU food law, such as food additives.

73. However, as the original applicant may have made a substantial investment in general new or proprietary data. In order to protect this investment and to promote innovation, the new EU Regulation provides a data protection system that could be applied in appropriate cases (as mentioned at paragraph 5e above). In qualifying cases, only the original applicant would be able to benefit from the authorisation. Other operators could also apply for authorisation, but they would have to provide their own data or seek permission from the original applicant to use that applicants data. This part of the new EU Regulation was modelled on Regulation (EC) No. 1924/2006 (as amended) on nutrition and health claims.

74. This change may provide benefits for the original applicant in cases where they are unable to rely on other systems that provide protection for intellectual property e.g. patents.

75. Where the data protection system does not apply, generic authorisation would benefit other operators who currently would have to notify their equivalent products under the simplified procedure, since generic authorisations will allow them to proceed directly to market.

Novel Food Market

76. No data are available on the size of the current or future EU market for novel foods. As in the EU impact assessment for the 2008 proposal it is very difficult to produce data on the size and extent of the novel food market in the UK, because it is not a single uniform market covering a broad range of different products. As such it would difficult to try and extrapolate an overall picture of the UK market for novel food products. So whilst there is potential for innovative food technologies and products, supporting data is not readily available. Overall, novel foods play only a minor role in the diet.

77. Phytosterols are probably the most successful of the products authorised under the 1997 EU Regulation, being widely available in a range of products aimed at people who wish to reduce their cholesterol levels. More recently the authorisation of chia seeds has seen successful commercialisation of this novel food product which is widely available to consumers in a range of food products. Other authorised novel foods are less widely available on the market, being found; for example, in a limited number of food supplements or more specialised products. In some cases, the products may not yet be introduced onto the market for commercial reasons unrelated to the Novel Food Regulation.

Competition Assessment

78. 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 investments by means of data protection) are expected to lead to increased innovation and potentially competition. Especially, if the time-to-market of new novel food products/ingredients is reduced.

Small and Micro Business Assessment (SMBA)

79. The UK food industry sector is comprised of mainly small and micro businesses and therefore the greatest impact from changes in from the new EU Regulation introduced in the UK will, in the vast majority of cases, be on small and micro businesses. For this reason the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

80. EU legislation generally applies to food businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. Due to the high ratio of small and micro food businesses in the UK it is often not feasible to exempt smaller businesses from new food measures as this would fail to achieve the intended effect of reducing risks to consumer health. That said, the

FSA makes every effort to minimise burdens on small and micro businesses and pays particular attention to impacts on them. In considering the likely impact on SMBAs the FSA believe the changes at EU level will help to simplify and increase efficiency of the regulatory procedures that apply to novel foods. This should in turn increase the ability of small firms to bring novel foods to the EU market.

Sustainable development

81. There are two possible impacts, related to the introduction of novel foods derived from natural sources:

a). ingredients could be derived by harvesting scarce natural resources. While, trade in products obtained from recognised endangered species would be illegal, a sudden increase in demand could significantly reduce the numbers of a given species if the ingredients obtained from plant or animals taken from the wild.

b). the authorisation of traditional foods from countries outside the EU could increase the innovation of wild species through horticulture and provide a valuable source of income for farmers developing countries.

Race/gender equality issues

82. The proposed Regulation does not impose any restrictive compliance to any person from a particular race, gender or with disability.