EXPLANATORY MEMORANDUM TO

The Novel Foods (Wales) Regulations 2017

This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Novel Foods (Wales) Regulations 2017. I am satisfied that the benefits justify the likely costs.

Vaughan Gething AM

Cabinet Secretary for Health and Social Services

16 November 2017

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Novel Foods (Wales) Regulations 2017

1. Description

Novel foods are foods or food ingredients that do not have a significant history of consumption within the EU before 15 May 1997. They are currently regulated in the EU by the Novel Foods Regulation (EC) No 258/97. The main purpose of the Regulation is to prohibit the sale of unauthorised novel foods, which could pose a risk to public health.

The Novel Foods Regulation (EC) No 258/97 is to be repealed and replaced by Regulation (EU) 2015/2283 on novel foods as of 1 January 2018. The Novel Food (Wales) Regulations 2017 will revoke and replace in Wales the Novel Food and Novel Food Ingredients Regulations 1997 (1997/1335), which provide for the enforcement of the Novel Foods Regulations (EC) No 258/97. The proposed Regulations will also revoke the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 (1997/1336) in relation to Wales and the Food Enzymes (Wales) Regulations 2009 (2009/3377). HM Treasury consent has been obtained to revoke the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to Wales.

2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee

None.

3. Legislative Background

The powers enabling the Regulations to be made are conferred by sections 6(4), 16(1)(a), (e) and (f), 17(2), 18(1)(a), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990, and section 56(1) of the Finance Act 1973.

The powers given by these sections, which were vested in UK Government Ministers prior to devolution, were transferred to the National Assembly for Wales in 1999 by the National Assembly for Wales (Transfer of Functions) Order 1999 (SI 1999/672) and were subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

The Regulations will be made by statutory instrument subject to the negative resolution procedure.

4. Purpose and Intended Effect of the Legislation

The purpose of the Novel Foods (Wales) Regulations 2017 is to:

- Ensure that those placing novel foods on the market within Wales are fully compliant with the new EU 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 against the imposition of an improvement notice 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 and the Novel Foods and Novel Food Ingredients (Fees) Regulations 1997 in relation to Wales.

5. Consultation

The FSA in Wales held a public consultation between 3rd April and 26th June 2017. There were no responses to the consultation.

6. Regulatory Impact Assessment

The figures used in the Impact Assessment to calculate the costs and benefits to businesses are on a UK wide basis. The FSA does not hold details of the number of businesses in Wales using novel foods and so these figures are not available on a disaggregated basis. Novel foods can be used by any business so they are unlikely to be registered as a 'novel foods business' and therefore identifiable as such. During the consultation for the Novel Foods (Wales) regulations 2017 the FSA asked local authorities to draw this to the attention of any business using novel foods in their areas. We received no responses to the consultation in Wales. On this basis UK figures have been used above to calculate the cost to industry.

What policy options have been considered?

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

This option will not prevent the new EU Regulation applying in Wales 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. This could also

lead to infraction proceedings being brought against the UK for failing to enforce the new EU Regulation as part of its legal obligations to the EU.

Option 2 – Make appropriate domestic Regulations for the execution and 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.

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.

There are no additional costs or benefits associated with this option. This is the baseline against which the alternative policy option is appraised. As noted above, failing to introduce the Regulations carries a risk of infraction proceedings and a fine from the EU.

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

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

This figure is calculated by firstly taking the 2016 Provisional ONS ASHE (Annual Survey of Hours and Earnings)[1] figure 'Production managers and directors' £25.54 and uprating it by 20%, according to the Standard Cost model[2], to account for overheads, giving a mean[3] hourly wage rate of £30.65. It is estimated that the reading and understanding of the EU Regulation and the proposed Regulations 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[4] across the UK will need to invest in

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1 https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

2 SCM methodology http://www.berr.gov.uk/files/file44503.pdf

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

4 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;

understanding the new legislation, thus yielding an approximate one-off familiarisation cost to firms across the UK of £92k.

Option 2 - Costs to Enforcement

One –off familiarisation cost

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 Regulation and the proposed Regulations and that it 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).

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)[5], 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 across England, Wales and Northern Ireland of £28k.

Within Wales there are 22 local authorities, including one Port Health Authority. Using the figures above for hourly rates and familiarisation time this would result in a cost for local authorities of £1500 and the Port Health Authority of £55. The total approximate one-off cost for enforcement bodies in Wales would be £1555.

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.

Option 2 – Benefits to Industry

Generic Novel Food Authorisations

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procedures for seeking authorisation of a novel food; and how to demonstrate that a product has a history of consumption in the EU.

5 https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

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

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.

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.

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).

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 protection restrictions that may apply. This move to generic authorisations has removed the need for SE applications.

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

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 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.

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.

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.

The cost to an applicant of making a novel application will vary from case to 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[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).

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'

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 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

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6 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.

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).

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.

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 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).

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'

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.

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"

The establishment of a 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"

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.

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 the requirements for authorisation are seen by exporters as unduly onerous and burdensome.

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 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.

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.

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"

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

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.

Competition Assessment

The competition filter test	
Question	**Answer** **yes or no**
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market	No

The competition filter test	
Question	**Answer** **yes or no**
structure, changing the number or size of firms?	
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

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. This is especially the case, if the time-to-market of new novel food products/ingredients is reduced. These regulations will support businesses to be able to bring a wider range of products to market quicker.