

Commission Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food – implementation in Scotland

Date: 18 January 2019
Stage: Final
Source of intervention: Scotland
Type of measure: SSI
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1. Title of Proposal

Commission Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.

2. Purpose and intended effect

(i) Objectives

The overall aim of the Regulation is to ensure that food businesses put in place steps to mitigate acrylamide formation where practicable to ensure levels in food are as low as reasonably achievable through the application of appropriate mitigation measures by all food business operators along the food chain. This Regulation is intended to be enforced in Scotland by the Food Hygiene (Scotland) Regulations 2006 (as amended), further to consultation on the relevant statutory amendments.

(ii) Background

Acrylamide is a chemical that naturally forms in starchy food products during high-temperature cooking, including frying, baking, roasting and also industrial processing, at +120°C and low moisture. The main chemical process that causes this is known as the Maillard Reaction; it is the same reaction that 'browns' food and affects its taste. Acrylamide forms from sugars and amino acids (mainly one called asparagine) that are naturally present in many foods. It was first detected in foods in April 2002 although it is likely that it has been present in food since cooking began. Acrylamide also has many non-food industrial uses and is present in tobacco smoke. It is considered to be a chemical hazard in the food chain and a probable genotoxic carcinogen in humans.

The most important food groups contributing to acrylamide exposure are fried potato products, coffee, biscuits, crackers, crisp bread and soft bread.

In June 2015 the European Food Safety Authority (EFSA) produced its full Scientific Opinion on the risks related to the presence of acrylamide in food, and concluded that the current level of acrylamide in foods is a concern for public health. Of the population groups affected children are the most exposed age group on a body weight basis. This position was supported by EU and as a result Regulation (EU) 2017/2158 establishing mitigation measures and Benchmark Levels for the reduction of the presence of acrylamide in food, came into force 11 April 2018. This Regulation applies directly to food businesses across the EU.

Article 5 of Regulation (EC) No 853/2004 requires all Food Business Operators FBOs to put in place, implement and maintain HACCP¹-based Food Safety Management Systems (FSMS). This is to ensure that food safety hazards associated with the production of food are identified and monitored and that controls are in place to mitigate risks to consumers. The Regulation requires (FBOs) to consider chemical contaminant hazards (e.g. acrylamide) within the scope of their FSMS. Additionally Regulation (EC) No 853/2004 also provides significant flexibility which allows HACCP-based FSMS to be tailored to the size and nature of the business without

¹ All food businesses must have a food safety management system based on Hazard and Critical Control Points (HACCP) principles.

compromising food safety itself. This Regulation formalises how this should be approached by certain businesses producing affected products.

The Regulation applies to all FBOs that produce and place on the market the foods listed below. However, the extent to which the Regulations affect specific businesses will depend on business type.

Foods affected are those that typically have a high starch content, and are cooked at high temperatures through frying, roasting, toasting and baking. Per Article 1(2) of the Regulation, foodstuffs within the scope of the Regulation are set out in the table below.

Table 1

<ul style="list-style-type: none">-French fries, other cut (deep fried) products and sliced potato crisps from fresh potatoes; -Potato crisps, snacks, crackers, and other potato products from potato dough;-Bread; -Breakfast cereals (excluding porridge; -Fine bakery wares: cookies, biscuits, rusks, cereal bars, scones, cornets, wafers, crumpets and gingerbread, as well as crackers, crisps bread and bread substitutes. In this category, a cracker is a dry biscuit (a backed product based on cereal flour); -Coffee: (i) roast coffee; (ii) instant (soluble) coffee, coffee substitutes; -Baby food and processed cereal-based food intended for infants and young children as defined in Regulation (EU) No. 609/2013
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FBOs are required to adopt relevant mitigation measures set out in the Regulation. In general, FBOs are expected to be aware of acrylamide as a food safety hazard and have a general understanding of how acrylamide is formed in the food they produce. FBOs are also required to take necessary steps to mitigate acrylamide formation in the food they produce, ensuring that levels are reduced, where possible, to meet with ALARA (As Low As Reasonably Achievable) principles as part of their HACCP-based FSMS

Where required, FBOs must also undertake representative sampling and analysis to monitor the levels of acrylamide in their products as part of their assessment of the mitigation measures. In addition, where required, FBOs must keep appropriate records of the mitigation measures undertaken to demonstrate ALARA together with sampling plans and results of any testing undertaken

The measures are intended to be proportionate to the nature and size of the business so as to ensure that small and micro-businesses are not burdened disproportionately.

The Regulation sets out the three different categories of FBOs affected and the mitigation measures that are applicable. Manufacturers; local independent businesses; and franchises/large operations.

The mitigation measures relevant to the food businesses affected are set out in Annex I and II of the Regulation. These measures are not intended to lead to any significant changes in the quality and organoleptic properties of foods.

In practice compliance means:

- Obtaining assurance that the FBO understands how acrylamide is formed in the food they produce
- Confirming evidence of documented procedures that demonstrate how the business has put in place relevant mitigation measures as part of their HACCP-based FSMS – where practical and appropriate for the products produced.
- Evidence that these procedures are followed, and that they are reviewed and updated where necessary
- For manufacturers; evidence of how the food business controls the presence of acrylamide, such as sampling and analysis of products/product types

Manufacturers and franchises/large operations are required to document and maintain suitable records in order to demonstrate that the relevant mitigation measures have been applied per product or product group as part of their HACCP-based FSMS, to reduce the levels of acrylamide.

The documents should show:

- How the FBO has applied the relevant mitigation measures, including the main procedures or methods used in the business to mitigate acrylamide formation
- How the FBO has selected the mitigation measures
- The sampling plan, evidence of review, where appropriate, and the results of analytical testing undertaken.

Local, independent businesses are required to maintain evidence that mitigation measures are being applied in their premises and/or to the products they produce. This should be incorporated into their HACCP-based FSMS. This could include SOPs, manufacturers' instructions, colour charts/guides and/or procedures based on best practice industry guidance to demonstrate their due diligence in fulfilling their obligations to identify and implement mitigation measures to reduce the levels of acrylamide in food.

Annex IV of the Regulation sets out benchmark levels (BMLs). These are performance indicators to be used to verify the effectiveness of the mitigation measures. BMLs are to be used by FBOs to gauge the success of the application of the relevant mitigation measures. The main aim is to ensure that the levels of acrylamide in their products comply with ALARA principle. BMLs are not maximum limits and are not to be used for enforcement purposes. Exceeding a BML in a product does not therefore mean that the products cannot be placed on the market.

However, and FBO should be able to demonstrate relevant steps are being taken and reviewed.

It is important to note that some foods within the scope of the Regulation will not be able to consistently achieve the BMLs or, in some cases, meet the BMLs at all, despite FBOs taking appropriate mitigation steps to reduce the levels of acrylamide. This may be due to variable factors such as seasonality, geographic conditions and the organoleptic and traditional characteristics of the product.

For example:

The concentration of acrylamide precursors (reducing sugars and asparagine) in potato varies depending on the potato varieties, season of the crop, storage and climatic conditions, which could in turn affect the acrylamide formation in the potato product during cooking.

Different types of coffee may have different levels of acrylamide depending on the coffee bean and the coffee blend as well as the degree of roasting. Therefore, due to many characteristics that affect the levels of acrylamide in coffee, it is not possible for the level of acrylamide in all coffee to be consistently below the BML. Additionally the Regulation itself recognises where there is such a broad food category there may be specific production, geographic or seasonal conditions or product characteristics for which it is not possible to achieve the BML despite the application of all mitigation measures.

(iii) Rationale for Government intervention

In 2015, the European Food Safety Authority published its first full risk assessment of acrylamide in food. This reconfirmed previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups.

Acrylamide is a natural by-product of the cooking process and has always been present in our food. It is important to appreciate that it is not possible to completely eliminate acrylamide from foods, but actions can be taken to ensure that acrylamide levels are as low as reasonably achievable.

As for all directly applicable legislation it is necessary to ensure that statutory obligations can be enforced in domestically. It is proposed therefore that the Food Hygiene (Scotland) Regulations 2006 be amended to include Regulation (EU) 2017/2158 within the list of community provisions that are enforced by those regulations.

This intervention is therefore necessary to ensure that FBOs put in place the necessary mitigation measures throughout the food chain in order to provide a high level of protection of human health.

3. Consultation

(i) Within Government

The draft EU Regulation on acrylamide was discussed extensively at European Commission Working Group Meetings, and further mitigation proposals continue to be discussed at an EU level. Food Standards Agency (FSA) represents UK Government interests at these working groups and FSS has actively engaged in discussions with FSA on this matter.

Scottish Local Authorities and Public Analysts, have been regularly updated following these meetings and asked for comments.

Food Standards Scotland has also prepared guidelines for Local Authorities on the implementation of Commission Regulation (EU) 2017/2158. This guidance was published in January 2019 with engemnet with Local Authorities via the Scottish Food Enforcement Liaison Committee.

(ii) Public Consultation

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.

A four week consultation was carried out in Scotland on the statutory amendment that enforces these new provisions from 19 November 2018 to 17 December 2018. A total of three responses were received from five hundred fifty-eight stakeholders who received the consultation.

(iii) Business

A number of stakeholder engagement meetings and updates took place throughout 2017. FSS was involved in the development by a trade body, UKHospitality, of acrylamide guidance. UKHospitality represents 65,000 venues across the UK including restaurants, pubs and other catering establishments. UK wide engagement took place with industry stakeholders including the British Beer and Pub Association, the British Frozen Food Federation, Nationwide Caterers Association, National Federation of Fish Friers, Potato Processors Association, and Seafish. As a result of this engagement stakeholders were already familiar with the Regulation.

4. Options

Option 1 - Do nothing.

The new EU Regulation on acrylamide are already in force across the EU.

Doing nothing would mean that the new EU Regulation will still apply but a failure to explicitly include the EU Regulations in the list of community provisions that are enforced by the Food Hygiene (Scotland) Regulations 2006 (as amended) might leave enforcement of the provisions open to challenge. Under EU Law the UK is obliged to provide for the enforcement of EU Regulation. Whilst infraction proceedings against the UK are considered highly unlikely it is considered appropriate that the relevant community provisions that apply to food businesses are explicitly set out in domestic enforcement regulations.

Option 1 is therefore disregarded as an option but it is the baseline against which other options are appraised.

Option 2 - Make appropriate domestic regulations to provide for the enforcement of the new EU Regulation on acrylamide.

This option will provide enforcement authorities with the necessary powers to enforce the new EU Regulation; which are intended to protect public health, should such action be considered necessary, and remove any associated risk of Scotland incurring infraction proceedings.

This is the preferred option.

(i) Sectors and groups affected

Businesses

Manufacturers, caterers and retailers are the main groups affected by the Regulation.

Enforcement Authorities

Enforcement of the Regulation 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.

Consumers

It is expected measures to reduce the presence of acrylamide in food will have positive long term health benefits to consumers.

Option Appraisal: Costs and Benefits

(a) Benefits - Non-Monitised

Acrylamide is present in a wide range of everyday foods, this health concern applies to all consumers but children are the most exposed age group on a body weight basis. The most important food groups contributing to acrylamide exposure are fried potato products, coffee, biscuits, crackers, crisp bread and soft bread.

In 2015 the European Food Safety Authority published its first full risk assessment of acrylamide in food. This reconfirmed previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups. Therefore, as stated above, it is expected measures to reduce the presence of acrylamide in food will have positive long term health benefits to consumers.

(b) Costs

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

Business

The Regulation sets out the three different categories of FBOs affected and the mitigation measures that are applicable;

- Manufacturers (referred to in Article 2.1 of the Regulation)
- Local and/or independent businesses such as cafes, fish and chip shops and restaurants (referred to in Article 2.2 of the Regulation)
- Franchises/large operations such as restaurants, hotels and café chains (referred to in Article 2.3 of the Regulation)

(i) Manufacturers

FBOs which produce and place on the market foodstuffs listed above shall apply mitigation measures provided for in Annex I of the Regulation. Annex I of Regulation sets out specific requirements for these FBOs to adopt in order to mitigate acrylamide formation in the foods listed in the Regulation.

Not all the mitigation measures are relevant to all food manufacturers. It is expected that an FBO will choose the relevant measures for their products and apply as appropriate to ensure that the levels of acrylamide in their products comply with the ALARA principle.

(ii) Local independent businesses

Part A of Annex II outlines the relevant mitigation measures applicable for businesses which perform retail activity, and or directly supply only local retail establishments.

FBOs should have in place appropriate procedures so that they are following the mitigation measures. In practice, this could include manufactures instructions, colour charts/guides and/or procedures based on best practice industry guidance.

Where products have instrincally high levels of acrylamide (such as American style, flame grills, wood fired pizzas, etc), then only limited acrylamide mitigation steps in such businesses may be possible. In such cases, businesses should be encouraged to reduce acrylamide in general terms, including across the wider range of products on offer, where possible, and in line with ALARA principle.

Table 2 contains a summary of actions required for this sector:

Table 2: relevant mitigation measures applicable for businesses which perform retail activity, and or directly supply only local retail establishments.

Products	Actions
Potato Products; French fries and other cut (deep fried) potato products	General steps: <ul style="list-style-type: none">• Potato varieties with lower sugar content shall be used, when available and insofar as compatible with the desired food product to be obtained.

	<ul style="list-style-type: none"> • Potatoes shall be stored at a temperature higher than 6 °C. <p>Before the frying process:</p> <p>One of the following measures shall be taken with raw French fries to reduce the sugar content, where possible and insofar as compatible with the desired food product to be obtained:</p> <ul style="list-style-type: none"> • Washing and soaking preferably for 30 minutes up to 2 hours in cold water. Rinse the strips in clean water before frying. • Soaking for a few minutes in warm water. Rinse the strips in clean water before frying. • Blanching of potatoes results in lower levels of acrylamide and therefore where possible, it is appropriate to blanch potatoes. <p>Exception: Frozen potato products, for which cooking instructions shall be followed</p> <p>During the frying process:</p> <ul style="list-style-type: none"> • Frying oils and fats shall be used which allows to fry quicker and/or at lower temperatures. Cooking oil suppliers shall be consulted for the best suited oils and fats. • Frying temperatures shall be below 175 °C and in any case as low as possible taking into account the food safety requirements. • Frying oils and fats quality shall be maintained by skimming frequently to remove fines and crumbs. • For the cooking of French fries, it is appropriate that the FBOs make use of available colour guides* providing guidance on the optimal combination of colour and low levels of acrylamide.
Bread and fine bakery wares	<ul style="list-style-type: none"> • Insofar possible and compatible with the production process and hygiene requirements: • The extension of yeast fermentation time; • The moisture content of the dough for the production of a product with low moisture content, shall be optimised; • The lowering of oven temperature and the extension cooking time. • Products shall be baked to a lighter colour endpoint and dark roasting of crust shall be avoided where the strong roasting and not related to the specific composition or nature of the bread resulting in a dark crust.
Toasted Sandwiches	<ul style="list-style-type: none"> • When preparing sandwiches, the FBOs shall ensure that sandwiches are toasted to the optimal colour. • When using pre-packed bread or bakery products which are to be finished, cooking instructions are followed.

(iii) Franchises/large operations

These are FBOs which operate in facilities under direct control, and that are operating under one trademark or commercial license, as a part of, or franchise of, a larger, interconnected operation and under the instructions of the food business operator that centrally supplies the foodstuffs listed in the Regulation.

Examples of Article 2(3) FBOs covered in this category include large restaurants, hotels and café chains. It does not include local independent operators that may have a few outlets or interconnected businesses.

In addition to the mitigation measures set out in Table 2 above, food businesses covered by Article 2(3) are also required to adopt the relevant mitigation measures detailed in Part B of Annex II of the Regulation.

This is intended to place some extra obligations on certain FBOs in addition to those referred to in Article 2(2). The requirement typically applies to larger, centrally controlled and centrally supplied chains with standardised menus and operating procedures. The mitigation measures, referred to in Part B of Annex II, are to be applied by the FBOs. The requirement to demonstrate that sampling and analysis has been undertaken to assess the effectiveness of the mitigation measures may be satisfied by the central business rather than the individual outlet.

Table 3 summarises actions required for this sector in addition to those outlined in Table 2 (though not all the mitigation measures outlined in the box below may be applicable in specific circumstances)

Table 3 Additional requirements for franchises/large operations.

1. General requirement

FBOs shall accept products referred to in Article 1(2) only from FBOs that have implemented all mitigation measures set out in Annex I.

2. French fries and other cut (deep fried) potato products

FBOs shall (where appropriate):

- follow the instructions on storage of provided by the FBOs or the suppliers or provided for in the relevant mitigation measures in Annex I;
- work with SOPs and calibrated fryers equipped with computerised timers and programmed to standard settings (time-temperature);
- Monitor the level of acrylamide in finished products to verify that the mitigation measures are effective in keeping acrylamide levels below the BML.

3. Bakery products

FBOs shall monitor the level of acrylamide in finished products to verify that the mitigation measures are effective in keeping acrylamide levels below the BML.

4. Coffee

FBOs shall ensure that the level of acrylamide in supplied coffee is lower than the BML specified in Annex IV taking into account however that this may not be possible for all coffee types depending on blend and roast characteristics. In these cases a justification is provided by the supplier.

One of the mitigation steps FBOs are required to apply when making french fries and other cut (deep fried) potato products (e.g. chips, fried roast potatoes) is the use of Standard Operating Procedures and calibrated fryers equipped with computerised timers and programmed to standard settings (time-temperature). However, it is not anticipated that FBOs should immediately purchase such equipment, if their current equipment is operationally fit for purpose and well maintained.

It should be noted that, in the absence of calibrated fryers, FBOs are expected to follow the measures set out in Part A of Annex II under 'French fries and other cut (deep fried) potato products' where these products are produced.

Sampling and analysis

Article 4 of the Regulation sets out the sampling and analysis requirements for manufacturers and franchises/large operations. These are further elaborated in Annex III of the Regulation. FBOs, where required, are expected to undertake representative sampling and analysis to monitor the levels of acrylamide in their products as part of their assessment of the mitigation measures.

The Regulation requires manufacturers and franchises/large operations to have a sampling plan that:

- Is representative of product types they produce. This does not mean that every single product line must be sampled.
- Revised at least annually for products that have a well-known and well controlled acrylamide levels.
- Is devised on a risk basis and is proportionate, with a focus on foods that are likely to have higher levels of acrylamide and for which further mitigation measures are feasible.
- Where there are significant changes to a recipe or process that are likely to impact acrylamide levels, representative sampling and analysis should be undertaken.
- The sampling plan and results should be available to relevant Authorised Officer (AO) upon request. The information should also include any mitigation steps taken to reduce acrylamide levels where the BMLs have been exceeded.

For franchises/large businesses, the sampling and analysis plans and results may be made available by the central business rather than each individual outlet/chain.

One-off familiarisation costs to industry

It is estimated that it would take one industry professional 20 minutes in total to understand this Regulation, in addition to familiarisation discussion with the EHO.

The median hourly pay rate for these industry professionals has been obtained using ASHE Provisional 2017 figures, estimated as £23.14 plus 20% overheads = £27.81

Business numbers data has been obtained from Annual Business Survey, ONS 2018. These figures also take into consideration that business types will be impacted to different degrees. For example, 100% bakery businesses will be impacted, however for public houses and bars, to take into account those that do not prepare or serve food but it is estimated about 50% will be impacted.

Total number of businesses affected by the Regulation 10,950

Estimated familiarisation time = 20 minutes

£27.81 hourly rate / 20 minutes = 9.27 x 10,950 businesses = £101,506

Broken-down as follows:

Small and micro businesses - number of businesses affected 10,517.5

£27.81 hourly rate / 20 minutes = 9.27 x 10,517.5 businesses = £97,497.22

Medium business - number of business affected 292.5

£27.81 hourly rate / 20 minutes = 9.27 x 292.5 businesses = £2,711.47

Large business - number of businesses affected 140

£27.81 hourly rate / 20 minutes = 9.27 x 140 businesses = £1,297.80

Ongoing Costs to Industry

Ongoing costs to industry should be minimal, as after the one-off familiarisation process, it is expected business will implement set practices. In general FBOs should be able to provide enforcement officials with appropriate documentation to show how the relevant mitigation measures have been applied, and information on how best practice has been identified and implemented. This may include Standard Operating Procedures (SOPs) as part of their food safety management plans.

Costs to Enforcers

Learning and Dissemination Costs

Local Authority Environmental Health Officers will need to become familiar with the mitigation measures set out in the Regulation.

Familiarisation costs are quantified by multiplying the time it will take for an official to familiarise themselves with the Regulations, by median hourly wage rate of the

official, uplifted by 20% to allow for overheads, and the number of enforcement authorities affected.

In Scotland, for LA's we estimate that Environmental Health Officers (EHO) will need to spend 1 hour familiarising themselves with the new Regulations. In Scotland the median hourly rate for Scotland Environmental Health professionals is around £15.29 (ASHE Provisional 2017). £15.29 plus 20% uplift = £18.38 x 130 estimated affected enforcers = £2,389. This is likely to be a conservative estimate as Local Authorities have already been advised of the new Regulation requirements.

Ongoing Costs to enforcers

Enforcers must continue to monitor businesses to ensure compliance with other regulatory requirements. It is not expected that the requirements for this Regulation will require additional inspection visits, rather discussions with FBOs would be expected to take place within the programmed inspection schedule. Inspection frequencies are for LAs to determine in line with the Code of Practice.

The following are calculations that capture costs to EHOs engaging with relevant food businesses via a conversation during regular inspection - this might not occur all within the same year, no distinction has been made for which or over how many years these costs fall over. They are expected to be one-off costs. The time spent discussing with the business will depend on the size of the business and dedicated resources.

Business numbers data have been obtained using the same method as above.

EHO hourly rate of £18.38 worked out as above.

Small and micro businesses - number of businesses affected 10,517.5

Estimated time for one EHO to speak to business = 15 minutes

£18.38 EHO hourly rate / 15 minutes = 4.595 x 105,175.5 businesses = £48,327.91

Medium business - number of business affected 292.5

Time for one EHO to speak to business = 10 minutes

£18.38 EHO hourly rate / 10 minutes = 3.063 x 292.5 businesses = £896.02

Large business - number of businesses affected 140

Time for one EHO to speak to business = 10 minutes

£18.38 EHO hourly rate / 10 minutes = 3.063 x 140 businesses = £428.82

Total familiarisation and ongoing cost to enforcers across Scotland is therefore estimated to be £52,041.75

5. Scottish Firms Impact Test

The consultation was circulated to industry, Local Authority Environmental Health departments and trade bodies. They were also requested to consider all the questions posed in the partial BRIA and cost estimates. The trade body raised points concerning costs for food businesses and EHO. These costs have been reviewed and have been reflected in the final BRIA. The independent professional research body and Local Authority Environmental Health department did not raise concerns and agreed with the familiarisation estimates.

Competition Assessment

The Regulation 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.

Test run of business forms

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

6. Legal Aid Impact Test

Commission Regulation (EU) 2017/2158 will not introduce new criminal sanctions or civil penalties therefore there are no legal aid implications. It is not anticipated that enforcement of these provisions will result in an increase in the number of businesses seeking legal assistance.

7. Enforcement, sanctions and monitoring

i. Enforcement

Enforcement of the Regulations in Scotland will be the responsibility of Local Authorities.

It is not expected that the requirements for this Regulation will require additional inspection visits, rather discussions with FBOs would be expected to take place within the programmed inspection schedule. Inspection frequencies are for LAs to determine in line with the [Food Law Code of Practice](#)

In general FBOs should be able to provide enforcement officials with:

- Information on how best practice has been identified and implemented. This may include Standard Operating Procedures (SOPs) that show practical steps being taken by the food business to mitigate acrylamide in their products
- Appropriate documentation to show how the relevant mitigation measures have been applied

ii. Sanctions

Where an FBO cannot demonstrate appropriate mitigation steps have been considered and are being implemented, the AO may consider taking further action including formal action. The Regulation is to be enforced in Scotland by the Food Hygiene (Scotland) Regulations 2006 (as amended).

iii. Monitoring

The effectiveness and impact of the Regulation will be monitored via feedback from stakeholders, including AOs, as part of the ongoing policy process.

8. Implementation and delivery plan

Regulation (EC) 2017/20158 came into force on 11 April 2018. Amendments to the Food Hygiene (Scotland) Regulations 2006 are subject to consultation. The publication of the Food Standards and Food Hygiene (Miscellaneous Amendments) (Scotland) Regulations 2019 will be communicated to stakeholders by means of an Interested Parties' letter. This will be done shortly after the SSI has been published on the legislation.gov.uk website. The Food Standards and Hygiene (Miscellaneous Amendments) (Scotland) Regulations 2019 will come into force 28 March 2019.

9. Post-implementation review

The benchmark levels will be regularly reviewed by the Commission with the aim to set lower levels, reflecting the continuous reduction of the presence of acrylamide in food. Consideration will also require to be given in a UK context as to potential changes in this area in future.

10. Summary and costs benefits table

Option	Total benefit per annum: -economic, environmental, social	Total cost per annum: -economic, environmental, social -policy and administrative
1	Do nothing therefore no financial cost	Cost to public health has not been quantified; possible costs associated with infraction proceedings considered minimal.
2	Identification and monitoring food safety hazards associated with the production of food and controls in place to mitigate risks to consumers. No infraction fines due to introducing the new Scottish Statutory Instrument	Industry: Familiarisation and ongoing cost: £101,506 Enforcement: Familiarisation and ongoing cost: £52,041

Option 2 is considered the preferred option. It ensures that appropriate public health controls are applied in Scotland and that Scottish Ministers meet their obligations to implement 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 signatureJOE FITZPATRICK

Minister's titleMINISTER FOR PUBLIC
HEALTH, SPORT AND WELLBEING

Date

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