

To: Lead Food Officers

Cc: REHIS, SFELC

29th January 2018

Ref: FSS/ENF/18/003

Dear Colleague

Draft Acrylamide Regulation Guidance

Views are requested on the draft information note to Local Authorities setting out guidelines on the interpretation and implementation of Commission Regulation (EU) 2017/2158 (the acrylamide Regulation). A copy of the guidance is provided in the annex. The deadline for responses is 16 February 2018. Please send your response directly to will.munro@fss.scot.

[Regulation \(EU\) 2017/2158](#) establishing mitigation measures and benchmark levels (BMLs) for the reduction of the presence of acrylamide in food will apply directly to UK food businesses from 11 April 2018, and is implemented in Scotland by 'The Food Hygiene Regulations (Scotland) 2006'. The Regulation promotes and supports best practice in managing acrylamide as a food safety hazard throughout the food chain. The draft information note is intended to help relevant authorised officers with the interpretation and implementation of the Regulation.

If you should have any queries please do not hesitate to get in contact.

Yours sincerely

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DRAFT

INFORMATION NOTE SETTING OUT GUIDELINES FOR LOCAL AUTHORITY ON THE IMPLEMENTATION OF COMMISSION REGULATION (EU) 2017/2158

This information note is intended to help relevant authorised officers with the interpretation and implementation of [Commission Regulation \(EU\) 2017/2158](#).

Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food was published in the Official Journal of the European Communities on the 21 November 2017. The Regulation will apply directly to UK food businesses from the 11 April 2018.

The information provided in this note does not represent an authoritative interpretation of the law and is no substitute for an understanding of the legal requirements. This note is not legally binding and it should be read in conjunction with Commission Regulation (EU) 2017/2158.

Introduction

Acrylamide is a chemical substance formed by a reaction between amino acids and sugars, typically in foods with high starch content, when cooked at high temperatures such as in frying, roasting, toasting and baking. Acrylamide is considered to be a probable genotoxic carcinogen in humans.

Why was the Regulation introduced?

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 food is a concern for public health. It highlighted that further work is needed to reduce the occurrence of acrylamide in food.

Following the EFSA opinion, the European Commission and Member States agreed that further risk management measures were needed to ensure that acrylamide levels in food are consistently as low as reasonably achievable (ALARA) through the application of appropriate mitigation measures by all food business operators (FBOs) along the food chain.

Regulation (EU) 2017/2158 promotes and supports best practice in managing acrylamide as a food safety hazard throughout the food chain. The overall aim of the Regulation is to ensure that food businesses put in place steps to mitigate acrylamide formation where practicable. The focus of the legislation is on an ALARA approach, and it applies to UK FBOs that produce and place on the market foods listed in paragraph 2.2 of **Annex A**. However, it should be noted that for some particular products such as coffee, the mitigation measures are limited. Detailed explanation of the Regulation is provided in **Annex A**.

The Regulation sets out practical steps that can be incorporated into food safety management systems (FSMS) based on Hazard Analysis and Critical Control Point (HACCP) principles to mitigate acrylamide.

The benchmark levels set out in Annex IV of the Regulation are similar to the indicative values previously used in Commission Recommendation 2013/647/EU, which will be repealed/replaced once the Regulation comes into force. Benchmark levels are not maximum levels; they are to be used by FBOs to gauge the success of the implementation of the relevant mitigation measures but should not be used for enforcement purposes.

Regulation (EU) 2017/2158 is implemented by the relevant food hygiene Regulations¹ in England, Scotland, Wales and Northern Ireland.

What is expected of a food business operator?

In general, an FBO is 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
- Take necessary steps to mitigate acrylamide formation in the food they produce, ensuring that levels are reduced to meet with ALARA principles. This would be demonstrated by adopting the relevant mitigation measures set out in the Regulation as part of their FSMS. This includes good practice Industry guidance.
- Undertake representative sampling and analysis where required, to monitor the levels of acrylamide in their products as part of their assessment of the mitigation measures

¹The following legislation will be applicable in England, Scotland, Wales and Northern Ireland

- The Food Safety and Hygiene (England) Regulations 2013
- The Food Hygiene Regulations (Wales) 2006
- The Food Hygiene Regulations (Northern Ireland) 2006
- The Food Hygiene Regulations (Scotland) 2006

- Keep appropriate records of the mitigation measures undertaken to demonstrate ALARA together with sampling plans and results of any testing undertaken.

Enforcement approach

In accordance with the usual expectations for assessment of food safety practices, relevant authorised officers are responsible for verifying that FBOs comply with the legislation.

Most large food manufacturers are aware of the required mitigation measures and are taking necessary steps to reduce the acrylamide in their product. **It is recommended that local authorities act in accordance with the Food Law Code of Practice and their enforcement policies to achieve compliance.**

FBOs should be able to provide enforcement officials with appropriate documentation to show how the relevant mitigation measures have been applied and how best practice has been identified and implemented. This may include Standard Operating Procedures that show practical steps being taken by the food business to mitigate acrylamide in their products.

Relevant authorised officers may wish to take samples on a risk basis in line with the provisions of Regulation (EC) 882/2004 to check the levels of acrylamide in food, although this is not necessary for assessing compliance with Regulation (EU) 2017/2158.

Annex A: The legislation in detail

1. Purpose

- 1.1. The main purpose of Regulation (EU) 2017/2158 is to promote and support best practice for acrylamide mitigation in a broad range of foods. The Regulation is made under Article 4(4) of the food hygiene Regulation (EC) No 852/2004.
- 1.2. Food businesses are required to adopt relevant mitigation measures set out in the Annex to the Regulation, as part of their FSMS based on HACCP principles. This is to ensure that the levels of acrylamide in food are as low as reasonably achievable (ALARA). The measures recommended are intended to be proportionate to the nature and size of the business. This is to ensure that small and micro-businesses are not burdened disproportionately.
- 1.3. FBOs must consider chemical contaminant hazards (e.g. **acrylamide**) within the scope of their FSMS. European Parliament and Council Regulation (EC) No 852/2004 on hygiene of foodstuffs set out general requirements for all FBOs (other than those undertaking primary production activities). Article 5 requires all Food Business Operators (FBOs) to put in place, implement and maintain a FSMS based on Hazard Analysis and Critical Control Point (HACCP) principles to ensure the food produced in their premises is safe to eat. This ensures 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.
- 1.4. Regulation (EC) No 852/2004 also provides significant flexibility without compromising food safety to allow food safety procedures to be tailored to the size and nature of the business.

2. Scope: who is affected?

- 2.1. The Regulation applies to all FBOs that produce and place on the market the foods listed below. Food businesses are required to adopt the relevant acrylamide mitigation measures set out in Annex I and II to the Regulation within their FSMS.

Box 1: List of foodstuffs in Article 1 (2)

- 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, crisp breads and bread substitutes. In this category, a cracker is a dry biscuit (a baked 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);

2.2. The mitigation measures applicable to FBOs categorised in Article 2 are in line with the principles of the general EU hygiene legislation that allow food safety procedures to be proportionate to the risk and to the size and nature of businesses.

2.3. Article 2 sets out the different categories of FBOs affected and the mitigation measures that are applicable.

- **Article 2(1)** states that: *Food business operators, which produce and place on the market foodstuffs listed in Article 1(2) shall apply mitigation measures provided for in Annex I.*

This refers to all food manufacturers other than those covered by Article 2(2) and 2(3). Annex I also set out the sector-specific requirements for these FBOs to adopt in order to mitigate acrylamide formation in food.

- **Article 2(2)** states that: *By way of derogation from paragraph 1, food business operators producing foodstuffs listed in Article 1(2), which perform retail activities, and/or directly supply only local retail establishments shall apply mitigation measures provided for in Part A of Annex II.*

These apply to local and/or independent FBOs selling food directly to the consumer and/or directly into local retail. Part A of Annex II outlines the mitigation measures applicable for these food businesses. Examples of such businesses include independent cafes, fish and chip shops and restaurants.

- **Article 2(3)** states that: *Food business operators referred to in paragraph 2 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 referred to in Article 1(2)*

This is intended to place some extra obligations on large-scale FBOs in addition to the FBOs referred to in Article 2(2).

Examples of businesses 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.

The FBOs implicated are typically large, centrally controlled and centrally supplied chains with standardised menus and operating procedures. The mitigation measures referred to in 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.

2.4. Local Authorities are reminded that some level of flexibility and discretion may be required in terms of what is expected of small and micro-businesses. Account should be taken of what is reasonable and proportionate to a specific FBOs situation and resources. The main consideration is that acrylamide is being addressed in their FSMS and that good practice is being observed.

3. **Compliance**

3.1. The purpose of the Regulation is to promote and support best practice in managing acrylamide as a food safety hazard.

3.2. FBOs are required to implement the relevant measures listed in the Annexes to the Regulation within reason, as part of their FSMS. This is to reduce the levels of acrylamide in their products to what is as low as reasonably achievable (ALARA) and below the benchmark levels.

3.3. Food businesses are required to provide evidence to demonstrate that the appropriate FSMS are in place to ensure the relevant mitigation measures have been implemented. In practice, compliance means:

- **Obtaining assurance that the FBO understands acrylamide**
- **Confirming existence of written procedures that demonstrate how the business has adopted the relevant mitigation measures as part of their FSMS in order to mitigate acrylamide in their products**
- **Evidence that these procedures are followed, and that they are reviewed and updated where necessary**
- **Evidence of how the food business controls the presence of acrylamide, such as sampling and analysis of products/product types.**

4. Mitigation measures

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.

4.1. Mitigation measures applicable to FBOs (food manufacturers) under Article 2(1)

- Annex 1 sets out the sector-specific requirements for these FBOs to adopt, in order to mitigate acrylamide formation in the foods listed in **Box 1** under paragraph 2.1.
- Not all the mitigation measures are relevant to all food manufacturers. It is expected that an FBO will choose the relevant measures for their product(s) and apply as appropriate to ensure that the levels of acrylamide in their products are as low as reasonable achievable.

4.2. Mitigation measures applicable to FBOs under Article 2(2)

- Part A of Annex II outlines the relevant mitigation measures applicable for small and micro food businesses. This general cooking advice suitable to independent FBOs is designed to support and promote best practice in helping FBOs to minimise acrylamide in their food. Not all the mitigation measures may be applicable in all cases.
- Food businesses should have Standard Operating Procedures (such as colour charts) and/or good procedures based on good practice industry guidance to mitigate acrylamide in their products such as French fries, bread, toast or toasted sandwiches and fine bakery ware as listed under paragraph 2.1. Acrylamide should generally be managed in foods with high starch content cooked at high temperatures e.g. potatoes. For a limited number of foods (e.g. French fries, toast or toasted sandwiches) colour guides may be an appropriate form of best practice in reducing the levels of acrylamide to ALARA. The **BHA Industry Guide to Acrylamide for Catering and Food Service** can also be used as a good practice guide to mitigate acrylamide.
- Relevant authorised officers should place emphasis on Standard Operating Procedures (such as colour charts) and/or procedures based on good practice industry guidance, including those assured under Primary Authority.

4.3. Mitigation measures applicable to FBOs under Article 2(3)

- In addition to the mitigation measures set out in Part A of Annex II, food businesses covered by Article 2(3) are also required to adopt the relevant mitigation measures detailed in Part B of Annex II. Not all the mitigation measures may be applicable in all cases.
- One of the mitigation steps FBOs are required to apply when making French fries and other cut (deep fried) potato products is the use of Standard Operating Procedures and calibrated fryers equipped with computerised timers and programmed to standard settings (time-temperature). However, the Regulation **does not** require FBOs to immediately purchase such equipment once it comes into force, 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'.

- There are no significant mitigation measures for coffee. Therefore, it is expected that FBOs will source their coffee from reputable suppliers who should be working to ALARA as far as possible. However, for certain roasts of coffee it is not possible for the levels to be consistently below the benchmark level.
- Food businesses should have in place Standard Operating Procedures and/or procedures based on good practice industry guidance on how they mitigate acrylamide in bakery products. FBOs may also want to consider putting in place practical steps to reduce the levels of acrylamide in other foods *susceptible to acrylamide formation not covered by the Regulation*.

5. **Benchmark levels**

- 5.1. The benchmark levels (BMLs) set out in Annex IV of the Regulation are similar to the indicative values previously in Recommendation 2013/647/EU to be repealed/replaced. BMLs are generic performance indicators for the broad food categories covered by the Regulation. They are **not** maximum limits and are **not** to be used for enforcement purposes. They 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 are as low as reasonably achievable.
- 5.2. It should be noted that some foods within the broadly defined categories specified in Article 1 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 instance:

- **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 benchmark level.**

- 5.3. An exceedance of a BML in a product does not mean that the product cannot be placed on the market. However, an FBO should be able to demonstrate relevant mitigation steps are being taken and reviewed where appropriate.
- 5.4. Where very high levels of acrylamide (typically multiples of the BML) are found this may be considered a health risk, and the product would therefore be unsafe, which would be a breach of Article 14 of Regulation 178/2002 (subparagraph 1 of which states that food shall not be placed on the market if it is unsafe). Any risk management action must be based on a risk assessment. This would be undertaken by FSA/FSS, who will advise on appropriate action(s) to be taken.

6. Sampling and analysis

- 6.1. **Article 4** of the Regulation sets out the sampling and analysis requirements for FBOs. These are further elaborated in Annex III. 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.
- 6.2. The Regulation requires FBOs except for those referred to in Articles 2(2) to have a sampling plan that:
- is reviewed at least annually
 - is representative of product types they produce. This does not mean that every single product line must be sampled
 - 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, in order to ensure that ALARA is maintained.
- 6.3. The sampling plan and results should be available to relevant authorised officers upon request. The information should also include any mitigation steps taken to reduce acrylamide levels where the BMLs have been exceeded. For businesses covered by Article 2(3), the sampling and analysis plans and results may be made available by the central business rather than each individual outlet/chain.

7. Record keeping

- 7.1. FBOs referred to in Articles 2(1) and 2(3) 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 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.
- 7.2. Food businesses referred to in Article 2(2) 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 FSMS. It could include appropriate Standard Operating Procedures (such as colour charts) and/or procedures based on good 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.

Sources of advice and information for FBOs on acrylamide reduction

- **FSA communication on how to reduce acrylamide at home**
<https://www.food.gov.uk/science/acrylamide>
- **FSA information to Food Businesses on the new legislation**
- <https://www.food.gov.uk/enforcement/regulation/europeleg/legislation-on-acrylamide-mitigation-in-food#overlay-context=user>
- **The FoodDrinkEurope Acrylamide Toolbox**
<http://www.fooddrinkeurope.eu/publications/category/toolkits/>
- **BHA Industry Guide to Acrylamide for Catering and Food Service**
[DN: this is being finalised]