

**FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Materials and Articles in Contact with Food (Scotland) Amendment Regulations  
2019**

**Date:** 28 January 2019  
**Stage:** Final  
**Source of intervention:** EU  
**Type of measure:** Secondary  
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## **1. Title of Proposal**

- 1.1. The Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2019.

## **2. Purpose and intended effect**

### **Objectives**

- 2.1. The purpose of the draft regulations, which will amend the Materials and Articles in Contact with Food (Scotland) Regulations 2012, is to provide for the effective execution and enforcement in Scotland of:
  - Commission Regulation (EU) No 2016/1416 (“the revised Plastics Regulation”) amending Commission Regulation (EU) No 10/2011 (“the Plastics Regulation”) on plastic materials and articles intended to come into contact with food;
  - Commission Regulation (EU) No 2018/213 on the use of bisphenol A (BPA) in varnishes and coatings intended to come into contact with food and in plastic food contact materials (“the BPA Regulation”).

### **Background**

- 2.2. Regulation (EC) No 1935/2004<sup>1</sup> of the European Parliament and of the Council (“the Framework Regulation”) lays down the general safety rules for all materials and articles intended to come into contact with food. Article 5(1) of the Framework Regulation allows for specific measures for groups of materials and articles. The Plastics Regulation is such a specific measure and establishes the specific rules for plastic materials and articles intended to come into contact with food.

### **The Plastics Regulation**

- 2.3. The Plastics Regulation is routinely amended to improve the clarity of the rules and to keep up with technological innovation. Applicants apply to the European Food Safety Authority (EFSA) for evaluation of new substances that they wish to use in food contact plastics. The EFSA evaluates the risk to public health arising from the migration of these substances into food. If these substances are considered safe by the EFSA, the Commission amends the Plastics Regulation to include these substances.
- 2.4. Commission Regulation (EU) No 2016/1416 (“the revised Plastics Regulation”) amending and correcting Regulation (EU) No 10/2011<sup>2</sup> (“the Plastics Regulation”) on plastic materials and articles intended to come into contact with food, was published in the OJ on 25 August 2016<sup>3</sup>. The revised Plastics Regulation came into force on 14 September 2016, and is directly applicable throughout the EU. There was a transition period of one year allowing materials and articles that were compliant before entry into force of this Regulation to remain on the market, whilst the new migration limits

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<sup>1</sup> OJ Ref L338, 13.11.2004, pg. 4-17 Available to download from the Eur-Lex website.

<sup>2</sup> OJ Ref L12, 15.01.2011, pg. 1-89 Available to download from the Eur-Lex website.

<sup>3</sup> OJ Ref L 230, 25.08.2016, pg. 22-42 Available to download from the Eur-Lex website.

for aluminium and zinc, set out in point 2(a) of the Annex, and the assignments of food simulants in point 3(c) of the Annex, applied from 14 September 2018.

### **Changes made by the revised Plastics Regulation to the Annexes of the Plastics Regulation**

- 2.5. The changes to the Annexes to the Plastics Regulation do not require any changes to be made through the enforcement provisions in the 2019 Regulations because of the existing ambulatory reference in the 2012 Regulations. Ten new substances that can be used in the manufacture of food contact plastics and amendments to six existing substances have been introduced by ambulatory references. The other main amendments to the Annexes include:
- The introduction of a migration limit of 1mg/kg for aluminium from plastics (Annex II point 1)
  - A reduction in the existing migration limit for zinc from plastics from 25mg/kg to 5mg/kg (Annex II point 1).
  - Allowing the testing in only one food simulant if appropriate scientific evidence is documented showing that that food simulant is the most severe (Annex III point 5).
  - Allowing the use of processing conditions used by business operators in food processing (such as pasteurisation or sterilisation) as testing conditions for migration testing (Annex V section 2.1.3 of chapter 2).
  - Allowing the use of a single screening test to screen compliance with the Regulation if the migration behaviour of a material or article is well established (Annex III point 5).
  - The introduction of specific migration testing methods for fruits and vegetables (Annex III table 2).
- 2.6. Several other minor clarifications and corrections have been made to the Annexes to remove any doubt about the application of the Plastics Regulation.

### **Changes made by the revised Plastics Regulation to the Articles in the Plastics Regulation (not covered by ambulatory references)**

- 2.7. Very minor changes are required to Schedule 1 to the 2012 Regulations to take account of changes made to the Articles in the Plastics Regulation by the revised Plastics Regulation.
- 2.8. The revised Plastics Regulation amends Articles 3, 6, 11, 13, 17 and 18 of the Plastics Regulation. The specific changes include:

- Article 3 was amended to revise the definitions for 'non-fatty food' and introduce a definition of 'hot fill'.
- Article 6 (3) was replaced to clarify that the derogation for specified metal salts of authorised acids, alcohols and phenols applies to multiple salts and not just double salts.
- Article 11 (2) was deleted to remove the requirement to test plastic materials that are not subject to specific migration limits with the generic specific migration limit of 60mg/kg.
- A new point 4 was added in Article 11 to clarify that where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.
- Article 13 (3) was amended to clarify that substances not listed in the Union list, nor the provisional list, should not migrate through a functional barrier in accordance with the newly amended Article 11 (4).
- Article 17 3(a) was amended to clarify how migration limits should be specified for caps, gaskets and stoppers and similar sealing articles.
- Article 18 (4) was amended to clarify that the whole of chapter 3 of Annex V is relevant for the verification of compliance with the overall migration limit for materials and articles not yet in contact with food.
- Article 18 (7) was amended to clarify that the correction factors in point 3 of Annex III and Chapter 4 of Annex V should be applied before comparing specific and overall migration test results with the migration limits.

## **The BPA Regulation**

- 2.9. BPA is a chemical substance used in the manufacture of certain food contact materials such as plastic (polycarbonates) and coatings (epoxy resins). Polycarbonate is mainly used in food contact applications such as water cooler bottles based on the properties that it provides compared to other plastics. BPA-based epoxy resin is used to make the coatings applied to the inside of metal food and beverage cans to act as a barrier to protect the surface of the packaging material against damage from certain foods.
- 2.10. BPA can migrate into food from the material or article with which it is in contact, resulting in exposure to BPA for consumers of those foods. Some studies suggest that BPA has a range of different possible side effects, including endocrine disrupting properties which are relevant to humans. Endocrine disruptors are chemicals that can interfere with endocrine (or hormone) systems at certain doses.

- 2.11. In accordance with Article 6 of the Framework Regulation, some Member States have adopted national provisions in those areas for which specific measures have not been established at European level.
- 2.12. Due to these divergent rules in some Member States, the Commission felt it necessary to introduce a specific measure on the use of BPA in coatings and varnishes applied to food contact materials. The BPA Regulation applied from 6 September 2018 and sets a Specific Migration Limit (SML) of 0.05mg/kg for the migration of BPA from varnishes and coatings applied to food contact materials. This SML is derived from the temporary tolerable daily intake (t-TDI) that the EFSA set for BPA in 2015. The t-TDI takes account of some remaining uncertainties in relation to potential health effects and exposure estimates and therefore the precautionary principle is applied. It is expected that on-going long-term research will help to reduce these uncertainties.
- 2.13. The EFSA concluded that the dietary exposure to BPA for the highest exposed groups, which includes infants, children and adolescents, is below the t-TDI, indicating that there is no health concern at the estimated levels of exposure. The BPA Regulation amends the Plastics Regulation, reducing the existing SML for BPA accordingly.
- 2.14. The BPA Regulation also specifies that there shall be no permitted migration of BPA from varnishes or coatings applied to materials and articles specifically intended to come into contact with either infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, or milk-based drinks and similar products specifically intended for young children.

### **Rationale for Government intervention**

- 2.15. Unregulated chemical migration from plastic materials and articles intended to come into contact with food, may potentially create a negative cost to others such as the NHS in Scotland, through detrimentally affecting consumer health. Consumers are unable to assess the risks involved when consuming a product that has been in contact with food contact materials because they cannot observe the level of chemical migration and do not have the information on the production methods. Therefore, they cannot make informed choices about such risk.
- 2.16. Government intervention to regulate such products reduces the chronic and acute health risks to consumers arising from chemical migration from food contact materials into the food they eat. The Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2019 will provide enforcement authorities with the necessary powers for the execution and enforcement of the provisions of the two European Regulations. This SSI provides for the continuation of consumer protection against adventitious migration of chemicals from food contact materials that could

carry a serious long-term and unacceptable risk to consumer health. This therefore helps to meet the outcome of “We live longer, healthier lives” as part of the Scottish Government’s National Performance Framework.

2.17. In addition, failure to enforce could result in infraction proceedings against the UK; therefore it is necessary to ensure that the EU requirements are implemented and can be enforced in Scotland.

### **3. Consultation**

- **Within Government**

3.1. Details of the consultation were discussed with Scottish Government officials in SGLD, the Directorate for International Trade and Investment (Food, Drink and Trade Division) and DG Economy (Zero Waste Delivery).

- **Public Consultation**

3.2. A shortened 6 week consultation was carried out in Scotland on the draft national legislation from 15 October 2018 to 26 November 2018 with only one response being received from a local authority Environmental Health Department who either agreed or had no comments to offer on the questions posed in our BRIA.

- **Business**

The consultation was circulated to a wide group of industry bodies, retailers and enforcement officers whose local knowledge would have been able to identify any other business who may be impacted by any of the two EU Regulations that will be enforced by the proposed Regulations. Prior to issuing the consultation, we contacted several potentially affected businesses in Scotland to gauge their interest in our proposal but received no feedback. We also received no feedback from a plastics trade body in Scotland who we asked for information on potentially affected businesses. During the consultation we continued to engage with stakeholders to obtain impact details from them, but without success. Stakeholders were kept informed as the EU Regulations developed with the most recent Interested Party letter sent on the 28<sup>th</sup> February 2018 regarding the new BPA Regulation.

### **4. Options**

#### **Option 1 – Do nothing.**

4.1. Regulation (EU) 2016/1416 amending Regulations (EU) 10/2011 on plastic materials and articles intended to come into contact with food and (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food will not be enforced. This option will not prevent the new EU Regulations applying in Scotland as they are already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce them. This would constitute a failure to comply with EU obligations. As an EU Member State, the UK is obliged to provide for the enforcement of EU legislation.

**4.2. Option 2 – Amend the Materials and Articles in Contact with Food (Scotland) Regulations 2012 to provide for the execution and enforcement of Regulation (EU) 2016/1416 amending Regulation (EU) 10/2011 and Regulation (EU) 2018/213.**

4.3. This is the preferred option and will help demonstrate that the UK is working to meet its obligations as an EU Member State. This approach will also provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the two EU Regulations in Scotland. In addition, penalties will be available to the Courts in the event of non-compliance being established.

**Sectors and groups affected**

4.4. England, Wales and Northern Ireland (E,W&NI) have used the Office of National Statistics (ONS) Interdepartmental Business Register (IDBR) to identify which sectors and industries may be affected by the policy. The IDBR is a comprehensive register of businesses, which covers 99% of UK economic activity. The data in the register is structured by the UK Standard Industrial Classification of Economic Activities (SIC 2007). Given the aggregate nature of the IDBR, it has been difficult to identify precise subsectors that will be affected by the Regulations. This means that the sectors identified and used in the analysis will be larger (in terms of number of businesses affected) than the number affected by the policy. For example: “manufacture of plastic packing goods” SIC-2222 refers to all plastic packaging manufacturers not exclusively those in contact with food. To minimise the impact of these uncertainties we have provided sensitivity analysis around the final costings (sector size of 50% and 80%, respectively, of the actual sector size in the available data), see Annex 2. The central estimate of 80% (which remains conservative) is used to calculate the best estimate of the costs and benefits.

4.5. The Scottish data included is taken from Businesses in Scotland 2017, Scottish Government; UK Business – Activity, Size and Location, Office for National Statistics. Both of these publications are based on data from the Interdepartmental Business Register. 2017 figures are available but 2016 figures have been used for comparison purposes across the UK. In the ONS’s publication enterprises are allocated to Scotland if their UK base/HQ is in Scotland. In the Scottish statistics given here we have included all enterprises that operate in Scotland regardless of their base/HQ. This approach results in a better reflection of potential costs to business as all relevant operators will likely be impacted regardless of whether they are the base/HQ or not.

**Industry The Revised Plastics Regulation**

4.6. Any costs to industry associated with the revised Plastics Regulation relate to businesses involved in the manufacture of plastic materials and articles intended to come into contact with food (including articles such as food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment),

not the whole packaging industry. This will apply equally to all businesses in this sector regardless of size.

### The BPA Regulation

- 4.7. FSS does not envisage that a reduction in the specific migration limit for BPA from plastics will change the existing cost of compliance for plastic manufacturers. There will be a cost for businesses associated with testing for compliance with the new SML for BPA from varnishes and coatings applied to food contact materials and articles. However, at present businesses are already required to demonstrate compliance with the Framework Regulation on food contact materials, Regulation (EC) No 1935/2004.
- 4.8. This Business and Regulatory Impact Assessment is based on Scotland and all costs and benefits are provided for Scotland only. However, as similar changes to the domestic legislation and familiarisation time will also be necessary in the rest of the UK we have provided analysis for Scotland, England, Wales & Northern Ireland; Table 1 summarises the distribution across S,E,W&NI of the sectors that are affected by the Regulations. A more detailed description of the SIC codes is provided in Annex 3. The SIC classifications used for this analysis include businesses not expected to be affected by the Regulations. It is unlikely that 100% of the business reported under these classifications deal with food contact materials relevant to these Regulations, however, no better source of evidence exists. Therefore it is assumed that 80% of the total number of businesses will be subject to the Regulations.(full sensitivity analysis can be found in Annex 2).

Table 1: Option 2 - Sectors affected by the Regulation by Country

Sectors	Scotland	England	Wales	Northern Ireland	Total
Plastics manufacturer (2222)	16	316	20	12	364
Food canners/coatings manufacturers (2529, 2592, 2561)	80	1325	60	40	1505

Source: IDBR 2016 and Businesses in Scotland 2017, Scottish Government; UK Business – Activity, Size and Location. Office for National Statistics. 2017 figures are available but 2016 figures have been used for comparison purposes across the UK. Totals do not necessarily sum up due to rounding, as in subsequent tables.

There is very little difference in the number of relevant businesses between 2016 and 2017.

For details and SIC codes see Annex 3



## Enforcement Authorities

4.9. Enforcement authorities will also be affected by the Regulations as they will be responsible for providing for the enforcement of the changes to the Plastics Regulation made by the revised Plastics Regulation and the BPA Regulation. There will also be one-off costs to enforcement bodies for familiarisation with the Regulations and the two EU Regulations. Table 2 shows the number of enforcement authorities throughout the UK that are affected by the Regulations. This includes Local Authorities (LAs), Port Health Authorities (PHAs – not applicable to Scotland) and Official Control Laboratories (OCLs).

## Consumers

4.10. Consumers will benefit from increased safety from new migration limits

Table 2: Number of LAs, PHAs and public OCLs in each country

Enforcement Body	Scotland	England	Wales	Northern Ireland
LA	32	353	22	11
PHA	0	34	2	0
OCL	4	16	6	1

Source:FSA and FSS internal data

### • Option Appraisal; Costs and Benefits

4.11. Option 1 – Do nothing

#### **Benefits**

##### **Consumers**

4.12. There are no consumer benefits with this option.

##### **Enforcement Authorities**

4.13. Enforcement Authorities would not have to spend time familiarising themselves with new legislation.

##### **Industry**

4.14. Industry will not have to be familiar with or comply with the new migration limits.

##### **Regulator**

4.15. There would be no cost to Government of producing an SSI.

4.16. These benefits would be far outweighed by the potentially high infraction penalties.

##### **Costs**

4.17. Consumers will not benefit from new migration limits.

- 4.18. The risk of infraction proceedings by the EU against the UK for failing to execute and enforce the EU Regulations. Infraction proceedings could lead to fines and Scotland would be required to pay a percentage of any UK fine if the infraction relates to a devolved matter.

## **Option 2 – Amend the Materials and Articles in Contact with Food (Scotland) Regulations 2012**

### **Benefits**

#### Industry

- 4.19. A benefit of the revised Plastics Regulation is that it allows industry to use ten new substances in the manufacture of plastic materials and articles to keep up with innovation. The requirement to test for compliance with the generic specific migration limit for substances for which no specific migration limit has been set has been removed as the migration levels from all substances are already subject to compliance with an overall migration limit. The removal of this overly burdensome testing requirement for approximately 400 substances used in plastic food contact materials will be a benefit to businesses. Another benefit of the revised Plastics Regulation is that it provides more flexibility in compliance testing.
- 4.20. Having all the national legislation in one place is helpful for smaller businesses if they are given confidence there is only one main regulation they need to reference to ensure compliance. Without this reassurance there will be concern that technical amendments such as these may be missed.

This option would also help to demonstrate that the UK is working to meet its EU obligations.

#### Enforcement authorities

- 4.21. The amendment will provide for the execution and enforcement in Scotland of Commission Regulation (EU) No 2016/1416 on plastics and Commission Regulation (EU) No 2018/213 on bisphenol A; provide for offences of contravening certain provisions of the two European Regulations and specify the penalties that the Courts may impose upon conviction for an offence.
- 4.22. Local authorities will benefit from a single consolidated piece of national legislation as it provides clarity on the EU Regulations they enforce - they are unlikely to miss the new requirements due to fragmentation of the legislation.

### **Consumers**

- 4.23. Consumers will benefit from increased safety from the new migration limits.

## Costs

### Industry Familiarisation (one-off costs)

- 4.24. Under Option 2, there will be a one-off cost to industry for reading and familiarising themselves with the revised Plastics Regulation and the new BPA Regulation.
- 4.25. Familiarisation costs are quantified by multiplying the time it will take for a manager to familiarise themselves with the Regulations, by the median hourly wage rate of that manager, uplifted by 20% to allow for overheads. Total costs in Scotland are calculated by multiplying total business cost by the number of businesses within that industry. We have assumed that for industry it will be one or more of either the regulatory, technical or production manager that will be responsible for familiarisation with the two EU Regulations. The median hourly wage rate for a production manager in manufacturing in Scotland in the Annual Survey of Hours and Earnings (ASHE) is £21.93, which uplifted for overheads is £26.31<sup>4</sup>. For the source of English calculations, see footnote below <sup>5</sup>. There is no median hourly wage posted for regulatory or technical managers within the ASHE. Therefore, the assumption has been made that their median hourly wage rate will be similar to that of a production manager for manufacturing, which will be taken as representative of the costs incurred for each role. **For comparison purposes across the UK, wage rates used here and for subsequent sections are from the same statistical release (2016 provisional)**. There have been modest increases in rates for provisional 2017 rates.<sup>6</sup>

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4.26. The businesses affected under this Option are:

- **A]** Manufacturers of plastic packaging goods and other plastic products that are intended to come into contact with food.
- **B]** Coatings manufacturers, can makers and food canners.

#### A] Familiarisation costs for plastic manufacturing industry

4.27. The revised Plastics Regulation is specific to food contact materials and articles manufactured from plastic. We have assumed that one production manager will be responsible for familiarisation.

We estimate that two hours are required for familiarisation; one hour for the revised Plastics Regulation and another hour to disseminate the information within the organisation. This results in a familiarisation cost per business in Scotland of £52.62,

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<sup>4</sup><https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashetable15>

<sup>5</sup><https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14> Includes an overhead of 20% (21.25\*1.2=25.50)

<sup>6</sup> For information, for Scotland, the 2017 provisional uplifted, median hourly wage rate for a production manager for manufacturing is £23.14 x 1.2 = £27.76

giving a total familiarisation cost to the 16 plastic manufacturing industries in Scotland of £841.92.

#### B) Familiarisation costs for coatings manufacturers, can makers and food canners

4.28. We have assumed that one production manager will be responsible for familiarisation with the BPA Regulation.

4.29. We estimate that two hours are required for familiarisation, one hour for the amendments and another hour to disseminate the information within the organisation. For Scotland, this results in a familiarisation cost per business of £52.62, giving a total familiarisation cost for coatings manufacturers, can makers and food canners of about £4,210.

#### **Other Costs**

##### Plastic manufacturers

4.30. The revised Plastics Regulation introduces a limit on the migration of aluminium from plastic food contact materials of 1 mg/kg. This is derived from the tolerable weekly intake for aluminium of 1 mg of aluminium per kilogram of bodyweight per week, as a significant part of the population exceeds this level. Assessing compliance with this migration limit will only affect those manufacturers that use aluminium in their processes. Similarly, the revised Plastics Regulation reduces the existing migration limit of zinc from plastic food contact materials.

4.31. The revised Plastics Regulation also introduces specific migration testing provisions for plastic materials and articles in contact with fresh unpeeled fruits and vegetables. This will offer improved consumer protection from substances that could migrate from such plastics. It is a requirement that a food simulant should be assigned to certain products for the purposes of testing but this may result in overestimation (depending on size and shape of the fruits and vegetables, and whether fruits and vegetables are peeled or not). The overestimation should be addressed with a correction factor. Depending on the circumstances (type of food simulant required), additional costs may be incurred.

##### BPA

4.32. The introduction of a SML for migration of BPA from coatings and varnishes applied to food contact materials has cost implications with regards to migration testing and possibly the frequency of such tests. The coatings industry has said that they will no longer be able to use total extraction to measure the migration of BPA.

4.33. Despite the costs of compliance, the industry was very keen to see this measure adopted as it will lead to harmonisation of the market, which is expected to outweigh their costs.

## Enforcement Authorities

### Familiarisation (one-off costs)

- 4.34. There will be a one-off cost to Enforcement Authorities (EAs) for reading and familiarising themselves with the new Regulations. In Scotland, Local Authorities (LAs) are responsible for enforcing food safety and food hygiene legislation in their respective areas (not Port Health Authorities) and as such, will need to be aware of the legislative changes. In addition, there will also be a one-off cost to Official Control Laboratories (OCLs) for reading and familiarising themselves with the changes to testing requirements.
- 4.35. Familiarisation costs are quantified by multiplying the time it will take for an official to familiarise themselves with the Regulations, by the median hourly wage rate of the official, uplifted by 20% to allow for overheads, and the number of enforcement authorities or laboratories affected.
- 4.36. In Scotland, following internal FSS discussion, for LAs, we estimate that each Environmental Health Officer (EHO) or Food Safety Officer (FSO) will need to spend 20 minutes familiarising themselves with the new regulations. There are no figures available for either EHOs or FSOs in ASHE so we have used the uplifted, median hourly wage rate for Scotland, Environmental Health professionals for 2016 provisional -  $£15.06 \times 1.2 = £18.07 \times 0.33 = £6.02 \times 210^7$  affected enforcers working in the 32 local authorities in Scotland = £1,264.
- 4.37. For the rest of the UK, calculations are based on a two-hour familiarisation time for enforcement authorities (one hour and one hour to disseminate to other staff) as per the original impact assessment and an assumption was made that one enforcement officer per EA is required for familiarisation. For LAs and PHAs, where appropriate, either an Environmental Health Officer (EHO) or a Trading Standards Officer (TSO) will be required to familiarise themselves with the new enforcement provisions. To account for the differences across enforcement authorities<sup>8</sup>, wage rates for both TSOs and EHOs are used to produce a range of values for hourly pay. As the lower bound we have used the uplifted, median hourly wage of a TSO (£17.83<sup>9</sup>) and as the upper bound the uplifted, median hourly wage rate of a EHO (£22.76<sup>10</sup>). For both, see Table 14.6a hourly pay excluding overtime for all employees. This gives a central estimate of £20.30. (For full sensitivity analysis, see Annex 1). For LAs and PHAs, this results in a lower bound familiarisation-cost of £35.66 and an upper bound familiarisation cost of £45.53 and a central-(mid-point) estimate of £40.60 per authority.

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<sup>7</sup> <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

<sup>8</sup> Note that TSOs or EEOs may be responsible for enforcing this legislation depending on resource in each local authority

<sup>9</sup> <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> Includes an overhead of 20% ( $14.86 \times 1.2 = 17.83$ )

<sup>10</sup> <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> Includes an overhead of 20% ( $18.97 \times 1.2 = 22.76$ )

- 4.38. There have been modest increases in rates for provisional 2017 rates <sup>11</sup>
- 4.39. For OCLs, again following FSS internal discussion, for Scotland, an ASHE median hourly wage rate estimate - Scotland, Science, research engineering and technology professional 2016 provisional rate of £19.67 x 1.2 = £23.06<sup>12</sup> has been used. We estimate that it will take 20 minutes for each of the four public analysts to familiarise themselves with the new legislation i.e. £23.06 x 0.33 x 4 OCLs = £30.
- 4.40. The total one-off cost to enforcement authorities and OCLs in Scotland affected by this proposal is therefore estimated to be £1,294.
- 4.41. For the rest of the UK appropriate 2016 equivalent rates have been used. However, again, calculations here are based on a two-hour familiarisation time for OCLs (one hour and one hour to disseminate to other staff) as per the original impact assessment and an assumption was made that one science professional per OCL is required for familiarisation. An ASHE median hourly wage estimate (2016, provisional) of £20.18 was used, which increases to £24.22 when adjusted for overheads and the familiarisation cost per authority is £48.43.
- 4.42. Multiplying the cost per authority by the number of authorities, taking into account the wage differences between PHAs/LAs and OCLs, results in a total familiarisation cost to S,E,W & NI of £19,540.
- 4.43. There have been modest increases in rates for provisional 2017 rates <sup>13</sup>

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<sup>11</sup> For information, for Scotland, the 2017 provisional uplifted, median hourly wage rate of an Environmental Health professional (provisional 2017) is £15.29 x 1.2 = £18.35

<sup>12</sup><https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

<sup>13</sup> For information, for Scotland, the 2017 provisional uplifted, median rate for a Science, research, engineering and technology professional £20.22 x 1.2 = £24.2

Table 3 : Table summarising the familiarisation costs by country

	Scotland	England	Wales	Northern Ireland	Total
LA	£1,264	£14,330	£893	£447	£16,934
PHA	£0	£1,380	£81	£0	£1,461
OCL	£30	£775	£291	£48	£1,144
Total	£1,294	£16,486	£1,265	£495	£19,540

Source ASHE provisional 2016 and Food Standards Scotland (FSS) analysis

Table Notes:

1: Totals may not sum due to rounding.

2: Costs are estimated by uplifting wage rates by 20% to account for overheads in Scotland; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

## 5. Scottish Firms Impact Test

5.1. Prior to consultation we attempted to engage with some food business operators and a relevant trade association on the impact of the Regulations but elicited no response. We made further attempts to engage with various Scottish businesses of different sizes and from various geographical areas during the public consultation period to seek their views on the likely impact on their business of the changes proposed in the draft SSI. However, none responded.

### Competition Assessment

5.2. The legislation will apply to all businesses and individuals involved in the UK plastic materials and articles intended to come into contact with food trade equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition. Using the Competition and Markets Authority competition assessment framework<sup>14</sup> developed by the former Office of Fair Trading, it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

### Small and Micro Business Assessment

5.3. As with the rest of the UK, in Scotland the food and drink packaging industry is comprised of mainly small and micro businesses and these will be impacted the most

<sup>14</sup>[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/284451/OFT1113.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284451/OFT1113.pdf) The Competition and Markets Authority is now responsible for this area of work.

by changes in the new EU Regulations. For this reason, FSS assesses the impact on small and micro businesses as medium.

- 5.4. The potential commercial impact of the proposals applies equally to all businesses involved, small or large. 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 Scotland, highlighted within this assessment, it is not feasible to exempt smaller businesses from new food safety measures. This is because it would fail to achieve the intended effect of reducing risks to consumer health. That said, FSS makes every effort to engage and minimise burdens on small and micro businesses and pays particular attention to impacts on them. During this consultation we had received no replies from businesses or trade bodies.

#### **Race/Gender/Disability/Equality Issues**

- 5.5. There will be no impacts on existing health, wellbeing or other social inequalities, on human rights, on levels of crime or crime prevention, or on skills and education. There will be no differential impact on rural or urban areas, nor are there any specific local or regional effects.

#### **Test run of business forms**

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

### **6. Legal Aid Impact Test**

- 6.1. The Materials and Articles In Contact with Food (Scotland) Amendment Regulation 2019 will not introduce new criminal sanctions or civil penalties, therefore there are no legal aid implications.

### **7. Enforcement, sanctions and monitoring**

#### **Enforcement**

- 7.1. Enforcement of the Regulations will be the responsibility of Local Authority Environmental Health departments. Enforcement should be risk based and proportionate, in line with the approach taken with the current Scottish legislation on medical foods. Enforcement officers would not be expected to initiate separate inspections in relation to the enforcement of these new provisions, but instead to include these as part of their existing regimes

#### **Sanctions**

- 7.2. Regulation 20 of the Materials and Articles in Contact with Food (Scotland) Regulations 2012 lays down that any person who commits an offence under these Regulations is liable depending on the offence;



- On conviction or indictment to a fine or to imprisonment for a term not exceeding two years or both; or
- On summary conviction to a fine not exceeding the statutory maximum
- On summary conviction to a fine not exceeding level 5 on the standard scale

7.3. The proposals outlined in this BRIA do not introduce new sanctions or penalties in the regulations.

### **Monitoring**

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

## **8. Implementation and delivery plan**

8.1. The requirements of Commission Regulation (EU) No 2016/1416 came into force on 14 September 2016, and is directly applicable throughout the EU. Materials and articles compliant prior to 14 September 2016 were subject to a one-year transitional period. Migration limits for aluminium and zinc, in point 2(a), and the assignments of food simulants in point 3(c) of the Annex, applied from 14 September 2018.

8.2. **Commission Regulation (EU) 2018/213** has been in force since March 6, 2018 and was directly applicable from 6th March to allow businesses to make the changes. As of the Regulation's application on 6 September 2018, no more than 0.05mg of BPA may be released from varnishes and coatings per kilogram of food with which they are in contact. The Regulation further provides that , as a derogation from the above, from 6 September 2018, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with either infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, or milk-based drinks or similar products specifically intended for young children.

8.3. The European Commission has also been working on authorisations required for businesses wishing to produce food grade materials out of recycled plastics. FSS originally intended to include the enforcement provisions for the anticipated Commission Authorisation Decision as part of this package. We had expected these to be published by the end of 2018. However this is now unlikely to happen before July 2019. Grouping the work in this way has led to a slight delay in introducing the enforcement provisions for the other two EU measures.

8.4. These requirements will be enforced and executed in Scotland by the Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2019 which will come into force on 28<sup>th</sup> March 2019.

8.5. The publication of the Scottish Regulations will be communicated to stakeholders by email and, to local authority Environmental Health Departments. This will be issued shortly after the Scottish Statutory Instrument has been published on the legislation.gov.uk website.

## 9. Post-implementation review

9.1. A review to establish the actual costs and benefits and the achievement of the desired effects will take place in 10 years from the date the Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2019 come into force.

## 10. Summary and recommendation

10.1. Option 2 – This is the preferred option.

## 11. Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental social policy and administrative
1	No cost to Government as a result of the introduction of the	Possible infraction fines.
2	No infraction fines. Enforcement authorities will be working to a consistent legal standard throughout EU	Minor one off familiarisation costs of around: £1,294 for local authorities, £4,210 for coatings manufacturers, can makers and food canners, and £842 for the plastic manufacturing industry.

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

## 12. 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.

Ministers signature

Ministers title                      MINISTER FOR PUBLIC HEALTH, SPORT AND WELLBEING

Date

### **Contact point**

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**Sensitivities of One-off Familiarisation Costs under Different Wage Rates (Central, Low or High) per Local Authority, Port Health Authority and Official Control Laboratory by Country**

	<b>Scotland</b>	<b>England</b>	<b>Wales</b>	<b>Northern Ireland</b>
LA	32	353	22	11
PHA	0	34	2	0
OCL	4	16	6	1
<b>Low</b>				
Low	£1,264	£12,589	£785	£392
Central	£1,264	£14,330	£893	£447
High	£1,264	£16,071	£1,002	£501
<b>Central</b>				
Low	£0	£1,213	£71	£0
Central	£0	£1,380	£81	£0
High	£0	£1,548	£91	£0
<b>High</b>				
Central	£ 30	£775	£291	£48
<b>Total (Low)</b>				
<b>Total (Low)</b>	<b>£1,294</b>	<b>£14,577</b>	<b>£1,147</b>	<b>£441</b>
<b>Total (Central)</b>				
<b>Total (Central)</b>	<b>£1,294</b>	<b>£16,486</b>	<b>£1,265</b>	<b>£495</b>
<b>Total (High)</b>				
<b>Total (High)</b>	<b>£1,294</b>	<b>£18,394</b>	<b>£1,383</b>	<b>£549</b>

Note – For Scotland – a) PHAs are not relevant and b) for LAs, only the 2016 pay rate for a Scotland, Environmental Health professional has been used.

**Sensitivities of One-off Familiarisation Costs under percentages of plastics manufacturers involved in food contact materials (Central, Low or High)**

E,W&amp;NI

<b>Cost</b>	<b>Description</b>	
80% of businesses	Familiarisation costs	£22,185.00
100% of businesses	Familiarisation costs	£27,731.25
50% of businesses	Familiarisation costs	£13,865.62

Scotland

<b>Cost</b>	<b>Description</b>	
80% of businesses	Familiarisation costs	£5,368
100% of businesses	Familiarisation costs	£6,697
50% of businesses	Familiarisation costs	£3,375

## Description of the SIC codes

<b>Industry</b>	<b>SIC Code</b>
<b>Manufacturing: Food Contact Plastics</b>	
Manufacturer of plastic packaging goods	2222
Manufacture of other plastic products	2229
<b>Manufacturing</b>	<b>SIC Code</b>
Manufacture of other tanks, reservoirs and containers of metal	2529
Treatment and coating of metals	2561
Manufacture of light metal packaging	2592