

## POLICY NOTE

### THE NOVEL FOODS (AUTHORISATIONS) AND SMOKE FLAVOURINGS (MODIFICATION OF AUTHORISATIONS) (SCOTLAND) REGULATIONS 2022

#### SSI 2022/168

The above instrument was made by the Scottish Ministers in exercise of the powers conferred by Articles 12(1) and 32A(3) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001, Article 11(4) of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods, and all other powers enabling them to do so. The instrument is subject to negative procedure.

#### Summary Box

The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport in relation to five novel foods, authorising four new novel foods for placement on the market in Scotland and one extension of use for an already authorised novel food. The instrument also authorises the transfer of authorisation holder for five smoke flavourings.

#### Policy Objectives

These Regulations are required to give legislative effect to the Minister's decision with respect to authorisation of four new novel foods for placement on the market in Scotland, one extension of use for an already authorised novel food and the transfer of authorisation holder for five smoke flavourings. The Regulations will add the new novel foods to the list of authorised novel foods set out in Regulation (EU) 2017/2470 and will update the entry in that list for the novel food for which there is an authorised extension of use. They will also update the list of authorised smoke flavourings set out in Regulation (EU) 1321/2013 with the details of the new authorisation holders.

At the end of the Implementation Period the UK inherited the EU Commission's legal obligation to process applications for the authorisation of regulated food products. Assessing food safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'food safety authority'.

The authorisation of these novel foods and smoke flavouring transfers of authorisation holder rests with the Scottish Ministers. The retained law obligates the Scottish Ministers to prescribe authorisation of the relevant novel foods and the modification of smoke flavouring authorisations, including the transfer of authorisation holders, in law. This SSI comprises the authorisations by the Scottish Ministers of applications made to them either for a new novel food authorisation or extension of use of a currently authorised novel food, or the transfer of authorisation holder for a currently authorised smoke flavouring. This instrument will apply to Scotland only.

This SSI aligns Scotland with England and Wales and similar EU legislation for these novel food products, all of which have now been authorised by the EU Commission. This SSI will also align Scotland with England and Wales regarding the transfer of authorisation holder for

smoke flavourings. While only one transfer is currently being progressed in the EU, the businesses concerned have been informed that they should submit applications for transfer with the EU separately. All relevant information on the authorisation of the novel food products will be entered in the list of authorised novel foods in Regulation (EU) 2017/2470 and all relevant information on the smoke flavouring transfers of authorisation holder will be entered into the list of authorised smoke flavourings in Regulation (EU) 1321/2013.

Further information in relation to the lists of authorised novel foods and smoke flavourings can be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB 11 5RL.

### **Consultation**

In compliance with the requirements of Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, there has been open and transparent public consultation during the preparation and evaluation of this SSI. There were two consultations, the first ran from 17 December 2021 until 11 February 2022 and the second from 31 March 2022 until 13 April 2022.

There were no responses to the first consultation and there were four to the second. Of the four responses to the second consultation, three were regarding the smoke flavouring transfers and one was regarding the novel foods. All responses were supportive, with one concern raised that the smoke flavouring transfers need to come into force before 30 June 2022, which this instrument enables them to do. This concern was addressed and responded to. Summaries of the consultation responses and replies to these were published on the consultation pages on Citizen Space for both the [first](#) and [second](#) consultations. A list of those who replied to the consultation and who agreed to publication of their details and response was included in these summaries published on Citizen Space.

### **Impact Assessments**

FSS consider that a specific BRIA (Business and Regulatory Impact Assessment) is not required for these novel food authorisations or smoke flavouring transfers. The costs to businesses are contained in Regulation (EU) 2015/2283 on novel foods, which requires authorisation for novel foods to be placed on the market or for extensions of use of current authorisations. Similarly, the costs to businesses are contained in retained Regulation (EC) No. 2065/2003 on smoke flavourings which requires authorisation for modifications of smoke flavourings, including transfers of authorisation holder. This SSI gives legislative effect to the Minister's decisions and does not introduce any new costs to businesses or industry. The new novel food authorisations will likely result in the reallocation of wealth from existing to new product lines. No other impact assessments are required.

### **Financial Effects**

The Minister for Public Health, Women's Health & Sport confirms that a BRIA is not necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Food Standards Scotland  
18 May 2022