

Government Response: *The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022*

Five Technical Scrutiny points have been raised, three pursuant to Standing Order 21.2(v), and two pursuant to 21.2(vi). A single Merit Scrutiny point has been raised pursuant to Standing Order 21.3(ii).

Technical Scrutiny point 1:

Maximum levels of Docosahexaenoic acid (DHA) in these products for the specified food category of infant formula (“IF”) and follow-on formula (“FoF”) are to be identified by reference to EUR 2013/609. EUR 2013/609 provides for compositional and information requirements for IF and FoF. Article 4 provides that IF and FoF can only be marketed if it complies with the Regulation. Articles 6, 9 and 10 contain general requirements. Article 15(6) requires substances belonging to categories not listed in Article 15(1) added to food within scope of Article 1(1) (including IF and FoF) to satisfy the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11. EUR 2016/127 contains the relevant specific compositional and information requirements for IF and FoF. Minimum and maximum levels for DHA can be found in Annex 2, paragraph 4.6. The maximum levels set out in EUR 2016/127 must, however, be applied within the context of the wider general requirements in EUR 2013/609.

This approach has been taken in order to ensure consistency with corresponding provision within existing entries for authorised novel foods listed in EUR 2017/2470. It is also consistent with the authorisation of these products as applicable within Northern Ireland (and the EU) as set out in the corresponding entries in the list within Regulation (EU) 2017/2470 as that Regulation continues to apply in the EU and Northern Ireland.

Technical Scrutiny point 2:

For these purposes, the Welsh Government does not consider that there is a distinction between “infants and children under 3 years of age” and “infants and young children”.

The intention here is to ensure that the labelling requirements for products under the authorisations across GB are the same as the labelling requirements that apply to the same products in Northern Ireland (and the EU) under the corresponding entries within Regulation (EU) 2017/2470 as that Regulation continues to apply within the EU and Northern Ireland.

Technical Scrutiny point 3:

The headings to the Schedules reflect the different nature of the provisions being made within each Schedule.

Schedules 2 and 3 concern two specific strains of “*Schizochytrium sp. oil*”. Those strains are already authorised to be placed on the market under the general entry for “*Schizochytrium sp. oil*” (which apply to all strains). The new entries inserted by Schedules 2 and 3 create separate entries for the two strains, for the listed specific food uses, which are already partly authorised under the existing general entry.

Schedules 4 and 5 insert new entries authorising the placing on the market of new novel foods for the first time.

Technical Scrutiny point 4:

The Government agrees that the reference in Schedule 5 to “6'-sialyl-lactulose” is a typographical error. It should read “6'-sialyl-lactulose”.

The error appears only in the narrative text of the section headed ‘Description’, the substantive reference in the section headed ‘Characteristics/Composition’ is correct.

The Government will seek to correct this typographical error by correction slip.

Technical Scrutiny point 5:

The Government accepts the point.

The typographical errors appear in the headings to regulations 6 and 7, and in the opening text identifying the location of the proposed amendments to EUR 2013/1321. The Government does not consider there is a risk of confusion as to which entries within EUR 2013/1321 are being amended – it is not possible to confuse the entries with any of the other entries in the list. Further the ‘unique codes’ of the products are correctly cited.

However, as the errors relate to the name of the products, the Government does consider correction to be appropriate – and will seek for this to be done by correction slip.

Merit Scrutiny point:

Part 2 of this instrument inserts new entries into the list of authorised novel foods within EUR 2017/2470. Those amendments are being made pursuant to the determinations of six separate applications made under EUR 2015/2283. As noted in paragraph 12 of the Explanatory Memorandum – two of those applications concerned separate requests for authorisation of the same product (“*Schizochytrium sp.* (FCC-3204) oil”) for two distinct food uses. The authorisation pursuant to the determination of those two applications is included within the entry inserted by Schedule 2 to this instrument.