

SL(6)207 – The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

Background and Purpose

These Regulations amend retained EU legislation to make provision on regulated food product authorisations in relation to Wales.

Part 2 and the Schedules to the Regulations update the list of authorised novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (the “**2017 EU Regulation**”). The provisions authorise a series of novel foods for use in milk-based drinks and similar products intended for young children, food supplements, infant formula and follow-on formula and other specified food categories.

Part 3 of the Regulations contains modifications to existing authorisations for five smoke flavouring primary products in the Annex to Commission Implementing Regulation (EU) 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods (the “**2013 EU Regulation**”). The amendments change the names and addresses of the authorisation holders of the respective product authorisations.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

The following 5 points are identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation.

Schedules 2 and 3 to these Regulations insert new entries in the Annex to the 2017 EU Regulation, which have the effect of (amongst other things) authorising the placing on the market of “*Schizochytrium sp. (FCC-3204) oil*” and “*Schizochytrium sp. (WZU477) oil*” as novel foods for use in the specified food category of infant formula and follow-on formula.



For both of those novel foods, the Annex to the 2017 EU Regulation (as amended by these Regulations) specifies "Maximum levels of DHA" in accordance with "Regulation (EU) No 609/2013", the effect of which is not immediately clear.

We ask the Welsh Government to clarify how maximum levels of DHA are to be identified by reference to Regulation (EU) No 600/2013 for the specified food category of infant formula and follow-on formula for these novel foods.

2. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation.

Paragraph 1 of Schedule 2 to these Regulations authorises "*Food Supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and children under 3 years of age*" [emphasis added] as a specified food category for the novel food "*Schizochytrium sp. (FCC-3204) oil*".

Similarly, paragraph 1 of Schedule 4 and paragraph 1 of Schedule 5 to these Regulations authorise (amongst other things) "*Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children*" [emphasis added] as a specified food category for the novel foods "*3'-Sialyllactose (3'-SL) sodium salt (microbial source)*" and "*6'-Sialyllactose (6'-SL) sodium salt (microbial source)*" respectively.

We ask the Welsh Government to clarify the distinction (if any) between "*children under 3 years of age*" and "*young children*" in these authorisations.

3. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation.

The headings in Schedules 2 and 3 to these Regulations each refer to the "*Authorisation of...*" specific foods as novel foods. However, the headings in Schedules 4 and 5 to these Regulations each refer to the "*Authorisation for the placing on the market of...*" specific foods as novel foods.

We ask the Welsh Government to clarify the distinction (if any) between "Authorisation of" and "Authorisation for the placing on the market of" in the context of the Schedules to these Regulations.

4. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.

Paragraph 2 of Schedule 5 to these Regulations inserts a specification for the novel food "*6'-Sialyllactose (6'-SL) sodium salt (microbial source)*" in the 2017 EU Regulation.

In the specification, under the heading "Description", there is a reference to that novel food containing "*6'-sialyl-lactulose*". However, also in that specification, under the heading "Characteristics/Composition", the same term is referred to as "*6'-Sialyl-lactulose*".



This error appears in the corresponding English version of these Regulations (the Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022 (S.I. 2022/560)) and was subsequently corrected by the UK Government pursuant to the Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Amendment) (England) Regulations 2022 (2022/619), which replaced the term “6'-sialyl-llactulose” with “6'-sialyl-lactulose”.

5. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.

Regulations 6 and 7 of these Regulations seek to amend the 2013 EU Regulation in relation to smoke flavouring primary products “SmokEz C-10” and “SmokEz Enviro-23” respectively.

However:

- regulation 6 and the associated heading refers to product “SmokEz C-10” as “SmokeEz C-10”; and
- regulation 7 and the associated heading refers to product “SmokEz Enviro-23” as “SmokeEz Enviro-23” [**emphasis added**],

which do not reflect those terms as listed in the Annex to the 2013 EU Regulation.

Merits Scrutiny

One point is identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd.

Paragraphs 11 and 12 of the Explanatory Memorandum accompanying these Regulations refers to the determination of “six novel food applications in favour of authorisation” by the Welsh Ministers – three “human-identical milk oligosaccharides (HiMOs)” and three “Docosahexaenoic acid (DHA) rich oils”.

However, Part 2 and the Schedules to these Regulation appear to authorise (or amend an existing authorisation) of 5 novel foods only. We ask the Welsh Government to clarify whether all of the applications referred to in the Explanatory Memorandum are authorised by these Regulations.

Welsh Government response

A Welsh Government response is required.

Committee Consideration

The Committee considered the instrument at its meeting on 20 June 2022 and reports to the Senedd in line with the reporting points above.

