



Llywodraeth Cymru  
Welsh Government

CLOSED CONSULTATION, DOCUMENT

# Infant or follow-on formula made from protein hydrolysates

We would like your views on proposals to amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020.

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This is to reflect an amendment made to the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476). It delays triggering of new rules to 22nd February 2022 instead of 22nd February 2021.

We are consulting on plans to introduce domestic legislation to:

- reflect the amendment of the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476)
- update the domestic enforcement regime

## Summary

This consultation concerns proposals to amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020 to reflect an amendment made to the the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476). These regulations will amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020 and will bring into force the new rules around infant formula or follow-on formula made from protein hydrolysates on 22nd February 2022 instead of 22nd February 2021.

## Background

In 2016, the EU implemented The Food for Specific Groups Regulation (EU) 609/2013 (the FSG EU Regulation) which sets general compositional and labelling rules for the following four food categories: infant formula and follow-on formula (IFFOF):

- processed cereal-based food and baby foods
- food for special medical purposes (FSMP) (foods necessary for the

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- management of particular medical conditions)
- total diet replacement for use in energy restricted diets for weight reduction

Four Delegated Regulations sit under the FSG EU Regulation and supplement the FSG EU Regulation to reflect developments in a particular area. The four Delegated Regulations provide for the detailed composition and labelling requirements for each of the four food categories listed above.

One such Delegated Regulation is (EU) 2016/127. This Regulation set specific compositional and labelling requirements for infant formula and follow-on formula (IFFOF). The majority of these requirements applied from 22nd February 2020 but, the requirements relating to IFFOF made from protein hydrolysates were not due to come into force until 22 February this year. Until 22 February 2021, infant and follow-on formula manufactured from protein hydrolysates will continue to be regulated by Commission Directive 2006/141/EC.

The use of protein hydrolysates as a source of protein in infant formula and follow-on formula has been allowed for many years and its use in the manufacturing of formula is widespread in the market. This is due in part to the associated health claims that infant formula manufactured from protein hydrolysates ‘reduces the risk of developing allergy to milk proteins’.

Under 2016/127 health claims such as ‘easy to digest’, or ‘reduce the risk of developing allergies to cows’ milk’ will be prohibited unless substantiated by scientific assessment.

Last month it was brought to the attention of DHSC that the EU had issued an amendment to Delegated Regulations 2016/217 Regulations 2016/217 to delay the implementation of the new requirements until 22 February 2022 (1 year delay) <https://data.consilium.europa.eu/doc/document/ST-5528-2021-INIT/en/pdf>.

Last month the UK Government followed the EU in delaying the implementation of the new requirements until 22 February 2022. This was implemented on behalf of the whole of Great Britain by way of the Nutrition (Amendment) and Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment) Regulations 2021 ('the 2021 GB SI').

As with the EU the UK is still finalising an assessment process for the consideration of dossiers submitted by industry on claims on infant formula manufactured from protein. Delaying implementing of the new rules will ensure the UK continues to align with Northern Ireland where as a consequence of the Northern Ireland protocol EU rules automatically apply avoiding unintended divergence between GB and Northern Ireland. This approach will also avoid market discrepancy and legal confusion and allow the UK time to implement the necessary scientific assessment regime.

## Changes to domestic legislation

The Infant Formula and Follow-on Formula (Wales) Regulations 2020 ('the domestic SI') need to be amended as currently they provide that the new rules relating to IFFOR products made from protein hydrolysates apply from 22 February 2021. These new rules now come into force from 22 February 2022.

This is purely a technical amendment which corrects a reference which is now obsolete. The SI will not impose any new requirements on businesses or enforcement bodies nor will it impose any new costs.

## Consultation process

This consultation will last for a 4-week period, to provide interested parties in

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Wales with the opportunity to comment on the proposal. Any responses received as part of this consultation will be given careful consideration and a summary of the responses received will be published on the Welsh Government website within 3 months of the end of the consultation period.

## Other consultations

England have already concluded the consultation of The Nutrition (Amendment) and Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment) Regulations 2021 GB which included domestic enforcement provision for England and which will amend the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

## Costs and benefits

### Industry

As the status quo remains until the new provisions come into effect, there is no material change as products will continue to remain compliant with the existing legislation. Furthermore there are no known manufacturers of these products in Wales.

### Public sector

As the status quo remains until the new provisions come into effect, there is no new burdens on enforcement bodies.

An Equalities Impact Assessment for this policy has not been completed. We

consider that the proposed legislation will not have any effect on equality in relation to any of the protected characteristics under the Public Sector Equality Duty (age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, or sexual orientation), or disproportionately impact on any particular group. The policy will also have no effect on family relationships and functions.

## **Benefits**

There are no incremental benefits associated with the proposal as it does not impose additional or new burdens on business and enforcement bodies.

## **Consultation questions**

### **Question 1**

Do you agree with the approach proposed to amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020?

### **Question 2**

Do you agree with the impacts that have been identified in this consultation?

### **Question 3**

Are you aware of any impacts that have not been identified in this consultation?

## Question 4

Do you have any other comments to make on this matter?

## How to respond

Submit your comments by 7 June 2021, in any of the following ways:

- complete our online form
- download, complete our [response form](#) and email [Lifestyles@gov.wales](mailto:Lifestyles@gov.wales)
- download, complete our response form and post to:

Healthy and Active Branch  
Public Health Division  
Welsh Government  
Cathays Park  
Cardiff  
CF10 3NQ

## Your rights

Under the data protection legislation, you have the right:

- to be informed of the personal data holds about you and to access it
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- to (in certain circumstances) object to or restrict processing
- for (in certain circumstances) your data to be 'erased'

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- to (in certain circumstances) data portability
- to lodge a complaint with the Information Commissioner's Office (ICO) who is our independent regulator for data protection

For further details about the information the Welsh Government holds and its use, or if you want to exercise your rights under the GDPR, please see contact details below:

## Data Protection Officer

Data Protection Officer  
Welsh Government  
Cathays Park  
CARDIFF  
CF10 3NQ

e-mail: [Data.ProtectionOfficer@gov.wales](mailto:Data.ProtectionOfficer@gov.wales)

## Information Commissioner's Office

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Tel: 01625 545 745 or 0303 123 1113

Website: <https://ico.org.uk/>

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## UK General Data Protection Regulation (UK GDPR)

The Welsh Government will be data controller for any personal data you provide as part of your response to the consultation. Welsh Ministers have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions. Any response you send us will be seen in full by Welsh Government staff dealing with the issues which this consultation is about or planning future consultations. Where the Welsh Government undertakes further analysis of consultation responses then this work may be commissioned to be carried out by an accredited third party (e.g. a research organisation or a consultancy company). Any such work will only be undertaken under contract. Welsh Government's standard terms and conditions for such contracts set out strict requirements for the processing and safekeeping of personal data. In order to show that the consultation was carried out properly, the Welsh Government intends to publish a summary of the responses to this document. We may also publish responses in full. Normally, the name and address (or part of the address) of the person or organisation who sent the response are published with the response. If you do not want your name or address published, please tell us this in writing when you send your response. We will then redact them before publishing.

You should also be aware of our responsibilities under Freedom of Information legislation. If your details are published as part of the consultation response then these published reports will be retained indefinitely. Any of your data held otherwise by Welsh Government will be kept for no more than three years.

## Further information and related documents

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