

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

C(2023)4687 FINAL + ANNEX

COMMISSION REGULATION (EU) / AMENDING ANNEX XVII TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS FORMALDEHYDE AND FORMALDEHYDE RELEASERS

Submitted by Department for Environment Food and Rural Affairs

11th January 2024

SUBJECT MATTER

1. The European Commission is implementing an amendment to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) within the European Union (EU), restricting the placing on the market or use of formaldehyde and formaldehyde releasers.
2. EU REACH is listed in Annex 2 of the Windsor Framework and therefore this amendment will apply in Northern Ireland (NI).
3. Officials across the UK (including those from Devolved Governments) are currently not aware of any negative impact this EU legislation may have on NI-GB Trade. Widespread voluntary compliance with the new legislation already appears to be in place across UK business.

Background to REACH Restrictions

4. REACH restrictions are applied to the manufacture, placing on the market and use of certain chemicals to mitigate unacceptable risks to human health or the environment. New restrictions, or amendments to existing ones, are made by legislation.

Background on Formaldehyde

5. Formaldehyde is classified as acute toxicant category 3, mutagen category 2, carcinogen category 1B, skin corrosive category 1B and skin sensitiser category 1 in both the UK and the EU, under the Classification, Labelling and Packaging Regulations¹. Formaldehyde also occurs naturally in the environment, and is produced by humans and animals, with low level exposure not expected to cause adverse health effects.
6. Manufacture of formaldehyde occurs in large quantities, and it has a wide range of uses. The primary use of formaldehyde is as a chemical intermediate in the production of other chemicals, formaldehyde-based resin, and thermoplastics.

¹ Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

Within the EU, 98% of formaldehyde is used for this purpose. Formaldehyde-based resins are used as adhesives and binders in a large range of articles including wood products, plastics, wallpapers, foams, insulating material, coating and textiles, pulp and paper, synthetic fibres and parts for road vehicles and aircraft.

7. In the UK, as part of the UK REACH Work Programme 2022/23, a Regulatory Management Options Analysis (RMOA) was initiated by the Health and Safety Executive (HSE), as the Agency for UK REACH. The RMOA is expected to be completed in early 2024, and will help assess the risks posed by formaldehyde to the general public, as well as identifying any regulatory measures to address any uncontrolled risks under UK REACH.

Proposed Regulation of formaldehyde and formaldehyde releasers in the EU

8. The EU Annex XVII amendment aims to address the risks to the health of the general public as a result of formaldehyde in indoor air and road vehicle interiors. The restriction sets limits on the levels of formaldehyde of 0,062 mg/m³ for furniture, wood-based articles, and the interior of road vehicles and of 0,080 mg/m³ for all other articles.
9. It will mean that articles cannot be placed on the EU market or in NI if they exceed the set limits from 6th August 2026 (36-month deferral), with a later date of 6th August 2027 (48-month deferral) for road vehicles, due to complexities involved in the development and production of road vehicles.
10. Articles exclusively for outdoor use are excluded from the restriction, as are articles used outside the building shell and vapour barrier which do not emit formaldehyde into indoor air, and articles/road vehicles that do not lead to exposure of the general public which are used exclusively for industrial or professional use. Second hand articles/road vehicles are also excluded from the restriction as are articles where the formaldehyde present is exclusively naturally present in the production materials.
11. Exclusions also apply for products which are already subject to other rules limiting formaldehyde. These are articles for which the restriction laid down in entry 72 applies; articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council; devices within the scope of Regulation (EU) 2017/745; personal protective equipment within the scope of Regulation (EU) 2016/425; articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004.

SCRUTINY HISTORY

12. The Parliament Scrutiny history relevant to this Explanatory Memorandum is contained in Annex A.

MINISTERIAL RESPONSIBILITY

13. The Secretary of State for Environment, Food and Rural Affairs has responsibility for this policy area, alongside Welsh and Scottish Ministers whose consent is required for the introduction of equivalent measures in GB.

INTEREST OF THE DEVOLVED GOVERNMENTS

14. This proposal covers a policy area that is subject to the provisional Common Framework on Chemicals and Pesticides. The devolved governments (DGs) have been consulted in the preparation of this Explanatory Memorandum (EM). Their comments are included below.
15. NI Officials from the Department of Agriculture, Environment & Rural Affairs, the Department for the Economy and the Health & Safety Executive NI have an interest in this proposal, as it falls within the scope of the Windsor Framework. Officials are currently not aware of any negative impact that this might have on NI industry or on NI-GB trade. Officials will continue to engage with their Defra and Devolved Government colleagues as they assess what action to take under UK REACH. Input has been provided at official level and does not represent the views of NI Executive Ministers.
16. The Scottish Government has an interest in this proposal as some aspects relating to chemicals policy are devolved. The Scottish Government highlighted the potential for regulatory divergence from EU REACH depending on the regulatory path taken under UK REACH. Consequently, Scottish Government officials are engaging with the Department for Environment, Food and Rural Affairs, other devolved governments and the HSE, the regulatory authority for UK REACH, to consider regulatory options under UK REACH.
17. The Welsh Government is awaiting the findings of the RMOA on formaldehyde and formaldehyde releasers produced by HSE before considering a joint decision with Defra and the Scottish Government on the recommendations of the formaldehyde RMOA.
18. Defra will work closely with the Northern Ireland Executive, Scottish and Welsh Governments when considering impacts of the EU amendment on the UK. The RMOA being produced by HSE will provide a clearer picture of the potential risks associated with formaldehyde in GB and we will work closely with the DGs when considering potential regulatory action in GB, taking into account potential impacts on the UK internal market.

LEGAL AND PROCEDURAL ISSUES

19.

i. Legal Base

The legal basis for this amendment is Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

ii. Voting Procedure

The procedure used for amendments to Annex XVII is Regulatory with scrutiny (Art. 5a par. 1-5), with a qualified majority required.

iii. **Timetable for adoption and implementation**

The regulation was adopted by the Commission on 14th July 2023 with general articles exceeding the set limits of formaldehyde not to be placed on the market from 6th August 2026, and from 6th August 2027 for road vehicles. HSE (as the Agency for UK REACH) is nearing completion of a RMOA on formaldehyde and formaldehyde releasers and Defra and the DGs expect to review its recommendations in early 2024. Following the RMOA we will have a clearer understanding of any potential future regulation of formaldehyde in GB.

POLICY AND LEGAL IMPLICATIONS

20. Formaldehyde is recognised as having hazardous properties and is subject to existing regulation in the UK including a workplace exposure limit (WEL). The RMOA initiated under UK REACH is expected to be completed in early 2024. It will help assess the risks posed by formaldehyde to the general public, as well as identifying regulatory measures to address any uncontrolled risks, with any subsequent decisions taking into account impacts on the UK internal market.
21. Under the Windsor Framework, formaldehyde and formaldehyde-containing products placed on the market in NI need to comply with EU REACH and will need to comply with the formaldehyde limits introduced by the updated EU regulation. Industry intelligence indicates that compliance with the new EU limits is already very high across the UK, thanks to long-standing voluntary industry schemes which have reduced formaldehyde levels since 2006.
22. No impacts or concerns have been raised by stakeholders. We will continue to monitor the situation, including liaising with industry.
23. Following completion of the RMOA, the socioeconomic impacts of any recommended regulatory approach in GB will be assessed, including any impacts if the proposed GB approach is different to that adopted by the EU. If the need for a UK REACH restriction is identified, Defra and the DGs will be mindful of opportunities to support trade flows through equivalent standards, if deemed appropriate.

CONSULTATION

24. As part of the production of a RMOA on formaldehyde, HSE issued a 60-day call for evidence which closed on 25th June 2023. Only one GB-based company responded to the call for evidence. This respondent did not identify any concern about trade with NI or potential UK-EU divergence. To improve the response rate, HSE emailed around 30 stakeholders which UKHSA had identified from their initial work. Those stakeholders were invited to participate in the call for evidence. These included relevant trade associations, consumer organisations and two university research departments with an interest in indoor air quality. This did not yield further information. Defra also invited chemical trade association representatives to comment on the impact of the EU amendment. Only one response was received, which confirmed that the sector anticipates no impacts from the EU restriction, as

it is already overwhelmingly abiding by the new EU standards, thanks to long-standing voluntary initiatives.

FINANCIAL IMPLICATIONS

25. There are no financial implications for the UK Government.

A handwritten signature in blue ink, appearing to read 'R. Moore', is positioned above the printed name.

**ROBERT MOORE MP
MINISTER FOR WATER AND RURAL GROWTH
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS**

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

COMMISSION REGULATION (EU) / AMENDING ANNEX XVII TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS FORMALDEHYDE AND FORMALDEHYDE RELEASERS

C (2022) 2142 :COMMISSION REGULATION (EU) .../... OF 8.4.2022 AMENDING ANNEX XIV TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)

DEFRA EM DATED 13/07/2022

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
ESC COMPLETED SCRUTINY ON 1/9/22 (REPORT 7, 22/23) AS RAISING INSUFFICIENT ISSUES TO REPORT TO THE HOUSE	DRAWN TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 22; 21/7/22)

6916/18, COM(18)116: COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE COMMISSION GENERAL REPORT ON THE OPERATION OF REACH AND REVIEW OF CERTAIN ELEMENTS CONCLUSIONS AND ACTIONS

DEFRA SUBMITTED AN EM DATED 18/02/2018

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
POLITICALLY IMPORTANT CLEARED (AGENDA FOR REPORT NO 32; 20/6/2018). POLITICALLY IMPORTANT NOT CLEARED, FURTHER INFORMATION REQUESTED (AGENDA FOR REPORT NO 25;25/4/2018)	CLEARED BY MINISTERIAL LETTER DATED 23/10/2018. NOT CLEARED, SIFTED FOR EXAMINATION TO ENERGY AND ENVIRONMENT (CHAIRMAN'S SIFT 1688 - 18/04/2018)

EM 5479/18,COM(2018) 32 FINAL: COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS ON THE IMPLEMENTATION OF THE CIRCULAR ECONOMY PACKAGE: OPTIONS TO ADDRESS THE INTERFACE BETWEEN CHEMICAL, PRODUCT AND WASTE LEGISLATION

DATE EM SIGNED: 31/01/2018

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
NOT IMPORTANT CLEARED (AGENDA FOR REPORT NO 21 ;21/3/2018)	CLEARED (BUT SENT FOR INFORMATION TO ENERGY AND ENVIRONMENT) AT CHAIRMAN'S SIFT 1682 - 23/02/2018

EM 5864/13,COM(2013) 49 FINAL: GENERAL REPORT ON REACH REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS IN ACCORDANCE WITH ARTICLE 117(4) OF REACH AND ARTICLE 46(2) OF CLP, AND A REVIEW OF CERTAIN ELEMENTS OF REACH IN LINE WITH ARTICLES 75(2), 138(2), 138(3) AND 138(6) OF REACH (TEXT WITH EEA RELEVANCE) {SWD(2013) 25 FINAL}

DATE EM SIGNED: 18/02/2013

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
CLEARED AS NOT LEGALLY OR POLITICALLY IMPORTANT - REPORT 33 - 27/02/2013	CLEARED AT CHAIRMAN'S SIFT 1497 - 26/02/2013