EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

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COMMISSION DELEGATED REGULATION (EU) …/... of 16.2.2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Submitted by the Department of Work and Pensions on 24 March 2022

SUBJECT MATTER

1. This Explanatory Memorandum (EM) relates to **Commission Delegated Regulation (EU) of 16.2.2022 ('the delegated act') amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures ('CLP Regulation')**. This delegated act makes technical and scientific changes to the CLP Regulation by introducing, revising or removing harmonised classifications for hazardous chemical substances by amending the list of classifications in Part 3 of Annex VI of the CLP Regulation.

2. The CLP Regulation is a directly applicable European Union (EU) Regulation that has applied to the supply of chemicals (substances and mixtures) in the EU and European Economic Area (EEA) since January 2009. The CLP Regulation requires suppliers to classify and label their chemicals in accordance with an internationally agreed system, the UN Globally Harmonized System of the classification and labelling of chemicals (GHS) and to package them safely before they place them on the market. These requirements apply throughout the supply chain down to the point of use and ensure that workers, professional users, and consumers are given important hazard information about chemicals so that they can be supplied, handled, and used safely.

3. Harmonised classifications are mandatory minimum classifications for substances that create a level playing field in the EU/EEA for the supply of chemicals. Suppliers established in the EU/EEA, meaning manufacturers, importers, downstream users and distributors of substances and mixtures, must use the same harmonised classification and labelling for substances for some hazard classes. The harmonised classifications are based on a technical and scientific assessment and evaluation by the independent European Chemicals Agency's (ECHA) Committee for Risk Assessment (known as RAC) and are presented as recommendations in RAC Opinions.

4. RAC prepares Opinions on harmonised classifications for substances reflecting intrinsic hazards to human health and the environment. RAC members are independent and are appointed by Member States based on their scientific and regulatory expertise. RAC Opinions seek to amend harmonised classifications in line with technical and scientific progress.

5. Following a RAC Opinion, updates are made to Part 3 of Annex VI of the CLP Regulation through delegated acts (commonly as Adaptations to Technical Progress (ATP)). ATPs are usually undertaken annually.

6. This delegated act, known informally as the '18th' ATP', introduces new harmonised classifications for 39 substances, revises 17 existing entries and removes one existing entry (replaced by two new entries) from Part 3 of Annex VI of the CLP Regulation. The harmonised classifications in the delegated act come from RAC Opinions adopted in 2020. The Commission adopted the delegated act on 16 February 2022.

7. It should be noted that the Government is seeking to find a new balance in the Northern Ireland Protocol (NI Protocol) in order to place it on a more sustainable footing. The Command Paper (published on 21 July 2021) includes proposals such as to establish a dual regulatory regime, in order to ensure that consumers in Northern Ireland do not face barriers in accessing goods from Great Britain (GB). This would enable goods made to UK rules to circulate and be placed on the market in Northern Ireland. In such a scenario, it is anticipated that the rules above would apply only where goods were to be made to EU rules in order to be able to access both the Northern Ireland market and the EU market.

The Government's initial assessment of the merits or otherwise of these EU regulatory proposals

8. The proposed new and revised harmonised classifications in the delegated act are technical changes that are generally helpful to industry in the context of the EU Single Market and are protective of human health and the environment.

SCRUTINY HISTORY

9. The Parliamentary Scrutiny history relevant to this Explanatory Memorandum is contained in **Annex A**.

MINISTERIAL RESPONSIBILITY

10. The Secretary of State for Disabled People, Health and Work, advised by the Health and Safety Executive (HSE), has the main responsibility for policy questions arising from this document.

11. The HSE has lead responsibility across Government for classification and labelling of chemicals, including the GHS. This responsibility is exercised in consultation with other interested Departments, Agencies, and the devolved administrations (the Scottish and Welsh Governments, the Northern Ireland Executive and other Northern Ireland departments).

INTEREST OF THE DEVOLVED ADMINISTRATIONS

12. The delegated act will not apply in GB but will be implemented directly in Northern Ireland under the NI Protocol and relates to the recently published UK Chemicals and Pesticides Provisional Common Framework, which is being developed jointly by the UK government and the devolved governments. All provisional frameworks are shared with committees across UK Parliament and devolved legislatures to enable parliamentary scrutiny before final review.

13. Chemical policy engages a mix of reserved and devolved competence. In GB, occupational safety and health, consumer safety, and product labelling are reserved matters under the devolution settlements while environmental protection and public health are devolved competences to the devolved administrations.

14. Accordingly, Scottish and Welsh Ministers have an interest in the environmental protection and public health aspects of chemicals legislation such as the retained 'GB' CLP Regulation as these areas are devolved and, in most cases, the exercise of the Secretary of State's functions under the CLP Regulation are subject to the consent of the devolved Ministers.

15. In Northern Ireland, occupational health and safety, environmental protection, public health, and the safety of civil explosives are transferred under the devolution settlements.

16. The Northern Ireland Executive Ministers have a particular interest in this delegated act because it will impact on Northern Ireland directly by virtue of the UK/EU Withdrawal Agreement and the NI Protocol. Officials in the Department for Economy, the Department of Justice, HSE Northern Ireland (HSE NI) and other Northern Ireland Executive departments such as the Department of Agriculture, Environment and Rural Affairs (DAERA) have been consulted in the preparation of this EM.

17. Scottish Ministers and Welsh Ministers also have an interest in the delegated act and officials have been consulted in the preparation of this EM.

LEGAL AND PROCEDURAL ISSUES

i. Legal basis

18. The CLP Regulation (Regulation (EC) No. 1272/208) is made under Article 114 of the Treaty on the Functioning of the European Union). The legal base for the delegated act is Article 37(5) and Article 53 of the CLP Regulation which empowers the Commission to amend Annex VI of that regulation by delegated acts. The procedure that the Commission is required to follow for the delegated act is set out in Article 53a.

ii. Voting Procedure

19. The European Parliament and/or Council may object to the delegated act within two months of the Commission adopting the act, which will prevent it from coming into force. To exercise their right of objection, a majority in the European Parliament is necessary, or a qualified majority in the Council.

iii. Timetable for adoption and implementation

20. The EU Commission adopted this delegated act on 16 February 2022. The European Parliament and Council have been notified. There is an objection period of 2 months which may be extended by 2 months by the European Parliament or Council. If no objection is raised, the delegated act will be published in the Official Journal. The delegated act will enter into force twenty days after publication. We expect the delegated act to come into force by the end of April or early May 2022. The amended harmonised classifications are likely to apply to businesses in the EU/EEA (including NI) from 1 November 2023.

iv. Does the proposal affect the substance of EU law that will remain in effect under the NI Protocol or is it likely to be the subject of a request by the EU to be added to the NI Protocol under Article 13(4) thereof?

21. The NI Protocol provides that limited areas of EU law will continue to apply to and in the UK in respect of Northern Ireland. Article 5(4) states that provisions of Union law listed in Annex 2 to the NI Protocol shall continue to apply in respect of Northern Ireland. The CLP Regulation is listed in Annex 2 under paragraph 23. Article 13(3) of the NI Protocol confirms that reference to Union legislation in the NI Protocol is a reference to that legislation as amended or replaced. The delegated act will amend Annex VI of the CLP Regulation when it comes into force. Therefore, once the CLP Regulation is amended, it will apply in Northern Ireland by operation of Article 13(3).

POLICY IMPLICATIONS

Implications for the application of EU law under the NI Protocol

22. Northern Ireland (NI)-based businesses that are suppliers of substances in the delegated act will be required to classify and label the substances placed on the EU Single Market in accordance with the new or revised harmonised classifications and must also make any changes to labels for their substances and mixtures without undue delay where the hazard classification is more severe.

23. NI-based suppliers will have the possibility to apply the new harmonised classification and labelling provisions on a voluntary basis before the date of application. Suppliers are usually allowed up to 18 months to adapt the labelling of substances and mixtures to the new or revised harmonised classifications unless the hazard classification is more severe and to sell existing stocks subject to the pre-existing regulatory requirements. The application date is expected to be 1 November 2023.

24. Under the Government's commitments to Northern Ireland's unfettered access to the rest of the UK market, substances included in the delegated act that meet the technical requirements to be placed on the market in Northern Ireland will be able to be placed on the GB market as long the Northern Ireland trader completes an online notification to confirm the hazard classification of its chemical(s). Additionally, businesses seeking to change the name of their chemical would be required to notify the UK regulator and complete the process, which is free of charge, to make sure the UK regulator is aware of the chemicals on the GB market.

Domestic UK approach to the policy and whether vital national interests are at stake

25. The delegated act of itself does not raise immediate matters of vital national interest to the UK.

26. GB now has its own stand-alone mandatory classification and labelling (GB MCL) system with its own administrative procedures independent of the European Commission, ECHA and the EU Parliament and Council. HSE as the GB CLP Agency ('the Agency') is responsible for operating the GB MCL system under the retained GB CLP Regulation.

27. The GB MCL system continues to recognise the importance of the EU market, and the value and sophistication of the system it has in place to regulate the classification, labelling and packaging of hazardous chemicals. For these reasons, the GB MCL system is required to consider published RAC Opinions and the recommendations for harmonised classification and labelling of substances under the Article 37 procedure.

28. Parliament agreed this approach that changes to GB MCLs which are technical and scientific changes can be made administratively rather than as regulatory changes.

Implications for GB-based businesses

29. Importers have a legal obligation to ensure their substances and mixtures are compliant with CLP Regulation requirements – therefore, it is NI-based business who import substances or mixtures that have a legal obligation, rather than GB based suppliers. However, where supply chains from GB to Northern Ireland exist, the Agency encourages GB-based suppliers and NI-based businesses, through a number of channels - including website guidance, e-bulletins and stakeholder engagement presentations - to work together and co-operate to meet classification and labelling requirements by sharing any necessary information, evidence or data wherever possible and where business contracts permit.

30. Some GB-based businesses may become dissuaded from engaging with the Northern Ireland market when faced by regulatory barriers in particular if policies in England, Scotland or Wales move in a different direction while Northern Ireland's options are constrained by the NI Protocol.

Practical implications of this delegated act for regulatory divergence between Great Britain and Northern Ireland and for movement of such products between them

31. The effects of the NI Protocol, and the primacy of European Union law in that territory, establish two distinct regulatory CLP regimes; one in GB, the other in the EU and Northern Ireland (the EU Single Market).

32. The practical implications of regulatory divergence will depend on the direction of supply (GB to Northern Ireland / Northern Ireland to GB) and the final destination of the substances and mixtures. Where GB diverges from the EU in determining

mandatory (harmonised) classification and labelling, businesses supplying to either market must comply with the regulatory requirements of that market.

33. The practical implications for both GB-based and NI-based businesses will arise from different hazard labelling requirements in each regulatory jurisdiction to reflect the different hazard classifications required by the retained GB CLP Regulation and the CLP Regulation respectively. However, provided a compliant CLP hazard label appears on supplied substances and mixtures in each jurisdiction, CLP does not introduce any hindrance to that supply.

34. In the medium term, there will be some non-alignment between GB and Northern Ireland markets for the affected substances where different labelling will be required. The substances included in this delegated act are currently being considered through the GB MCL system but final decisions on GB MCLs will not be come into force until October 2023 at the earliest with potentially an additional 18-month period for full compliance.

What steps, if any, the Government plans to take to address such regulatory divergence, for instance through the introduction of equivalent measures in England or Great Britain, as the case may be, and the timetable for doing so.

35. Under the GB MCL system, the Agency is required to consider the published RAC Opinions and recommendations for harmonised classification and labelling of substances. The Agency expects to make similar decisions because the same scientific information and datasets are being used to inform the Agency Opinion on whether to align with the RAC Opinion, under the procedures in Article 37 of the GB CLP Regulation.

Timetable for GB decisions in respect of the RAC Opinions

36. The timetable for GB decisions in respect of the RAC Opinions is set out in Article 37 of the retained 'GB CLP Regulation'. This ensures that action is taken in a timely way by the Agency to assess and evaluate the proposed harmonised classification and labelling in RAC Opinions.

37. The timetable for the assessment of 2020 RAC Opinions for entries included in the delegated act is as follows:

    - Following the publication of the RAC Opinion, the Agency must produce a Technical Report (TR) within **6 months**.

    - For the 18th ATP RAC Opinions published **before** 31st December 2020, the 6-month period started from Implementation Period completion day (31 December 2020) and so the TRs were published **29 June 2021.**

    - For RAC Opinions published **after** 31st December 2020, the 6-month period starts from the date of **publication** of the RAC Opinion, not adoption of the Opinion at a RAC meeting.

- The Agency must then publish an Agency Opinion **within 12 months** of the TR publication date.

- The Agency will submit the recommendation to the Secretary of State and a copy to the Scottish and Welsh Governments **within 12 months** of the Agency Opinion publication. Secretary of State decisions with the consent of Scottish Government Ministers/Welsh Government Ministers are then expected to be published **within 3 months**.

- The Agency will update the GB MCL list **within one month** of being notified of the Secretary of State's decision. New entries are expected to be included in the GB MCL List by **October 2023.**

38. For the majority of the Technical Reports, the Agency has agreed with all the proposed hazard classifications in the RAC Opinions. The final GB MCL will not be agreed and/or adopted in GB in the GB MCL List until after Agency Opinions have been published, recommendations have been sent to Ministers and decisions taken by the Secretary of State with the consent of Scottish and Welsh Ministers.

39. Under the new GB MCL System, the UK is now free to decide independently its own regulatory positions to ensure the continued protection of people, the environment, and the interests of UK business. The Agency will determine whether any mitigation measures are required through an impact and policy assessment as part of the Agency Opinion, which assesses wider policy implications and possible socio-economic impacts of a new or revised GB MCL.

40. It is anticipated that there will continue to be a degree of alignment with the EU especially for active substances and in relation to priority hazard classes (carcinogenicity, mutagenicity, toxic for reproduction (CMR) and respiratory sensitisation). This is because the underlying scientific evidence used for decision making will be the same in respect of the RAC Opinion as it would be under the GB MCL system. As now, most classifications in RAC Opinions will be uncontroversial and it is likely that the Agency will recommend adoption in the GB MCL List if the scientific evidence is convincing and persuasive.

41. The Agency also has the option to pursue a GB-only MCL proposal under the Article 37A procedure. This could lead to non-alignment between EU harmonised classification and labelling and GB MCL, but only following GB public consultation on the GB MCL proposal, an Agency Technical Report and Agency Opinion, before a recommendation and Ministerial decision with the consent of Scottish Ministers and Welsh Ministers.

The Government's approach to engagement with the EU on the proposal, including any relevant discussions undertaken within the Joint Consultative Working Group, Northern Ireland Specialised Committee, or the Joint Committee

42. There was no direct UK Government engagement with the delegated act. In line with UK Government policy, from September 2019 onwards UK experts on RAC did not participate in formal RAC meetings or in discussions of the RAC Opinions relating to substances subsequently included in the delegated act. UK Government representatives did not attend discussions about the draft Commission proposals for the delegated act at meetings of the Competent Authorities for REACH and CLP (CARACAL), the Expert Group, during 2020 and 2021.

43. No discussions were undertaken within the Joint Consultative Working Group, Northern Ireland Specialised Committee, or the Joint Committee.

The relevance and impact of the proposal for Northern Ireland's participation in UK Common Frameworks

44. As no GB MCL decisions have been taken to date, the Minister for the Economy in Northern Ireland, whose Department is the CLP Competent Authority for Northern Ireland, has not raised any concerns at this time.

The impact, if any, of the proposal for Northern Ireland's participation in UK Free Trade Agreement

45. International Trade policy is an area of reserved competence for the UK Government. Free Trade Agreement requirements will need to take account of the UK's existing obligations under the NI Protocol as UK Free Trade Agreements will continue to apply to Northern Ireland.

CONSULTATION

What consultation, either by the Government or the Northern Ireland Executive, has taken place with key stakeholders (such as businesses based in or trading with Northern Ireland) on the impact of the EU legislation

46. There has been no formal public consultation by HSE of key external stakeholders on the impact of this delegated act because this relates to a directly applicable delegated act that will not apply in GB as a result of the UK's exit from the EU but will apply automatically in Northern Ireland by virtue of the UK/EU Withdrawal Agreement and NI Protocol.

47. ECHA held 60-day public consultations on the proposed harmonised classifications for each of the substances included in the delegated act as part of the scientific assessment and evaluation of the proposals by RAC. These public consultations were open to companies, organisations representing industry or civil society, individual citizens, as well as public authorities from the EU or beyond.

48. To assist with this process, HSE encourages UK businesses to respond to ECHA public consultations where they are affected and also asks them to alert HSE to any anticipated significant impacts. Stakeholders are also encouraged to respond and use such consultations as a conduit to share information with other actors in the supply chain and with HSE. This continues under the new GB MCL system.

49. The European Commission also undertook its own consultation with industry and EU Member States in advance of this delegated act through the CARACAL expert group.

Consultation with the Devolved Administrations

50. HSE has consulted officials in relevant Northern Ireland departments on this delegated act and how this relates to the GB MCL system. Concerns have been raised as follows:

- Officials in the Department for the Economy have proposed a new approach on delegated acts (ATPs) to assist officials to improve the Agency's impact and policy assessment process;
- DAERA have expressed concerns about the small number of pesticide manufacturers in Northern Ireland and their capacity to calculate the impact of changes on the availability of pesticides; and
- the need for a mechanism for Northern Ireland Department of Justice officials to identify substances with explosive properties.

51. HSE met recently with Northern Ireland officials to discuss and resolve the concerns that have been raised. HSE officials reached an agreement with Northern Ireland officials in the Department for the Economy to work with them to identify substances in the delegated act where risk control measures are likely to be triggered in downstream legislation. This was with the intention of developing a process to help them to alert the responsible officials in other departments who have greater knowledge of the substance type and downstream consequences, to contribute to the broader impact and policy assessment under the GB MCL system. This process will be kept under review. This is in addition to 'Ways of Working' arrangements being developed under an Agency Agreement between the Department for the Economy Northern Ireland, the Department of Justice Northern Ireland and HSE relating to the classification, labelling and packaging of substances and mixtures.

52. HSE consulted officials in Scotland and Wales on this delegated act and how this relates to the GB MCL process. Officials have previously expressed their interest to be kept informed about substances going through the GB MCL system but have not raised any specific concerns about this delegated act.

53. HSE continues to work closely with officials in the Scottish and Welsh Governments to make sure they are engaged and are consulted on the GB MCL Process and are involved in the drafting of impact and policy assessments and Agency Opinions. Further consultation will take place during the process of seeking the consent of ministers in the Scottish and Welsh Governments to give legal effect to GB MCLs under the GB MCL system.

FINANCIAL IMPLICATIONS

Whether the Government has, or plans to undertake, a cost or impact assessment of the proposals for Northern Ireland.

54. A formal impact assessment is not required from the Commission for routine technical Commission Delegated Regulations nor do such measures fall within the scope of the EU's better regulation arrangements.

55. The Government has no plans to undertake a cost or impact assessment other than an impact and policy assessment as part of the Agency Opinion to enable the Agency and the ministers of England, Wales and Scotland to understand the policy impacts, wider socio-economic impacts and other aspects of the new or revised mandatory classifications under the GB MCL system.

Direct costs

56. New and revised harmonised classifications in the delegated act will result in some direct costs for Northern Ireland suppliers to comply with any changes to the CLP Regulation arising from the delegated act. These costs arise in four main areas:

- familiarisation costs for chemical manufacturers, importers and downstream users;
- familiarisation costs for employees who may need to be aware of the hazard classifications at the point of import, manufacture or formulation;
- relabelling of packaging for the affected substances or mixtures placed on the market; and
- re-labelling to comply with two regulatory regimes in Northern Ireland and GB where the decisions on hazard classification does not align.

57. These direct costs are the same as costs incurred for changes to harmonised classifications arising from previous delegated acts relating to adaptations to technical progress.

58. There are no significant direct costs for Northern Ireland suppliers from changing labels and safety data sheets to reflect the new/revised classifications. Average relabelling costs based on 2021 present values are estimated to fall within the range of £155-£505 per substance per company based on a previous assessment of the impact of changes affecting poison centres produced by the Department of Health, in conjunction with HSE. The scale of potential costs is expected to be in line with compliance costs relating to previous delegated acts. Changes to harmonised classifications may result in a reduced cost to businesses where, in the past, they may have had to undertake self-classification for the substances in question.

59. There may be some indirect costs arising to GB-based businesses, but these are costs arising from the UK's withdrawal from the EU. There are likely to be no significant costs associated with regulatory divergence considering that non-alignment between GB, the EU and Northern Ireland will be temporary and given

that the Agency has recommended to agree with the majority of EU decisions on hazard classification and labelling for substances in the delegated act.

CHLOE SMITH

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ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO THIS EXPLANATORY MEMORANDUM

1. The European Council's proposal for the directly applicable CLP Regulation was first subject to Parliamentary Scrutiny on 17 July 2007 - Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006. At the time, the Department of Work and Pensions submitted an Explanatory Memorandum. The relevant document number was 11497/07, COM(07)355.

2. The CLP Regulation was cleared as politically important by the House of Commons European Scrutiny Committee on 30 April 2008 (22nd Report, Session 2007-2008) following a previous report that the proposal had raised issues of political importance (on 10/10/2007 36th Report, Session 2006-07). The House of Lords European Union Select Committee cleared the document from scrutiny on 23 November 2007 (Progress of Scrutiny - 1st Report, Session 2007-2008). The Report was published on 23 November 2007.

3. Parliamentary Scrutiny did not apply to subsequent Commission Regulations relating to ATPs to the CLP Regulation or more recently to Commission Delegated Regulations because the proposed changes to harmonised classification were considered technical and scientific, and because they related to a directly applicable EU Single Market Regulation which applied to Member States without further implementation action.

4. The Department of Health and Social Care submitted an Explanatory Memorandum on Commission Delegated Regulation (EU) …/... of 29.10.2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response. This was subject to Parliamentary Scrutiny and an EM produced on 16 January 2020. The relevant document number was EM 13598/19, C(2019) 7611 final. The House of Commons European Scrutiny Committee cleared the document as not legally or politically important on 4 June 2020 (Tenth report of Session 2019-21). The House of Lords European Union Select Committee cleared the document from scrutiny in Chairman's Sift no.1671 on 22 January 2020 (Progress of Scrutiny - 1st Edition, Session 2019-21).

5. Most recently, the Department of Work and Pensions submitted an Explanatory Memorandum on 1 April 2021 on Commission Delegated Regulation (EU) …/... of 11.3.2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. This was subject to Parliamentary Scrutiny on 8 April 2021. The relevant EU document number was

EM 7007/21, C(2021)1533 final. The House of Commons European Scrutiny Committee cleared the document as not legally or politically important on 12 May 2021 (First report of Session 2021-22). The House of Lords European Union Select Committee sifted the document for examination by the House of Lords Protocol on Ireland/Northern Ireland Sub-Committee on 22 April 2021 (Chairs' Sift no.1 – 22 April 2021). The Sub-Committee considered this document at its meeting on 19 May 2021. The Chair of the Sub-Committee wrote to the Government seeking further information in Ministerial correspondence during 2021. Substantive scrutiny of this Delegated Regulation was closed following the Chair's letter to the Minister of 14 January 2022.