<u>Notifica</u>	tion under Part 3 of Schedule 6B of the Northern Ireland Act 1998 ("Stormont Brake")
23 Octob	nent EU Act: <b>Regulation (EU) 2024/2865 of the European Parliament and of the Council of</b> er 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging nces and mixtures
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19 Decen	nber 2024

<u>Criteria:</u> "The content or scope of the Union act as amended or replaced by the specific Union act significantly differs, in whole or in part, from the content or scope of the Union act as applicable before being amended or replaced."

At its meeting on 24 October 2024, the Windsor Framework Democratic Scrutiny Committee (WFDSC) received legal advice which indicated that Regulation (EU) 2024/2865 significantly differs, in part, from the content or scope of the EU instrument which it amends.

In our assessment, this replacement EU act amends Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) in a number of important and substantive respects:

- The addition of six new hazard classes to support the classification of substances and mixtures deemed very harmful for human health or the environment:
  - o endocrine disruption (ED) for human health and the environment;
  - o endocrine disruption (ED) for the environment
  - o persistent, bioaccumulative, toxic (PBT);
  - o very persistent, very bioaccumulative (vPvB);
  - o persistent, mobile, toxic (PMT); and
  - o very persistent, very mobile (vPvM)
- A 6-month deadline for updating labels when the classification and labelling of a hazardous chemical is changed to include a new or more severe hazard class.
- Minimum requirements for hazard communication labelling, including obligatory formatting rules, such as minimum font size, line spacing and colour.
- Specific rules for selling chemicals with less severe hazards in refillable containers
- New provisions for distance and online sales. All online sales will require a supplier established in the EU to ensure that a substance or a mixture placed on the EU market through distance sales meets CLP requirements.
- More hazard information would be required in advertisements of hazardous substances and mixtures, including hazard class, pictograms, signal words and hazard statements. Providers of online marketplaces are required to design and organise their online interfaces in a way that enables suppliers to comply with these obligations.
- Obligations for distributors which rebrand or relabel substances and mixtures, or supply those substances and mixtures across borders, to submit relevant information to poison centres for emergency health response.
- Voluntary digital labelling of chemicals. Information that is not instrumental in the protection of health and the environment could be moved to the digital label without being included on packaging.
- Ability for the European Commission to initiate and fund harmonised classification and labelling dossiers.
- Provisions on the use of fold-out labels.

These provisions extend beyond merely technical amendments. They also mark a clear and significant departure from the United Nation Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS), the internationally recognised system used by Great Britain and the Rest of World countries since 1992. The EU opted to introduce the new six hazard classes prior to pursuing UN GHS agreement.

<u>Criteria:</u> "The application in Northern Ireland of the Union act as amended or replaced by the specific Union act, or of the relevant part thereof as the case may be, would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist."

Having considered the body of evidence available, it is our assessment that this replacement EU act would have a significant and sustained impact specific to everyday life in Northern Ireland.

Trade data collected by His Majesty's Revenue & Customs (HMRC) indicates that movements of chemicals between Great Britain and Northern Ireland in the different tariff chapters covered by EU Regulation 1272/2008 were worth over £1bn in 2023. The application of new labelling requirements under the amended CLP regulation would generate additional and ongoing costs for impacted suppliers to, and within, Northern Ireland. In the case of manufacturers and distributors based in Great Britain, the additional requirement for a supplier to be established in NI in or EU would result in some businesses withdrawing from the NI market and, by extension, the discontinuation of some products to local businesses and consumers.

The Chemical Industries Association (CIA), a leading trade association dedicated to chemical and pharmaceutical companies across the United Kingdom, has advised the Windsor Framework Democratic Scrutiny Committee (WFDSC) that Regulation (EU) 2024/2865 would have a significant negative impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist. In written evidence to the WFDSC, the Association noted the following:

"We have some concerns around the formatting rules for new labels. These rules are very stringent and specific, particularly the prescription of new minimum font sizes and spacing requirements that make current label sizes unusable for the majority of products.

The increases implemented in the EU CLP Revision are impractical, with minimal (if any) real returns on label legibility, and they come with increased resource (time & cost) burdens. Companies may require new or updated software to design/generate these labels, or new label printing infrastructure to cope with increased label sizes.

It should also be noted that this is a divergence from GB CLP as it currently stands, which provides additional trade friction for the flow of products between GB and NI.

Whilst these trade barriers are reflective of wider frictions that will be introduced in any GB -> EU supply lines, and they are not exclusive to GB -> NI, nevertheless there is a danger that these will be more keenly felt in any supply chains where the supply is exclusively into NI. This is because the small market size may lead to withdrawal of product supply from the NI market, or at the very least, GB companies being unable to adhere to the cost-prohibitive new rules and subsequent burdens being pushed onto the NI recipient, who would be legally bound to reformat and relabel to maintain compliance with EU CLP."

On 25 November 2024, the Department for the Economy (DfE) published its initial assessment of impact in relation to Regulation (EU) 2024/2865. This included a summary of an initial analysis by the Health and Safety Executive (HSE) in Great Britain in relation to the UK Government's updated explanatory memorandum. Significantly, this analysis concluded that:

• the new requirement for a supplier to be established in the EU or Northern Ireland when placing a chemical on that market "will likely cause non-EU/NI-based businesses (including GB) to incur ongoing compliance costs." Furthermore,

- "some exporters to EU/NI may consequently withdraw from supplying the EU/NI markets, causing downstream supply chain disruption."
- changes to labelling rules will result in increased costs for duty holders to redesign and relabel products, which may lead to temporary gaps in supply.
- amendments to the supply of less hazardous chemicals via refill is expected to give rise to significant ongoing costs for suppliers implementing risk management measures, including:
  - minimising human exposure and uncontrolled use by children;
  - providing immediate assistance when operating refill stations outdoors;
  - ensuring staff are sufficiently trained; and,
  - providing labels for the hazardous chemicals supplied.
- in cases where compliance in respect of refill proves unviable, suppliers may ultimately restrict supply in applicable markets including NI.
- there are likely to be adverse resource implications arising from familiarisation and compliance for NI-based businesses subject to the mandatory obligation on certain distributors, including re-labellers and re-branders, to submit emergency heath response information to poison centres.

These represent significant and residual impacts for businesses serving the Northern Ireland market and customers and end users affected. We are concerned, and indeed sceptical, about why later correspondence from the HSE, as well as the Government's final updated explanatory memorandum published just days later - makes little to no reference to these clearly detailed impacts on trade flows within the UK internal market.

In February 2023, the UK Government published an initial assessment of Regulation (EU) 2024/2865, providing an approximate estimate of the total administrative annual costs for NI-based suppliers of £88,000 per annum. It was noted that this will largely arise from the relabelling of packaging for affected substances or mixtures when they are placed on the market or imported from a non-EU state or GB. The costs for small and medium-sized enterprises were also expected to be higher in relative terms, as these businesses benefit less from economies of scale and have less capacity to absorb fixed costs.

The updated EM made available on 4 December 2024 does not repeat these assumptions. Crucially, however, it also does not provide evidence to challenge their veracity. There is also an acknowledgement that if the replacement EU act was applied:

- there may be some differing requirements around the manufacture and placing of certain substances and mixtures on the market in NI compared with GB;
- there may be costs incurred by actors in the supply chain, including manufacturers, importing businesses and end users; and
- impacts of distance-selling measures and conditions for refill, and how businesses will choose to respond, are still being explored.

On this basis, we continue to hold the view that the application of this Regulation would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist.

Given that chemicals policy is a devolved matter, the application of the amended CLP regulation in Northern Ireland would also have tangible impacts on the Health and Safety Executive for Northern Ireland and Northern Ireland departments in terms of new requirements regarding enforcement, inspection and surveillance.

<u>Criteria:</u> "MLAs have sought prior substantive discussion with the UK Government and within the Northern Ireland Executive to examine all possibilities in relation to the Union act; taken steps to consult businesses, other traders and civic society affected by the relevant Union act; and made all reasonable use of applicable consultation processes provided by the European Union for new Union acts relevant to Northern Ireland."

The Windsor Framework Democratic Scrutiny Committee (WFDSC) identified the proposed EU act, COM/2022/748: Proposal for a Regulation amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, as an act that might have a significant impact, and was likely to be notified as a published act before the end 2024. Therefore, the Committee agreed that consideration of the proposed act should be given priority even though it had not been the subject of a notification from the UK Government.

In light of this, substantive engagement took place with Northern Ireland departments, the UK Government and business and civil society stakeholders. This included:

- Consideration the UK Government Department for Work and Pensions Explanatory Memorandum (EM) on the proposed EU act, dated 1 February 2023, as well as relevant reports published by the House of Commons European Scrutiny Committee and correspondence published by the House of Lords European Affairs Sub-Committee on the Windsor Framework
- Writing to the UK Government on 25 October seeking examining all possibilities in relation to the replacement EU act, including:
  - the steps the UK Government (UKG) has taken to mitigate divergence in this area;
  - UKG's engagement with the EU on the proposed act through the Windsor Framework structures;
  - UKG's discussions through the Common Framework, and engagement with Northern Ireland departments and stakeholders;
  - the views of the other devolved administrations; and,
  - UKG's policy intentions in this area.
- Forwarding correspondence to His Majesty Revenue & Customs requesting information on the scale of trade between Great Britain and Northern Ireland in the chemicals sector.
- Seeking views, via Citizen Space, from stakeholders identified by the Assembly's Research and Information Service as being affected, or who would be affected, if the proposed replacement EU act was to apply in Northern Ireland.
- Commissioning legal advice, which indicated that the proposed replacement EU act significantly differs, in part, from the content or scope of the EU instrument which it amends.
- Requesting initial impacts assessments from the Departments of Health, Justice and Economy in Northern Ireland.
- Scheduling a briefing with Legal Services and an oral evidence session with departmental officials.

The WFDSC subsequently agreed to launch an inquiry into Regulation (EU) 2024/2865 on 28 November 2024 - upon receiving formal notification from the Cabinet Office on 21 November 2024 that the act had been published in the Official Journal of the European Union. Further to this, the Committee took the following steps:

o Key stakeholders identified as being affected, or who would be affected, if the replacement EU act was to apply in Northern Ireland were again consulted. The Committee opted to use Citizen Space as a platform to facilitate this engagement and a survey asking for views on the impact of the published replacement EU act was launched on 29 November 2024. The survey, which

- was publicised widely, was also open for response by any other representatives of business and civil society as well as members of the public. Two responses were received; one from the Chemical Industries Association (CIA) and one from an anonymous individual. Both noted that the EU replacement act would have a significant negative impact.
- On 29 November, the WFDSC wrote to the Cabinet Office seeking the UK Government assessment of whether it appeared likely that applying, or not applying, the replacement EU act would have a significant impact specific to everyday life of communities here in a way that is liable to persist. This letter also requested the Government's comments on a previous consultation response from Fuels UK to the Committee's consultation on the proposed Regulation. A response was received on 11 December 2024.
- As part of its consideration, the Committee also requested, and considered, revised assessments
  of impact from the Departments for Economy, Health and Justice in Northern Ireland in relation
  to the likely impacts of the replacement EU act. Updated legal advice was also received.
  Moreover, members received oral evidence from officials of each Department.
- On 5 December, DfE officials informed the WFDSC that the Health and Safety Executive carried out engagement with stakeholders across GB regarding the potential impact of the EU Regulation, resulting in approximately 400 responses. On 6 December, the Committee wrote to the Health and Safety Executive in GB requesting that the feedback from this consultation be shared with the Committee to assist in its consideration of impact and the Government's response. A response was received on 11 December, however the information requested was withheld.

A complete account of the WFDSC's deliberations, including discussion and consultation with relevant parties on likely impacts and possibilities, is provided as part of the final inquiry report and annexes, which are publicly available.

Finally, we would draw attention to the fact that the initial legislative proposal underpinning this replacement EU act was adopted on 19 December 2022, prior to agreement on the democratic scrutiny provisions provided for under Schedule 6B of the Northern Ireland Act 1998. This also predated the publication of the Government's unilateral declaration on the Involvement of the institutions of the 1998 Agreement, which established the requirement to make all reasonable use of applicable EU consultation processes. In this regard, we do not consider this test to be applicable, relevant or valid in respect of Regulation (EU) 2024/2865.

<u>Criteria:</u> "The notification is only being made in the most exceptional circumstances and as a last resort, having used every other available mechanism."

We regard this notification to be exceptional and unavoidable for a number of reasons.

Firstly, although we have used every other available mechanism to advance our concerns in relation to the potential impact of Regulation (EU) 2024/286, the UK Government has failed to provide a concrete or timebound commitment to incorporating all measures contained in the revised EU CLP regulation, including changes to product labelling, into the domestic regime applicable in Great Britain. Specifically, no undertaking is given in the updated Government Explanatory Memorandum (EM) to extending the six new hazard classes introduced by the EU replacement act to Great Britain. This approach, we assert, will give rise to legal divergence, with disruption to supply chains between GB and NI.

The UK Government has said it 'is investigating the scientific and technical basis and the wider policy context...that may justify the incorporation of similar revision measures into the assimilated CLP Regulation.' However, this assurance is framed in the context of ongoing analysis of business survey data that has not been disclosed as well as established processes under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Given the number of actors involved in the UN GHS, and need for international agreement, this process is likely to be highly protracted. Consequently, we do not regard it to be a viable route to redress for trade concerns arising from this replacement EU act, particularly in the context of the deadline laid down under Section 11(3) of Schedule 6B to the Northern Ireland Act 1998.

A number of additional factors arise which, in our assessment, necessitates, and justifies, the triggering of the 'Stormont Brake' in this case:

- The UK Government has not carried out a regulatory impact assessment of the impacts of the proposal in Great Britain. Given the scale, and integrated nature, of supply chains between GB and NI, this undermines the legitimacy of the Government's assertion that the replacement act will have limited NI-specific implications.
- Despite requests by the WFDSC, the UK Government via the Health and Safety Executive has formally declined to provide any data, responses or feedback from a survey of manufacturers, importers, downstream users and distributors in GB and Northern Ireland which was conducted in September 2024. The purpose of this survey was to collect operational data on how the current GB CLP system was working and what impact any changes, including relabelling and label formatting, might have. Although all unionist representatives on the WFDSC were satisfied that EU Regulation 2024/286 would have a significant negative impact on communities in Northern Ireland in a way liable to persist, and voted accordingly when agreeing the Committee's inquiry report, the failure of the UK Government to disclose this pertinent survey data was undoubtedly an obstacle to the WFDSC reaching an agreed position on the impact of the replacement EU act.
- The UK Government confirmed that separate engagement took place with industry on 8 October 2024, with Ministers insisting that the overwhelming majority of substances and mixtures sold across the UK will continue to be in line with the general approach of the updated CLP Regulation. No data or read-out of that meeting has been published or provided to the WFDSC to substantiate this claim. This is a significant omission, particularly given that the Chemical Industries Association (CIA) has indicated that it raised concerns with both the HSE and Windsor Framework Taskforce. DfE officials informed the WFDSC on 5 December that HSE has asked the stakeholders to revert to the body before Christmas with any further information, including detail, for example, on the potential costs of changing labels. However, any detail on this

engagement will not be available until January at the earliest - in conflict with the deadline for pulling the Brake.

- In oral evidence to the WFDSC on 5 December 2024, DfE officials confirmed that the Department has 'not delved into individual product groups and how they are affected' by the revised EU Regulation. It was noted that the 'CLP is a wide regulation that applies to a huge range of substances and mixtures across different regulatory regimes. Many thousands of things are within scope, and we will examine something only if somebody has raised a specific issue.' This, in our view, demonstrates another significant limitation in the evidence base available to members to scrutinise the ramifications of this replacement EU act within the statutory timeframe afforded by Schedule 6B of the NI Act 1998.
- The Government has said that impacts of distance-selling measures and conditions for refill, and how businesses will choose to respond, are still being explored - again, this assessment is not expected prior to the above deadline.
- There is no evidence that GB-based businesses are choosing to self-classify in accordance with the new hazard classes introduced into EU CLP. We are not aware of any cases of GB dutyholders applying the new EU CLP hazard classes to substances or mixtures being placed on the GB market. This evidently raises concern that NI businesses and consumers will no longer have access to substances and mixtures produced and labelled in Great Britain.
- DfE have indicated that plans to establish a Chemical Stakeholders Forum in Northern Ireland will not be advanced until at least the first quarter of 2025.

Subsequently, we believe this notification is a last resort in terms of preventing the creation of new trade barriers between Great Britain and Northern Ireland and associated supply issues, and protecting local manufacturers and suppliers against additional and ongoing costs when placing their products on the market.