Annex: Submission from CHEM Trust on the draft REACH (Amendment) Regulations 2023, with the response from the Department for Environment, Food and Rural Affairs in italics

This SI was laid in Parliament under the draft affirmative procedure on 20th April 2023.

Background to UK REACH

1. While many industrial chemicals have improved the quality of our lives, many are harmful to people's health or the environment or both. The protection of our health and environment from serious harm relies on an effective system of chemical management. The UK was one of the driving forces behind the creation of EU REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation in 2007, and was covered by this system up until the end of 2020. The principle of 'no data, no market' is a defining feature of this regulation. This is the requirement on manufacturers, importers and users of chemicals to provide sufficient safety data for all chemicals they place on the market at over 1 tonne p/a (with more detailed information requirements for higher tonnage bands), so the regulator can check that industry understands the risks of the chemicals they use and to provide a basis for regulatory decisions and controls. At the start of 2021, the UK left EU REACH to establish UK REACH, a separate system for regulating hazardous chemicals covering Great Britain. UK regulators have the challenging task of establishing a duplicate database of chemicals safety and use, to which UK industry must submit safety data on substances already registered in EU REACH.

The REACH (Amendment) Regulations 2023

2. This SI pushes back deadlines for registration data by three years to October 2026, October 2028 and October 2030, depending on the tonnage and hazard profile of the substance. The earliest deadline, for example, is for substances imported or produced at the highest tonnage band per year (1,000 tonnes or more) or those that fall into certain hazard categories (e.g. carcinogens). It also extends the deadline for the UK Regulator, the HSE (Health & Safety Executive), to complete compliance checks for 20% of registrations in line with these new deadlines.

3. **This is the second time Defra has pushed back deadlines** for companies to submit safety data on substances also registered in EU REACH. **The first delay** was due to the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020, which extended the deadline from 31st December 2022 to the current staggered deadlines of October 2023, Oct. 2025 and Oct. 2027. This SI was **drawn to the special attention of the House by the Secondary Legislation Scrutiny Committee, and was subject to a 'motion of regret' in the Lords**. Many of concerns raised by Parliamentarians in 2020 have still not been addressed. In addition, although Defra consulted on a shorter extension for low volume substances, it instead opted to defer data on them until the end of the decade. It did so on the basis that this was the preference of the majority of respondents to its consultation, although this is not surprising when the vast majority of responses came from businesses or industry bodies.

4. The delay responds to industry concerns about the cost and practicability of providing registration data within the current timeframes and aims to provide time to develop an alternative model for transitional registrations. We are concerned, however, that the **new model under development will be weaker** and less protective of health and the environment than the model it replaces. For example, as it aims to minimise the need on companies to replicate costly EU REACH data packages it will be **more reliant on publicly**

available hazard data (from the EU primarily). This may be insufficient for the regulator to conduct conclusive assessments, particularly for substances with complex endpoints. There is also little detail on **whether the model will match** much needed i**mprovements** to information requirements which are in the pipeline **at EU level**. It also signals a **move away from the precautionary principle** and towards a risk-based approach without consultation. This requires lots of resources and data on uses and exposure of chemicals and includes many uncertainties – such unknown uses to which a chemical will be put in the circular economy or what a safe exposure limit is. It generally takes many years, during which time exposure continues and may increase.

Defra response

As we state in the Explanatory Memorandum, this SI is being introduced to give the government enough time to develop and introduce an Alternative Transitional Registration model (ATR) for EU registrations transferred to Great Britain.

Contrary to what is implied in the note, Defra consulted on two options: the changes contained in this SI and a shorter transitional period. The reason for the government's final decision are explained in the response to the consultation. There was overwhelming agreement from respondents that the changes will not significantly impact on the high levels of protection. Both options we consulted on were consistent with Article 1 of REACH, as is a requirement in the provisions in the Environment Act, in ensuring a high level of protection of human health and environment as evidenced in the Consistency Statement and impact assessment which accompanied the public consultation.

The ATR model itself is intended to address a number of the issues raised in previous parliamentary debates on REACH, including the potential costs to business and the risk of duplicating tests, especially animal tests.

The new model is still under development and Defra are working with Industry and NGOs, including CHEM Trust who are members of the stakeholder Oversight Group, to develop a model that would address the costs to industry, while continuing to ensure high levels of protection of Human Heath and the Environment.

This SI and its associated documentation do not provide for or consider the ATR model itself, as it is still under development. That model will involve a much wider range of issues which will be examined in its own consultation process and impact assessment in due course.

'Doing nothing', as suggested by some of the NGOs who responded to the consultation, including ChemTrust, is not a viable option as it could lead to industry having to expend considerable resources providing full registrations by October 2023 according to the existing regulatory requirements when those requirements are likely to change under the ATR model.

UK REACH remains underpinned by the precautionary principle. This is established in Article 1 of REACH, which is listed as a 'protected provision' in Schedule 21 to the Environment Act 2021, meaning that it cannot be amended under the Act. Any amendments to UK REACH using the powers in the Environment Act must also be consistent with Article 1. The regulatory procedures in REACH are clearly linked to the assessment of risk, which does not contradict the precautionary principle.

5. **There is uncertainty about the deliverability of the new model under development – which** is echoed by the Impact Assessment which says 'if a suitable model is found' - and therefore little to prevent further delays in future. The Government's initial impact assessment estimated that it will cost the industry approx. £2 billion and potentially as

much as £3.5 billion in re-registering chemicals. Since then, Defra has said it doesn't "have a really clear view on costs" but acknowledged if costs are higher it might need to go back to the drawing board. It is also unclear if intellectual property laws could make it difficult to publish some of the publicly available data. We are concerned that the **core principle of 'no data, no market'** – which lies at the heart of good chemicals regulation – **keeps getting kicked down the road**.

Defra response

The Alternative Transitional Registration model (ATR model) is still being developed and will examine a much wider range of issues than the current draft SI. Those issues will feature in a further consultation and impact assessment in due course. Our assessment of the potential costs of the existing regulatory requirements remain those which are analysed in the impact assessment published alongside this draft SI.

Q: What is its latest estimate of the total costs to industry of transitional registrations?

Defra response

The estimate remains the same as in the final impact assessment which was published alongside this draft SI.

The IA estimates that the current regulatory requirements could cost industry ~£2 billion by 2027. This figure is highly uncertain but is expected to fall within the range £1.3bn- £3.5bn, although the final cost would depend heavily on industry behaviour.

Q: The IA finds that UK REACH "will still be able to ensure a high level of protection". Can Defra confirm that (a) during extended transition period and (b) under the alternative model, UK REACH will provide the same level of protection for health and the environment as (a) EU REACH and (b) the registration model it is replacing?

Defra response

The statement of consistency with Article 1 of REACH, which is required by Schedule 21 to the Environment Act 2021,was published alongside the consultation. It concluded that both options in the consultation would continue to provide a high level of protection of human health and the environment. The IA deals with impacts/cost within the period in which the deadlines are being extended, it does not consider the ATR model given it is still under development. The aim of the ATR model is to ensure high levels of environment and human health protections, and the consultation and IA for this model will address the associated costs, benefits and impacts in due course.

Q: If publicly available data is insufficient for evaluating a substance, will the regulator have the right to request full chemical safety data submitted to EU REACH?

Defra response

There are already processes in UK REACH (under Articles 36, 41 and 46) whereby the regulator can require companies to provide additional information. These powers remain unchanged under the provisions in this draft SI. Regulatory assurance is an important factor in the development of the ATR model and various options are being considered as part of the development of the ATR model.

Q: How will the department address current incentives for industry to delay providing crucial safety data needed for regulatory action, which is already a problem and could be exacerbated under the new system (see question above)?

Defra response

The impact assessment as well as the Consistency statement address how HSE will continue to undertake its regulatory activities during the extended period. Regulatory assurance is an important factor in the development of the ATR model but there are already processes in UK REACH (under Articles 36, 41 and 46) whereby the regulator can require companies to provide additional information; these processes include the power to impose legally-binding timescales.

Q: Will the department match improvements to information requirements in the pipeline at EU level, for example to enable effective identification of critical hazards such as endocrine disruptors and substances that are persistent, mobile and toxic?

Defra response

The provisions in this draft SI have no impact on this question. Nevertheless, we are currently focussing on improving use & exposure information as part of the ATR model which is also an area of interest to EU REACH.

While it is not an area we are currently looking at as part of the ATR model, we may consider the case for extending information requirements in UK REACH to aid identification of these hazard groups in the future. We will consider the evidence available and draw on a range of expertise to inform policy development including keeping a close eye on work as it develops in the EU. For example, the persistent, mobile and toxic (PMT - and vPvM) hazard criteria are not formal regulatory triggers under UK REACH. However, work is being undertaken to assess the potential use of PMT/vPvM criteria in chemical hazard and risk assessment.

Q: Is the department confident the current model can be legislated and delivered within the latest timeframes?

Defra response

Our aim remains to legislate in 2024.

6. **There is little detail on what measures will be taken to mitigate the impact of the delay on health and environmental protections**. Having to operate a system without this data makes it harder for the UK regulator to assess and evaluate risks from harmful substances and to implement and legally defend controls on them. This will increase the risk of unsafe or inadequately assessed chemicals on the market. The IA identifies the risk of "reduced regulatory oversight and regulatory delays" and a recent note to the Scottish Parliament's Net Zero, Energy & Transport Committee said that it "could result in delays to additional controls to protect human health and the environment, causing divergence from EU REACH". At an EAC oral evidence session last year, the Chemicals Minister was asked how she would ensure there is no drop in standards during this period. She said Defra would monitor 'growing concerns' about any substances that have been grandfathered from the EU system but made no commitment to match any risk management decisions. For example, UK REACH has deprioritised ten substances for regulatory action that have been targeted for restriction by the EU.

7. Reviews by National Audit Office and Public Accounts Committee found that **a lack of operational capacity** and loss of data is having a negative impact on HSE's ability to assess risks and carry out its work. We are also concerned about regulatory capacity, as UK REACH is selecting fewer substances for control than the EU which is resulting in the UK

falling behind EU protections for the environment and human health. Measures are needed to close the protective gap that's opening up to avoid the dumping of products on the UK market that no longer meet higher EU standards. There is an alternative model that would ensure our health and environmental protections are pegged to the highest standards, while avoiding re-registration costs on industry. The Swiss system does not require full registration data for chemicals that are registered in EU REACH but mirrors EU risk management decisions on harmful chemicals.

Q: During this extended delay without full information on chemical safety, will the UK government adopt the risk management decisions made by the EU, which has access to the full data and can properly evaluate the risks?

Defra response

We considered this in paragraph 36 of the Impact Assessment. We do not believe it would be appropriate to adopt all future EU decisions under UK REACH. This is because the EU no longer consider the impact of their decisions on GB, including the use and exposure patterns in Great Britain. Nevertheless, the UK will continue to monitor EU decisions and consider whether they are right for GB.

Q: Does HSE has sufficient capacity and staff to take on its new role from the European Chemicals Agency, and is UK REACH's prioritisation of fewer EU controls on harmful substances a short-term measure until it reaches capacity?

Defra response

The provisions in this draft SI have no impact on this question; however, the HSE continues to increase its capacity. The May 2022 NAO report details the increased staffing levels at the HSE, with increased staffing levels in its Chemicals Regulation Division going up by 46% between September 2020 and March 2022. HSE have continued to build capacity in the last year.

What steps will the department take to prevent dumping of products on the UK market which no longer meet higher EU regulatory standards?

Defra response

The provisions in this draft SI have no impact on this question; however, the duties and obligations on industry of EU REACH have been carried into UK REACH unchanged. This includes the principle that it is for businesses to ensure that they manufacture, place on the market and use chemicals that do not adversely affect human health and the environment. And the lists of restricted and authorised chemicals at the point of exiting the EU were carried directly into UK REACH.

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