

#### **BRIEFING PAPER**

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# End of Brexit transition: chemicals regulation (REACH)



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# Summary

#### What is EU REACH?

REACH is the main EU legislation for the regulation of chemicals in the EU (the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation). It is a single market measure applying in the European Economic Area (EEA), which includes the EU in addition to Norway, Iceland and Lichtenstein.

REACH requires substances that are manufactured in or imported into the EEA to be registered with the European Chemicals Agency (ECHA). It then provides a regulatory framework to control or restrict the use of hazardous substances based on those registrations.

REACH is important for improving the protection of human health and the environment from hazardous chemicals and for facilitating trade in chemicals across the single market.

#### The UK chemical industry

The chemical industry is a key manufacturing sector in the UK, accounting for 9% of total UK goods exports. Trade in chemicals is highly intertwined with the EU; 57% of chemical exports in 2019 went to EU Member states, and 73% of chemical imports came from the EU. Further, chemical products are used in many other manufacturing sectors.

#### Brexit implications and challenges

REACH is an example of EU legislation that is not straightforward to copy across into UK law. This is because the regulation relies on the integrated role of the ECHA and is closely tied to the single market.

REACH is a regulatory requirement for trade that impacts many UK manufacturing sectors that rely on chemicals. Manufacturing industries often have complex supply chains with chemicals crossing UK-EU borders many times.

#### **REACH** in the transition period

Following the UK's withdrawal from the EU on 31 January 2020, REACH continued to have effect in the UK until the end of the transition period in accordance with the Withdrawal Agreement. The Health and Safety Executive (HSE), however, no longer participated in ECHA decision making during this time.

#### **REACH** after the transition period: A UK REACH

The UK Government stated that the UK would not participate in the ECHA or the EU regulatory framework for chemicals after the transition period. EU REACH ceased to have effect in Great Britain from 1 January 2021. The Government has put in place a separate UK REACH regime that applies to businesses that import, make, sell or distribute chemicals in Great Britain, whether as raw materials or in their finished state.

REACH, and other chemicals regulations, were retained in domestic legislation at the end of the transition period via the <u>European Union (Withdrawal) Act 2018</u>. Secondary legislation has also been passed that would amend REACH in the UK to make it work in a UK-only context from that point.

The UK REACH Regime was initially designed to establish a UK-wide market for chemicals applying to all chemical substances manufactured and imported into the UK, with the Health and Safety Executive (HSE) established as the UK REACH Competent Agency, taking over the functions of the ECHA. Under the Northern Ireland Protocol, however, the EU REACH Regulation will continue to apply to Northern Ireland after the end of the

transition period, while UK REACH will regulate the access of substances to the market in Great Britain, as set out in the <u>REACH etc. (Amendment etc.) (EU Exit) Regulations 2020.</u> The Government says that the proposed UK REACH regime replicates the EU system as closely as possible, maintaining the fundamental aims and purposes of REACH including high standards of health and environmental protection. Industry and environmental stakeholders, however, have raised concerns that the UK REACH regime will be costly for industry and lacks transparency.

The <u>Environment Bill 2019-21</u> contains provisions that would give the Secretary of State powers to amend the UK REACH regime with the exception of certain listed protected provisions.

#### UK-EU Trade and Cooperation Agreement

Chemical and manufacturing industry stakeholders called for an agreement with the EU that ensured frictionless trade and regulatory consistency, ideally aligning as close as possible to REACH. The Trade and Cooperation Agreement between the UK and the EU contains an Annex on the trade, regulation, import and export of chemicals. It includes provisions for data sharing (where the information is 'non-confidential') and cooperation, particularly around international standards. While the chemicals industry has welcomed the free trade agreement, and no tariffs or quotas being applied to trade in goods, concerns have been raised about the absence of a data-sharing agreement on chemicals between the UK and EU. Currently, there is no provision for the UK to access the ECHA's REACH database – containing detailed information about the intrinsic properties of chemical substances, for the purposes of human and environmental safety – thereby increasing the likelihood that this information will need to be re-registered on a UK-only database.

# 1. What is EU REACH?

EU REACH – the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (No <u>1907/2006</u>) – is the main EU legislation for the regulation of chemicals in the EU.<sup>1</sup> It is a single market measure that applies throughout the European Economic Area (EEA), this means EU Member States as well as Norway, Iceland and Lichtenstein.

REACH requires substances that are manufactured in, or imported into, the EEA to be registered with the European Chemicals Agency (ECHA), along with safety information about the chemical and its uses.<sup>2</sup> This is referred to as the "no data, no market" principle – without providing the necessary safety data, companies cannot place their products on the market. REACH then provides a system for controlling or restricting the use of hazardous substances based on this data (see section 1.2).

REACH has several aims, including:

- to protect human health and the environment from the risks that can be posed by chemicals;
- to place responsibility onto industry (manufacturers and importers of chemicals) for understanding and managing the risks associated with the use of chemicals;
- to allow free movement of chemicals and substances in the EEA market, while also enhancing innovation and competitiveness in industry;
- to minimise animal testing by promoting the use of alternative methods of safety assessment and by facilitating data sharing of testing results.<sup>3</sup>

REACH is managed by the <u>European Chemicals Agency</u> (ECHA), based in Helsinki. The <u>Health and Safety Executive</u> (HSE) is the enforcing authority in the UK, and the Department of Environment, Food and Rural Affairs (Defra) is the lead Government department with overall policy responsibility across the UK.

#### How were chemicals regulated before REACH?

<u>REACH</u> came into force in June 2007. Prior to REACH, chemicals regulation across the single market was a patchwork of different regulations with different rules for "new" and "existing" chemicals.<sup>4</sup> REACH was developed to have a single system of rules for all chemicals across the single market. Significantly, REACH placed the burden of undertaking risk assessments for substances onto industry, rather than on public bodies.<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> There is also specific EU legislation for certain types of chemicals (such as biocides and cosmetics) and for the labelling and packaging of chemicals. For background information, see the Library briefing paper: <u>Chemicals Regulation</u> (11 August 2016).

<sup>&</sup>lt;sup>2</sup> In quantities of more than 1 tonne and there are some specific exclusions, for example, radioactive substances and some naturally occurring low-hazard substances. See: HSE, <u>What is REACH?</u> [accessed 31 July 2018]

<sup>&</sup>lt;sup>3</sup> Health and Safety Executive, <u>What is REACH?</u> [accessed 22 August 2018]

<sup>&</sup>lt;sup>4</sup> European Commission, <u>REACH in brief</u>, February 2007.

<sup>&</sup>lt;sup>5</sup> European Commission, <u>REACH in brief</u>, February 2007.

## 1.1 Why is REACH significant?

The chemical industry is an important manufacturing industry in the UK (see Section 2). Chemical substances also feed into the supply chains of many other manufacturing sectors. More than 22,000 substances are registered under REACH.<sup>6</sup> This includes substances that are used in key UK manufacturing sectors, such as the aerospace, automotive and pharmaceutical sectors. It also includes substances used in the manufacture of everyday products such as cleaning fluids, paints, plastics, fabrics and electronics. Trade in chemicals is highly integrated within the single market and complex supply chains mean that products often cross borders multiple times.

In addition to its importance to trade, REACH regulates the safe use of chemicals to minimise harm to human health and the environment by providing a framework under which the use of harmful substances can be restricted.<sup>7</sup> REACH also plays a role in keeping animal testing to a minimum, by requiring that animal testing can only be used to meet registration requirements as a last resort and by facilitating data sharing of testing results (see Box 1).<sup>8</sup>

# 1.2 How does REACH work?

#### Registration

Companies are required to register substances that they manufacture or import into the EEA (in quantities of more than 1 tonne). The registration (called a registration dossier) must provide information about the properties and hazards of the substance, and any risk management measures associated with its use. The dossier must be supported by scientific evidence such as the results of safety testing experiments.

REACH is based on the "one substance one registration" principle.<sup>9</sup> This means that companies must submit joint registrations where they are manufacturing/importing the same substance, including sharing access to testing data (Box 1).

As of 14 February 2020, UK companies held 8995 EU REACH registrations (9% of total), encompassing 4898 substances (21%) and 1350 companies (8%).<sup>10</sup>

<sup>&</sup>lt;sup>6</sup> European Chemicals Agency, <u>REACH registration statistics</u>, accessed 13 February 2020.

<sup>&</sup>lt;sup>7</sup> ECHA, <u>Understanding REACH</u>, [accessed 11 September 2018].

<sup>&</sup>lt;sup>8</sup> European Chemicals Agency, <u>How to avoid unnecessary testing on animals</u>, accessed 20 September 2018.

<sup>&</sup>lt;sup>9</sup> ECHA, <u>Registration</u> [accessed 26 February 2020].

<sup>&</sup>lt;sup>10</sup> European Chemicals Agency, <u>REACH registration statistics</u> and <u>infographic</u> [accessed 14 February 2020].

#### Box 1: Data sharing under REACH

Registrants are expected to share safety and testing data needed for registration to avoid duplicate/unnecessary testing. This plays an important role in minimising the number of animal testing experiments carried out.<sup>11</sup>

REACH requires registrants to make every effort to reach an agreement on sharing data. Firms negotiate and purchase access to the data required to support their REACH registrations; often this means the right to refer to the data in the registration dossier (through a Letter of Access), not full access to the data. REACH requires that the costs for sharing information for a registration are determined in a "fair, transparent and non-discriminatory way".<sup>12</sup>

The ECHA webpages and guidance on <u>data sharing</u> provides more information.

#### Evaluation, authorisation and restriction

REACH provides a framework for banning or restricting the use of hazardous chemicals if risks cannot be managed.

National authorities (the HSE in the UK) evaluate registration dossiers and identify substances for which regulatory action should be prioritised by the ECHA.

Some examples of regulatory action include:

- Substances may be added to the Candidate List of Substances of Very High Concern (SVHC) which carries additional reporting responsibilities and may lead to further regulatory action.<sup>13</sup>
- Substances placed on the "Authorisation List" require an "authorisation" decision from the European Commission to use the substance for a particular purpose. Substances requiring authorisation are listed in Annex XIV of REACH.
- Substances considered to pose risks requiring EU-wide action can be "restricted". Restrictions can take many forms, for example a total ban on a substance, bans on certain uses or concentrations, or requirements for technical measures or specific labelling. Restrictions are listed in Annex XVII of REACH.

#### ECHA committees and decision making

There are several ECHA scientific sub-committees that inform the ECHA's decision making and advice to the European Commission. For example, the Committee for Risk Assessment, the Member State Committee and the Committee for Socio-economic Analysis.<sup>14</sup>

Most decisions for regulatory action under REACH – for example whether a substance should be restricted or subject to authorisation – are taken by the European Commission considering the advice of the ECHA and following consultation with Member States, the European Parliament and Council. Some decisions are taken by the ECHA directly, for example, to classify a substance as a SVHC.

<sup>12</sup> ECHA, <u>Registration: Data Sharing</u> [accessed 26 February 2020].

For further information see:

Understanding REACH (ECHA)

REACH Explained (HSE)

<sup>&</sup>lt;sup>11</sup> ECHA, <u>Registration: Data Sharing</u> [accessed 26 February 2020].

<sup>&</sup>lt;sup>13</sup> These substances are included on the ECHA "<u>Candidate List of Substances of Very High Concern for authorisation</u>" but are not listed in the regulation.

<sup>&</sup>lt;sup>14</sup> ECHA, <u>Committee for Risk Assessment</u>, <u>Committee for Socio-economic Analysis</u>, <u>Member State Committee</u>, [accessed 10 March 2020].

# 1.3 How do non-EEA countries trade chemicals with the EU?

Only companies registered/based in EEA Member States can register substances directly with the ECHA. Companies in non-EEA countries that wish to trade chemicals with the EEA market have the option to nominate an "<u>only representative</u>" agent registered in an EEA country to take over the responsibility of complying with REACH on their behalf.<sup>15</sup> Alternatively, the obligation for compliance with REACH will fall to the importer of the substance to the EEA.

Switzerland<sup>16</sup> and Turkey<sup>17</sup> (where REACH does not apply) have enacted legislation that mirrors REACH but is developed and implemented separately in those countries. Swiss and Turkish companies wanting to sell products in the EEA market must still comply with REACH (as explained in the above paragraph).

The ECHA has "<u>cooperation agreements</u>" with regulatory agencies in Australia, Canada, Switzerland, Japan and the USA, which support exchanging information, best practice and knowledge regarding the management of chemicals (but not confidential business information).<sup>18</sup>

<sup>&</sup>lt;sup>15</sup> European Chemicals Agency, <u>Only Representative</u>, [accessed 22 April 2020].

<sup>&</sup>lt;sup>16</sup> Swiss Common Notification Authority for Chemicals Website, <u>Chemicals Legislation</u> and <u>Guidelines</u>, [accessed 22 April 2020].

<sup>&</sup>lt;sup>17</sup> Chemical Watch, <u>Turkey publishes law modelled on REACH</u>, 29 June 2017.

<sup>&</sup>lt;sup>18</sup> European Chemicals Agency, <u>Cooperation with peer regulatory agencies</u>, [accessed 27 February 2020].

# 2. Chemical industry in the UK

## 2.1 Summary

The following table summarises the economic contribution of the chemicals manufacturing industry in the UK.<sup>19</sup>

<b>Chemicals manufacturing industry</b> UK, 2019							
		% of UK total					
Economic output	£11.2 billion	0.6%					
Employment	93,700	0.3%					
Businesses	3,030	0.1%					
Exports	£31.5 billion	8.6%					
Imports	£34.9 billion	6.4%					

Sources: ONS, <u>GDP Low level aggregates</u>; <u>Business Register & Employment Survey</u>; <u>Business counts</u>; HMRC, <u>UKTradeInfo</u>;

Industry defined as SIC code 20; Trade is for SITC product code 5, excluding 54 (pharmaceuticals) Note: Economic output is Gross Value Added; Trade is goods only; Businesses excludes small businesses with no employees and turnover below the VAT threshold (£85,000).

In 2019 the chemicals industry contributed £11.2 billion to the UK economy, 0.6% of total economic output. This was 6% of economic output from the manufacturing sector.<sup>20</sup>

Employment in the chemicals manufacturing industry in 2019 in the UK was 93,700, 0.3% of total employment.<sup>21</sup>

In 2019, there were 3,030 business in the sector, 0.1% of all businesses in the UK.  $^{\rm 22}$ 

Exports of chemical products (excluding pharmaceutical products) totalled £31.5 billion, 9% of UK goods exports by value.<sup>23</sup>

Chemical products imports totalled £34.9 billion, 6% of goods imports by value.

<sup>&</sup>lt;sup>19</sup> Industry defined as <u>Standard Industrial Classification (SIC) code 20</u>: the transformation of organic and inorganic raw materials by a chemical process and the formation of products.

<sup>&</sup>lt;sup>20</sup> In terms of Gross Value Added (GVA); Source: ONS, <u>GDP Low Level Aggregates</u> <u>Tables</u>, February 2020

<sup>&</sup>lt;sup>21</sup> ONS, *Business register and employment survey*, 2019; data table 2.

<sup>&</sup>lt;sup>22</sup> Excludes small businesses with no employees and turnover below the VAT threshold (£85,000). ONS, <u>Business counts</u>, 2019, via Nomis database

<sup>&</sup>lt;sup>23</sup> HMRC, <u>UK Trade Info database</u>, SITC code 5 (chemical and related products), excluding SITC code 54 (pharmaceutical products). Accessed December 2020

# 2.2 Chemical products trade

The following table gives more details on the chemical products trade in the UK.

UK trade in chemicals, 2019									
	Exports	Imports	Exports	Imports					
	£ billion		%						
EU	18.0	25.4	57%	73%					
Non-EU	13.5	9.5	43%	27%					
Total	31.5	34.9	-	-					

Source: HMRC, <u>UK TradeInfo Database</u>, accessed December 2020

Product code 5 (Chemicals and related products) excluding 54 (pharmaceuticals)

Chemicals are a major UK export, worth £31.5 billion in 2019; 9% of all UK goods exports. Imports of chemicals were worth £34.6 billion; 6% of all goods imports.

UK chemicals trade is focussed on the EU. 57% of exports were to the EU, and 73% of imports were from the EU in 2019.

## 2.3 Employment by region

Employment in the chemicals manufacturing industry in 2019 in the UK was 93,700, 0.3% of total UK employment.<sup>24</sup>

The following chart gives an indication of where in the UK chemical manufacturing industry employment is concentrated.

Chemical manufacturing employment in the North West of England was 19,000 or 20% of UK total chemicals manufacturing. The South East had 13,000 chemicals manufacturing employees (14% of the total); Yorkshire & the Humber had 12,000 (12%).



Source: ONS, <u>Business Register and Employment Survey</u>, 2019 (via <u>NOMIS</u> and Northern Ireland <u>data tables</u>).

<sup>24</sup> ONS, *Business register and employment survey*, 2019; data table 2.

# 3. REACH and the transition period

## 3.1 REACH and the Withdrawal Agreement

The UK left the EU on 31 January 2020 on the terms of the <u>Withdrawal</u> <u>Agreement</u> agreed between the EU and the Johnson Government in October 2019. The Withdrawal Agreement was implemented in UK law by the <u>EU (Withdrawal Agreement) Act 2020</u>.

Under the Withdrawal Agreement, REACH continued to have effect in UK law until the end of the transition period (also called the implementation period), on the 31 December 2020. This meant that UK companies could continue to register chemicals with the ECHA and registrations and authorisations remained valid in both the UK and EU markets during this time. During this period, however, the UK no longer participated in meetings or decision-making of the ECHA and the Health and Safety Executive no longer acted as a leading authority to conduct assessments under REACH.<sup>25</sup>

The following Library papers provide further information about the Withdrawal Agreement in general terms:

- <u>The October 2019 EU UK Withdrawal Agreement</u>, 18 October 2019
- <u>Constitutional implications of the Withdrawal Agreement</u> <u>legislation</u>, 20 February 2020.

# 3.2 Protocol on Ireland/Northern Ireland

The Protocol on Ireland/Northern Ireland in the Withdrawal Agreement set out the arrangements that would take place to maintain an open border between Northern Ireland and Ireland, if the UK and EU were unable to conclude a new future relationship agreement by the end of the transition period. The <u>Library briefing paper on the Withdrawal</u> <u>Agreement</u> explains the Protocol in detail.

Under the Protocol, Northern Ireland remains mostly aligned to the EU's regulations for goods at the end of the transition period, including REACH.<sup>26</sup> This means that EU REACH continues to apply in Northern Ireland after the end of the transition period. The <u>REACH etc.</u> (Amendment etc.) (EU Exit) Regulations 2020, approved by both the Commons and Lords in early December 2020, implemented the Northern Ireland Protocol by enabling the EU REACH regime to continue operating in Northern Ireland, as well as providing for the continued access of Northern Ireland goods into Great Britain (see section 4.4 below). The UK

<sup>&</sup>lt;sup>25</sup> Withdrawal Agreement, Article 128(6). HSE, <u>Regulating chemicals (REACH) during the transition period</u>, accessed 18 February 2020. See also the <u>Library briefing paper on the October 2019 Withdrawal Agreement</u> (18 October 2019) that describes institutional arrangements in the transition period.

<sup>&</sup>lt;sup>26</sup> Article 7, Protocol on Ireland/Northern Ireland

REACH regime will apply to Great Britain (England, Scotland and Wales) only.

# 4. UK REACH: Regulating chemicals in the UK

The Government was clear that it did not seek to participate in the EU REACH framework after Brexit and thus took legislative steps to establish a separate UK regime for regulating chemicals, called UK REACH. This section looks at the legislation in further detail. Section 5 looks at the debate over how to regulate chemicals after Brexit and negotiations with the EU.

# 4.1 Legislation

At the end of the transition period (formally on 'implementation period completion day') REACH was retained in domestic legislation as retained direct (principle) EU legislation in accordance with the *EU (Withdrawal) Act 2018 (as amended)*.<sup>27</sup> This means that the version of REACH that is operative immediately before implementation period completion day was retained in UK law. It includes the lists of restricted chemicals contained in the REACH Annexes and the substances contained on the ECHA's Candidate List for substances of very high concern.<sup>28</sup>

Secondary legislation was passed in March 2019 that would amend the retained EU REACH Regulation in the UK to make it work in a UK-only context: *The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019* (as amended)."<sup>29</sup> The Government has since laid two amending instruments to amend the REACH EU Exit SI to correct technical gaps raised by industry:

- <u>The REACH etc. (Amendment etc.) (EU Exit) (No. 2) Regulations</u> <u>2019</u> (SI 858/2019, made on 11 April 2019) – this fixes a gap that left some firms not covered by the transitional provisions.<sup>30</sup>
- <u>REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019</u> (SI 1144/2019, made on 2 July 2019) – this instrument concerned a gap regarding authorisation applications that are pending a decision by the European Commission.<sup>31</sup>

<sup>&</sup>lt;sup>27</sup> Section 3 of the <u>EU (Withdrawal) Act 2018</u> (as amended). For further information see Library briefing on the <u>Constitutional implications of the Withdrawal Agreement legislation</u> (Section 8), 20 February 2020 and the <u>Library Briefing on the new EU Withdrawal Agreement Bill</u>, 6 January 2020.

<sup>&</sup>lt;sup>28</sup> The <u>Candidate List</u> is not contained in the REACH regulation itself but maintained by the ECHA. <u>The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019</u> (SI 2019/758) (as amended), Schedule 1 paragraph 46, inserts a requirement for the HSE to include on its Candidate List all substances included on the ECHA's candidate list immediately before implementation period completion day.

<sup>&</sup>lt;sup>29</sup> <u>The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019</u> (SI 2019/758) (as amended).

<sup>&</sup>lt;sup>30</sup> For further information, see: <u>Explanatory Memorandum for SI 858/2019</u> and <u>DEFRA</u> <u>makes 'Rolls-Royce' amendment to UK-REACH</u>, *ENDS Report*, Gareth Simkins, 24 June 2019

<sup>&</sup>lt;sup>31</sup> For further information, see: <u>Explanatory Memorandum for SI 1144/2019</u> and <u>DEFRA makes 'Rolls-Royce' amendment to UK-REACH</u>, *ENDS Report*, Gareth Simkins, 24 June 2019.

The Explanatory Memoranda for each SI provides further details.<sup>32</sup>

The Government also laid and approved the <u>REACH etc. (Amendment</u> <u>etc.) (EU Exit) Regulations 2020</u> in early December 2020 (see section 4.4 below for discussion). This Statutory Instrument (known as the 'REACH EU Exit SI') came into force on implementation period completion day (31 December 2020). It was made under section 8 of the *EU (Withdrawal) Act 2018*, which provides the power to correct "deficiencies" in legislation arising from withdrawal from the EU.

Together, the EU REACH Regulation (as retained EU law) as amended by the REACH EU Exit SI will, for the purposes of this paper, be referred to as the "UK REACH regime". Speaking at the Chemicals Stakeholder Forum in February 2021, a Defra official stated that the Department was working with the Government Legal Service on consolidating the REACH regulations though it is not clear when this piece of work will be completed.<sup>33</sup>

Section 4.2 sets out the key features of the UK REACH regime; commentary is provided in Section 4.3.

#### Environment Bill 2019-21

The <u>Environment Bill 2019-21</u> contains provisions that would give the Secretary of State powers to amend the UK REACH regime by regulations. There are certain listed protected provisions which would not be amendable by regulations, such as Article 1 on the aim and purpose of REACH and Article 5, the "no data no market" principle, amongst others.

The Government states that this power is required to ensure a "smooth transition" to a UK chemicals regime following the UK's departure from the EU, and to keep the legislation up to date in the future.<sup>34</sup> However, the provisions have prompted concerns from environment groups and some MPs about the potential for divergence between UK and EU regimes (see Section 5.2).<sup>35</sup> For example, Greener UK called for additional articles to be added to the protected list:

We are concerned about granting the Secretary of State such a sweeping power to amend the main UK REACH text, as this could be used to reduce the level of protection for the public and the environment from hazardous chemicals. [...]

We will be examining the individual REACH articles in depth to establish which ones should be added to the protected list. As a minimum, we believe that Article 33 on information in the supply chain and a right to know for consumers should be added to the protected list.<sup>36</sup>

Several amendments were tabled by the Opposition at the Commons Committee stage of the Environment Bill that aimed to increase the

<sup>&</sup>lt;sup>32</sup> Explanatory Memorandum for SI 858/2019; and Explanatory Memorandum for SI 1144/2019.

<sup>&</sup>lt;sup>33</sup> DEFRA seeks to consolidate UK REACH regulations, ENDS Report, 11 February 2021

 <sup>&</sup>lt;sup>34</sup> Defra, <u>Environment Bill: Policy Statement</u>, 30 January 2020, section 7.
 <u>35</u> <u>HC Deb 26 February 2020</u>, c150; Greener UK, <u>Briefing for Commons Second</u>

 <sup>&</sup>lt;u>Reading of the Environment Bill (PDF)</u>, February 2020.
 <sup>36</sup> Greener UK, <u>Briefing for Commons Second Reading of the Environment Bill (PDF)</u>,

<sup>&</sup>lt;sup>36</sup> Greener UK, <u>Briefing for Commons Second Reading of the Environment Bill (PDF)</u> February 2020, page 22.

number of articles on the protected provisions list. The amendments, however, were either defeated on division or rejected without a vote. In addition, the Opposition unsuccessfully moved four amendments which broadly aimed to ensure that the starting regulatory framework for UK REACH was as close as possible to EU REACH and did not "regress" from what there was before.<sup>37</sup>

The Bill has completed its Committee stages in the House of Commons and had one (out of two) days of its Report Stage. The Bill will be <u>carried over</u> to the next Parliamentary session.

The <u>Commons Library analysis of the Environment Bill</u> (March 2020) provides more information and commentary; Section 9 of the paper covers the REACH provisions. Further details about the Committee stage can be found in the Commons Library briefing on <u>Environment Bill</u> <u>2019-21: Report on Committee Stage</u> (January 2021).

## 4.2 UK REACH: key features

The Government states that the UK REACH regulation aims to replicate EU REACH "as closely as possible". It creates a GB-wide market for chemicals that would apply to all chemicals manufactured in or imported into Great Britain. It is based on the "no data no market" principle: all substances manufactured or imported into Great Britain must be registered to be placed on the market.

The Government's <u>Explanatory Memorandum</u> provides further detailed information on the REACH EU Exit SI.

#### HSE as the UK Chemicals Agency

The Health and Safety Executive (HSE) is now the chemicals Agency in the UK (known as 'the Agency'), taking over the functions of the ECHA with input from the Environment Agency (EA) and the devolved environment regulators on environmental matters.

The functions of the European Commission (such as decisions on restrictions and authorisations) are transferred to the Secretary of State.

The HSE published <u>guidance</u> which set out what businesses needed to do ahead of the end of transition period, as well as actions to take from 1 January 2021.

In addition, the Department for Environment, Food & Rural Affairs published guidance on <u>How to comply with REACH chemical</u> <u>regulations</u>, last updated 27 January 2021.

#### **Devolved Administrations**

The UK REACH regime was initially intended to apply UK-wide (see section 4.4 for recent changes to its geographical application to Great Britain only).

The Secretary of State would make decisions with the consent of the devolved Administrations in areas of devolved competency (e.g. environmental protection), with the devolved Administrations permitted

to take urgent temporary restriction action in some cases, which would then be followed up through a UK-wide procedure.<sup>38</sup> The Scottish and Welsh Governments were content for devolved matters to go in the UKwide SI.<sup>39 40</sup>

As explained in section 3.2 above, under the Northern Ireland Protocol in the Withdrawal Agreement, the EU REACH Regulation continues to apply in Northern Ireland, following the end of the transition period, with the domestic UK REACH system applying across Great Britain.

#### UK chemicals database and IT system

Establishing a UK chemicals regime requires setting up a UK database of registered substances, in effect replicating the ECHA system.

Defra's internal Digital Data and Technology Services Directorate has been developing the UK REACH IT system.<sup>41</sup> The Government has stated that the UK system will operate "very much like" the ECHA system, with the "same software requirements" and processes.<sup>42</sup> The Government stated in October 2019 that the cost of establishing the UK REACH IT system had been £14.32 million up to that point.<sup>43</sup> Once established, the Government has estimated that it will spend:

about £13 million per year on the UK's new REACH regulatory system. This figure covers the costs of operation and maintenance of the REACH IT system and staff resource in the three organisations.<sup>44</sup>

#### **UK REACH registrations**

Existing EU REACH registrations and authorisations held by UK companies are automatically transferred ("grandfathered") from the EU to UK system without a fee.<sup>45</sup>

UK companies need to notify and submit registration data to the HSE within a period of transition that began after the regime came into force (Box 2).<sup>46</sup> The transitional provisions for data submission have been the focus of concern from industry stakeholders (see Section 4.3 below).

<sup>&</sup>lt;sup>38</sup> Explanatory Memorandum, para 7.9-7.10.

<sup>&</sup>lt;sup>39</sup> Letter from Cabinet Secretary for Environment, Climate Change and Land Reform to the Scottish Parliament Environment, Climate Change & Land Reform Committee, 27 November 2018. Available on the Scottish Parliament webpage: <u>Statutory</u> <u>Instruments - European Union (Withdrawal) Act 2018</u> [accessed 31 January 2019]

<sup>&</sup>lt;sup>40</sup> Welsh Government, <u>Written Statement</u>, 11 January 2019. Available on Welsh Assembly webpage <u>WS-30C-076 - The REACH etc. (Amendment etc.) (EU Exit)</u> <u>Regulations 2019</u> ("2019 Regulations") [accessed 31 January 2019].

<sup>&</sup>lt;sup>41</sup> PQ243377 15 April 2019 [Chemicals: Regulation].

<sup>&</sup>lt;sup>42</sup> <u>HC Deb 26 February 2020</u>.

<sup>&</sup>lt;sup>43</sup> <u>PQ453, 22 October 2019.</u>

<sup>&</sup>lt;sup>44</sup> PQ 82142 [on Chemicals: Regulation], 8 September 2020

<sup>&</sup>lt;sup>45</sup> Explanatory Memorandum, Para 13.1.

<sup>&</sup>lt;sup>46</sup> The legislation currently reads that the transition periods begin on "exit day" (defined as 31 January 2020). It is expected that data submission dates in the REACH EU Exit SI will be updated in due course to be refer to "IP completion day" rather than "exit day". See: Burges and Salmon, <u>The road to UK REACH - what happens</u> <u>next?</u>, Simon Tilling, 17 February 2020.

#### Box 2: Transitional provisions for data submission

The legislation establishes a two-stage process for which companies must provide information to the HSE to support "grandfathered" EU registrations:

- Within 120 days, UK companies with EU registrations have to notify the HSE and provide basic data such as company name, company details, substances registered, quantities produced and evidence of their existing ECHA registration.
- Within two years, companies would need to submit full information to support the registration, such as information and data on the properties of the substance and its safety. The data requirements are the same as for EU REACH.

Companies importing chemicals to the UK from the EEA would have new registration obligations under the UK REACH regime that they did not have under EU REACH. This is because while the UK was in the EEA these companies were moving chemicals within the single market and therefore did not have registration obligations under EU REACH.

A different notification timeframe is therefore provided for companies importing substances from the EEA. The deadlines for submitting information to the UK Chemicals Agency under this scenario, however, were recently amended by the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020:

- within 300 (rather than the original 180) days, companies would be required to notify the HSE of the substances they import from the EEA, including basic information about the substance and its safe use;
- a full information package to support the registration would be required and has been extended to run in a "phased manner by 2, 4 and 6 years. This would mean a total of 2, 4 and 6 years + 300 days to supply the full information. The phasing will operate by reference to tonnage bands and hazard profile, with the highest tonnages and most significant hazards coming first".<sup>47</sup> Under the previous deadlines, all registrants (irrespective of tonnage band) were required to submit full information within two years. The staggered registration period will start from 28 October 2021.

#### Scientific advice and input

The UK REACH regime places a duty on the HSE to commission external scientific advice when developing its opinions on regulatory measures, except in circumstances where there are "justifiable reasons" not to. The Explanatory Memorandum to the REACH EU Exit SI explains that one justifiable reason may be where the ECHA has already published a robust opinion on a substance.<sup>48</sup> The HSE is required to consult on and publish a statement on how it will exercise its duty to commission scientific advice within three months (of the regime coming into force).<sup>49</sup>

#### Appeals against HSE decisions

The UK REACH regime has a different mechanism for appeals against HSE regulatory decisions compared to the EU regime. Appeals against HSE decisions would be heard by the <u>First-Tier Tribunal</u> (which already hears appeals against government regulatory bodies on environment enforcement matters, such as appeals against Environment Agency fines). Under the EU REACH regime there is a specific body for hearing appeals against ECHA decisions (called the ECHA Board of Appeals).

<sup>&</sup>lt;sup>47</sup> Explanatory Memorandum, Draft REACH etc. (Amendment etc.) (EU Exit) Regulations 2020, para 7.10

<sup>&</sup>lt;sup>48</sup> Explanatory Memorandum, para 7.13.

<sup>&</sup>lt;sup>49</sup> <u>The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, Schedule 1, Part 10</u>. The legislation currently reads that the HSE must publish the statement within 3 months of "exit day" having not yet been amended to take account of the regime coming into force on implementation period completion day.

An article from law firm Burges and Salmon <u>summarises the similarities</u> <u>and differences between the two bodies</u>. For example, that the First-Tier Tribunal hearings are adversarial in nature whereas the ECHA Board of Appeal takes more the form of an independent review. The article also notes the potential for divergence in decision making between the UK and EU systems if there are two different adjudicating bodies.<sup>50</sup>

### 4.3 Commentary on the UK REACH regime (prior to the UK-EU Trade and Cooperation Agreement)

#### Parliamentary debate on the REACH EU Exit SI 2019

The REACH EU Exit SI was subject to the affirmative procedure and approved by the <u>House of Commons</u> on 25 February 2019,<sup>51</sup> and the <u>House of Lords</u> on 26 March 2019.<sup>52</sup> There was strong opposition raised in the debates in both Chambers. In the House of Lords, the following motion of regret was passed which articulated and placed on the record the main concerns (further commentary on each point is provided in the following sections):

#### At the end insert

"but this House regrets that the draft Regulations fail to fulfil the Prime Minister's intention to maintain the United Kingdom's participation in the European Chemicals Agency, which would have avoided

(1) the duplication of registrations and the consequential increased costs to United Kingdom manufacturers, downstream users and importers,

(2) the duplication of testing procedures, including animal testing, and

(3) the pressure on the resources and expertise of the Health and Safety Executive and the environment agencies, which could increase the risks to United Kingdom citizens' health, and to our environment;

and calls on Her Majesty's Government to make continued United Kingdom participation in the European Chemicals Agency and REACH an objective in negotiations with the European Union".<sup>53</sup>

#### Data submission deadlines

Industry stakeholders are concerned about the need to submit full registration data to the HSE under the UK REACH regime and the timeframes for doing so. The data sharing arrangements facilitated through REACH (see Box 1) means that companies may not have access to all the scientific data and test results that support their REACH registrations. A survey conducted by the Chemical Business Association in February 2019 found that three-quarters of the 38 companies

<sup>&</sup>lt;sup>50</sup> Burges Salmon, <u>UK-REACH and the new appeal system after Brexit</u>, 1 April 2019 and <u>Chemicals regulation: government reveals blueprint for UK REACH</u>, 14 January 2019.

<sup>&</sup>lt;sup>51</sup> <u>HC Deb 665, 25 February 2019</u> [Exiting the European Union (Consumer Protection)]

<sup>&</sup>lt;sup>52</sup> <u>HL Deb, 796, 26 March 2019</u> [REACH etc. (Amendment etc.) (EU Exit) Regulations 2019]

<sup>&</sup>lt;sup>53</sup> <u>HL Deb, 796, 26 March 2019</u> c1755.

surveyed (holding 351 registrations) did not own all the data studies for their EU registrations.<sup>54</sup>

Industry stakeholders argue that getting access to full supporting data necessary to support UK REACH registrations (which has the same data requirements as the EU system) would create significant costs. Potential costs cited include fees for new commercial data sharing agreements, administrative costs and potentially costs for further testing if data cannot be shared. Industry argues these costs would impact the competitiveness of the UK chemicals industry and could result in fewer substances being registered in the UK system while bringing "no commercial or environmental benefit".<sup>55</sup>

The German chemicals firm BASF is quoted in *The Economist* as estimating that registration with UK REACH will cost the company £70m.<sup>56</sup> Without an information sharing deal, BASF has warned that some chemicals may "disappear" from the UK market, as they did when EU REACH was introduced:

Many substances previously available in the EU were not registered under Reach and thus removed from the EU market. Without some form of information-sharing deal, we have no reason to believe that the situation in the UK will be different.<sup>57</sup>

In addition, industry argues that the 2-year time period originally set out in the UK REACH regime to provide data is not feasible in practice if further testing is required.<sup>58</sup>

During a Westminster Hall debate in February 2020, Parliamentary Under-Secretary of State for Defra, Victoria Prentis, explained that full data was required by the HSE to enable it to properly understand the risks of chemicals and operate an effective regulatory regime:

In short, we need it because we will not be able to rely on the fact that the data has already been sent to the ECHA. Registration is how a company shows its understanding of the hazards and risks of a chemical. It does not mean that the ECHA has, in legal terms, approved a chemical or endorsed it as safe. The data is necessary for any regulator, such as the Health and Safety Executive, to operate an effective regulatory regime, to understand the hazards and risks of chemicals, and to ensure their safe use.<sup>59</sup>

The Government has said it would "keep under review" the timeframes for the submission of the full technical information.<sup>60</sup> The <u>Delegated</u>

<sup>&</sup>lt;sup>54</sup> Chemical Business Association, <u>CBA survey confirms industry's concerns about UK</u> <u>REACH post Brexit</u>, 18 February 2019 [accessed 5 September 2019].

<sup>&</sup>lt;sup>55</sup> Chemical Industries Association and Cefic, <u>REACH related issues in the future</u> <u>relationship between the EU-27 and the United Kingdom (PDF)</u>: 14 February 2020; Ready for Brexit, <u>interview with Richard Carter, BASF Plc UK and Ireland</u>, undated, accessed 19 February 2020; Chemical Industry Association, <u>A costly challenge for</u> <u>the UK chemical industry under a 'no-deal' Brexit</u>, 24 September 2018, accessed 5 November 2018.

<sup>&</sup>lt;sup>56</sup> What a grand chemistry experiment reveals about Brexit, The Economist, 12 December 2020

<sup>&</sup>lt;sup>57</sup> Brexit may put some chemicals out of GB's Reach, Chemistry World, 2 December 2020

<sup>&</sup>lt;sup>58</sup> Alliance of Chemical Associations, <u>Letter to Therese Coffey MP dated 31 October</u> <u>2018</u> [accessed 5 November 2018].

<sup>&</sup>lt;sup>59</sup> HC Deb 26 February 2020 c159WH.

<sup>&</sup>lt;sup>60</sup> <u>HC Deb 26 February 2020</u>.

<u>Powers Memorandum</u> published by the Government alongside the *Environment Bill 2019–21* (see section 4.1 above) indicated that the Government "anticipated" that the data submission deadlines may need to be amended and that the powers contained in the Bill would allow this.<sup>61</sup>

On the 2 September 2020, the Parliamentary Under Secretary of State at Defra, Rebecca Pow, wrote to the Chair of the Environmental Audit Committee. She explained that the government planned to make changes to the deadlines for businesses to provide the data to support their registrations under UK REACH:

The principle of "no data, no market" is central to UK and EU REACH. The provision of data to the regulator gives public assurance that industry understands the risks of the chemicals they use and gives the UK regulators a full evidence base to inform future regulatory decisions. Therefore, in considering the findings from the evidence gathering exercise we looked at options which would enable industry to mitigate costs without reducing important environmental and health protections.

We have concluded that the most effective way of achieving this is to extend the transitional data submission timetable in a phased, risk-based, manner. This also reflects suggestions made by industry.<sup>62</sup>

The proposed changes were set out in REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 (see section 4.4 below) and highlighted in Box 2 above.

#### Concerns about animal testing

One of the key aims of REACH is to minimise animal testing by requiring that animal testing can only be used as a "last resort" (that is, if there is no other way of testing the safety of a substance). Data sharing obligations under REACH (see Box 1) helps ensure that tests on animals are not duplicated.

There have been concerns raised by environmental and animal welfare groups that a separate UK REACH system could result in animal tests being duplicated if UK and EU companies are not able to easily share existing data on test results between the regulatory systems.<sup>63</sup> Industry stakeholders have also raised this concern.<sup>64</sup>

In the Westminster Hall debate in February 2020, Defra Parliamentary Under-Secretary of State Victoria Prentis said that the UK will "continue to be at the forefront of opposing animal tests where alternative approaches can be used".<sup>65</sup> During oral questions in the House of Lords,

<sup>&</sup>lt;sup>61</sup> <u>Delegated powers memorandum</u> to the Environment Bill 2019-20 (PDF), 29 January 2020, para 521.

<sup>&</sup>lt;sup>62</sup> Letter from Rebecca Pow MP Parliamentary Under Secretary of State, Defra, to Rt Hon Philip Dunne MP Chair of the Environmental Audit Committee, 2 September 2020

<sup>&</sup>lt;sup>63</sup> House of Lords, Select Committee on the European Union, Energy and Environment Sub-Committee, <u>Brexit: Chemical Regulation</u>, 2017-19, HL215, 7 November 2018, para 31 and 35; <u>HC Deb 26 February 2020</u>.

<sup>&</sup>lt;sup>64</sup> Chemical Industries Association, <u>Chemical Industry making Brexit work for the UK and the EU</u> press release and <u>position paper</u> (PDF), 14 February 2020; <u>UK-EU</u> <u>Negotiations</u> and <u>joint views on the future relationship</u> (PDF), 25 February 2020.

<sup>&</sup>lt;sup>65</sup> <u>HC Deb 26 February 2020</u>, c158WH.

Defra Minister Lord Goldsmith suggested that a "more rigorous approach" to animal welfare could be one area where the UK could improve on the EU system.<sup>66</sup>

#### Scientific advice and oversight

The Environmental Audit Committee (EAC), House of Lords EU Energy and Environment Sub-Committee along with environmental campaign groups, such as CHEM Trust, have raised concerns that the scientific oversight committees and stakeholder engagement mechanisms that inform decisions under the EU REACH regime (see Section 1.2 above) are not replicated in the UK regime, arguing that this could result in less transparent decision making.<sup>67</sup>

A group of organisations, including CHEM Trust, Friends of the Earth and Breast Cancer UK, wrote jointly to the Secretary of State for Environment, Food and Rural Affairs in October 2020, expressing concern that the scrutiny mechanisms in UK REACH were "inadequate":

There are currently inadequate mechanisms for oversight and scrutiny and for stakeholder engagement and public participation. This would result in a more closed and less transparent system than ECHA's, that would be more susceptible to industry lobbying. By comparison, the committee structure within ECHA helps to ensure its work can be challenged and the best information is available for these discussions, helping to avoid mistakes and to ensure that decisions are made more independently and transparently.<sup>68</sup>

In its July 2019 report on <u>Toxic Chemicals in Everyday Life</u>, EAC recommended that the HSE, in its statement on how it will comply with the duty to commission external scientific advice, should "outline a formal role in the substance evaluation process for the Committee on Toxicity and Hazardous Substances Advisory Committee. It should also establish a forum for engagement with stakeholders."<sup>69</sup> In response to the Committee, the Government stated that existing stakeholder mechanisms, such as the UK Chemicals Stakeholder Forum would continue under the new regime.<sup>70</sup>

#### HSE and Environment Agency resources

There have been concerns raised about whether the HSE and the Environment Agency (EA) would have the financial and staffing resources to manage the additional regulatory responsibilities of the UK REACH regime.<sup>71</sup> For example in the February 2020 Westminster Hall

<sup>&</sup>lt;sup>66</sup> <u>HL Deb 16 March 2020</u>, c1273.

<sup>&</sup>lt;sup>67</sup> CHEM Trust, <u>CHEM Trust challenges UK Government on Brexit pesticides plans</u>, 13 June 2019; House of Lords, Select Committee on the European Union, Energy and Environment Sub-Committee, <u>Brexit: Chemical Regulation</u>, 2017-19, HL215, 7 November 2018, para 37-38; <u>HC Deb 665</u>, 25 February 2019 c89.

<sup>&</sup>lt;sup>68</sup> Letter to Secretary of State for Environment, Food and Rural Affairs on <u>GB REACH</u>, from CHEM Trust et al, 7 October 2020

<sup>&</sup>lt;sup>69</sup> House of Commons Environmental Audit Committee, <u>Toxic Chemicals in Everyday</u> <u>Life</u>, 2017-19, HC 1805, 16 July 2019, para 140.

Government Response to the Committee's Twentieth Report of Session 2017–19, HC 160, 19 October 2019, para 132 and 133.

<sup>&</sup>lt;sup>71</sup> Burges and Salmon, <u>The road to UK REACH - what happens next?</u>, Simon Tilling, 17 February 2020; <u>HL Deb 16 March 2020</u>, c1310; <u>HL Deb, 796, 26 March 2019</u> [REACH etc. (Amendment etc.) (EU Exit) Regulations 2019;

debate, Shadow International Trade spokesperson Bill Esterson raised the question of the extent to which the HSE would replicate the ECHA's workload:

Concerns have also been raised about the capacity of the HSE and the legal framework it will follow. It could either repeat the work of ECHA or rely on the work ECHA has carried out. The former would be hugely expensive, time consuming and dependent on a level of scientific expertise that may not be available. The latter could leave it open to challenge on the grounds that it should not be reliant on EU evidence and should have made its own assessment of risk. Either approach is potentially problematic.<sup>72</sup>

In the House of Commons debate on the REACH EU Exit SI in February 2019, Mary Creagh, then Chair of EAC, raised concerns about the HSE's budget, compared to the ECHA's:

The working budget for the European Chemicals Agency is €100 million a year, compared to the roughly £2.2 million the HSE currently spends regulating chemicals. Given the recent budget cuts to the HSE, it is worth noting that it took the EU five years to fully staff the European Chemicals Agency.<sup>73</sup>

In that debate, then Defra Minister, Dr Thérèse Coffey, stated that it expected the future cost of running UK REACH to be £13 million per year and that the EA would be recruiting an extra 10 staff and the HSE would be taking on 35-40 additional staff. The HSE, she added, would be building on existing expertise and highlighted that the ECHA covers a much larger market (28 Member States).<sup>74</sup> However, as law firm Burges and Salmon point out, the ECHA despite being a large organisation with significant technical expertise "does not do everything itself", it draws on the resources of the Member States for "complex work" such as substance evaluation.<sup>75</sup>

Defra subsequently told the Lords Secondary Legislation Scrutiny Committee in November 2020 that the HSE was recruiting 130 extra staff "to cover the transition to the domestic system".<sup>76</sup> Defra added that it aimed "to have 100 recruits in post by January and 130 by the end of the financial year — these will be split over all the chemical regimes but around 40 of these staff will be specifically for REACH".<sup>77</sup>

In response to the Committee's concerns that "the HSE will not have all the staff in post that it will need to exercise its regulatory functions under the new regime from 1 January 2021"<sup>78</sup>, the Defra Minister, Lord Goldsmith, stated that it was "not necessary to have a fully staffed organisation on day one":

<sup>&</sup>lt;sup>72</sup> HC Deb 26 February 2020, 151WH.

<sup>&</sup>lt;sup>73</sup> HC Deb 665, 25 February 2019 c93.

<sup>&</sup>lt;sup>74</sup> <u>HC Deb 665, 25 February 2019</u> c78, 96.

<sup>&</sup>lt;sup>75</sup> Burges and Salmon, <u>Chemicals regulation: government reveals blueprint for UK REACH</u>, 14 January 2020, accessed 21 February 2020.

<sup>&</sup>lt;sup>76</sup> Secondary Legislation Scrutiny Committee, <u>34th Report of Session 2019-21</u>, 19 November 2020, HL Paper 172, para 21

<sup>&</sup>lt;sup>77</sup> Secondary Legislation Scrutiny Committee, <u>34th Report of Session 2019-21</u>, 19 November 2020, HL Paper 172, para 22

<sup>&</sup>lt;sup>78</sup> Secondary Legislation Scrutiny Committee, <u>34th Report of Session 2019-21</u>, 19 November 2020, HL Paper 172, para 25

Instead, the approach to recruitment gives time to train and build up the functions and services of UK REACH before key deadlines on registration and evaluation kick in".<sup>79</sup>

## 4.4 REACH etc. (Amendment etc.) (EU Exit) Regulations 2020

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 were laid on the 19 October 2020 and approved by the House of Lords and House of Commons on the 8 and 9 December 2020 respectively. The draft Explanatory Memorandum to the Regulations explains that the instrument introduces several changes. First, it redefines the geographical application of the new domestic REACH regime so that it now only applies to Great Britain (England, Scotland and Wales) rather than to the whole of the UK as originally intended.

This change is to ensure the UK meets its obligations under the Northern Ireland Protocol. The 2020 Regulation therefore amends both the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758) and the REACH Enforcement Regulations 2008 (S.I. 2008/2852) so that the EU REACH regime continues to apply to Northern Ireland after the end of the transition period, with Great Britain subject to UK REACH.

Second, the Regulation addresses the barriers to trade between Northern Ireland and Great Britain arising from two separate REACH regimes so as to ensure that "Northern Ireland goods [can] enter the GB market with minimal regulatory disruption". The Defra Minister, Lord Goldsmith, explained the change as follows:

The instrument permanently removes the requirement for a full REACH registration for chemicals that are, or are in, qualifying Northern Ireland goods being placed on the GB market. It replaces that with a light-touch notification process, which will ensure that the HSE will know what chemicals are being placed on the GB market. Information necessary to ensure safe use will also still be passed down the supply chain within Great Britain. Substances of very high concern entering Great Britain from Northern Ireland will still need a UK REACH authorisation.<sup>80</sup>

Third, it extends the existing deadlines for the submission of registration data to the domestic REACH system by existing registrants and downstream users. Under the 2020 Regulations, the initial notification stage for existing downstream users (that will become importers of chemicals from the EU/European Economic Area (EEA) or Northern Ireland after the end of the transition period) is extended from 180 to 300 days, starting from 1 January 2021. The deadline for submitting full registration information is replaced by phased approach that spreads the duty over two, four and six years – depending on the tonnage and hazardous nature of the chemical – starting from the end of the 300-day period. According to Lord Goldsmith, the change represents a:

risk-based approach by requiring the submission of data on the highest tonnages and most hazardous chemicals first. The aim is

<sup>&</sup>lt;sup>79</sup> HL Deb 8 December 2020 c1158

<sup>&</sup>lt;sup>80</sup> <u>HL Deb, 8 December 2020 c1156</u>

to give companies more time and capability to comply with the legislation by reducing and spreading costs, and giving them more time to negotiate mutually beneficial data-sharing arrangements with other companies in the UK and the EU.<sup>81</sup>

A non-fatal motion to the instrument was tabled by Baroness Hayman (Labour) stating:

this House regrets that the Regulations (1) fail to provide an analysis of the costs of the new domestic Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regime, (2) introduce additional costs and administrative burdens for United Kingdom businesses, and (3) create unacceptable risks around the availability of chemicals safety data; notes concerns about the ability of the Health and Safety Executive to fulfil its additional responsibilities when the domestic REACH regime becomes operable on 1 January 2021; and further regrets that Her Majesty's Government have not addressed concerns raised by Parliament when proposals for a domestic REACH regime were debated in 2019.

Concerns about additional costs incurred, access to chemicals safety data, and HSE's staffing and resources were reiterated by other Peers during the debate. Baroness Hayman withdrew the motion, stating that while the Minister had "not answered the many concerns raised" there would be "opportunities to consider the matter further during debate on the Environment Bill".<sup>82</sup>

## 4.5 UK Chemicals Strategy

The Government's <u>25 Year Environment Plan</u> (11 January 2018) promised a Chemicals Strategy that would set out the Government's approach as it leaves EU to managing chemicals with potential to cause harm.<sup>83</sup>

The Environmental Audit Committee's July 2019 report on Toxic Chemicals in Everyday Life recommended that the Strategy should "lay out a plan for remediation of harmful regulated substances in the environment with binding targets and a ring-fenced budget". The Committee stated the Strategy should "take full account of the human health impacts of chemical", highlighting the role that public health bodies should play.<sup>84</sup>

The <u>Government's response</u> to the Committee provided the following description of what the Strategy would contain:

15. The Strategy will be a vehicle for exploring options to develop an early warning system for identifying emerging chemical issues, considering how to address the tracking of chemicals in products, and working internationally on the standardisation of methods that assess chemical safety. It will be developed to ensure a holistic approach to the safe management of chemicals, building on existing government strategies, such as the Resources and

<sup>&</sup>lt;sup>81</sup> HL Deb, 8 December 2020 c1156

<sup>&</sup>lt;sup>82</sup> HL Deb 8 December 2020 c1179

<sup>&</sup>lt;sup>83</sup> Defra, <u>25 Year Environment Plan</u>, 11 January 2018.

<sup>&</sup>lt;sup>84</sup> House of Commons Environmental Audit Committee, <u>Toxic Chemicals in Everyday</u> <u>Life</u>, 2017-19, HC 1805, 16 July 2019, para 132-133.

Waste and Clean Air Strategies, both of which have been successfully delivered in line with 25YEP commitments.

16. We expect a Chemicals Strategy to play a key part in enabling the transition towards a circular economy approach, building on existing commitments in our Resources and Waste Strategy

[...]

18. The Chemicals Strategy will set out our approach to the safe and sound management of chemicals. It will take account of the Chief Medical Officer's recommendations to consider the impact of chemicals and chemical mixtures on human health. It will incorporate the Government's priorities for our domestic regulation and reflect our future relationship with the EU. We are committed to maintaining the UK's existing high standards in the safe and effective regulation of chemicals after we leave the EU.

19. The Strategy will also address concerns related to endocrine disruptors (EDCs) and the use of potentially toxic substances in furniture and household goods.

In February 2020 the Government stated that it was engaging with a range of stakeholders and that a Call for Evidence would be published in the spring.<sup>85</sup> Parliamentary Under-Secretary of State for Defra Victoria Prentis stated in February 2020 that the Strategy would "aim to drive sustainability, circularity and innovation in the chemicals industry, while protecting human health and the environment from harmful chemical exposure".<sup>86</sup>

Specialist Environmental news journal *ENDS Report* reported in April 2020 that Defra's the work on the chemicals strategy had been delayed due to the coronavirus outbreak.<sup>87</sup> In response to a Parliamentary Question on the development of the Chemicals Strategy in December 2020, the Defra Minister, Rebecca Pow, explained that work on the Strategy was underway:

It will build on a robust statutory regime and our international obligations and set out direction of travel on important policies. The next key milestone is the Call for Evidence in 2021. It will help inform the development of a draft Strategy for consultation.<sup>88</sup>

<sup>&</sup>lt;sup>85</sup> PQ13970, 17 February 2020.

<sup>&</sup>lt;sup>86</sup> HC Deb 26 February 2020.

<sup>&</sup>lt;sup>87</sup> Coronavirus: DEFRA pauses work on Chemicals Strategy as HSE changes inspection regime, Simon Pickstone, *ENDS Report* [subs only], 6 April 2020, accessed 7 April 2020.

<sup>88</sup> PQ 123726 [on Chemicals], 9 December 2020

# 5. Negotiating a future relationship

A UK-EU Trade and Cooperation Agreement was reached on 24 December 2020 and included an Annex on chemicals. This section examines what the trade agreement means for the UK's chemicals regulation regime, provides background to the negotiations and highlights where there are regulatory issues that are still to be worked out.

For general background information on the negotiations see the Library briefing papers on <u>The UK-EU future relationship negotiations: process</u> and issues (CBP8834, 2 March 2020), <u>The UK-EU future relationship</u> negotiations: Level playing field (CBP 8852, 19 June 2020) and Library Insight <u>What is happening in the UK-EU future relationship</u> negotiations? (7 April 2020).

### 5.1 UK-EU Trade and Cooperation Agreement

The Trade and Cooperation Agreement between the UK and the EU contains an Annex on the trade, regulation, import and export of chemicals. It includes provisions for data sharing (where the information is 'non-confidential') and cooperation, particularly around international standards. Specifically, it states that the:

Parties commit to facilitating the exchange of non-confidential information between their responsible authorities, including through cooperation on electronic formats and tools used to store data.<sup>89</sup>

At a more general level, the free trade agreement means there are no tariffs or quotas being applied to trade in goods, though customs declarations and associated compliance costs will apply.

#### Environmental protection and non-regression provisions

The Agreement contains reciprocal commitments not to reduce the level of environmental or climate protection in a way that has an impact on trade or investment. It states that a party:

shall not weaken or reduce, in a manner affecting trade or investment between the Parties, its environmental levels of protection or its climate level of protection below the levels that are in place at the end of the transition period, including by failing to effectively enforce its environmental law or climate level of protection.<sup>90</sup>

<sup>&</sup>lt;sup>89</sup> Trade and Cooperation Agreement Between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part, <u>Annex TBT-3: Chemicals</u>, 24 December 2020

<sup>&</sup>lt;sup>90</sup> Trade and Cooperation Agreement Between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part, <u>Article 7.2</u>, 24 December 2020

The definition of "environmental protection" remained the same as that set out in the draft treaty, namely:

(ix) the prevention, reduction and elimination of risks to human and animal health or the environment arising from the production, use, release and disposal of chemical substances.<sup>91</sup>

Article 7.5 of the Agreement sets out how the non-regression provisions will be enforced. It includes a commitment that both the UK and EU will rely on "domestic authorities" to monitor and enforce the relevant laws, and that they will make sure "administrative or judicial proceedings are available" for an interested party to pursue an alleged violation of domestic law. There is also a 'dispute settlement' procedure which includes having recourse to a panel of experts to examine the matter (see Article 9.2). For further overviews see:

- Institute for Government, <u>Level playing field</u> (not dated)
- Commons Library, <u>The UK-EU Trade and Cooperation Agreement:</u> <u>governance and dispute settlement</u>, 19 February 2021

#### Rebalancing

In instances where "significant divergences" occur between UK and EU policies that have "material impacts on trade or investment between the Parties", Article 9.4 of the UK-EU Trade and Cooperation Agreement states that appropriate "rebalancing measures" can be taken to address the situation. In short, if one side raises its standards and the other does not, the concerned party can impose countermeasures, such as tariffs, subject to independent assessment by an arbitration panel. Over the longer-term, there is a mechanism for a review of the balance of the trade pillar of the Agreement to be triggered after four years.

The campaign group CHEMTrust suggests that this mechanism is "potentially significant" for the chemicals industry:

The rebalancing process is potentially significant in the case, for example, of new EU policies like the Chemicals Strategy for Sustainability, where if it could be demonstrated that this created 'material impacts on trade and investment' then some sort of rebalancing measures could be taken by the EU against the UK.<sup>92</sup>

Further information about the EU Chemicals Strategy for Sustainability is set out in section below.

# 5.2 Stakeholder commentary

#### Industry stakeholders (prior to the agreement)

Both the UK and European chemical industries, and other manufacturing industries have been clear in wanting the UK to remain as closely aligned to REACH as possible to reduce regulatory trade

<sup>&</sup>lt;sup>91</sup> Trade and Cooperation Agreement Between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part, Article 7.1(g), p201

<sup>&</sup>lt;sup>92</sup> CHEMTrust, <u>The Brexit trade deal: what it means for the UK's protection from hazardous chemicals</u>, 28 December 2020

barriers.<sup>93</sup> Industry stakeholders argued that having separate UK and EEA-based regulatory systems would lead to extra costs for businesses that would compromise the competitiveness of the UK chemicals industry, disrupt supply chains or reduce the availability of chemicals in the UK/EEA markets.<sup>94</sup>

A joint position paper (PDF) published on 14 February 2020 by the UK Chemicals Industries Association (CIA) and European chemical industry trade body (Cefic) stated that the "immediate cost" of two regulatory systems was "expected to be £1 billion".<sup>95</sup> When asked about the accuracy of that number during oral questions in the House of Lords in March 2020, Defra Minister Lord Goldsmith stated that the Government could not put a precise figure on the cost involved to businesses:

I am afraid I am not able to give a precise figure—I do not think anyone is capable of doing so—but we have had these discussions with industry and, as I say, with BEIS. It is the case that industry estimates are not a million miles away from our own but we cannot put a precise figure on them at this stage.<sup>96</sup>

The UK Chemical Industries Association (CIA) and European chemical industry trade body (Cefic) published their joint views on the future relationship negotiations (PDF) on 25 February 2020.<sup>97</sup> The industry called for a "deep and comprehensive free trade agreement" including tariff and quota free trade in chemicals. The industry stated its "ideal scenario" would be the UK remaining in the EU REACH framework as an "active participant" in the ECHA, arguing this would be the best outcome to avoid market disruptions and maintain high environmental, safety and health standards:

...the UK and EU chemical industry needs an agreement that recognises the economic and environmental logic of remaining closely connected with regard to the REACH regulation, addressing the safety of chemicals and their placement on the market. Realising that ambition will be good for business, good for jobs and good for the health and safety of European workers and citizens on both sides of the Channel.<sup>98</sup>

The industry welcomed that the UK Government's negotiating mandate appeared open to the possibility of negotiating a shared database for registration data,<sup>99</sup> but said that a future trade agreement should go "beyond existing cooperation agreements" between ECHA and non-EEA countries.<sup>100</sup> See section 4.3 for a discussion of data challenges for

<sup>98</sup> CIA and Cefic, <u>UK-EU Negotiations</u>, 25 February 2020.

<sup>&</sup>lt;sup>93</sup> Chemical Business Association, <u>Regulatory alignment vital for chemicals sector</u>, 27 January 2020 [accessed 19 February 2020]; British Coatings Federation, <u>BCF Blog -</u> <u>Brexit and a Future Trade Agreement with the EU</u>, 23 January 2020.

<sup>&</sup>lt;sup>94</sup> Chemical Industries Association, <u>Chemical Industry making Brexit work for the UK and the EU</u> press release and <u>position paper</u> (PDF), 14 February 2020; <u>UK-EU Negotiations</u>, 25 February 2020.

<sup>&</sup>lt;sup>95</sup> CIA and Cefic, <u>REACH related issues in the future relationship between the EU-27 and the United Kingdom (PDF)</u>, February 2020.

<sup>&</sup>lt;sup>96</sup> <u>HL Deb 16 March 2020, </u>c1275.

<sup>&</sup>lt;sup>97</sup> CIA and Cefic, <u>UK-EU Negotiations</u> press release and joint views on the future relationship negotiations (PDF), 25 February 2020.

<sup>&</sup>lt;sup>99</sup> Chemical Business Association, <u>CBA welcomes potential access to chemicals</u> <u>database</u>, 4 March 2020.

<sup>&</sup>lt;sup>100</sup> CIA and Cefic, <u>UK-EU Negotiations</u> press release and joint views on the future relationship negotiations (PDF), 25 February 2020.

a separate UK REACH regime. The Government states that the transitional provisions included in the UK REACH regime are intended address industry concerns regarding cost and continuity of supply.<sup>101</sup>

#### Response to the Trade and Cooperation Agreement

Reaction to the Trade Agreement by the chemicals industry focused predominately on two issues; first the lack of a data sharing agreement and, second, that there are outstanding issues regarding how the chemicals industry will be regulated.

#### Data sharing

There is no provision in the Trade and Cooperation Agreement for the UK to access the ECHA's REACH database. The database contains detailed information about the intrinsic properties of chemical substances, for the purposes of human and environmental safety. The absence of a data sharing provision increases the likelihood that this safety information will need to be re-registered on a UK-only database.

Speaking to the *Financial Times*, Steve Elliott, chief executive of the Chemical Industries Association (CIA), cautioned that the failure to secure access to data under EU REACH would "leave the industry facing a bill of more than £1bn in unnecessarily duplicating that work for a new UK regime".<sup>102</sup> He set out his concerns in further detail in a blog on the CIA website:

Unfortunately, although the UK and EU were able to agree on a chemicals annex as part of the trade deal, this annex focuses more on the potential for future collaboration and "facilitation of non-confidential information exchanges". It does not include the possibility of the UK government accessing EU REACH data for the purposes of informing its own future chemicals regulatory regime – UK REACH – despite the fact that UK businesses have been the second largest contributor to that data set, after German chemical companies.

Such an outcome leaves UK chemical companies with not only the ongoing need to respond to the requirements of EU REACH if they are to retain their EU market interests, but also to reproduce duplicate data for UK REACH purposes – a potential cost of over £1 billion that will provide very little, if any, additional health or environmental benefit and divert significant amounts of expenditure that could be better spent in future capital and R&D investment.<sup>103</sup>

Similar points were made by the Director General of Cefic (the European Chemical Industry Council), Marco Mensink, who warned that the Agreement did not provide many details about chemicals regulation:

The specific chemical annex seems very thin and falls short of securing data access of UK authorities and companies to the Reach database in Helsinki [where the EU's regulator ECHA headquarters are located]. This means duplication of work and a

<sup>&</sup>lt;sup>101</sup> <u>HC Deb 26 February 2020</u> cc157-159WH.

<sup>&</sup>lt;sup>102</sup> Businesses welcome zero-tariff Brexit deal but warn of hard months ahead, Financial Times, 24 December 2020

<sup>&</sup>lt;sup>103</sup> Chemical Industries Association, <u>The Deal - An Important Omission</u>, 4 January 2021

potential bill of more than  $\in$ 1.0bn to establish the new UK regime.<sup>104</sup>

In February 2021, the *Financial Times* reported that 25 business heads had jointly written to the Government, calling on it to adopt "'a more proportionate, effective and efficient' UK Reach model to avoid causing serious harm". In the letter, it was estimated that the cost of compliance to UK REACH for one jurisdiction would be:

double the £500m UK companies have already spent over the past decade in complying with EU Reach and its, now, 27 markets [...].<sup>105</sup>

In response to this letter, a group of scientists also wrote to the Government in April 2021, asking them "to resist proposals to reduce costs by lowering requirements for chemical safety data in UK REACH, and instead explore securing UK access to the EU REACH chemicals safety database".<sup>106</sup>

Giving evidence to the Lords EU Environment Sub-Committee in early February 2021, the Defra Secretary, George Eustice, stated that the Government had "tried very hard to get the EU to agree to data-sharing [...] since it is in everyone's interest" but that it was "refused by the European Commission". He noted that the current arrangements for registering products as part of UK REACH (set out in Box 2 above) give:

the maximum possible time for industry to come up with sharing agreements so that they can all get the data they need to register the products they want to register. None of that prevents us, of course, from keeping an open door to the European Union, should it want to adopt a more constructive stance in this space. That is obviously what we will continue to do.<sup>107</sup>

#### Concerns about lowering chemical safety standards

The UK version of REACH that came into force at the end of the transition period retained EU standards on chemicals at that point (see Section 4). A separate UK chemicals regime means that the UK is not obliged to follow EU decisions such as on authorisations or restrictions of chemicals going forward. This has led to concerns about potential lowering of chemical safety standards in the UK if the UK diverges from EU REACH. For example, press reports and chemical safety campaigners have raised concerns that a trade deal with the US could see chemicals that are restricted in the EU allowed into the UK.<sup>108</sup>

<sup>&</sup>lt;sup>104</sup> Brexit deal mixed bag for chems, unresolved regulatory issues risk 'huge cost', Independent Commodity Intelligence Services, 28 December 2020

<sup>&</sup>lt;sup>105</sup> Call for UK to rethink £1bn Brexit red tape plan for chemicals, Financial Times, 10 February 2021

<sup>&</sup>lt;sup>106</sup> Scientists' Letter to UK Ministers about Chemical Data Requirements Under UK <u>REACH</u>, Paul Whaley, 30 April 2021; <u>UK REACH 'at risk of sliding backwards'</u>, <u>ministers told</u>, *ENDS Report*, 30 April 2021

 <sup>&</sup>lt;sup>107</sup> House of Lords Select Committee on the European Union EU Environment Sub-Committee, <u>Oral evidence: Future UK-EU relations: energy, environment and health</u>, 3 February 2021, Q46

<sup>&</sup>lt;sup>108</sup> <u>US trade deal 'could flood Britain with toxic cosmetics'</u>, Jamie Doward, *The Observer*, 21 March 2020; <u>Global Justice Now</u>, <u>How a US-UK trade deal threatens our protection from hazardous chemicals</u>, Kate Young, 11 November 2019 [accessed 22 April 2020]

Environmental NGOs Greener UK and Green Alliance have commented that any substantial deregulation could "lead to a regrettable loss of transparency and increased risk of harm to people and the environment". It added that there was pressure from the "chemicals industry" for the UK regulator to "draw up a list of prioritised chemicals of concern, based on publicly available information, that it could request full safety data on". This approach, it said, would resemble:

the discredited, ineffective and old-fashioned EU 'Existing Chemicals' process that was replaced by REACH. That system was beset by delays, and resulted in regulatory inaction.<sup>109</sup>

Campaign groups such as CHEMTrust and Greener UK have called for the Government to accept alignment with EU chemical-related laws to "ensure the best protection of our health and the environment".<sup>110</sup> In a letter to the Secretary of State for Environment, Food and Rural Affairs in October 2020, a group of organisations including CHEM Trust, Friends of the Earth and Breast Cancer UK stated that there was a "risk of GB becoming a dumping ground for chemicals and products that do not meet EU regulations, without a mechanism for matching EU controls on chemicals".<sup>111</sup>

The House of Commons Environmental Audit Committee (EAC) in their July 2019 report on <u>Toxic Chemicals in Everyday life</u> recommended that the UK remain aligned to the ECHA's candidate list for substances of very high concern and that "deviation should only happen where the intention is to increase safety standards by moving more quickly to restrict a substance of concern".<sup>112</sup> Similar concerns have been raised by MPs and Peers during debates in the House of Commons<sup>113</sup> and the House of Lords.<sup>114</sup>

The Government has repeatedly stated that any decisions taken on chemicals as an independent UK regime "would be consistent with the fundamental aims and principles of REACH" and would be based on "rigorous assessment of the scientific evidence".<sup>115</sup> In response to questions in the House of Lords in March 2020, Defra Minister Lord Goldsmith stated that the Government may consider divergence from EU rules where it is in UK interests but that "does not mean reducing standards":

We will take decisions based on science and on the best available evidence, including looking at approaches taken by other chemicals regimes right across the world, well beyond the European Union. We will not seek ongoing alignment with the EU regulatory system but we will not diverge simply for the sake of it.

<sup>&</sup>lt;sup>109</sup> Ruth Chambers and Libby Peake, <u>Why the government must hold the line on chemicals safety</u>, Green Alliance blog, 15 February 2021

<sup>&</sup>lt;sup>110</sup> CHEMTrust, <u>Brexit and Chemical Protections</u>, [accessed 26 February 2020]; Greener UK, <u>Briefing for Commons Second Reading of the Environment Bill (PDF)</u>, February 2020.

<sup>&</sup>lt;sup>111</sup> Letter to Secretary of State for Environment, Food and Rural Affairs on <u>GB REACH</u>, from CHEM Trust et al, 7 October 2020

<sup>&</sup>lt;sup>112</sup> House of Commons Environmental Audit Committee, <u>Toxic Chemicals in Everyday</u> <u>Life</u>, 2017-19, HC 1805, 16 July 2019, para 26.

<sup>&</sup>lt;sup>113</sup> <u>HC Deb 26 February 2020</u> c155WH and <u>HC Deb, 25 February 2019</u>, c89.

<sup>&</sup>lt;sup>114</sup> <u>HL Deb 26 March 2019, c1741</u>

<sup>&</sup>lt;sup>115</sup> <u>PO 7151, 4 February 2020</u> [Chemicals: Regulation].

There may be good reasons for taking a different approach on a particular substance to reflect UK circumstances, but that does not mean reducing standards or levels of protection. [...]

The core principle is that it will be our choice.<sup>116</sup>

Under the UK-EU Trade and Cooperation Agreement, there is a 'rebalancing mechanism' (as outlined in section 5.1 above) whereby, if "significant divergences" in the level playing field occur that impact trade or investment, either party can impose temporary tariffs to counteract it.<sup>117</sup> Longer term, a review process can be triggered to examine any persistent divergences.

According to the campaign group CHEMTrust, both the rebalancing mechanism and the non-regression provisions provide important safeguards against the lowering of environmental and safety standards with regards to chemicals:

[...] the trade agreement will also present problems for any attempt by the UK to become a new dirty man of Europe, e.g. by allowing the use of hazardous chemicals in order to stimulate the development of a deregulated production base in the UK.

If such an approach was taken (i.e. it had a material impact on trade or investment) then it would immediately get into trouble with either the non-regression provisions (if there was an attempt to deregulate laws that were in place at the end of the Transition period) or the rebalancing provisions, that will address areas where the EU has moved ahead of the UK.<sup>118</sup>

# EU Chemicals Strategy for Sustainability – increasing the possibility of divergence?

On 14 October 2020, the European Commission adopted the EU <u>Chemicals Strategy for Sustainability</u>.<sup>119</sup> It proposes actions to:

- account for the cocktail effect of chemicals when assessing risks from chemicals
- phase out the use of per- and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential
- boost the investment and innovative capacity for production and use of chemicals that are safe and sustainable by design, and throughout their life cycle
- promote the EU's resilience of supply and sustainability of critical chemicals
- establish a simpler "one substance one assessment" process for the risk and hazard assessment of chemicals

<sup>&</sup>lt;sup>116</sup> HL Deb 16 March 2020, c1273 and 1275.

<sup>&</sup>lt;sup>117</sup> Institute for Government, <u>Level playing field (not dated)</u>

<sup>&</sup>lt;sup>118</sup> CHEMTrust, <u>The Brexit trade deal: what it means for the UK's protection from</u> <u>hazardous chemicals</u>, 28 December 2020

<sup>&</sup>lt;sup>119</sup> The Commission states that it invites the European Parliament and the Council to endorse the strategy and to contribute to its implementation, see European Commission, <u>Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability. Towards a Toxic-Free Environment. COM(2020) 667 final, 14 October 2020</u>

• play a leading role globally by championing and promoting high standards and not exporting chemicals banned in the EU

The Commission has indicated that the Strategy will require amendments to existing EU legislative acts. In its analysis of the Strategy, the Commons European Scrutiny Committee noted that, under the terms of the Withdrawal Agreement, Northern Ireland must remain aligned to a number of these Acts, including the:

- Industrial Emissions Directive;
- <u>"REACH" Regulation;</u>
- Food Contact Materials Regulation;
- <u>Cosmetic Products Regulation;</u>
- <u>Toy Safety Directive;</u>
- General Product Safety Directive;
- Classification, Labelling and Packaging (CLP) Regulation;
- Biocidal Products Regulation;
- <u>Food Additives Regulation</u>; and the
- <u>Detergents Regulation</u>.<sup>120</sup>

Industry in the UK has raised concerns that the implementation of the Strategy may lead to greater divergence between UK REACH and EU REACH. Cefic, the European Chemical Industry Council, has stated that, if fundamental changes to the EU REACH system are made in parallel with the establishment of UK REACH, "we also introduce a wider gap with our neighbours".<sup>121</sup> More recently, Cefic stated that the UK would need to take decisions quickly about if and how it would engage with any changes made to EU REACH:

As the EU rolls out the Chemical Strategy for Sustainability, the UK will have to decide if it follows these new legal developments in the EU from the first day the new trade deal is in place. It is likely the two regulatory regimes will differentiate from the start, which is a concern to all of us.<sup>122</sup>

In an <u>Explanatory Memorandum</u> (published in October 2020), setting out the Government's position on the EU Strategy, the Defra Parliamentary Under-Secretary of State, Rebecca Pow MP, stated:

The UK Government agrees with the broad objectives of the EU Strategy [...] Authorities in the UK are working on many of the issues discussed in the EU Strategy. For example, on PFAS [*Perand polyfluoroalkyl substances*] authorities are undertaking stakeholder engagement on possible definitions of essential use and exploring grouping approaches that could be employed to regulate these chemicals. Risk assessment, monitoring and

 <sup>&</sup>lt;sup>120</sup> European Scrutiny Committee, <u>Thirty-seventh Report of Session 2019–21</u>, 16
 February 2021, HC 229-xxxii

<sup>&</sup>lt;sup>121</sup> Brexit may put some chemicals out of GB's Reach, Chemistry World, 2 December 2020

<sup>&</sup>lt;sup>122</sup> Brexit deal mixed bag for chems, unresolved regulatory issues risk 'huge cost', Independent Commodity Intelligence Services, 28 December 2020

evidence generation is being undertaken to help inform future policy in respect of the GB market.<sup>123</sup>

In its assessment of the EU Strategy, the Commons European Scrutiny Committee noted that, while EU and UK chemicals policy and legislation is currently aligned, the "status quo will fall away at some stage, leaving some very important issues to be addressed":

The ultimate effect of divergence between the two regulatory systems is that a chemical—or "cocktail" of chemicals—could be deemed safe in GB, but unsafe in the EU and Northern Ireland, and vice versa. That has real implications for the manufacture and sale of products including those substances. As Northern Ireland must remain aligned with EU chemicals policy, the impacts could well affect not only GB-EU trade but also the UK internal market.<sup>124</sup>

In late March 2021, Defra <u>announced</u> the start of an official review process for considering restrictions under UK REACH for lead ammunition and per- and polyfluoroalkyl substances (PFAS) used in tattoo inks. These would be the first restrictions initiated under UK REACH.<sup>125</sup> CHEMTrust, however, described the announcement as the "first signs of UK regulatory divergence on chemicals", stating that UK REACH:

will consider only two of over a dozen relevant EU hazardous chemical restrictions that are either in the last stages of the EU's REACH restriction process or have been adopted by the European Commission since the end of the Brexit transition period. This will mean the UK's controls will start to fall behind those in the EU.<sup>126</sup>

A Parliamentary Question was tabled on 15 April 2021, asking when "UK REACH plans to initiate restrictions on each of the 11 hazardous substances on which opinions have been adopted by the European Chemicals Agency". The Defra Minister, Rebecca Pow, responded:

The UK REACH Work Programme will be published annually, setting out the Health & Safety Executive's priorities, including work on restrictions. We will continue to identify further measures to safeguard human health and the environment based on robust science and the best available evidence, including considering evidence developed by the European Chemicals Agency. Restriction dossiers that we ask the Health & Safety Executive to prepare in future Work Programmes will address issues that we consider to be most pressing in Great Britain.<sup>127</sup>

#### Advantages of a separate UK system?

During a February 2020 Westminster Hall debate, Parliamentary Under-Secretary of State for Defra Victoria Prentis stated that a UK REACH

<sup>&</sup>lt;sup>123</sup> Explanatory Memorandum, submitted by the Department for Environment, Food and Rural Affairs on 'Chemicals Strategy For Sustainability Towards A Toxic-Free Environment', 30 October 2020

<sup>&</sup>lt;sup>124</sup> European Scrutiny Committee, <u>Thirty-seventh Report of Session 2019–21</u>, 16 February 2021, HC 229-xxxii, para 1.13

<sup>&</sup>lt;sup>125</sup> Press release: Plans announced to phase out lead ammunition in bid to protect wildlife, Department for Environment, Food & Rural Affairs, 23 March 2021; <u>News</u> story: Restrictions under new chemical regime announced for first time, Department for Environment, Food & Rural Affairs, 23 March 2021

<sup>&</sup>lt;sup>126</sup> <u>UK REACH restrictions: first signs of UK regulatory divergence on chemicals</u>, CHEM Trust, 26 March 2021

<sup>&</sup>lt;sup>127</sup> PO 181429 [on Chemicals: Regulation], 23 April 2021

regime would give the Government the "freedom to do things differently where we consider that in our best interest".<sup>128</sup>

One criticism of REACH is that the process for making regulatory decisions at the EU level is slow.<sup>129</sup> There are also concerns about the level compliance in REACH registrations.<sup>130</sup> One potential advantage of a UK REACH system could be for the UK to improve on the efficiency of the EU system.<sup>131</sup> In oral questions in March 2020 Lord Goldsmith, Defra Minister, referred to animal testing as one example of where UK could diverge from the EU to improve the UK system:

For example, for many years the UK has been at the forefront in opposing animal tests where alternative approaches can be used—the last-resort principle. We could be more rigorous in applying this principle in the future and there are many other examples where we might want to diverge.<sup>132</sup>

The Institute of Economic Affairs argued in September 2018 that withdrawing from REACH would provide an opportunity to implement "pro-competitive regulation".<sup>133</sup> A European Commission report from October 2016 considered the impact of REACH on international competitiveness of the EU industry in comparison to regulations in China, Japan, the USA, Canada, and South Korea.<sup>134</sup> It concluded that "REACH does have a minor negative impact on the competitiveness of the EU industry in relation to their third-country competitors" although extent of this varies between different market situations and countries. In terms of cost to place a new chemical on the market, the EU fell within the middle of the range of countries considered, with costs being higher than in the US but less than compared to Canada, Japan and China.

### 5.3 Background to the negotiations

This section looks at how the negotiations progressed, particularly during 2019 and 2020, on key matters relating to the regulation of chemicals.

Theresa May's Government also published an <u>analysis of the long-term</u> <u>economic impact of Brexit</u> in November 2018. This used economic models to compare how big the economy would be (measured by GDP)

<sup>&</sup>lt;sup>128</sup> <u>HC Deb 26 February 2020</u>, c257WH.

<sup>&</sup>lt;sup>129</sup> Brussels criticised for delays in banning toxic chemicals, Matthew Taylor, *The Guardian*, 11 June 2018 [accessed 5 September 2019].

<sup>&</sup>lt;sup>130</sup> ECHA Newsletter, <u>REACH compliance – an Agency priority for 2019</u>, 21 February 2020l; <u>Why two thirds of REACH registrations could be breaking the rules</u>, Gareth Simkins, *ENDS Report* [subs only], 6 June 2019.

<sup>&</sup>lt;sup>131</sup> House of Lords, Select Committee on the European Union, Energy and Environment Sub-Committee, <u>Oral evidence: The future of REACH regulations post-Brexit</u>, 18 July 2018, Q26.

<sup>&</sup>lt;sup>132</sup> <u>HL Deb 16 March 2020</u>, c1273.

<sup>&</sup>lt;sup>133</sup> Institute of Economic Affairs, <u>PLAN A+ Creating a prosperous post-Brexit U.K.</u>, 24 September 2018.

<sup>&</sup>lt;sup>134</sup> European Commission, <u>Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry</u>, October 2016.

in different future UK-EU trading scenarios relative to a 'baseline' scenario of the UK staying in the EU.<sup>135</sup>

#### Participation in the ECHA?

The <u>Political Declaration on the future UK-EU Relationship</u> agreed between the Johnson Government and EU in October 2019 included a commitment to "explore the possibility of cooperation" with the ECHA. Neither the <u>UK Government</u> nor <u>EU</u> opening negotiating mandates (February 2020), however, referred to cooperation with the ECHA explicitly.<sup>136</sup>

In a <u>February 2020 Westminster Hall debate</u> (on regulatory divergence and the UK chemical industry) Parliamentary Under-Secretary of State for Defra (Victoria Prentis) stated clearly that the Government would no longer participate in the ECHA or the EU regulatory framework for chemicals after the transition period:

Through various emanations, we have reached a position where we are definitely leaving the single market and the customs union, and we will no longer participate in the ECHA or the EU regulatory framework for chemicals.<sup>137</sup>

She stated that the UK would establish its own chemicals regulatory regime (UK REACH) that would retain the fundamental approach of REACH but have the "freedom to do things differently where we consider that in our best interest."<sup>138</sup> Section 4 of this paper provides information and commentary on the UK REACH Regime that came into force at the end of the transition period.

Several opposition MPs raised concerns during the debate about the Government's approach, highlighting that a separate regulatory framework would negatively impact the UK chemicals industry.

In November 2020, during the Lords <u>Secondary Legislation Scrutiny</u> <u>Committee's examination</u> of the Draft *REACH etc. (Amendment etc.) (EU Exit) Regulations 2020*, Defra was once again questioned on the possibility of co-operation with ECHA and remaining within, and aligned to, EU REACH. The Department responded:

The Government's position on not remaining within the jurisdiction of the European Courts of Justice (ECJ), means that we are not seeking alignment with EU REACH or participation in the European Chemicals Agency (ECHA).<sup>139</sup>

The Johnson Government's position regarding the ECHA is a change in approach compared to Theresa May's Government. The May Government's preferred approach to chemicals regulation following the UK's withdrawal from the EU was to agree with the EU a form of "associate membership" or "active participation" in the ECHA (and

<sup>&</sup>lt;sup>135</sup> HM Government, <u>EU Exit Long-term economic analysis</u> November 2018, Cm 9742

<sup>&</sup>lt;sup>136</sup> PM's Office, <u>Our approach to the Future Relationship with the EU</u>, 27 February 2020; 79 <u>Council Decision authorising the opening of negotiations with the United Kingdom of Great Britain and Northern Ireland for a new partnership agreement</u>, 25 February 2020.

<sup>&</sup>lt;sup>137</sup> HC Deb 26 February 2020, c157WH.

<sup>&</sup>lt;sup>138</sup> HC Deb 26 February 2020, c157WH.

 <sup>&</sup>lt;sup>139</sup> Secondary Legislation Scrutiny Committee, <u>34th Report of Session 2019-21</u>, 19 November 2020, HL Paper 172, para 14

other EU agencies in heavily regulated sectors).<sup>140</sup> The May Government's position was welcomed by chemical industry stakeholders<sup>141</sup> and by the House of Lords EU Energy and Environment Sub-Committee in their <u>November 2018 report</u> on Brexit and chemicals regulation.<sup>142</sup>

Neither participation in the ECHA, nor alignment with EU REACH, formed part of UK-EU Trade and Cooperation Agreement signed in December 2020. The Annex on Chemicals in the Agreement provides "for cooperation between Union and United Kingdom responsible authorities", though this mainly appears to be in the context of implementing international guidelines and sharing 'non-confidential' information.

#### An Annex on chemicals in the EU-UK trade agreement Data sharing

The UK Government's <u>approach to the UK-EU future relationship</u> <u>negotiations</u> (February 2020) proposed that the agreement include an Annex on chemicals. The Government proposed that the parties could agree data sharing mechanisms in line with existing provisions in REACH for non-EEA country cooperation as well as committing to developing a Memorandum of Understanding to "enhance cooperation further":

Annex on chemicals

16. This annex should facilitate trade in chemical substances and related products and ensure high levels of protection for the environment and human and animal health. It could provide for cooperation between UK and EU authorities, including on implementing the Global Harmonised System of Classification and Labelling of Chemicals. In order to ensure high levels of protection and to support UK and EU businesses to meet the separate regulatory requirements of the two markets, the parties could agree data and information sharing mechanisms, in line with the relevant provisions set out in UK and EU regulation and existing third-country mechanisms.

17. This annex should also include a commitment to develop a memorandum of understanding (MOU) to enhance cooperation further, similar to the MOUs that the European Chemicals Agency has agreed with Australia and Canada.<sup>143</sup>

See Section 1.3 of this paper for information about cooperation agreements with non-EEA countries on REACH. An Annex on chemicals (<u>Annex 5-E</u>) was subsequently published by the UK government in May 2020 with the aim of forming the basis for discussions on the trade, regulation, import and export of chemicals between the EU and the

<sup>&</sup>lt;sup>140</sup> Prime Minister's Office, <u>PM speech on our future economic partnership with the European Union</u>, 2 March 2018; HM Government, <u>The Future Relationship between the United Kingdom and the European Union</u>, 12 July 2018, Cm 9593.

<sup>&</sup>lt;sup>141</sup> CIA, <u>UK and EU chemical industry welcome draft Brexit agreement</u>, 22 November 2018.

<sup>&</sup>lt;sup>142</sup> House of Lords, Select Committee on the European Union, Energy and Environment Sub-Committee, <u>Brexit: Chemical Regulation</u>, 2017-19, HL215, 7 November 2018, para 20.

<sup>&</sup>lt;sup>143</sup> PM's Office, <u>Our approach to the Future Relationship with the EU</u>, 27 February 2020.

UK.<sup>144</sup> An update provided by Defra to the Lords Secondary Legislation Scrutiny Committee in November 2020 indicated that the proposals in the Annex had not, to date, been welcomed by EU countries:

In February, the Government published its approach to negotiating a future relationship with the EU. That includes a proposal for a chemicals annex as part of the EU Free Trade Agreement. A deal on data sharing with the EU could mitigate the need for industry to provide full data packages.

We continue to push for it, but the EU continues to reject any sectoral annexes. However, securing the chemicals annex is still very much our preferred outcome. This would be in the interests of both UK and EU businesses, including those who will want to continue selling their chemicals into the GB market.".<sup>145</sup>

The main provision in REACH relevant to data sharing with non-EEA countries is Article 120, which reads:

Article 120

Cooperation with third countries and international organisations

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (1) or under Article 181a(3) of the Treaty, provided that both the following conditions are met:

- a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation
- b) the third party protects the confidential information as mutually agreed.<sup>146</sup>

As noted above, the Annex on Chemicals in the UK-EU Trade and Cooperation Agreement does not contain a comprehensive deal on data sharing with the EU that would "mitigate the need for industry to provide full data packages" to UK REACH; instead the Annex states that the:

Parties commit to facilitating the exchange of non-confidential information between their responsible authorities, including through cooperation on electronic formats and tools used to store data.<sup>147</sup>

<sup>&</sup>lt;sup>144</sup> HM Government, <u>Draft UK Negotiating Document Annexes to the Draft Working</u> <u>Text for a Comprehensive Free Trade Agreement Between the United Kingdom and</u> <u>the European Union</u>, May 2020

 <sup>&</sup>lt;sup>145</sup> Secondary Legislation Scrutiny Committee, <u>34th Report of Session 2019-21</u>, 19
 November 2020, HL Paper 172, para 17

<sup>&</sup>lt;sup>146</sup> <u>Regulation (EC) No 1907/2006</u>, Article 120.

<sup>&</sup>lt;sup>147</sup> Trade and Cooperation Agreement Between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part, <u>Annex TBT-3: Chemicals</u>, 24 December 2020

# 6. UK access to EU market

From 1 January 2021, UK companies wishing to export chemicals to the EEA single market need to comply with EU REACH (and any other relevant regulations).

Only companies based in the EEA may register directly with the ECHA. This means that after the end of the transition period, UK-companies' EU REACH registrations would become invalid. To preserve EEA market access, UK companies need to transfer their registrations to an EEAbased entity before the end of the transition period. This may be an affiliate/subsidiary company or an "<u>only representative</u>" agent (see section 1.3 of this paper).

The ECHA has explained that setting up a company "on paper" is not enough to satisfy REACH registration requirements:

A registrant is responsible for the substances covered by their registrations. This means that the responsible staff and relevant documentation must be present at the address of the registrant – setting up a company on paper only in the EU-27 or EEA is not sufficient.<sup>148</sup>

Alternatively, without a valid REACH registration, the obligation for compliance with REACH falls to the importer of the substance (i.e. GB chemical companies' EEA-based customers).

The European Commission reported that as of mid-August 2019, 52% of UK REACH registrants had transferred their registrations to an EU27 entity.<sup>149</sup> The Chemical Business Association highlighted in April 2018 that a significant number of their member companies were planning to, or had already, created subsidiaries in other EU member states to ensure access to the EU market.<sup>150</sup>

The <u>ECHA's webpage on the UK's Withdrawal from the EU</u> provides advice for UK and EU companies and is updated on a regular basis.

UK Government guidance for industry can be found on gov.uk (<u>How to</u> <u>comply with REACH chemical regulations</u>) and on the Health and Safety Executive's Brexit webpages (<u>Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) regulation at the end of the transition period</u>).

<sup>&</sup>lt;sup>148</sup> ECHA, UK Withdrawal from EU: <u>UK-based REACH registrant</u> [accessed 22 April 2020]

<sup>&</sup>lt;sup>149</sup> European Commission, <u>Finalising preparations for the withdrawal of the United Kingdom from the European Union on 1 November 2019</u> ("6<sup>th</sup> Brexit Preparedness Communication) 4 September 2019, page 7.

<sup>&</sup>lt;sup>150</sup> Chemical Business Association (CBA), <u>Growing Concerns On EU Market Access Post-Brexit</u>, 27 April 2018 [accessed 27 July 2019].

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