

Annex 12A of USMCA November 2020

1. CHEM Trust is a UK registered charity that works at EU, UK and international levels to prevent manmade chemicals from causing long-term damage to wildlife or humans, by ensuring that harmful chemicals are substituted with safer alternatives.
2. We welcome the opportunity to set out our concerns in writing about Annex 12A on Chemical Substances of the Sectoral Annexes chapter of USMCA (excluding the sections on ICT, energy performance, medical devices, pharmaceuticals), including in relation to the GRP chapter 28, as well as Annex 3-D on food additives.
3. In summary and in light of the types of provisions the US seeks to include in its trade agreements, close regulatory cooperation with the US along the lines of the US-Mexico-Canada-Agreement (USMCA) could see the import of US products that contain chemicals that are banned or restricted in the EU and could even result in aspects of the US system getting imported into the UK, including areas in which it is at its weakest and least protective.

Key differences between the two systems

4. The EU system is not perfect, but the gulf between it and the US is particularly wide on chemicals. Under the US Toxic Substances Control Act, the burden of proof falls on the regulator to demonstrate proof of harm. Under REACH, it's on the companies seeking to bring a chemical to market, who have to generate enough data about it to demonstrate safety. A lack of adequate safety and use data is a pervasive problem in chemical regulation and can result in a perverse incentive where the regulatory system rewards those who do not deliver safety data to the regulator.
5. Advocates of the US system often falsely depict it as a 'risk' based system versus an EU 'precautionary' or 'hazard' based system. However, the EU's chemical regulatory systems, including REACH, use a combination of both 'specific risk assessment' where an in-depth analysis is made of exposure to a specific chemical, and 'generic risk assessment'. The latter says that chemicals that are particularly hazardous – e.g. those that cause cancer – shouldn't be present in products used in broad groups of applications, like in toys or cosmetics or sprayed in open fields. The broader approach taken under REACH to understanding risk can involve the application of the precautionary principle in cases where the scientific evidence is uncertain, but the risks are high (for example a chemical that accumulates in human breast milk but has not yet been shown to be toxic).

6. The US system mainly uses specific risk assessment, which is much slower and more time consuming and can give a false sense of accuracy. It also requires safety data which is frequently not available. For example, for uses regulated by the EPA (the Environmental Protection Agency) the regulator needs to show a chemical presents an 'unreasonable' risk of injury to health and the environment, making it much harder to control harmful chemicals. The EPA is then caught in a regulatory Catch 22 in that it needs prior evidence that a substance presents a potential risk before it can start its own testing – and ask for more info from the manufacturer – but it's primarily this information that shows whether or not there is a risk.

USMCA

7. The USMCA goes further than, and builds on, US regulatory cooperation provisions in the proposed Transatlantic Trade and Investment Partnership (TTIP) between the EU and US about which there was considerable alarm expressed at the time by public health and environmental organisations. For CHEM Trust's view of regulatory co-operation in TTIP see <https://chemtrust.org/ttip-talks-re-start-and-threaten-our-protection-from-hazardous-chemicals/>

Requirements for an exclusively risk-based approach

8. Articles 12.A.4.3 and 12.A.4.4 of the Chemicals Annex respectively state that trading partners '*shall endeavor*' to use a risk-based approach to assessing chemical substances and mixtures and "to align risk assessment and management measures".
9. If the UK agrees to adopt the US's exclusively risk-based assessment approach, this will set much higher thresholds and evidential requirements for taking regulatory action to protect the public and the environment from harm. The US could also challenge UK bans of US exports that are restricted on the basis of hazard-based criteria.

Regulatory cooperation

10. The sectoral annexes to Chapter 12 establish **specific requirements** for governments seeking to regulate chemical substances (12-A) and cosmetics (12-B). These are **in addition** to the requirements of the Good Regulatory Practices (GRP) Chapter 28 and the main TBT Chapter, although the language is stronger and more mandatory than the GRP text.
11. Chapter 28 sets out:
 - a. Binding mechanisms by which proposed regulations must be presented. In particular, it obliges parties to publish annually a list of regulations they plan on introducing and to receive comments on them, treating input from any person within USMCA regions equally in the regulation's final development. Under Article 28.9(2), regulators are to "take into account the comments received and, as appropriate, make revisions to the text of the regulation published".

- b. Requirements on all parties to create procedures to retroactively review regulations to “determine whether modifications or repeal is appropriate” (Article 28.13(1)).
 - c. Countries which already undertake regulatory impact assessments (RIAs), as the UK already does, are required to provide explanation of why the new rule is needed, a list of all feasible regulatory and non-regulatory alternatives that could also address the same problem, their costs and benefits and the grounds for selecting one option over the other (Article 28.11).
12. Such mechanisms would effectively gift foreign companies and governments with binding mechanisms to scrutinise new regulations at the earliest stages of development and to identify and obstruct anything perceived as a trade barrier.
13. The chemicals annex (12-A) sets out mandatory regulatory cooperation in specific areas. It states the Parties “shall strengthen their cooperation on chemical substances and chemical mixtures” identifies a list six other potential areas for cooperation on chemicals (Article 12.A.4.6). There are a number of risks to the UK’s regulation of chemicals if it agrees to similar provisions.
14. There are risks to the **process for identifying Substances of Very High Concern (SVHC)**. This process has its own section in the list of US industry grievances about REACH, that are documented by the United States Trade Representative (USTR) in its annual trade barriers report.¹ This report is compiled by the USTR from representations it receives from US companies, and the barriers listed in the report provide a useful indication of those regulations the US will seek to target in negotiations. In particular, companies do not feel they have enough notice to comment on the process by which substances are screened for the SVHC Candidate List and then after authorisation, restricted or banned. The consultation mechanism could allow US chemical companies access to the process by which the UK prioritises substances for evaluation and to ask that the UK revises any decision to identify a chemical of very high concern. In REACH, these substances are prioritised in the Community Rolling Action Plan (CoRAP) over a period of three years, and in the UK these substances will similarly be placed on an equivalent Rolling Action Plan (RAP). A process that required the regulator to inform trade partners about proposed regulation and respond to comments, could result in significant delay and disruption to this process and even threaten to reduce the number of chemicals undergoing risk assessment.
15. Agreeing to new mechanisms by which US companies could have a say on emerging issues could result in ‘regulatory chill’; making it harder for the UK to introduce stronger protections even if new evidence revealed chemical-related harms to human health or the environment. **Specifically, it could slow the drive to control endocrine disrupting chemicals.**
16. As BEUC said in relation to regulatory cooperation provisions in TTIP, which very much applies to the USMCA: “the regulatory ‘philosophies’ informing chemicals

¹ United States Trade Representative (USTR) ‘2020 National Trade Estimate report on foreign trade barriers’, March 2020, https://ustr.gov/sites/default/files/2020_National_Trade_Estimate_Report.pdf, p.180-181.

legislation on either side of the Atlantic are too different with regard to fundamental principles – and convergence would from a European perspective inevitably come at the expense of consumer safety and environmental protection”.²

Information that can be used by government to support regulation and can be accessed by downstream users and the public

17. The information provided to regulators under the US and EU systems is very different. Unlike the US system which continues to put the responsibility on the regulator to prove unreasonable risk, REACH requires manufacturers, importers and users of chemicals to provide sufficient safety data on which to make a decision about risk assessment and risk management. REACH is rooted in putting the onus on companies to provide better information on their chemicals and, if a substance of very high concern, to provide evidence it can be used safely for a specific use.
18. Article 28.5 of the USMCA on “information quality” defines what information should be used to support regulations. This specifies relying on the “best, reasonably obtainable” and “relevant” scientific, technical, economic or other information, which, as Sharon Treat of the IATP has argued, “can actually function to place limits on what information regulators may seek in support of a standard or regulatory approval”.³
19. Article 12.A.5.2 requires each party to “adopt or maintain procedures to prevent the disclosure of confidential information that appears in the data or assessments”. From our perspective, the greater scope for companies to claim data as Confidential Business Information (CBI) in the US system is particularly problematic, with the EU taking a much more restrictive approach about what can be claimed as CBI. In the EU, access to information across the supply chain is set out in articles 26-34 of REACH, as well as via the Aarhus Convention which places requirements on the disclosure of certain environmental information.
20. Art. 12.A.4(6) states that parties “shall cooperate with a view to minimizing the differences in the use of safety data and safety data sheets”. There is no equivalent US duty to EU requirements for manufacturers to communicate information on hazardous chemicals across the supply chain, under Articles 26-34 REACH. The US trade barriers report lists the requirements on companies to provide safety data sheets to their customers as a particular gripe of industries exporting into the EU.⁴ This could result in a weakening of important Articles 32 and 34 which establish a duty to communicate information down and up the supply chain (respectively).

² BEUC (The European Consumer Organisation) ‘The incompatible chemistry between the EU and US: BEUC position on chemicals in TTIP’, 22 Jan 2016, https://www.beuc.eu/publications/beuc-x-2016-007_beuc_ttip_and_chemicals_position_paper.pdf.

³ Sharon Anglin Treat “New NAFTA” imposes hurdles to delay and weaken public protections’, 17 October 2018, <https://www.iatp.org/documents/new-nafta-imposes-hurdles-delay-and-weaken-public-protections>.

⁴ United States Trade Representative (USTR) ‘2020 National Trade Estimate report on foreign trade barriers’, March 2020, https://ustr.gov/sites/default/files/2020_National_Trade_Estimate_Report.pdf, p.181.

Annex 12-B Cosmetic Products

21. The differences between the US and EU systems are also clear when it comes to **regulating cosmetics**. While EU cosmetics regulations include, for example, restrictions on Carcinogens, Mutagens and Reproductive Toxins and on others known to provoke allergic reactions or skin sensitization, in US federal law, the regulator needs prior evidence that an unreasonable risk exists for each substance before it can even start its own testing. This gives the regulator, the FDA, very little pre-market power to require testing of, or even to review, cosmetic ingredients. As a result, the FDA has restricted only 11 substances or groups of substances for use in cosmetics and the EU has banned 1623. For example, the EU has more thoroughly restricted the use of some phthalates and parabens in cosmetics, unlike the US.
22. The USMCA includes an annex devoted to cosmetics (12-B) which includes Technical Barriers to Trade (TBT) provisions which requires that domestic rules cannot be used to prevent imports of another party's cosmetics, that should "be accorded treatment no less favorable than that accorded to like products of national origin" (Article 12.B.5.1). This could oblige the UK to disregard EU-derived rules that do not allow imports of cosmetics into the EU, unless they meet its standards. A further appendix which applies just to Canada, additionally extends regulatory compatibility for products recognised as being at the interface of cosmetics and drugs, and specifies products including those for acne, sunscreens, deodorants and toothpaste (Appendix 1 Enhancing regulatory compatibility for products recognised as being at the interface of cosmetics and drugs').
23. The very wide divergence between the EU and US systems would not support the proposition that standards and regulatory processes developed in the US should be accorded such a presumption of equivalence with UK regulatory requirements.
24. Annex 12-B also has fairly extensive regulatory cooperation provisions which are particularly prescriptive about the areas in which the two regulatory systems should be harmonized. Indeed, the level and extent of this cooperation would effectively involve aligning with US norms and processes.
25. Firstly, it includes provisions which require each Party to "apply a risk-based approach to regulating the safety of cosmetic products for human health". Harmonising the UK's pre-market testing along the US's 'demonstrable risk' lines could significantly undermine the EU's broad limits on carcinogens, mutagens, reproductive toxicants, and allergens and skin sensitizers.
26. Secondly, it follows the US 'market first, regulate later' approach, so that "no party shall require a marketing authorization for a cosmetic product, unless a Party identifies a human health or safety concern, and a less trade-restrictive alternative, such as a notification or post-market surveillance, is not reasonably available to effectively address the risks at issue"(Article 12.B.5.3(a)). In the same breath it disables the effectiveness of such post-market surveillance measures by stipulating that parties cannot require cosmetic products to "be labeled with a notification number" (Article 12.B.5.3(c))

Food additives

27. One of the more shocking examples of gaps in US regulation, which allows food additives to be designated as generally regarded as safe, has made its way into the USMCA.
28. Paragraph 3(a) of Annex 3-D limits regulators' requests for information relating to proprietary formulas for pre-packaged foods or food additives "to what is necessary to achieve its legitimate objective." This necessity test could make it much more difficult for the UK Food Standards Agency to compel companies to provide information on food additives. Paragraph 3(b) goes on to say a Party *shall* "protect the confidential information received about products originating in the territory of another Party in the same manner as for domestic products". This applies the necessity test to food labelling and could restrict the ability of the UK to label food additives in US imports.
29. US food additive regulations allow companies to state that substances are 'generally recognised as safe', without having to give the safety data to the regulator. The USMCA approach seeks to keep this information away from the public and regulators of its trading partners.

GHS – cooperation around international standard

30. In its published objectives for UK-US trade negotiations, the UK confirms it is seeking to reduce Technical Barriers to Trade (TBT) and in a more detailed section on reducing non-tariff barriers on goods, gives a case example of a multinational chemical manufacturer.⁵ The case study gives the example of a chemical manufacturer that believes "that seeking alignment on the basis of the consistent building-block approach set out in UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and achieving harmonisation of classifications, would improve market access and reduce costs".
31. These standards do not, however, provide the same level of protection as REACH – international standards are often the minimum any country must meet – as they only describe an approach to classification and labelling of the properties of a chemical and not the controls on the use of the chemical. The EU was heavily involved in the creation of GHS, but the EU still uses some classifications that go beyond GHS. In addition, REACH sets out additional requirements for substances that fall into particular hazard classifications. So that those which are identified as carcinogenic, mutagenic, reprotoxic (CMR) are automatically restricted from use in consumer products and those classified as CMRs and persistent, bioaccumulative, and toxic (PBT) are identified as Substances of Very High Concern that are eventually destined to be phased out. Furthermore, the EU's Classification, Labelling and Packaging (CLP) Regulation is based on the GHS, but the European Commission has announced in its new "Chemicals Strategy for Sustainability" that they plan to extend it next year to include new hazard categories for endocrine disruption, PBTs/vPvBs and persistent and mobile substances – setting higher

standards than the GHS - that it will then propose to the UN GHS in 2022-24. The UK already has stronger rules than GHS, and should not base alignment on rules that only relate to one part of chemicals regulation, and to a weaker standard.

Conclusions

32. Given the very wide divergence between the EU and US systems, neither regulatory harmonisation nor mutual recognition is feasible or desirable in the area of chemicals.
33. In our assessment aligning more closely with the US regulatory approach would be considerably more beneficial to US businesses. Moving away from alignment with the EU could negatively affect UK manufacturers who may have to find new export destinations for their produce while being undercut by lower standard US imports that are cheaper to produce, that could ultimately put downward pressure on UK production and standards. While the UK complies with the higher EU chemicals standard, this does not stop us from exporting to the US, while harmonising with the weaker US regulation has much greater benefits for the US in facilitating more US to UK trade.
34. It would be better for the UK to align with the EU and harmonize standards upwards. There are strong economic benefits of remaining aligned with EU chemical regulations, including new REACH controls. The industry has little to gain from any deviation from EU rules and will need to ensure its products are REACH compliant at the point of sale anyway in order to access the EU single market, its biggest export market. Coming out of REACH will also cost companies an estimated £1 billion to provide duplicate safety data to the new UK regime, which is already available under REACH. Given the significance of chemicals regulation as a trading standard, a mid-Atlantic position is unfeasible; the UK is not going to start setting international trading standards on its own.