EXPLANATORY MEMORANDUM TO

THE CONFORMITY ASSESSMENT (MUTUAL RECOGNITION AGREEMENTS) (AMENDMENT) REGULATIONS 2022

2022 No. 1400

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 The instrument makes provision to give effect to a mutual recognition agreement("MRA") between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation ("the Swiss MRA"), copies of which can be downloaded from https://www.gov.uk/guidance/uk-switzerland-mutual-recognition-agreement. It amends another instrument: the Conformity Assessment (Mutual Recognition Agreements) and Weights and Measures (Intoxicating Liquor) (Amendment) Regulations 2021 (SI 2021/730) ("the 2021 Regulations") to ensure that specific products assessed by bodies in Switzerland recognised under the MRA can be placed on the market in Great Britain; and, to enable the Secretary of State to designate and monitor UK conformity assessment bodies to assess products against Swiss requirements.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument (that is, the jurisdictions which the instrument forms part of the law of) varies between regulations. There is 1 regulation that applies to England and Wales and Scotland, and the remaining regulations apply to England and Wales, Scotland and Northern Ireland.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the same as its extent.

5. European Convention on Human Rights

5.1 The Minister for Enterprise and Markets, Kevin Hollinrake, has made the following statement regarding Human Rights:

"In my view the provisions of the Conformity Assessment (Mutual Recognition Agreements) (Amendment) Regulations 2022 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument makes certain changes to implement a UK trade agreement. The instrument amends the 2021 Regulations which were made to give effect to the UK's MRAs with other countries that were signed from 2018 to 2020 and which entered into force in 2021. These amended 2021 Regulations will give legal certainty that, in accordance with the Swiss MRA, the UK will recognise products assessed against certain regulations of Great Britain by designated bodies based in Switzerland.

6.2 The purpose of product safety legislation is to ensure that products that are placed on the market are safe, accurate and compliant with relevant technical requirements. To this end, legislation places obligations on economic operators throughout the supply chain (manufacturers, importers, distributors and, in certain product legislation, authorised representatives appointed by manufacturers). Generally, there is a requirement that the product is assessed to demonstrate compliance with the relevant requirements (conformity assessment), sometimes by a third party, prior to being placed on the market. Third party conformity assessment can be performed by conformity assessment bodies ("CABs"). In the UK, these bodies must be approved by the Secretary of State to assess products that will be placed on the market in Great Britain or Northern Ireland. CABs authorised for Great Britain are known as "approved Bodies" or "appointed bodies", while CABs that are notified to the European Commission for products that will be placed on the market in Northern Ireland are known as "notified bodies".

6.3 The Swiss MRA replicates as far as possible the arrangements the UK had with Switzerland as an EU member immediately before exit day (the "EU MRA").

6.4 The Swiss MRA allows certain CABs in Switzerland, designated by Switzerland and recognised by the UK under the MRA, to carry out conformity assessment for certain product sectors (specified in the MRA, by reference to legislation) against the technical requirements of Great Britain. The instrument provides that conformity assessment by these recognised CABs should be treated as if it had been carried out by an approved body or, as the case may be, an appointed body. Products positively assessed by these recognised CABs can therefore be placed on the market in Great Britain. The Swiss MRA gives reciprocal treatment to CABs in the UK which have been duly designated by the Secretary of State and recognised by Switzerland, so that UK CABs can benefit from savings related to simplified accreditation and designation arrangements. To the extent that these Regulations contain provision in the areas of the protection of human or animal life or health or environmental protection, the provision is consistent with maintaining UK levels of statutory protection in that area.

6.5 The 2021 Regulations, as amended by this instrument, provide for products assessed by recognised CABs within Switzerland to be placed on the market in Great Britain. For products placed on the market in Northern Ireland, CABs within Switzerland will be recognised under the EU MRA with Switzerland, in accordance with the Northern Ireland Protocol.

7. Policy background

What is being done and why?

7.1 This SI makes provision to give effect to the Swiss MRA which has been agreed to provide continuity for businesses and consumers who were already used to the benefits of the EU MRA. The MRA will help facilitate businesses from Switzerland to

continue to be able to access the market in Great Britain with minimum disruption. And for GB business to market products on the Swiss market.

7.2 Before some products are placed on the market, a conformity assessment must be carried out by a CAB, which must be designated by the relevant national authority. MRAs allow countries to agree to recognise the conformity assessment results of the other country's CABs assessing against their own requirements.

7.3 Conformity assessment plays a critical part in ensuring products placed on the market are safe for consumers and business. It is the process of determining whether a product meets certain requirements to enable it to be legally placed on the market.

7.4 The UK has MRAs with several countries agreed as part of arrangements made under the UK's trade continuity programme. Those MRAs promote trade in goods between the UK and third countries by reducing technical barriers to trade, specifically by enabling conformity assessment to be undertaken by CABs in an exporting company's home market in agreed circumstances.

7.5 Under the MRAs, manufacturers from third countries can place products on the market in Great Britain more efficiently and cheaply, passing these savings on to consumers. Manufacturers will be able to use an assessment of conformity carried out by a designated CAB recognised by the UK under an MRA in their home country which assesses their product against the requirements of Great Britain. To the extent that this assessment is the same as that performed to assess conformity with the requirements in the third country, this may reduce the need to duplicate conformity assessment. This will provide continuity, maintaining the affordability of products and maintaining choice for consumers. It will also have the benefit of saving time for manufacturers with products being able to be placed on the market quicker than if they were required to undergo a separate test of conformity in the UK to assess whether they meet the requirements of Great Britain. In addition, UK manufacturers can use designated UK CABs recognised by third countries under MRAs to assess conformity with requirements of third countries. To the extent that this assessment is the same as that performed to assess conformity with requirements in the UK, this may reduce the need to duplicate conformity assessment.

7.6 These conformity MRAs were implemented in the UK through the Conformity Assessment (Mutual Recognition Agreements) and Weights and Measures (Intoxicating Liquor) (Amendment) Regulations 2021. This instrument implements the Swiss MRA in a similar way by amending the 2021 Regulations. It amends Schedule 1 of the 2021 Regulations so that it includes all of the domestic Regulations which the UK may recognise Swiss CABs to test against under the Swiss MRA.

7.7 Since 1 January 2021 the UK and Switzerland have granted temporary bilateral access to goods conformity assessed against each other's regulations. Switzerland will currently no longer apply these temporary measures for new conformity assessment procedures carried out by bodies based in the UK after 31 December 2022. Under the reciprocal measures set out in the Swiss MRA, conformity assessment procedures issued before this date will still be recognised for goods placed on the market in 2023, ensuring continuity of trade between the parties. When the Swiss MRA enters into force in 2023, conformity assessment bodies will be permitted to issue new approvals for conformity assessment procedures once they are designated under the agreement.

7.8 The Swiss MRA specifies the products or sectors to which it applies, such as radio equipment. Schedule 1 of the amended 2021 Regulations include the domestic

Regulations which the UK may recognise Swiss CABs to test against under the MRA (as specified in the Swiss MRA).

7.9 The amended 2021 Regulations also set out the power of the Secretary of State to designate UK CABs for the purpose of assessing against Switzerland's requirements. The instrument amends Schedule 2 to the 2021 regulations to include Annex 1 (product sectors) of the Swiss MRA, which set out the products or legislation in Switzerland that the UK can designate UK CABs to test against.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 There are no plans to consolidate the legislation amended by this instrument.

10. Consultation outcome

10.1 The Government did not undertake a formal public consultation given that this instrument's provisions give legal effect to a signed agreement, fulfilling our international obligations. We have maintained a dialogue with the Devolved Administrations in relation to this SI.

11. Guidance

11.1 Documents related to the Trade Act 2021 can be found here https://www.legislation.gov.uk/ukpga/2021/10/contents/enacted.

11.2 Guidance on the UKCA marking and how to use it has been published and can be accessed here: https://www.gov.uk/guidance/using-the-ukca-marking.

11.3 Guidance on placing manufactured goods on the market in Great Britain which includes information on what businesses need to do to comply with regulations can be accessed here: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain.

11.4 Guidance on placing manufactured goods on the market in Northern Ireland which includes information on what businesses need to do to comply with regulations can be accessed here: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-northern-ireland.

11.5 Hard copies of the above pieces of guidance are available on request from the contacts noted in this EM.

11.6 Copies of the Swiss MRA can be accessed here: https://www.gov.uk/guidance/uk-switzerland-mutual-recognition-agreement.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because assessed costs have been deemed to be below the de-minimis threshold. It does not impose any significant costs to businesses, charities, voluntary bodies or the public sector.

12.4 The policy does not impose any new obligations on business. The policy enables, but does not require, Conformity Assessment Bodies in the UK to apply to the UK Accreditation Service (UKAS) to be accredited as competent to assess products under Swiss product regulations.

12.5 The main direct cost to business would be one-off familiarisation costs at a central estimate of £2,300 associated with this new piece of legislation. More specifically, as of 11 October 2022 this instrument would only have familiarisation impacts on around 300 affected businesses who are involved in the manufacture and sale of the products within scope of the instrument and, who trade those products with Switzerland but not the EU.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise the regulatory burdens on small businesses as no significant costs are anticipated given the measures support continuity of arrangements with Switzerland.

13.3 The basis for the final decision on what action to take was because no significant costs to small businesses are anticipated as a result of this instrument.

14. Monitoring & review

14.1 The Department does not intend to monitor this instrument.

14.2 The Regulations do not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the Minister for Enterprise and Markets, Kevin Hollinrake, has made the following statement:

"The Department has not included a statutory review clause. This is because a review would be disproportionate when taking into account the economic impact of this instrument. The instrument also implements the United Kingdom's international obligations, and the instrument will need to remain in place for so long as these signed agreements are in force."

15. Contact

15.1 Robert Morris or email: opsslegislation@beis.gov.uk can be contacted with any queries regarding the instrument.

15.2 Craig Watson, Deputy Director for Borders, Accreditation, Measurement and Standards, at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

15.3 Kevin Hollinrake, Parliamentary Under Secretary of State (Minister for Enterprise and Markets), at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.