

EXPLANATORY MEMORANDUM TO
THE TOYS AND COSMETIC PRODUCTS (RESTRICTION OF CHEMICAL
SUBSTANCES) REGULATIONS 2022

2022 No. 659

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy (the Department) and is laid before Parliament by command of Her Majesty.

2. Purpose of the instrument

- 2.1 The objective of this Instrument is to prohibit or restrict the use of specified chemicals in certain toys and cosmetic products, following scientific assessment that they pose an unacceptable risk to human health. It does this by amending the domesticated version of the Cosmetic Products Regulation (EC) No 1223/2009 ("the Cosmetics Regulation") and the Toys (Safety) Regulations (S.I. 2011/1881) ("the Toys Regulations").

3. Matters of special interest to Parliament

- 3.1 None.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England, Wales, and Scotland.
4.2 The territorial application of this instrument is the same as its extent.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 This Instrument amends the Toys (Safety) Regulations 2011 ("the Toys Regulations") and retained Regulation (EC) No 1223/2009 ("the Cosmetics Regulation") to restrict or prohibit the use of specified chemical substances in toys and cosmetic products.
- 6.2 The European Union (Withdrawal) Act 2018 retained the Toys Regulations and Cosmetics Regulation. They were amended by S.I. No. 2019/696 (and other related instruments) to provide powers for the Secretary of State to update these pieces domestic legislation, in the same way that the European Commission can with respect to the relevant EU legislation, where there is technical or scientific developments or evidence affecting the assessment of safety.
- 6.3 Regulation 39B (1) of the Toys Regulations provides a power for the Secretary of State to make regulations to amend points 11 (permitted allergenic fragrances in toys) and 13 (migration limits on chemicals) of Part 3 of Schedule 2. Regulation 39C (1) provides a power for the Secretary of State to make regulations to amend Appendix C

to Schedule 2 (limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth).

- 6.4 This Instrument amends the Toys Regulations to prohibit the use of atranol, chloratranol and methyl heptine carbonate in toys. It also restricts the use of aluminium, aniline, and formaldehyde in toys. The Secretary of State, taking into account technical progress and scientific developments, considers it necessary to make changes to the Toys Regulations to update the list of chemicals set out in the above areas.
- 6.5 Article 31(1)(f) of the Cosmetics Regulation provides the Secretary of State with powers to add substances that have been classified as carcinogenic, mutagenic or reprotoxic (CMR) to Annex 2 (prohibited substances) of the Cosmetics Regulation. Article 31(1)(g)(i) provides the Secretary of State with a power to amend Annex 3 to allow a category 2 CMR substance where the Secretary of State considers that there is sufficient scientific evidence that the substance is safe for use in cosmetic products.
- 6.6 This instrument amends the Cosmetics Regulation to prohibit the use of the chemicals classified as CMR listed in the Schedule to the Instrument as well as deoxyarbutin in cosmetic products. The Instrument also amends the permitted level of use of salicylic acid for uses, other than as a preservative, at a concentration of up to 0.5% in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications. The Secretary of State considers that there is sufficient scientific evidence that salicylic acid is safe for use in the cosmetics products listed at a concentration up to 0.5%.

7. Policy background

What is being done and why?

- 7.1 Since leaving the EU, the UK makes its own decisions regarding products that can be placed on the GB market. The process for making these decisions is based on an assessment of the available scientific evidence. As such the government is responsible for keeping the toys and cosmetics schedules and annexes up to date and making amendments if evidence suggests that chemicals being used in the manufacture of toys or cosmetics may be unsafe.
- 7.2 This instrument amends the permitted levels of certain chemicals in both the Toys Regulations and the Cosmetics Regulation.
- 7.3 Toys Regulations will be amended to reduce the permitted limits of aluminium, aniline and formaldehyde as well as including provisions on three allergens used in fragrances, under the list of prohibited allergens in toys.
- 7.4 The Instrument also amends the Cosmetics Regulation to permit the use of salicylic acid for uses other than as a preservative only in specific product types, as well as prohibiting the use of deoxyarbutin and a set of chemicals classified as CMRs under GB Classification, Classification Labelling and Packaging (CLP) Regulations.
- 7.5 Without these amendments, there will be continued manufacture of toys and cosmetics for the GB market containing ingredients that could have public health and safety implications due to the risks these chemicals pose to human health.
- 7.6 All these changes already apply to Northern Ireland under the terms of the Northern Ireland Protocol.

Explanations

What did any law do before the changes to be made by this instrument?

- 7.7 The legislative framework for product safety operates via regulations covering specific product sectors including toys and cosmetics. These regulations function to ensure that only products that are considered safe can be placed on the market. They also make provisions to correct or remove unsafe or inaccurate products from the market so that consumers and other end users have reassurance about the safety of products available on the market.

Why is it being changed?

- 7.8 The provisions of this instrument are being introduced to ensure that only safe products can be placed on the GB market. There is no change to policy intentions or regulatory regimes. The technical amendments to the toys and cosmetics schedules or annexes are being proposed to reflect the most up to date scientific opinion represented by the advice offered by the Scientific Advisory Group on Chemical Safety (SAG-CS), whose role is providing the Secretary of State with scientific advice and risk assessment in the areas of public health and consumer safety. In addition, with regards to CMR substances, to meet the regulatory requirement that cosmetic products must not contain substances classified as CMRs under the CLP Regulations These are substances that are considered toxic, in order to receive this classification, there must be scientific evidence that a chemical can cause or promote cancer, genetic mutations and or damage the reproductive process.
- 7.9 Additionally, technical amendments being made to the underlying regulations will provide the necessary clarity and certainty for business, with regards to the specific chemicals that can no longer be used or the new levels that they are permitted to be used at.

What will it now do?

- 7.10 The SI will:
- amend Annex 2 to the Cosmetics Regulation to prohibit the use of deoxyarbutin;
 - amend Annex 3 to the Cosmetics Regulation to permit the use of salicylic acid for uses other than as a preservative at 0.5% in body lotion, eye shadow, mascara, eyeliner, lipstick, and roll-on deodorant applications;
 - amend Appendix C to Schedule 2 of the Toys Regulations to introduce specific (lower) limits for aniline and formaldehyde for toys intended for use by children under 36 months old or other toys intended to be placed in the mouth;
 - amend point 13 of Annex 2 to the Toys Regulations to reduce the permitted migration limits for aluminium amend Part 3 (chemical properties) of Schedule 2 of the Toys (Safety) Regulations 2009 to prohibit fragrance allergens atranol, chloratranol and methyl heptane carbonate;
 - add the additional CMR substances to Annex 2 (prohibited substances) and unless various conditions have been met where they are currently present in Annexes 3 to 6, they will be removed.

8. European Union Withdrawal and Future Relationship

- 8.1 This instrument amends Schedule 2 of the Toys (Safety) Regulations 2011, which were made in part under section 2(2) of the European Communities Act 1972. In accordance with the requirements of the European Union (Withdrawal) Act 2018 the Minister has made a statement setting out the good reasons for making these changes.

9. Consolidation

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

10. Consultation outcome

- 10.1 A formal consultation has not been completed for this instrument. The Department chose not to undertake a public consultation given that its provisions are limited to making only necessary technical amendments to the Toys and Cosmetics Regulation in order to reflect scientific assessment regarding potential risks to human health.
- 10.2 The Department has, however, undertaken extensive engagement with a variety of stakeholders.

11. Guidance

- 11.1 There is guidance on the UK's Regulations for toys and cosmetics, provided to support businesses, enforcement agencies and consumers, which can be found on the Office for Product Safety and Standards section of GOV.UK (<https://www.gov.uk/government/publications/cosmetic-products-enforcement-regulations-2013> and <https://www.gov.uk/government/publications/toys-safety-regulations-2011>).
- 11.2 We will continue to update this guidance when needed and provide specific advice when required to ensure both industry and the public continue to be informed of changes to regulations.

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 An Impact Assessment (IA) has not been prepared for this instrument because the impacts of The Toys and Cosmetic Products (Restriction of Chemical Substances) Regulations 2022 are expected to be de-minimis. The impact of this instrument is limited to businesses familiarising themselves with the updated regulations as well as changes to the product labels and chemical levels used within the cosmetics and toy products.

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.
- 13.3 The legal requirements on the industry do not differentiate between business in terms of their size and they are dependent on the type and nature of products being

manufactured and placed on the market. Therefore, we are unable to take any mitigating actions to reduce burdens on small business.

14. Monitoring & review

- 14.1 The Department does not intend to monitor this instrument.
- 14.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Paul Scully MP, Parliamentary Under Secretary of State (Minister for Small Business, Consumers and Labour Markets) at the Department for Business, Energy and Industrial Strategy can has made the following statement:
- 14.3 “A review would not be appropriate, given the technical nature of the amendments. However, to ensure that products placed on the GB market are safe the government keeps the regulatory framework under constant review, including the use of specific chemicals in particular products.”

15. Contact

- 15.1 Will Burrows at Office for Product Safety and Standards, Department for Business, Energy and Industrial Strategy, Telephone: 07442998687 or Email: will.burrows@beis.gov.uk can be contacted with any queries regarding this instrument.
- 15.2 Tony Thomas, Deputy Director Product Safety Policy, at Office for Product Safety and Standards, Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Paul Scully MP, Parliamentary Under Secretary of State (Minister for Small Business, Consumers and Labour Markets) at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriateness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Explanations where amending or revoking regulations etc. Made

- 1.1 The Parliamentary Under Secretary of State (Minister for Labour Markets), Paul Scully, has Under Secretary of State (Minister for Small Business, Consumers and Labour Markets), Paul Scully, has made the following statement regarding regulations made under the European Communities Act 1972:

“In my opinion there are good reasons for the Toys and Cosmetic products (Restriction of Chemical Substances) Regulations 2022 to amend the Toys (Safety) Regulations 2011 (S.I. 2011/1881) which were made in part under section 2(2) of the European Communities Act 1972 This is because the provisions to which this statement relates uses powers in the Toys (Safety) Regulations (S.I. 2011/1881), to make the necessary changes regarding chemicals used in the manufacture of toys in order to reflect the most recent scientific advice, and to meet our requirement to prohibit substances classified as CMRs. Without these amendments products containing chemicals or quantities of chemicals assessed to be a risk to human health will continue to be placed on the GB market.”