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CTFA Webinar

28 January 2021

Cosmetic, Toiletry and Perfumery Association

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Negotiations: Trade and Cooperation Agreement

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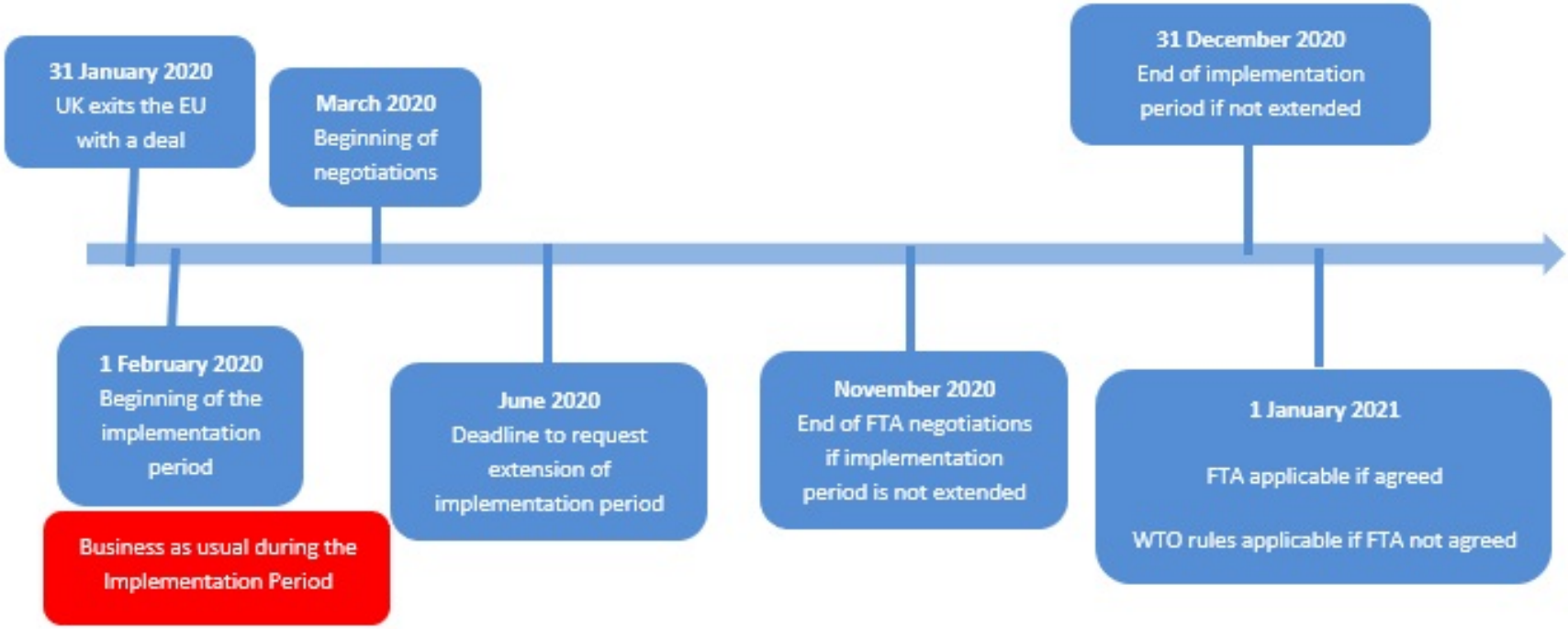
Timeline (Jan 2021)



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The end of the negotiations

- Conclusion of negotiations on the 24 December
- Introduction of European Union (Future Relationship) Bill on 29 December
- UK Parliament recalled on 30 December to approve and give Royal Assent.
- EU Commission approved provisional application on 29 December, with views on formal consent in March.

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Highlights

- Creation of a Partnership Council and dependant groups. Requirement for domestic Trade Advisory Groups.

- Powers of amendment for initial 5 years.

- Trade in goods:
  - Zero tariffs or quotas
  - Bilateral cumulation
  - Accounting segregation
  - Supplier declarations templates

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Rules of Origin

Chapter 33	**Essential oils and resinoids; perfumery, cosmetic or toilet preparations**
33.01	CTSH: A chemical reaction, purification, mixing and blending, production of standard materials, a change in particle size, isomer separation, or biotechnological processing is undergone; or MaxNOM 50% (EXW)
3302.10	CTH, however, non-originating materials of subheading 3302.10 may be used, provided that their total value does not exceed 20% of the EXW of the product
3202.90	CTSH: A chemical reaction, purification, mixing and blending, production of standard materials, a change in particle size, isomer separation, or biotechnological processing is undergone; or MaxNOM 50% (EXW)
33.03	Production from non-originating materials of any heading
33.04 - 33.07	CTSH: A chemical reaction, purification, mixing and blending, production of standard materials, a change in particle size, isomer separation, or biotechnological processing is undergone; or MaxNOM 50% (EXW)
Chapter 34	**Soap, organic surface-active agents, washing preparations, lubricating preparations, artificial waxes, prepared waxes, polishing or scouring preparations, candles and similar articles, modelling pastes, "dental waxes" and dental preparations with a basis of plaster**
34.01-34.07	CTSH: A chemical reaction, purification, mixing and blending, production of standard materials, a change in particle size, isomer separation, or biotechnological processing is undergone; or MaxNOM 50% (EXW)

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Highlights, the sequel

- Technical Barriers to Trade
  - Acknowledges freedom to regulate goods.
  - Establishes the WTO process for transparency and feedback
  - Sharing of information on dangerous and non-compliant products: EU Safety Gate
  - Annexes on sectorial considerations: Chemicals
    - Commitment to ongoing cooperation and exchange of non-confidential information.

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Highlights, the return

- Provisions on Digital Trade
  - “liberalising and modern” – commitment to cooperate on future issues

- SMEs
  - Support in the form of access to information

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UK Cosmetics Regulation

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Goods on the Market

- **Article 41 of the EU Withdrawal Agreement states that goods placed on the EU27 or UK markets before the end of the transition period (1 January 2021) may be further made available and circulate between the two markets until they reach the end consumer. Proof of when the goods were placed on the market will be required.**

'Placing on the market' *"The first making available of a cosmetic product on the market"*

'First making available' Applicable to each individual unit, the initial action whereby each item is put into stock and is available for supply.

Making available within the supply chain ('existing stock') Each individual unit for which the initial action of placing on the Community* market occurred on or before 29 March 2019. Stock continues to be made within the supply chain, on the UK market, after 29 March 2019.

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Northern Ireland Protocol

Products sold in…	Applicable legislation
Northern Ireland	EU Cosmetics Regulation, EU REACH
Northern Ireland and Republic of Ireland	EU Cosmetics Regulation, EU REACH
Northern Ireland and Great Britain	EU Cosmetics Regulation, EU REACH, UK Cosmetics Regulation, UK REACH → double compliance
Great Britain	UK Cosmetics Regulation, UK REACH

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Legal Text

- Schedule 34 of the Product Safety and Metrology Statutory Instrument, and its amendments
  - OPSS official guidance
- Applicable to the GB market from 1 January 2021
- NI continues to follow EU rules, in accordance with the NI Protocol in the UK/EU Withdrawal Agreement

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Transposed EU Law

EU Cosmetics Regulation	UK Cosmetics Regulation
• Responsible Person • Product Information File • Safety Assessment • Labelling • Cosmetic product definition • Claims self-regulation • Notification Portal (CPNP) • Cosmetovigilance • Ingredients monitoring and restrictions	• Responsible Person • Product Information File • Safety Assessment • Labelling • Cosmetic product definition • Claims self-regulation • Notification Portal (name TBC) • Cosmetovigilance • Ingredients monitoring and restrictions

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UKCR Article 3 and 10 – Safety and Safety Assessment

Article 3

- "*A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use*"

Article 10

- The cosmetic product must have undergone a safety assessment and a Cosmetic Product Safety Report (CPSR) is set up in accordance with Annex I
- The safety assessor must be in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by the Secretary of State

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UKCR Article 4 and 5 - Responsible Person Obligations

Article 4

- A cosmetic product may not be placed on the market unless there is a Responsible Person established in the United Kingdom
  - The manufacturer is considered the RP
  - The importer is considered the RP for imported cosmetics
  - An importer or a manufacturer established in the United Kingdom may by written mandate designate a person established in the United Kingdom as the RP

Article 5

- The RP shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1), (2) and (5), as well as Articles 20, 21, 23 and 24.

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UKCR Article 6 – Distributor Obligations

- Distributors shall act with due care in relation to applicable requirements
- Before making a cosmetic product available on the market distributors shall verify that:
  - the labelling information provided for in Article 19 is present;
  - the language requirements provided for in Article 19 are fulfilled;
  - the date of minimum durability specified, where applicable under Article 19, has not passed.
- Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation

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UKCR Article 11 - Product Information File (PIF)

- A Product Information File (PIF) is required for cosmetic products placed on the UK market, which must be made available to UK authorities at the RP address. The PIF must be in English. The PIF shall contain:
  - a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
  - the Cosmetic Product Safety Report (CPSR);
  - a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;
  - where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;
  - data on any animal testing performed by the manufacturer, their agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.
- The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

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UKCR Article 13 – Notification (1)

- Before placing a cosmetic product on the market, the RP must submit a notification via the UK notification database. The information for notification are:
  - the category of cosmetic product and its name or names, enabling its specific identification;
  - the name and address of the RP;
  - details of contact person to contact in the case of urgency;
  - where applicable, the following information: presence of substances in the form of nanomaterials; the identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation; and the reasonably foreseeable exposure conditions;
  - the name and the CAS or EC number of substances classified as CMR substances of category 1A or 1B under Regulation (EC) No 1272/2008;
  - the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties;
  - the original labelling and, where reasonably legible, a photograph of the corresponding packaging.
- Transitional provisions apply

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UKCR Article 13 - Notification (2)

Products placed on the market before 1 January 2021 and already notified on EU CPNP	Products placed on the market after 1 January 2021, not already notified on EU CPNP
○ the category of cosmetic product and its name or names, enabling its specific identification; ○ the name and address of the UK RP; ○ details of the contact person in the case of urgency; ○ the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties; Or just upload the zip file of the EU CPNP notification.	○ the category of cosmetic product and its name or names, enabling its specific identification; ○ the name and address of the UK RP; ○ details of contact person in the case of urgency; ○ where applicable, the following information: presence of substances in the form of nanomaterials; the identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation; and the reasonably foreseeable exposure conditions; ○ the name and the CAS or EC number of substances classified as CMR substances of category 1A or 1B under Regulation (EC) No 1272/2008; ○ the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties; ○ the original labelling and, where reasonably legible, a photograph of the corresponding packaging.

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UKCR Article 18 – Animal Testing

- The animal testing ban is maintained under UK Cosmetics Regulation for both finished cosmetic products and cosmetic ingredients

- The ban does not prevent the use of historic animal testing data in order to meet the requirements of this Regulation

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UKCR Article 19 – Labelling (1)

- Information to label on cosmetic products placed on the UK market in English:
  - the UK RP name and address (highlighted if more than one UK address is present on pack) – transitional provisions apply;
  - Country of origin for imported products;
  - nominal content (except packs less than 5 ml/g, free samples and single application products);
  - BBE date or PAO (same principles as current);
  - warnings and precautions for use;
  - batch number;
  - function of the product, unless it is clear from its presentation;
  - ingredients list preceded by the term ‘ingredient’ (same principles as current)
- Hand and book symbol exemption
- Provisions for non-prepackaged products

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UKCR Article 19 – Labelling (2)

Transitional provisions

"for a period of two years beginning on the day after the day on which IP completion day falls, point (a) – the RP name and address and country of origin for imported products - *is to be treated as satisfied where the requirements of Article 19(1)(a) of the EU Regulation (pre-exit) are complied with;"*

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UKCR Article 20 – Claims

- *"In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have"*
- Compliance with Commission Regulation (EU) No 655/2013 on the Common Criteria for Cosmetic Claims is mandatory

- UK advertising rules remain unchanged

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UKCR Article 14, 15, 16, 30, 31 – Ingredients, CMRs, N

Article 14

- Refers to restrictions for substances listed in the Annexes of the EU Cosmetics Regulation

Article 15

- Doesn't allow use of CMR substances of category 1A, 1B and 2 in cosmetics, unless the substance has gone through the exemption process and is included in any of Annexes III-VI

Article 16

- Nano notification does not apply to nano materials used as colorants, UV filters or preservatives regulated under Article 14

Articles 30 and 31

- Provide for amendment of Articles and Annexes of the UK Cosmetics Regulation, in particular in reference to management of cosmetic ingredients

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UKCR Article 22, 23 - Cosmetovigilance

Article 22

- Enforcement authorities must monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market

Article 23

- Provides for communication of serious undesirable effects – details of process to be defined

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The work continues…

- CTPA working with the UK Government (Office for Product Safety and Standards - OPSS)

  - Evolution of UK SCPN Portal
  - UK Cosmetic Ingredients Safety Panel (to provide independent scientific opinion on the safety of cosmetic ingredients)
  - UK Cosmetic Expert Advisory Group

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Labelling of Aerosols – UKCA Mark

- Schedule 13 of the Product Safety and Metrology SI gives the provisions for the UK Aerosols Regulations
- Amendment No 7 gives the requirement of the UKCA mark for aerosols;
  - after 31 December 2020 aerosols sold in GB can carry either the reverse epsilon (3) or the UKCA mark until 31st December 2021;
  - after 31 December 2021 all aerosols sold in GB must carry the UKCA mark. This mark can be applied as a sticker until 31st December 2022, if this is easier for marketers;
  - after 31 December 2020 aerosols sold in Northern Ireland (NI) must continue to carry the reverse epsilon (3) (as NI follows EU regulations), so after 31st December 2021 aerosols sold in both GB and NI must carry both the UKCA and reverse epsilon (3) mark to show conformity.
  - The conformity regime detailed in the GB Statutory Instrument is identical to the self-certification system currently required under the EU

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E-Commerce

- Compliance with the regulations is required also for products sold online!
- This is valid for goods sold to both the EU and the UK

Useful Resources

- OPSS Guidance for cosmetics
- Submit Cosmetic Products Notifications portal

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UK REACH

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REACH in the UK

- UK REACH SI and
  - 2nd amendment
  - 3rd amendment
  - 4th amendment

- The Health and Safety Executive (HSE) takes the role of the European Chemicals Agency (ECHA)
- Came into force on 1 January 2021 in GB
- Same principles and standards as EU REACH → no data, no market + 1 tonne/year limit
- NI continues to follow EU rules in accordance with the NI Protocol in the UK/EU Withdrawal Agreement

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REACH – Chemicals Legislation

EU REACH

- EU REACH will continue to apply to EU27 Member States, as is currently the case

UK REACH

- UK REACH as retained EU law
- Transitional requirements may depend on the outcome of negotiations

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UK REACH – 'New' Substances

'New' substances (not currently registered under EU REACH) manufactured or imported into the UK must be registered
For manufacturers outside of the UK, they can appoint an Only Representative in the UK to carry out obligations under UK REACH
Information to be submitted as part of the registration is highlighted in Regulation 10 of UK REACH SI (amending Article 10 of EU REACH); Article 12 of EU REACH doesn't have any amendments under UK REACH SI and gives the information to be submitted as part of the registration dossier, based on tonnage band of the chemical
Joint registrations will be allowed under Regulation 11 of the UK REACH SI (amending Article 11 of EU REACH)
Regulation 13 of UK REACH SI (amending Article 14 of EU REACH) gives the provisions for the chemical safety report and application of risk reduction measures
Data sharing and avoidance of unnecessary testing provisions are maintained under UK REACH
Provisions for communication within the supply chain are maintained
Obligations for downstream users are maintained
Provisions for evaluation, authorisation and restriction of chemicals are also maintained

UK REACH – Transitional Provisions

‘Existing’ substances (currently registered under EU REACH) manufactured or imported into the UK	
UK Registration Holder (Article 127B UK REACH)	**UK Downstream Users (article 127E UK REACH) – ONLY IF SUPPLIER DOESN’T REGISTER**
Submission of preliminary information within 120 days from 1 January 2021 (identity of the manufacturer/importer; identity of the substance; information on the manufacture and use of the substance; an indication that the information has been reviewed by an assessor having appropriate experience, registration number and registration date under EU REACH; any existing ECHA decision related to the registration)	Submission of Downstream User Import Notification (DUIN) within 300 days from 1 January 2021 (identity of the manufacturer/importer; identity of the substance; classification and labelling of the substance, only if it known; registration number under EU REACH, only if it is known; any substance authorisation if applicable; details of any restrictions; any other available and relevant information necessary for proper risk management measures)
EU companies can use a UK-based OR	
Full registration obligation from 28 October 2021 within: - 2 years for substances >1000 tonnes/year, CMRs, very toxic to aquatic organisms, candidate list substances (as of 31 December 2020) - 4 years for substances >100 tonnes/year, candidate list substances (as of 27 October 2023) - 6 years for substance >1 tonne/year	

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Useful Resources

- HSE UK REACH Guidance
- UK REACH IT system
- Defra UK REACH Q&A
- Chemical Industries Association REACH Ready

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Thank you!

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Q&A

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