

# **How to Comply with UK Post-Brexit Cosmetic Regulations**

25 February 2021

Cosmetic, Toiletry and Perfumery Association

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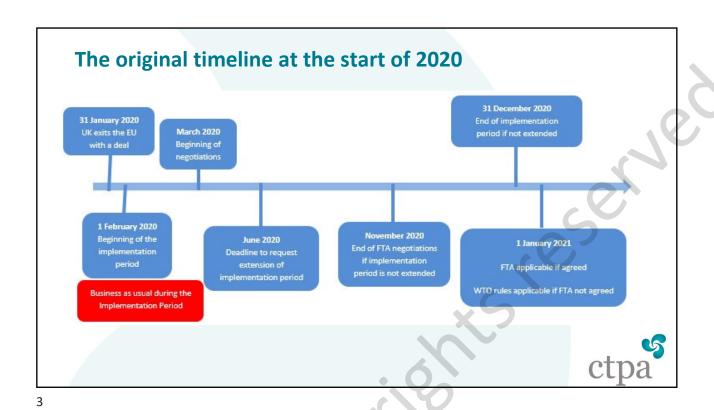
# **Negotiations: The UK-EU Trade and Cooperation Agreement**

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## **General Considerations of the UK/EU TCA**

#### **Governance:**

- Creation of a Partnership Council and dependant groups
- Requirement for domestic Trade Advisory Groups: British Manufactured and Consumer Goods Trade Advisory Group
- Powers of amendment for initial 5 years

#### **S** 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)



## Specific considerations of the UK/EU TCA

#### 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 / UK Product Safety Database
- Annexes on sectorial considerations: Chemicals
  - Commitment to ongoing cooperation and exchange of nonconfidential information.



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## Other matters in the UK-EU TCA

## Provisions on Digital Trade

"liberalising and modern" – commitment to cooperate on future issues

#### **SMEs**

• Support in the form of access to information



## Importing into the UK

- Existing Trade Agreements with non-EU Countries
  - The tariffs applicable will be contained within the FTA under the corresponding Rules of Origin.
- UK Global Tariff
  - Applicable to countries where no Trade Agreement has been reached
- **UK Generalised Scheme of Preferences** 
  - For developing countries



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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.

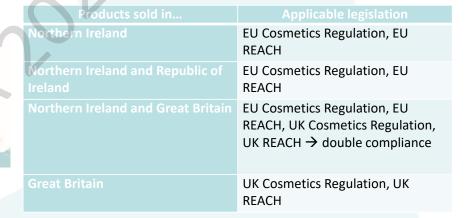
'Placing on the market' "The first making available of a cosmetic product on the market"

'<u>First</u> making available' Applicable to each individual unit, the <u>initial action</u> 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**





## **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

- Responsible Person
- Product Information File
- Safety Assessment
- Labelling
- Cosmetic product definition
- Claims self-regulation
- Notification Portal (CPNP)
- Cosmetovigilance
- Ingredients monitoring and restrictions

#### UK Cosmetics Regulation

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



#### **UKCR Article 2 – Definition of Cosmetic**

- "Cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours
- MHRA Guidance Note 8 remains unchanged



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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



### **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
  - o 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 5A – Responsible Person in NI**

- A business based in NI can be considered a UK RP if it already acts as an EU RP and if the cosmetic products imported into GB qualify as NI goods.
- A business based in NI can be considered a UK RP if it's a NI importer and the cosmetic products qualify as NI goods.
- Goods qualify as NI goods if they are "processed" in NI (e.g. manufactured, assembled, repaired, improved appearance, any other operation to ensure technical compliance) or "the goods are present in Northern Ireland and are not subject to any customs supervision, restriction or control which does not arise from the goods being taken out of the territory of Northern Ireland or the European Union".



### **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



## **UKCR Article 13 – Notification (2)**

#### Products placed on the market <u>before 1 January 2021</u> and already notified on EU CPNP

- the category of cosmetic product and its name or names, enabling its specific identification;
- o the name and address of the UK RP;
- o 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 (guidance available  $\underline{\text{here}}$ ).

#### Products placed on the market <u>after 1 January 2021</u>, 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;
- o details of contact person in the case of urgency;
- o 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



## **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;"



### **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 selfcertification system currently required under the EU



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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



## UKCR Article 14, 15, 16, 30, 31 - Ingredients, CMRs, Nano

#### **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



## **UKCR Article 25, 26 – Non-Compliance**

#### **Article 25**

Competent authorities shall require the RP to take all appropriate
measures, including corrective actions bringing the cosmetic product into
conformity, the withdrawal of the product from the market or its recall,
within an expressly mentioned time limit, commensurate with the nature of
the risk where there is non-compliance with these requirements

#### **Article 26**

Competent authorities shall require distributors to take all appropriate
measures, including corrective actions bringing the cosmetic product into
conformity, the withdrawal of the product from the market or its recall,
within a given reasonable time limit, commensurate with the nature of the
risk, where there is non-compliance with obligations laid down in Article 6



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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



#### **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



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## **Other Resources**

- **OPSS Guidance for cosmetics**
- **Submit Cosmetic Products Notifications portal**



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## **Cosmetics – Roles and Responsibilities**

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## Responsible Person (RP) – Manufacturer vs Importer

- 'Manufacturer' means any natural or legal person who manufactures a cosmetic product OR has such a product designed or manufactured, AND markets that cosmetic product under his name or trademark;
- 'Importer' means any natural or legal person established within UK, who places a cosmetic product from a third country onto the GB market;



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## Responsible Person (RP) - Mandate

**Article 4:** "An importer or a manufacturer established in the United Kingdom may by written mandate designate a person established in the United Kingdom as the responsible person."

- Only possible between UK entities
- Mandate must be written, followed by written acceptance of the mandated letter
- Name and address of the mandated person will appear on pack
- Different from a contractual agreement



#### Distributor - who?

"Distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market of Great Britain.

 "Making available" means any supply of a cosmetic product for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge.



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Distributor vs Importer

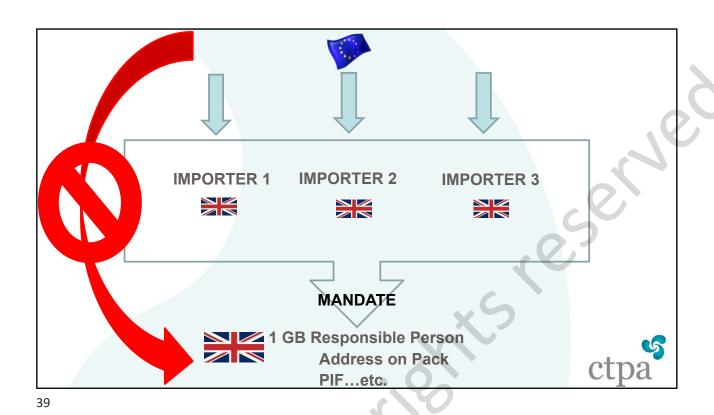
Non-UK Brand Owner

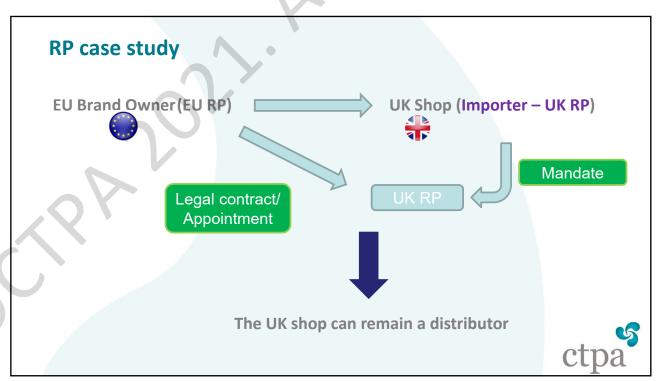
UK Distributor

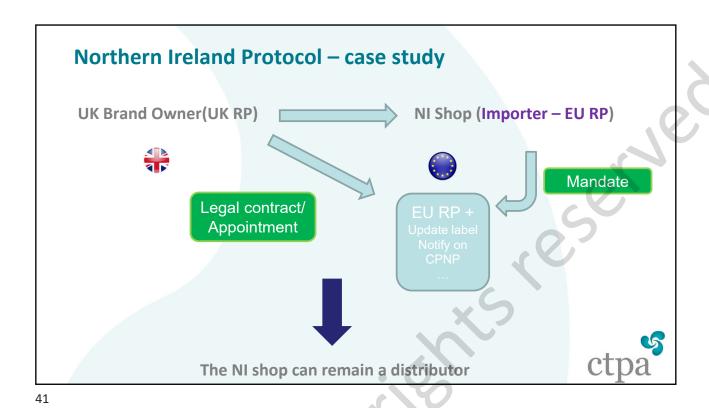
UK Retailers/Consumers

UK Retailers/Consumers

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Case study 1
Single Market and Customs Union – UK in the EU

EU Brand Owner (RP)

Post Brexit end of transition period (1 January 2021)

EU Brand Owner (EU RP)

UK Shop

Distributor



## **UK REACH**

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#### **REACH in the UK**

- **UK REACH SI** and
  - 2<sup>nd</sup> amendment
  - 3<sup>rd</sup> amendment
  - 4<sup>th</sup> 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



### **REACH – Chemicals Legislation**

## EU REACH \_ UK REACH

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

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)

## UK Downstream Users (article 127E UK REACH) – ONLY IF SUPPLIER DOESN'T REGISTER

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)

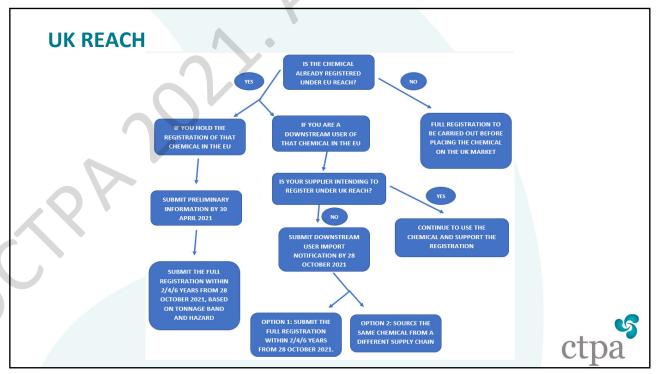
EU companies can use a UK-based OR

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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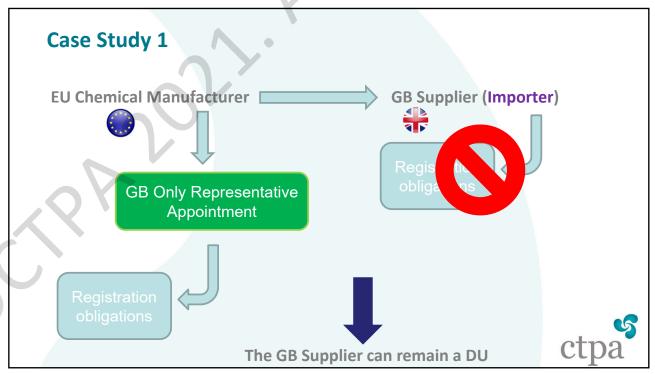


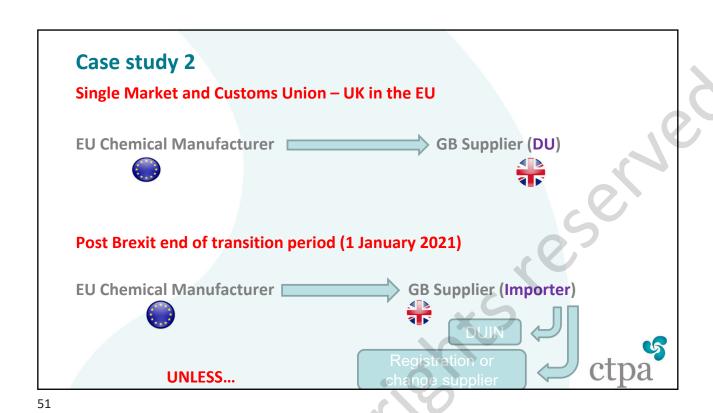
#### **NI Businesses**

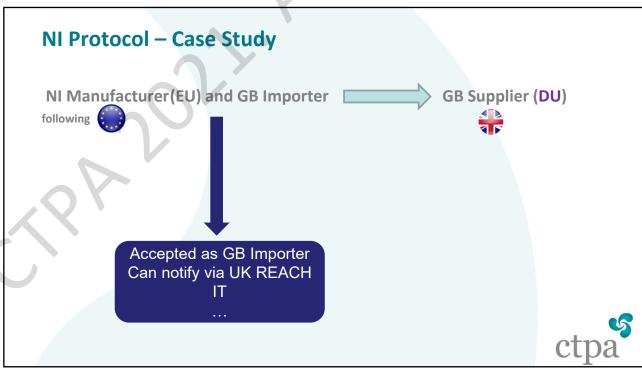
- A business based in NI (a manufacturer or importer of a chemical) who is a registrant or downstream user of a chemical registered under EU, and the chemical is a qualified NI good, can submit a Northern Ireland Notification directly to the HSE
- The GB business importing that chemical into the GB market, would be regarded as a downstream user and not as an importer



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## **Useful Resources**

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



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## **EU Member States Local Requirements**

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## **EU – Regulation vs Directive**

- Regulation → binding legislative act that must be applied in its entirety across the EU
  - EU Cosmetics Regulation 1223/2009
  - EU REACH Regulation 1272/2008
- Solution
  Directive → legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals
  - EU Single Use Plastics Directive 2019/904
  - EU Packaging and Packaging Waste Directive 94/62/EC



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## **EU – Member States Local Requirements**

- Additional local regulations might also apply in each Member States which have to be considered before marketing a cosmetic product in a specific
  - translation of labelling information
  - how non pre-packaged products are sold
  - waste and recycling
  - customs clearance
  - advertising

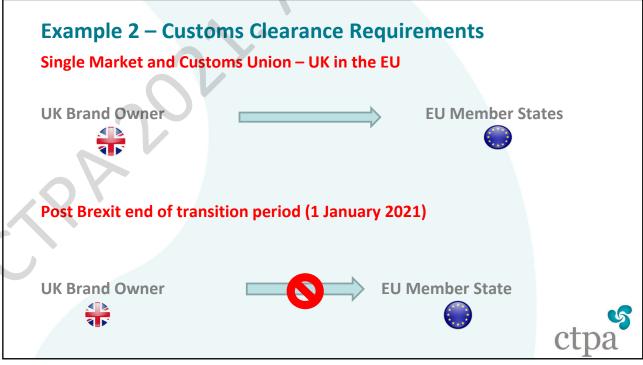


## **Example 2 – Customs Clearance Requirements**

- UK has become a third country to the EU, being formally out of the Single Market from 1 January 2021 → UK products introduced into the EU will count as imported goods (same treatment as products coming from US, China, etc.)
- Certain EU Member States have specific and strict import requirements when goods are imported from third countries



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## Q&A

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## CTPA OPEN WEBINAR ON UK REGULATIONS FOR COSMETICS 25 FEBRUARY 2021 - Q&A

All cosmetic products placed on the market of the United Kingdom (England, Wales, Scotland and Northern Ireland) intended for sale or to be given away for free in the course of a commercial activity must comply with:

- Schedule 34 of the Product Safety and Metrology Statutory Instrument (hereafter 'the UK Regulation') for cosmetics marketed in Great Britain (England, Wales and Scotland);
- Regulation EC 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (hereafter 'the EU Regulation') for cosmetics marketed in Northern Ireland. This is in accordance with the terms of the Northern Ireland Protocol to the UK/EU Withdrawal Agreement.

#### In particular:

- cosmetic products solely placed on the GB market must comply with the UK Regulation only;
- cosmetic products solely placed on the NI market must comply with the EU Regulation only.

The same applies to the Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation, where EU REACH is in force in NI and UK REACH is in force in GB.

For all information, please visit the <u>CTPA page</u> on regulations for cosmetic products; guidance on how to manufacture and supply cosmetic products is available <u>here</u>.

#### **UK Cosmetics Regulation (UKCR)**

#### Q. What are the differences in duties between a manufacturer and an importer?

A. A manufacturer is defined as a legal entity located in the UK and manufacturing cosmetic products which are then placed on the GB market under its own brand or trademark. An importer is defined as a legal entity located in the UK and placing products on the GB market from third countries (outside of the UK). Under the UKCR, both are automatically identified as the Responsible Person (RP) and therefore have the same obligations as per Article 5 of the UKCR. Only in the event where an importer cannot technically be the RP (because they don't have access to the Product Information File of the imported products), the importer shall mandate the RP role to another legal entity and therefore have different duties.

## Q. If an importer does not import directly from the brand owner, but another seller, how can the importer gain access to the Product Information File (PIF) to act as the Responsible Person (RP)?

A. Communication within the supply chain is extremely important. If an importer sources products from another legal entity who is not the brand owner, the importer shall ensure to have access to the PIF via the brand owner further up in the supply chain; or ensure that the brand owner has already designated an RP in the market of import, so that the importer can mandate the designated RP to be responsible for compliance of the imported products.

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#### Q. What Regulation must be complied with in Northern Ireland?

A. Northern Ireland follows the EU Cosmetics Regulation, in accordance with Annex II of the Northern Ireland protocol to the UK/EU Withdrawal Agreement.

## Q. What information has to be submitted as part of the simpler notification for products already on the market before 1 January 2021?

A. Only products placed on the market before 1 January 2021 can be notified using the simplified notification. Below is the list of information that has to be submitted as part of the simplified 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 the contact person in the case of urgency;
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties;

## Q. Do cosmetic products made at home from a small company have to comply with the UK Cosmetics Regulation? And what about micro-businesses?

A. All products placed on the UK (or EU) market have to comply with the requirements of the Cosmetics Regulation, whether they are sold for a price or given out for free. Sole traders or micro-businesses making cosmetic products and selling them (or giving them away for free) under their own trademark or name must ensure that the products comply with the UK Cosmetics Regulation. Cosmetic products are used on our bodies and the strict safety rules are in place to ensure our consumers' safety. It is also good to remember that ignorance of the legislation is no defence in a court of law.

#### Q. If I am a company located in a third country but I do not have a UK RP, what do I need to do?

A. In order to legally sell cosmetic products to the UK market, full compliance with the UK Cosmetics Regulation is mandatory. A UK RP must be in place, with its name and address on the product's label, a notification in the Submit Cosmetic Products Notification Portal (SCPN), and all other mandatory requirements.

#### Q. If a product is available in different sizes, does one notification count for all sizes?

A. Yes, one notification can be done for the same product available in different sizes.

#### Q. Can two RP addresses be displayed on one label?

A. Yes, two RP addresses of different markets can be on the label. There can only be one RP address per market on the label as there can be only one RP in either the EU or the UK. In practice, companies that are selling to both markets can label both the UK and the EU27 RP addresses on the same label, as it will be 2 RP addresses for compliance with 2 different Regulations (the EU and UK separately).

## Q. From an ingredients point of view, will the UK continue to follow the EU SCCS opinions and decisions?

A. The UK Cosmetics Regulation automatically adopts the Annexes of the EU Cosmetics Regulation, as implemented until 31 December 2020. From 1 January 2021, the UK follows its own ingredient management process, and any future implementation may differ from the EU.

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## Q. When does the EU RP address have to be added to the label to sell compliant products on the EU market?

A. According to the EU Commission <u>Technical Notice on cosmetics</u>, products placed on the market as of 1 January 2021 must have the EU RP name and address on pack.

#### Q. When does the UK RP address have to be added to sell compliant products on the UK market?

A. Article 19 of the UK Cosmetics Regulation provides a 2-year grace period for labelling the UK RP name and address and country of origin (for imported products) on pack. The 2-year grace period starts from 1 January 2021. This applies to products placed on the market from 1 January 2021.

## Q. Does the person submitting notifications via the UK Submit Cosmetic Products Notifications (SCPN) portal have to be located in the UK?

A. No, the person submitting the notifications to the SCPN portal can be located in any country. However, the main RP account of the SCPN portal must be of a UK RP.

#### Q. For completing the SCPN notification, does a company need to upload the picture of the product?

A. According to Article 13 of the UKCR the original labelling must be uploaded as part of the SCPN notification; where reasonably legible, a photograph of the corresponding packaging can also be added.

Q. When is it mandatory to submit the artwork as part of the notification in SCPN? When is it not? A. It is not mandatory to upload the artwork for products placed on the market before 1 January 2021, as these benefit for the "simpler" notification.

It is mandatory to upload the artwork and the full notification for products placed on the market after 1 January 2021.

## Q. If an EU-based company is selling products online to UK consumers, do the products need to comply with the UK Cosmetics Regulation?

A. Yes, the UKCR applies to all products placed on the UK market, including online selling. The EU Blue Guide gives detailed guidance about placing products on the market online in sections 2.1 and 2.4.

#### Q. Is the RP address needed on the primary and secondary packaging?

A. Yes, as is currently required under Article 19 of the EU Cosmetics Regulations and as it is required under Article 19 of the UK Cosmetics Regulation. The primary packaging is generally the main container of the product (e.g. jar, tube, bottle); the secondary pack is not always present and it's a second layer of packaging to the primary one (e.g. carton box).

#### Q. Is it possible to notify a product in different shades or colours only doing one notification?

A. A product with the same base formulation but different shades/colours, can be notified once by specifying the different shades at the relevant section of the notification.

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## Q. Distributors bringing products from outside of the EU or the UK will become importers, so each one of them will automatically be considered the RP. However, there can be only one RP per product; what is the solution to this?

A. Under Article 4 of the EU Cosmetics Regulation, the mandate is a solution to this matter. The difference between a commercial agreement and a mandate is that commercial agreements can happen between entities operating under different markets; a mandate is a handover of legal responsibility that can only happen between two entities under the scope of the same legislation (both in the UK or EU). The EU or UK importers bringing products into the EU or UK markets respectively will need to mandate the EU or UK RP chosen by that brand. If importers do not do this, then they will be automatically recognised as the RP.

For more information, please view this news item.

#### Q. Can you please clarify if only UK qualifications are recognised for a safety assessor?

A. No, also non-UK qualified safety assessors can carry out the safety assessment of a product placed on the GB market. However, their qualification has to be recognised as equivalent in the UK.

#### Q. How will non-UK safety assessors qualifications be recognised in the UK?

It is the responsibility of the Responsible Person to ensure that the safety assessment is carried out by a suitably qualified safety assessor that meets the criteria set out in Article 10 (2). There is not (and never has been) a formal recognition process or specific qualification awarded by the EU or UK regulators.

#### Q. What is the SUE reporting process for NI?

A. On 1 January 2021, the Office for Product Safety and Standards (OPSS), the UK Competent Authority for cosmetics, published the new Serious Undesirable Effect (SUE) reporting forms. Form 1 is for the Responsible Person (RP) or distributors to notify an SUE reported by a consumer or a health professional to OPSS.

RPs or distributors based in GB and NI should send SUE reports received from consumers or health professionals in the UK directly to OPSS using form 1 via the email address seriousundesirableeffects@beis.gov.uk.

#### Q. What are the UKCA mark requirements for aerosols? Is there a grace period?

A. Schedule 13 of the Product Safety and Metrology (UK Aerosols Regulation) provides new requirements which came into force following as of 1 January 2021 and are as follows:

- 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.

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The conformity regime detailed in the GB Statutory Instrument is identical to the self-certification system currently required under the EU Aerosol Dispenser Directive (i.e. no third-party/conformity assessment verification is needed).

We understand that the reverse epsilon (3) will not be prohibited on aerosols sold in GB, however they will have no significance under the UK framework.

#### Q. Will UK REACH have the 1 tonne/year threshold for obligations as EU REACH?

A. Yes, as is currently the case under EU REACH, UK REACH requirements will apply to chemicals manufactured or imported in the GB market above 1 tonne/year per legal entity.

#### Q. What are the requirements for registering substances not already registered under EU REACH?

A. Substances coming from outside of the EU/UK into the UK market, and not currently registered under EU REACH, must be registered using the general UK REACH process (which is replicated from EU REACH). The <u>UK REACH SI</u> has all provisions applicable to all substances manufactured or imported into the UK market above 1 tonne. 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. Further details are also available on the HSE guidance.

#### Q. What are the requirements for registering substances already registered under EU REACH?

A. The transitional provisions under UK REACH apply to substances already registered under EU REACH. Please visit the 'Sell in the UK' section of the CTPA Brexit public advice, which is still relevant. Guidance from the HSE is also available.

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