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Welcome

Key Product Compliance Issues: From Chemicals to Conflict Minerals to Connected Products
Louise Forrest
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At Compliance & Risks

We help our clients monitor and manage laws & regulations, standards and requirements to better mitigate risk.

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C2P Compliance Knowledge Management Platform

Regulations Management
- Monitor & manage on one platform
- Assessments & tasks
- Machine learning
- Advanced reporting

Standards Management
- Single search for regulations & standards
- Contextual linking to regulations
- Searchable versions & equivalences of standards
- Impact Assessment Tools

Requirements Management
- Managed in the platform
- 'Live' links to regulations & standards
- Easily updated
- Intelligent search

Content
- Breadth & depth
- Global monitoring
- Includes pending & proposed
- Regulatory insights

Alerts
- Daily emails
- Customized to your needs
- English summaries

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Regulatory Framework: Core Regulatory Content

Content

RAW MATERIALS › DESIGN › MANUFACTURING ›

END OF LIFE / WASTE

REUSE / RECYCLE

USE / REPAIR

PACKAGING & DISTRIBUTION

C2P

Batteries

Brexit News

California Proposition 65

Carbon Footprinting

Chemicals in Products

Chemicals Management

Chemicals & EH&S: Environment

Chemicals & EH&S: OH&S

Circular Economy

Climate Change

Conflict Minerals

Consumer Protection

Cybersecurity

Corporate Social Responsibility

Data Protection

Ecodesign

Ecolabeling

Electromagnetic Compatibility

Electronic Waste/WEEE

Energy Efficiency

EU REACH

Food Contact Materials

Globally Harmonized System

Human Trafficking and Slavery

Illegal Logging

Nanotechnology

Non-Financial Reporting Directive

Packaging

Product Safety

Single Use Plastics

Textiles

Transboundary Movements of Hazardous Waste

Transport of Dangerous Goods

Water Efficiency

Wireless

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60,000+
in force & pending regulations / standards /documents

23
languages spoken on the team

200
regularly monitored countries

1,633
ask our experts queries answered in 2019

30
global network of knowledge partners

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Agenda

- **C**hemicals - SCIP Database

- **C**hemicals - Update on RoHS & exemption

  renewals.

- **C**onflict Minerals - Upcoming deadline

- **C**onnected Products - regulatory developments

- **C**OVID-19 - regulatory impact

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SCIP

SCIP - what is SCIP ?

Directive (EU) 2018/851 amended Waste Framework Directive 2008/98/EC & is responsible for establishing the SCIP Database

Per the Directive, suppliers of articles containing Substances of Very High Concern (Candidate List) must provide information on the substances to be entered into SCIP Database. Thus, the SCIP Database will contain information on

*"**S**ubstances of **C**oncern **I**n articles, as such or in complex objects (**P**roducts)"*

Transposition Deadline for Member States: **5 July 2020**

Notification Obligations for Industry: **5 January 2021**

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SCIP - why establish SCIP ?

- The aim of SCIP is to make information on the presence of hazardous substance in articles available to both consumers and waste treatment operators.
  - It aims to help consumers make informed choices for safer products, thus increasing pressure to substitute substances of concern.
  - It aims to help waste operators in their treatment of waste and recycling of materials - improving risk management of chemicals during waste recovery & promoting non-toxic material cycles.

Overall, it is part of EU waste legislation package, contributing to the EU's Circular Economy Policy - EU Green Deal; Circular Economy Action Plan 2020; European Parliament's Resolution on Chemicals Strategy for Sustainability & Sustainable Products Initiative

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SCIP - who does it apply to ?

Manufacturers, assembers and importers of articles in the EU containing SVHCs > **0.1% w/w** from 1 January 2021.

Definition of "article" is the same as for REACH. Information is required for simple articles, as well as complex products.

There are exemptions: national interests in the area of defence; products made solely for export out of EU; products supplied directly to the end user and products that are repaired and end of life.

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SCIP - data requirements

SCIP dossier must contain substance data, article data and company data. Informations required includes:

- Name, location and concentration range of the SVHC in the article;
- Information that allows its safe use - information on how it should be properly managed when it becomes waste
- Identification of the article;
- Legal entity identification
- Optional data - such as photograph of the article

Submission must be to ECHA via SCIP database using IUCLID Dossiers. SCIP Database will formally open in the **last week of October** for submission of notifications.

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SCIP - industry readiness

Industry have expressed their discontent & serious concerns over last two years on workability, proportionality and value of SCIP. Plus, Industry was caught off-guard because the reporting requirement was introduced not through REACH, but via WFD and without prior stakeholder consultation & impact assessment.

Prompted letter from 40 different industry associations dated 21 September to the EU Commission requesting that the reporting deadline be postponed by 12 months.

The signatories of this letter ask President von der Leyen to take immediate action to:

1. Postpone the SCIP notification deadline of 5th January 2021 by at least 12 months after the database will be finalised;

2. Conduct a study on the usefulness, feasibility, proportionality and impact of the database, and;

3. Instruct the European Chemicals Agency (ECHA) to adapt the SCIP database according to the outcome of such study.

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Supported by:

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SCIP

25th September ECHA stated that it had no indication that the deadline would be postponed & encouraged companies to continue with preparations.

ECHA Webinar 19 November on "getting ready for submitting SCIP notifications" - provide demo on how to create and submit a SCIP notification and will show the tool that can be used to refer to information already successfully submitted to the SCIP database. Questions can also be put to the experts.

Webinar will be published on ECHA's homepage on 19th with instructions for joining a live Q&A.

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RoHS

Recent RoHS Developments - South Korea

- On 5 August 2020 South Korea notified a RoHS proposal to WTO

- Proposal will amend K-RoHS with the aim to strengthen the RoHS regime in South Korea and to bring it into line with Directive (EU) 2015/863 on phthalate restrictions (DEHP, BBP, DBP & DIBP).

- Draft was initially proposed as far back as October 2018, but floundered due to resistance from stakeholders.

- The South Korean Ministry of Environment succeeded in abridging the usual 60-day notification period to 20 days, citing the urgency of the measure to the TBT committee.

- Enforcement of the new provisions is planned for **1 January 2021**.

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Recent RoHS Developments - South Korea

Major features of the Proposal include:

- Addition of 4 phthalates
- Addition of 23 new products subject to restriction on use of hazardous substances
- Relaxation of requirements on retention of records for businesses subject to mandatory recycling and takeback
- Strengthening of penalties
- Addition of military equipment, large fixed industrial equipment, large fixed facilities and medical equipment to products excluded from restrictions, as well as recycling and take back obligations

The 23 new products include, among others, dehumidifiers, toasters, electric kettles, electric water heaters, electric frying pans, hair dryers, surveillance cameras, video game consoles (not including handheld game consoles) wired and wireless routers

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Recent RoHS Developments - Europe

Developments in RoHS continue at EU level and across Member States -

Amendments

 Filter

👁 (Proposed) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Proposed Amendment - (on extension of the validity period of an exemption for the use of mercury in intravascular ultrasound imaging systems) Draft Directive, July 2020

👁 (Proposed) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Proposed Amendment - (on exemption for the use of lead and hexavalent chromium in electric and electronic initiators of explosives for civil (professional) use) Draft Directive, July 2020

👁 (In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Amendment - (on exemption for hexavalent chromium as an anticorrosion agent of carbon steel cooling systems in absorption refrigerators) Directive (EU) 2020/361

👁 (In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Amendment - (on exemption for the use of cadmium in certain radiation tolerant video camera tubes) Directive (EU) 2020/364

👁 (In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Amendment - (on exemption for lead in solders and termination finishes used in certain hand-held combustion engines) Directive (EU) 2020/365

👁 (In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Amendment - (on exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and body fluids and gases) Directive (EU) 2020/366

👁 (In force) EU: Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU - Amendment - (on exemption for lead in platinized platinum electrodes used for certain conductivity measurements) Directive (EU) 2020/360

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Recent RoHS Developments - Europe

Developments in RoHS continue at EU level and across Member States -

Implementations

🔍 Filter

👁 (In force) Denmark: Restricting the Import, Sales and Manufacture for Export of Electrical and Electronic Equipment Containing Certain Hazardous Substances, Order No. 1216/2020

👁 (In force) Croatia: Restriction of Hazardous Substances in Electrical and Electronic Equipment, Pravilnik NN 20/2020 - Amendment - (on implementing directives EU 2020/360, 2020/361, 2020/364, 2020/365 and 2020/366) Pravilnik NN 87/2020

👁 (In force) Italy: Implementation of RoHS Recast Directive 2011/65/EU, Legislative Decree No. 27, 2014 - Amendment - (on implementation of Directive (EU) 2017/2102) Legislative Decree No. 42, 2020

👁 (In force) Croatia: Restriction of Hazardous Substances in Electrical and Electronic Equipment, Pravilnik NN 20/2020

👁 (In force) Lithuania: RoHS Market Surveillance Rules, Order 4-459, 2008 - Amendment - (on an exemption for lead and cadmium in certain products) Order No. 4-728, 2020

👁 (In force) Cyprus: Restrictions on Hazardous Substances in Electrical and Electronic Equipment, Regulation 203/2014 - Amendment - (on implementation of Directive 2017/2102) Regulation 40/2020

Ask our Experts   ❓ Help

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Recent RoHS Developments - Standard EN IEC 63000:2018

- On 18 May 2020 EU Commission published Decision (EU) 2020/659 in the OJ declaring Standard EN IEC 63000:2018 as a RoHS Harmonised Standard

- It replaces EN 50581:2012 and sets out the technical documentation to be used to show compliance with applicable chemical restrictions.

- A transition period has been provided until 18 November 2021, allowing manufacturers to use both standards to demonstrate conformity and giving them sufficient time to adapt to the new standard.

- Benefit of the new standard is that it can ensure same approach from manufacturers everywhere.

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Proposed RoHS Measures

- Brazil: Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment, Working Document, September 2018

- Argentina: Management of Waste Electrical and Electronic Equipment, Bill 0703-D-2016

- Indonesia: Applying Rules on Restrictions to Hazardous Substances in Electrical Equipment, Draft Guidelines 2016

- Jordan: Certain Hazardous Substances in Electrical and Electronic Equipment, Draft Technical Regulation, May 2012

- GCC: Restriction on the Use of Hazardous Substances in Electrical and Electronic Equipment, Draft Regulation, March 2018

- Nigeria: Communications Industry E-waste, Draft Regulations, 2018

- Bangladesh: Management of Waste Generated from EEE, Draft Regulations January 2019

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RoHS Exemptions - background

Ten substances restricted under RoHS Directive 2011/65/EU. Despite these restrictions, it is possible to use a restricted substances *if* there is an *valid exemption* for *your use* or application. Exemptions can be availed of by any company not just the applicant once your use falls within the exemption.

At least one of 3 criteria must be met to secure an exemption: -

- Substitution is technically impractical
- Reliability of substitute not ensured
- Overall environmental, health & social impact of substitute is greater than that of RoHS substance

Exemptions are temporary & will expire unless renewed.

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RoHS Exemptions - background

Many exemptions are in place and relate to different categories of products.

- Annex III - most product categories

- Annex IV - categories 8 & 9 (medical devices and monitoring & control instruments)

The maximum validity of an exemption in respect of Annex III is 5 years and for Annex IV it's 7 years. It takes approximately 18 months for an exemption request to be considered. If a request is made in respect of an existing exemption, the exemption will remain valid until a decision is made by the Commission to ensure business continuity.

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RoHS Exemptions - current status

Talking point currently due to a surge of renewal requests having to be made before January 2020 and now, coming down the tracks, there is a high volume of exemptions due to expire on 21 July 2021.

- Annex III - 57 requests
- Annex IV - 24 requests

To track requests EU maintains a useful spreadsheet listing pending requests and their status. Also, one can see documents submitted by applicants.

https://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm

The full list of exemption requests submitted to the Commission between November 2019 and January 2020 can be consulted here.

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RoHS Exemptions

Concern in Industry whether exemptions such as 6(a), 6(b) 6 (c) , 7(a) and 7(c)-1 of Annex III, which are set to expire in July 2021, will be renewed. The assessment of these requests was suspended due to the fact that the applicant, who submitted the renewal requests for these exemptions, could not provide sufficient information to proceed with the request despite several clarifying consultations. It is understood that these requests will remain valid and are due to be assessed under a new study work package.The study is currently going through the tendering process and the indicative timeline for its launch is October this year.

Raft of Consultant Questionnaires were published in October with a deadline for comments date of 2nd December 2020 on Exemptions 1, 1(a), 1(b), 1 (c), 2, 3, 5, 11, 13, 14, 15, 17, 26, 29, 31(a) & 39 under Annex IV.

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Conflict Minerals

Conflict Minerals - background

- EU Conflict Mineral Regulation (EU) 2017/821 - in force since **2017**

- Aims to help stem trade in tin, tantalum, tungsten & gold (3TG) - may be mined using force labour or finance armed conflict.

- It includes a list of covered minerals and metals - Annex I

- It applies to both individuals and companies

- It doesn't apply to

  - EU importers who import less than a certain amount

  - Recycled metals or stocks created before February 2013
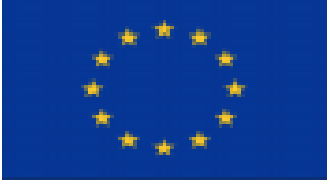
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Conflict Minerals - deadline approaching

- From **1 January 2021** - EU importers of 3TG will have to carry out due diligence on their supply chain - i.e. will have to check where the minerals and metals they import come from and whether they have been processed responsibly. This is to ensure there is no forced labour in the supply chain and that are not funding armed groups in areas of conflict.

Online portals being developed to submit information such as EC's Due Diligence Ready! Portal and another being developed by the European Partnership for Responsible Minerals (EPRM) called the EPRM Knowledge Portal.

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Conflict Minerals - due diligence reporting

Importers are to follow OECD Due Diligence Guidance 5 Step Framework

OECD Due Diligence Guidance 5-Step Framework	Corresponding article number in the EU Conflict Minerals Regulation
1 Establish strong company **management systems**	4
2 Identify and assess **risk** in the supply chain	5
3 Design and implement a **strategy** to respond to identified risks	5
4 Carry out an independent **third-party audit** of supply chain due diligence	6
5 **Report** annually on supply chain due diligence	7

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Conflict Minerals - proposed amendment

Proposed amendment to the Conflict Mineral Regulation - amends Annex I by establishing volume thresholds for 3TG and their ores. This is due to the fact that the volume thresholds were not included in the Annex I. It was proposed in June 2020 & will come into force 20 days after official publication in the Official Journal.

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Connected Products

Connected Products - background

With smart or connected products come sophisticated interdependencies between hardware, software, network & the data. Liability becomes more complicated, making it more difficult to determine who is responsible when something goes wrong. Is it the :

- Manufacturer
- Individual in their use of the product
- Software designer
- App provider
- Network provider
- 3rd party cyber attacker ?

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Connected Products - product liability

Developments in IOT, digitalisation, AI, robotics and concerns around cybersecurity, has prompted the EU to consider :

Whether the EU Product Liability Directive 85/374/EEC was fit for purpose?

This resulted in 2017 Public consultation which concluded it was still broadly fit for purpose, but that traditional concepts of "producer", "product", "defect" and "damage" were being challenged by the emergence of new technologies and increasingly complex products.

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Connected Products - product liability

In response, Commission set up an expert group on liability and new technologies with 2 formations:

- The 'product liability formation' will assist the Commission in drawing up guidance on the Directive.
- The 'new technologies formation' will assess the implications of emerging digital technologies for the wider liability frameworks at EU and national level.

In May 2020 Commission published a Commission Staff Working document on the Evaluation of the Directive, purpose being to evaluate the functioning & performance of Directive form 2000-2016 & also whether it remains fit for purpose. Concluded lack of empirical data to allow for conclusive statement on new technologies. Doesn't appear to be a significant number of incidents were Directive was unable to apply. More fact finding required.

Connected Products - product safety

In June, EU Commission launched a Consultation to conduct a review of General Product Safety Directive 2001/95/EC which ran until 1 September 2020. As the Directive was 20 years old, the Commission felt it was necessary to check whether it was keeping pace with developments.

Among the items to be considered was the challenges posed by connected products as they call into question the definition of the product and may give rise to new risks or alter the way existing risks could manifest and challenge the notion of placing products on the market.

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Connected Products - radio equipment

Additionally, the EU opened a Consultation on the RED Directive from May until 14 September on whether to introduce laws to deal with software that alters the safety or compliance of connected products.

It concerns the market access of radio equipment that can be reconfigured by certain software. Examples of radio equipment include mobile phones, laptops, radio connected-peripherals, smart domestic appliances, radio-controlled, wearables and more.

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Connected Products - cybersecurity

The EU Cybersecurity Act (CSA) 2019 sets out an EU cybersecurity certification framework with the aim of ensuring an adequate level of cybersecurity ICT products, services & processes. Under the Act ENISA (EU Agency for Cybersecurity) is tasked to prepare and develop candidate cybersecurity certification schemes with the involvement of stakeholders. On 2 July 2020 ENISA released a draft candidate scheme for cybersecurity certification for ICT equipment

- Applicable to ICT products;
- Certificate validity for five years, can be renewed;
- Allows for composite certification;
- Recognition in all EU Member States;
- Voluntary scheme;
- Harmonised conditions for vulnerability handling and disclosure;

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Covid-19 - regulatory impacts

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Covid 19 - regulatory impacts

Covid-19 Pandemic has brought disruption and uncertainty. Priorities have shifted, remote working has become commonplace and resources may be reduced making it more challenging across the board to get work done.

It has caused disruption in many areas, such as in the supply chain, around the certification & inspection of products. Can companies meet upcoming compliance deadlines ? We've seen deadlines being pushed out.

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Covid 19

Argentina: validity of energy performance certificates for household electrical appliances extended for the second time - 1 October 2020 (Resolution 252/2020)

Brazil: certificates issued by ANATEL may be maintained based on presentation of declarations, test reports & photos until 30 December 2020.

Thank you!

Today's webinar recording will be made available on the ECIA Training & Resources page. Visit www.ecianow.org.

Email Louise at l.forrest@complianceandrisks.com

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