

Agenda

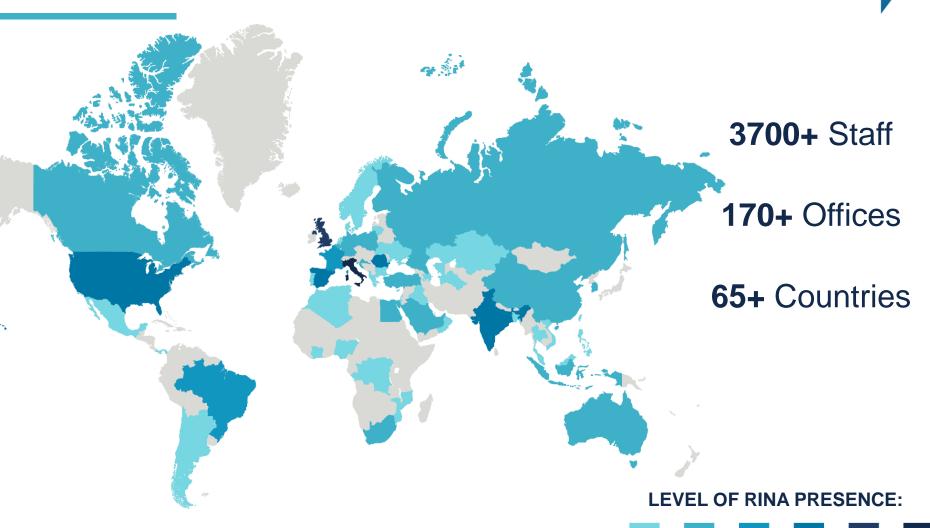


- 1. RINA in brief
- 2. SCIP database overview
- 3. What are the obligations
- 4. Confidential business information
- 5. SCIP database information requirements
- 6. Data simplification methods
- 7. On-going SCIP obligations
- 8. Recommendations and conclusions

RINA worldwide



→ high



RINA capability





About Product Regulatory Compliance



- We support the European Commission, manufacturers, importers and distributors of electrical and engineering products to identify, understand and meet technical and environmental legislation
- Compliance & Risks Knowledge Partner since 2008



SCIP Database Requirements





SCIP = Substances of Concern In articles, as such or in complex objects (Products) Database

 SCIP is a database set up by the European Chemicals Agency (ECHA) to collect data on REACH Substances of Very High Concern (SVHCs) in "articles"

What is it intended for?

- SCIP was adopted by the EU as part of the Waste Framework
 Directive. Its aims are stated (by the EU) to be:
 - To make available SVHC data to the public and business users
 - To provide information to recyclers (unclear how they would affectively use the information)

SCIP Database Scope



Scope and definitions

- Applicable to all "articles" supplied in the EU from <u>5 January 2021</u> containing SVHC's >0.1% w/w
- Articles are defined as products whose shape is more important than their composition
 - This is the same definition as the REACH Regulation
- Data is needed for all "simple articles" as well as for complex products that consist of many articles

Who will be required to submit data?

- All importers into the EU of articles
- All producers and assemblers of articles within the EU supply chain (except exporters of products out of the EU)

SCIP Database Scope



Circumstances where it will not be required to submit data?

Direct supply

 Articles supplied directly and exclusively to consumers, without the participation of a distributor or other actor in the supply chain

Repair

 Articles or complex objects that are repaired, provided that they are not supplied to another legal entity

Export

Items produced or assembled solely for export outside the EU

End of life

 Users of articles that reach their end of life and become waste do not need to submit data

Defence

 Member State may choose, where necessary, to allow for an exemption for the interests of defence

UK Obligations



- The scope of the regulation applies to all products, containing a SVHC >0.1% w/w within the EU
- UK Government has not released any plans indicating that there may be a UK SCIP requirement
- DEFRA have confirmed there is no requirement for NI based suppliers of articles, as it is not listed in Annex 2 of the Northern Ireland Protocol
- However, EU customers may request information to be able to support their submissions

SCIP Database Submission



- Submission is to ECHA via the EU SCIP Database using IUCLID Dossiers
 - Version 1 database now released (available since 28th October 2020)
 - Prototype database still available for trial submissions
 - >50,000 submissions already

- SCIP notification can be prepared by:
 - 1. Online in IUCLID Cloud



2. 'Offline' in company's own IT infrastructure in IUCLID 6



3. System-to-system method



SCIP Database



EUROPEAN CHEMICALS AGENCY				
			ECHA UNDOFAN CHEMICALS AGENCY	Need help?
ECHA Cloud Services Welcome to ECHA Cloud Services			Important information on ECHA apps availability	
			WELCOME Please enter your login information	
	Login If you already have an ECHA Account, for example to access REACH-IT, please log in here. Log in	Register If you do not have an ECHA Account, you can create one and then assign a legal entity to it. For more information please see the Q&A. Register	Username * Password * Forgot password * Login with "ECHA Account"	_
(https://ecs.echa.europa.eu/cloud/home.html)			Don't have an account? Create an ECHA account.	nt
			Login with "EU Login"	

- Requires an ECHA account with a Legal Entity assigned to it to be able to submit data
- Some of the data required is mandatory and submission is not possible if some of this is missing

Confidential Business Information



- The information in the SCIP database is made publicly available
- SCIP will not disclose the link between the Notification and its submitter
- Responsibility of confidentiality relies on the duty holder

Complex object identification



Name: Pencil sharpener

Brand: Deneb® Model: FC500

Identifier 558877899 (bar code) Article Category (CN Code): 821410

Component of a complex object identification

Name: Blade Brand: ALTAIR ® Model: Altan 500 Identifier 111xyz111zyx Article Category (CN Code): 821410

+ safe use instructions, disassembling instructions and characteristics

SCIP Database Information Requirements



What information is needed:

- 1. Identification of the article;
- 2. The name, concentration range and location of the Candidate List substances present in it; and
- 3. Information that allows its safe use notably information to ensure the article is properly managed once it becomes waste.







 Additionally, certain types of optional data may also be submitted (such as a photograph of the article, brand names, etc.)

SCIP Database Information Requirements



Mandatory Information

Article name

Primary article identifier

Article category

Is it produced in the EU?

Safe use instructions

Candidate List substance

Concentration range

Material category

Mixture category

Optional Fields

Article characteristics

Disassembling instructions

Changes between Prototype and V1:

- IUCLID 6.5- may require upgrade, details on IUCLID website.
 - Update substance package
- 'Candidate List Version' removed
- PICK lists have changed in items in Bold
- Visualisation and terms in the database

Data Simplification (1)



Ways of simplification by using suppliers SCIP numbers:

- Simplified SCIP Notification (SSN): no change (form/composition/data attributes), aimed at distributors
- Referencing: incorporation into a complex object



Benefits:

- No dossier required in the submission- Lower data management requirements
- Automatic Updates

Results in a New SCIP number (LE + Article Information)
Requires the communication of the SCIP number (voluntary basis)

Data Simplification (2)



Ways of simplification:

Quasi-identical articles: similar articles.

Grouping is allowed by ECHA when:

- The articles have the same function/use;
- The articles contain the same Candidate List substance;
- The material that the article is made of is the same; and
- The safe use instructions are the same for all articles in the group.

Requires the identification of each identical article (e.g. names and alphanumeric identifiers) are included in the notification- e.g. In other article identifiers

Data Simplification (3)



Ways of simplification:

- Representative article: worst case article (May contain Nuts)
 - Useful for 'multi-sourcing' issues
 - Concerns on right to know, ability to recycle and reduce pressure to find alternative
 - May not be supported by all Member States

ECHA recommendation: Could it be applied temporarily for certain very complex objects, at a company's own risk, while progressively adapting their IT tracking tools and reporting methods to the extent possible by aligning them with the criteria for grouping of quasi-identical complex objects?

On-going SCIP obligations



Dossier updates should be completed by same Legal Entity, using the same primary article identifier:

- Mandatory Update-at point of supply
 - A substance present in an article already notified is included in the Candidate List after 5 January 2021
 - An already listed SVHC on the Candidate List substance is incorporated in one of the component articles, due to e.g. a change in production or you become aware of the presence of that substance
 - A component in a complex object already notified requires a change in notification

On-going SCIP obligations



- Optional (although recommended by ECHA) Update
 - Removal of a Candidate List substance from a previously notified (component) article, for instance due to successful substitution effort, to indicate that the substance is no longer present

Conclusions



SCIP database – mandatory for any article supplied in the EU from 5th January 2021

- Scope all "articles" supplied within the EU
- Most producers/assemblers/importers within the EU will be required to submit data
- Requirement triggered when you become aware of a SVHC
- Need to obtain all mandatory data before submitting
- Reduce the data requirements where possible
 - Simplified Notification, Referencing, Quasi-identical articles and Representative article

RINA SCIP * Service







SCIP policy authoring



Business impact advice



Training



Supply chain engagement

- Legal obligation on all who supply articles in the EU from 5 January 2021
 - arises from the Waste Framework Directive
- RINA can help you
 - understand your obligations
 - prepare, simplify and validate your SCIP submissions
 - upload your SCIP submissions system-to-system



provide evidence of compliance

Copyright RINA Tech UK Ltd.

^{*} Substances of Concern In articles, as such or in complex objects (Products) Database



Questions?





Worldwide Regulation

Batteries

T. +44 1372 367350 productregulation@rina.org | www.rina.org Cleeve Road, Leatherhead, Surrey KT22 7SA, UK