

SVHCs in Articles –The SCIP Database

REACH: Legal Updates and Future Trends Academy of European Law

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SCIP – Outline

1. **Legal Framework**
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SCIP Legal Framework

DIRECTIVE (EU) 2018/851 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 30 May 2018
amending Directive 2008/98/EC on waste
(Text with EEA relevance)

“[Member States must] ensure that any **supplier** of an **article** as defined in point 33 of Article 3 of [REACH] provides the **information pursuant to Article 33(1)** of [REACH] to [ECHA] as **from 5 January 2021;**”
(Art. 9(1)(i))

“[ECHA] shall **establish a database** for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2021 and maintain it. [ECHA] shall provide **access** to that database to **waste treatment operators**. It shall also provide **access** to that database **to consumers upon request.**” (Art. 9(2))

SCIP Legal Framework

DIRECTIVE (EU) 2018/851 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 May 2018

amending Directive 2008/98/EC on waste

(Text with EEA relevance)

“When products, materials and substances become waste, the presence of hazardous substances may render that waste unsuitable for recycling or the production of secondary raw materials of high quality. Therefore, in line with the 7th Environment Action Programme, which calls for the development of non-toxic material cycles, it is necessary to promote measures to reduce the content of hazardous substances in materials and products, including recycled materials, and to ensure that sufficient information about the presence of hazardous substances and especially substances of very high concern is communicated throughout the whole life cycle of products and materials. In order to achieve those objectives, it is necessary to improve the coherence among the law of the Union on waste, on chemicals and on products and to **provide a role for the European Chemicals Agency to ensure that the information about the presence of substances of very high concern is available throughout the whole life cycle of products and materials, including at the waste stage**” (Recital 38)

SCIP Legal Framework

► **CI REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

- Art. 3(33): “supplier of an article: means any **producer** or **importer** of an **article**, **distributor** or other actor in the supply chain placing an article on the market;”
- Art. 33(1): “Any supplier of an article containing a substance meeting the criteria in Article 57 and **identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w)** shall provide the recipient of the article **with sufficient information, available to the supplier**, to allow **safe use of the article** including, as a minimum, the **name of that substance.**”

SCIP Legal Framework

► **REGLAMENTO (CE) Nº 1907/2006 DO PARLAMENTO EUROPEU E DO CONSELHO**

de 18 de Dezembro de 2006

relativo ao Registo, Avaliação, Autorização e Restrição de Produtos Químicos (REACH),

- Article 59(1): “The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).”
- Substances meeting the Article 57 Criteria: SVHCs, *i.e.*, Cat. 1A and 1B CMRs, PBTs, vPvBs, substances raising an equivalent level of concern (e.g., endocrine disruptors).
 - Candidate List currently includes around 209 substances and it is updated regularly

SCIP Legal Framework

What is an “article”?

- “Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition” (Article 3(3) REACH)

Case C-106/14

“The question whether a complex product itself may be classified as an article therefore turns solely on a determination according to the criteria laid down in Article 3(3) of that regulation” (para 50)

“only if the production of an object using a combination of more than one article gives that object a special shape, surface or design which is more decisive for its function than its chemical composition that that object may be classified as an article. Accordingly, unlike a simple assembly process, that production process must alter the shape, surface or design of the articles used as components” (para 51)

“That does not necessarily mean, however, that the articles used in that production process thereby cease to be articles.” (para 52)

ECHA SCIP Implementation



Requirements for SCIP notifications

October 2020



SCIP Database Notifications

How to prepare and submit a SCIP notification



Validation rules for SCIP notifications

October 2020

Q&As

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Waste Framework Directive - SCIP database

Background



Introduction

Webinar: Getting ready for submitting SCIP notifications

19 November 2020



Tools to refer to SCIP data already submitted to ECHA

August 2020

Ref. Ares(2019)3596110 - 20/06/2019



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Circular Economy & Green Growth
ENV.B.3 - Waste Management & Secondary Materials

Non-paper on the implementation of articles 9(1)(f) and 9(2) of the revised Waste Framework Directive 2008/98/EC

SCIP – Who Must Notify?

Legal Provisions

“any **supplier** of an **article**”
(Art. 9(1) (i) WFD)

REACH

“supplier of an article: means any **producer** or **importer** of an **article**, **distributor** or other actor in the supply chain **placing an article on the market**” (Art. 3 (33))

producer of an article: means any natural or legal person who **makes or assembles** an article within the Community” (Art. 3(4))

“importer: means any natural or legal person established within the Community who is responsible for import” (Art. 3(11))

“distributor: means any natural or legal person established within the Community, **including a retailer**, who only stores and places on the market a substance, on its own or in a, for third parties” (Art. 3(14))

“recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers” (Art. 3(35))

ECHA Implementation

1. EU Producers
2. EU Assemblers
3. EU Importers
4. EU Distributors

- Each and every supplier
- Not retailers (that are not producers or importers)
- Must be in the EU
 - “foreign user” functionality
- Foreign online platforms?
- Import for self-use?
- Referencing
- Simplified SCIP Notification

SCIP – When to Notify?

Legal Provisions

“any **supplier** of an **article** [...] provides the **information pursuant to Article 33(1) [of REACH]** as from **5 January 2021**”

(Art. 9(1)(i) WFD)

“[...] supplier of an **article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w)**”

(Art. 33(1) REACH)

“article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition” (Article 3(33) REACH)

Case C-106/14

- Complex articles

ECHA Implementation

“**after 5 January 2021**, if substances present in an article placed on the EU market in a concentration above 0.1% w/w are added to the Candidate List, **the supplier of that article needs to submit a SCIP notification or update a previous submitted SCIP notification for that article at the time of the next supply or placement on the market** to any customer or as a result of an import, after the substance has been included in the Candidate List”

- Each and every supplier (not retailers)
 - Simplified SCIP Notification
- Including articles in complex articles
 - Referencing
- Member States may provide military defense exemption
 - packaging of medicines in finished state intended for the final user?
 - (invasive or in direct physical contact) medical devices?

SCIP – What to Notify?

Legal Provisions

“any supplier of an article [...] provides the **information pursuant to Article 33(1)** [of REACH] as from 5 January 2021” (Art. 9(1)(i) WFD)

“Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with **sufficient information, available to the supplier**, to allow **safe use of the article** including, as a **minimum, the name of that substance**” (Art. 33(1) REACH)

“ensure that the information about the presence of substances of very high concern is available throughout the whole life cycle of products and materials, **including at the waste stage**” (Recital 38 of WFD)

Case C-106/14

- Complex objects

SCIP – What to Notify?

ECHA Implementation

1. Common Requirements for Articles and Complex Objects

- Identification of the duty holder and its contact details (Mandatory “M”)
- Name of the article (M)
- Other names (Optional “O”)
- Primary article identifier (M)
- Other identifiers (O)
- Article category (M)
- Production in the EU (Required “R”)
- Characteristics and picture of article (O)
- Statement that identification of Candidate List substance is sufficient to ensure safe use (R)
- Safe use instructions (R)
- Disassembling instructions (O)

2. Requirements for Complex Objects

- Links to a complex object component (M)
- Number of units (O)

3. Requirements for articles

- Identification of Candidate List substance (M)
- Concentration range of the Candidate List substance (R)
- Material category of the article (M)
- Additional material characteristics (O)
- Mixture category that contains the Candidate List substance (M)

Information submitted must be kept up to date!
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SCIP – ECHA Simplification Procedures

Grouping

1. **Identical articles:** (i) same function or use; (ii) same physical form (shape, surface and design); and (iii) same chemical composition
 2. **Quasi-identical articles:** (i) same function or use; (ii) contain the same Candidate List substance; (iii) same material or the Candidate List substance is incorporated in them by using the same mixture category; and (iv) safe use instructions are the same
 3. **Quasi-identical complex objects:** (i) same function or use; (ii) same components and subcomponents; and (iii) safe use instructions are the same
- **Identical articles:** one notification per supplier
 - **Quasi-identical articles:** one notification per supplier but need to identify each subgroup of fully identical articles
 - **Quasi-identical complex objects:** one notification per supplier but with a specific article primary identifier

SCIP – ECHA Simplification Procedures

Referencing

- Possibility for the notifier of a complex object to refer to the prior notification of an article or other complex object up the supply chain
- Reference to notification of the same or another notifier
- Conditions: (i) no changes in physical form or composition of referenced article/complex object; (ii) referenced article must be component of more complex object notified; (iii) referenced article cannot have additional components linked to it; and (iv) linking to suppliers' notification

SCIP – ECHA Simplification Procedures

Simplified SCIP Notification

- Possibility to refer to information already submitted to ECHA by submitting only the existing and relevant SCIP number (*i.e.*, without the need to prepare a dossier)
- Must receive the SCIP number of the article's or complex object's SCIP notification already submitted to ECHA
- The article or the complex object subject to the SCIP notification including all required information is the same as the article or complex object that has already been notified
- Main target –distributors in same supply chain
 - But also parallel imports
 - Sister companies within a group
 - Companies with exclusivity rights
 - Other?
 - There must be a contractual agreement among the notifiers

SCIP – Dissemination and CBI

Legal Provisions

“[ECHA] shall **establish a database** for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2020 and maintain it. [ECHA] shall provide **access** to that database to **waste treatment operators**. It shall also provide **access** to that database to **consumers upon request**”
(Art. 9(2) WFD)








Regulation (EC) No 1049/2001 on Access to Documents

- related case law on access to information on environmental emissions

ECHA Implementation

- Database with information will be publicly available: (i) waste operators; (ii) consumers; and (iii) authorities
- ECHA will publish information as received
- ECHA will not publish “required mandatory data” that would allow the establishment of links between actors in the same supply chain:
 - link between the SCIP notification and its submitter (Legal Entity)
 - specific names (*e.g.*, brand, model) or alphanumeric identifiers of components of complex objects
- Notifier is responsible for ensuring that submitted information is not CBI or sensitive

Implementation of Article 9(1)(i) of WFD (Work in Progress)

Member State	Implementation Status	Penalties / Enforcement Measures
 <p>Belgium</p>	<ul style="list-style-type: none"> Implemented at Federal Level by Royal Decree of March 23, 2020 	<ul style="list-style-type: none"> Imprisonment: between eight days and three years; and/or Criminal fine between €1,280 and €32 million Publication of the sanction decision Closure of business premises between four months and one year Prohibition to perform certain business activities for a period of maximum 10 years (only in case of recidivism)
 <p>France</p>	<ul style="list-style-type: none"> Implemented by Ordinance 2020-920 of July 29, 2020. It modifies Article L. 521-5 of the French Code of the Environment 	<ul style="list-style-type: none"> Administrative fine of up to €15,000 and a daily penalty of €1,500 Possible ban on the imports, production, marketing/ or withdrawal of the substances, mixtures, products, etc. from the market
 <p>Germany</p>	<ul style="list-style-type: none"> Implemented by "Gesetz zur Umsetzung der Abfallrichtlinie der Europäischen Union" of October 23, 2020 ("Law on the implementation of the Waste Framework Directive of the European Union") that adds a new Section 16f to the German Chemicals Law 	<ul style="list-style-type: none"> To be implemented
 <p>Italy</p>	<ul style="list-style-type: none"> Implemented by Legislative Decree 116/2020 that amends the Italian Code of the Environment (Legislative Decree 152/2006) 	<ul style="list-style-type: none"> To be implemented
 <p>Poland</p>	<ul style="list-style-type: none"> Not implemented yet Draft proposal submitted (still early stage in legislative process) 	<ul style="list-style-type: none"> Fine of between PLN 20 and PLN 5,000 (~ €4.6 and €1,100)
 <p>Portugal</p>	<ul style="list-style-type: none"> Not implemented yet 	<ul style="list-style-type: none"> To be implemented
 <p>Spain</p>	<ul style="list-style-type: none"> Not implemented yet Draft proposal submitted 	<ul style="list-style-type: none"> Fine of up to 10,000 EUR

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