

SCIP IT user group

28 Jan 2021





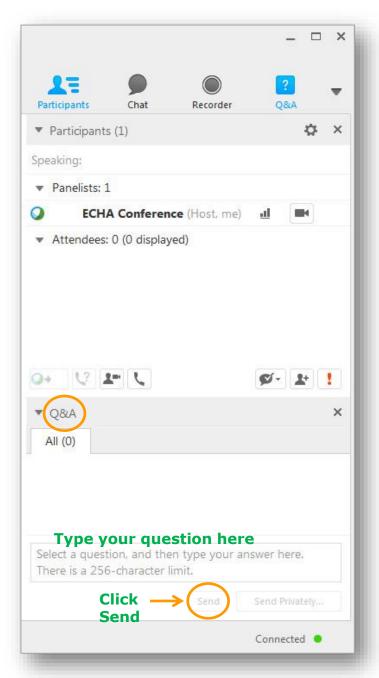
Opening remarks

- Practicalities
 - Webex instructions
 - For the floor, raise your hand
 - To ask a question: use the Q&A panel at any time.
 - Audio recording to support minutes

Additional comments and questions:

scip@europa.echa.eu

Include on the subject: "SCIP IT user group"







Today's agenda

- SCIP Figures
- Main questions received at Helpdesk
- Tips and recommendations for successful S2S integration
- Limit set for complex SCIP dossiers
- Candidate List & SCIP
- Share your experience
- SCIP Next phase

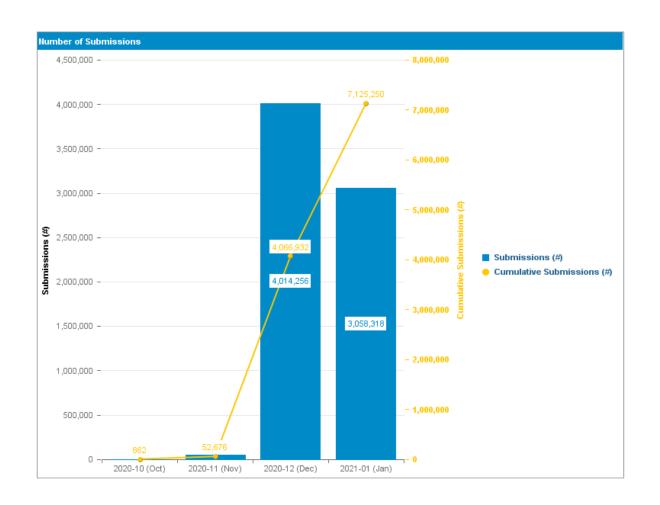
SCIP Figures

Clara Rueda & Saara Sumiala





Number of submissions



Time period: 26.10 - 27.01.2021

No of Legal entities 2,984



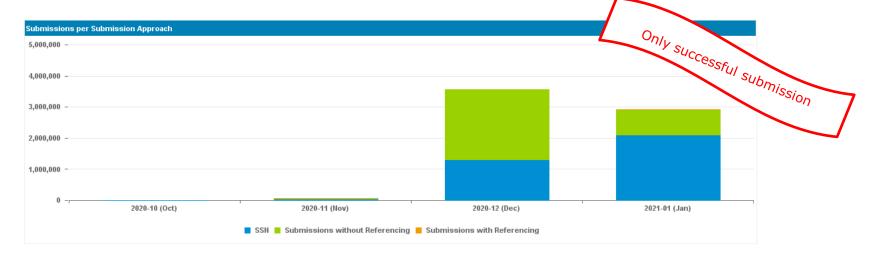
Submission Channel

	Submission from IUCLID Cloud		Upload in the portal and submit		Submission via S2S	
	(#)	(%)	(#)	(%)	(#)	(%)
October	107	12.41%	742	86.08%	13	1.51%
November	4,134	7.98%	18,272	35.26%	29,408	56.76%
December	25,551	0.64%	392,923	9.79%	3,595,817	89.58%
January	15,183	0.50%	464,521	15.19%	2,578,614	84.31%

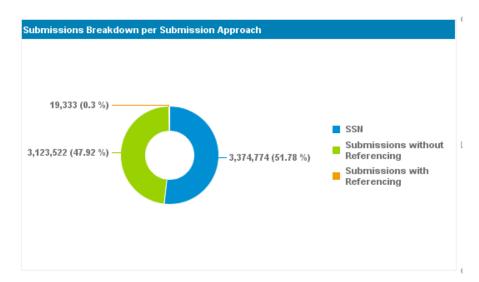
Time period: 26.10 - 27.01.2021



Submission approach



- Simplified SCIP notification
 (SSN) does not require the
 submission of a IUCLID dossier;
 Under this submission approach
 the duty holder (e.g. distributor)
 refers to information already
 submitted to ECHA by other duty
 holder.
- Both submissions with and without referencing require the submission of an IUCLID dossier



Time period: 26.10 - 27.01.2021



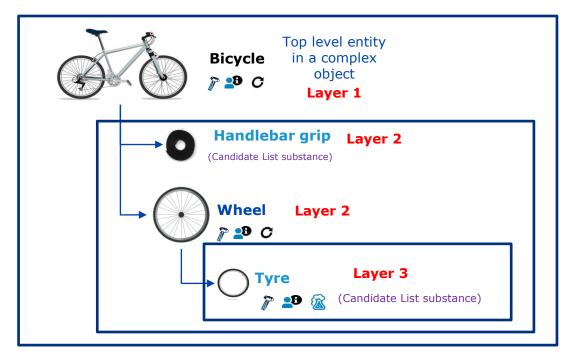
Complexity of dossiers – number of layers

Layer	Submissions (#)	(%)
L1	2,476,328	81.40%
L2	278,907	9.17%
L3	38,157	1.25%
L4	29,805	0.98%
L5	34,442	1.13%
L6	120,262	3.95%
L7	50,521	1.66%
L8	4,518	0.15%
L9	9,354	0.31%
Total	3,042,294	

The table displays the number of succeed submissions per each different layer number dossier.

Note: It does not include information about submissions using tools to refer to data already submitted.

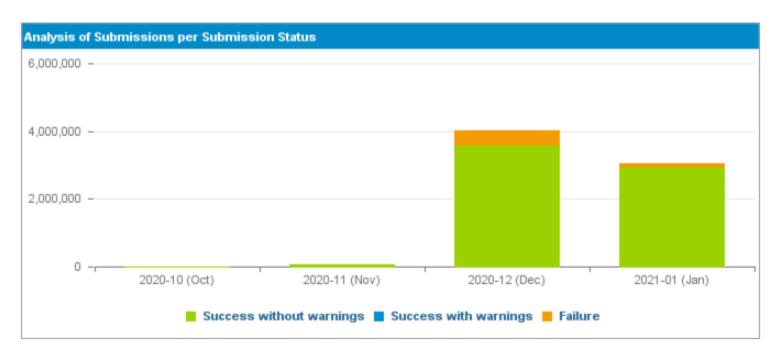








Successful/unsuccessful submissions



The failure rates (due to S2S tuning) has been stabilized. We published S2S recommendations and best practices to prevent the repetition of similar situations with new S2S users; We are updating our S2S manuals;

Success (with or without warnings): the submission has passed the validation checks and the dossier has been forwarded to the SCIP database.

Failure: the submission has failed the validation checks and the dossier has not been forwarded to the SCIP database. The validation checks have been implemented to ensure the submission of minimum requirements

Time period: 26.10.2020 - 26.01.2021



Success rate

The January success rate is:



Time period: 01.01.2021 - 26.01.2021



No of common errors on validations

[BR719] Same notification cannot be submitted multiple times.

[BR718] update dossiers **creation date must be newer** than the previously accepted dossiers creation date

[BR729] SSN: Same notification cannot be submitted multiple times.

[BR731] Non-EU companies are not allowed to submit SCIP notifications

[BR730] SSN: 'SCIP number' should be valid

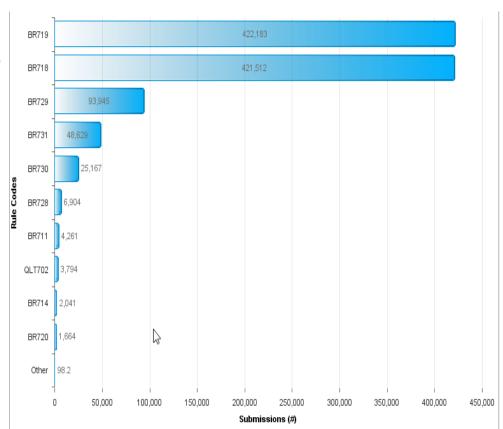
[BR728] SSN: The **'SCIP number**' that is used for referencing belongs to the **same legal entity** that is submitting the notification. Simplified SCIP notification cannot refer to a 'SCIP number' from the same legal entity.

BR711 'Article' cannot be reporting information regarding both 'Complex object component(s)' and 'Concern elements'.

QLT702 The provided 'Reference substance' has **conflicting identifiers**.

BR714 All the 'Concern element' blocks provided should be complete: 'Material category' or/and 'Mixture category' (EUPCS)' must be indicated. If 'Material category' is selected to be 'other:', then the adjacent field must be filled in.

BR720 Same 'Article' record cannot be reported more than once as 'Complex object component' from the same 'Article' record



Time period: 26.10.2020 - 26.01.2021





	Rule	Description	Portal / VA	Hits
1	[BR729]	SSN : Same notification cannot be submitted multiple times.	Portal	72 561
2	[BR731]	Non-EU companies are not allowed to submit SCIP notifications	Portal	31 299
3	[BR730]	SSN : 'The indicated 'SCIP number' must be related to successful submission in the ECHA Submission portal	Portal	23 728
4	[BR718]	If an SCIP notification is updated, then the update dossiers creation date must be newer than the previously accepted dossiers creation date.	Portal	8 867
5	[BR719]	Same notification cannot be submitted multiple times.	Portal	8 796

Time period: 01.01.2021 - 26.01.2021



Top 5 Validation rules (warnings) (January 2021)



	Rule	Description	Portal / VA	Hits
1	QLT702	The provided 'Reference substance' has conflicting identifiers	VA	1 820
2	QLT701	All reported 'Reference substances' must be mentioned in 'Candidate list'.	VA	163
3	QLT704	Other names: If you wish to provide information regarding 'Other names', then make sure that you have provided both the 'Type' and 'Name'	VA	102
4	QLT713	Characteristics: Volume: If you wish to provide information regarding 'Volume', then make sure that you have provided both the value and unit.	VA	9
5	QLT709	Characteristics: Width: If value was provided then the adjacent unit must be provided. If unit was provided then the value must be provided.	VA	5

Time period: 01.01.2021 - 26.01.2021



Help

SCIP Support

SCIP support

Support materials and questions and answers are available to help companies understand the SCIP database and to prepare their information on articles that contain Candidate List substances in a concentration above 0.1 % w/w. If you cannot find the information you are looking for, you can contact ECHA.



Information requirements

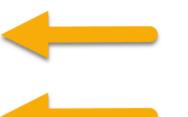


- Requirements for SCIP Notifications [PDF] [EN]
- Materials categories for the SCIP database [PDF] [EN]

SCIP Database Notifications



- Key tips for successful SCIP notifications [PDF] [EN]
- How to prepare and submit a SCIP notification [PDF]
 [EN]
- Tools to refer to SCIP data already submitted to ECHA [PDF] [EN]
- Validation rules for SCIP notifications [PDF] [EN]
- Dissemination and confidentiality in the SCIP Database [PDF] [EN]





Help

ECHAs SCIP Database pages 'News' section





Conclusions

- Failure rate is decreasing good trend ©
- (If the system is busy) avoid submitting same dossier multiple times - wait for response!

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Main questions received at Helpdesk

Rúben Gonzalez Vida





How can I determine whether I am a duty holder?

- 1. Determine your legal role
 - Based on REACH definitions and principles of national law
 - EU Member State-based entities
- 2. Understand whether you fulfil the criteria for duty holder

Articles placed on the EU market containing a SVHC above 0,1 w/w

EU suppliers of articles:

- EU producers/assemblers
- EU importers
- EU distributors of articles

*Exceptions for certain articles at national level

*Exceptions for certain actors

Q&A on SCIP duty holders

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How can the work between non-EU companies and EU companies be distributed?

- A. Non-EU companies <u>can</u> create SCIP dossiers/datasets
- B. EU duty holders <u>need</u> to submit SCIP notifications (or an external entity based on common agreement)

SEQUENCE

- 1. Create duty holder account via ECHA Accounts
- Duty holder to allow a <u>third party</u> to submit on their behalf if applicable
 - Foreign user via IUCLID-ECHA Submissions portal / S2S keys via SSN
- 3. Provide information to allow safe use of the articles to customers according to Art. 33(1) REACH

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How can I use SSN for 'sister' companies in the same corporate group?

1. Submit full SCIP notifications using a reference legal entity. Copy the SCIP numbers.

Upload and submission of simplified SCIP notifications in bulk

2. Submit applicable SCIP numbers using the respective 'sister' company account. New SCIP numbers generated.

3. Share new SCIP numbers with downstream users

Nov 2020 SCIP webinar include a DEMO on SSN (1:33 min)

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Please upload information on the articles you wish to notify using an excel file including in each row
- A SCIP number (mandatory information)
- An Article name (optional)
- A Primary article identifier type (optional)
- A Primary article identifier value (optional)



Keep SCIP notification up to date

When?

- a substance present in an article (in a concentration above 0.1% w/w) is included in the Candidate List after 5 January 2021
- a request from a Member State authority to submit additional information to a SCIP notification (e.g the submitted information does not ensure compliance with the SCIP notification duty)
- a change in the composition of a complex object, in terms of components and subcomponents incorporating articles as such containing Candidate List substances;
- any changes that the submitter considers relevant to update a SCIP notification on a voluntary basis (e.g Candidate List substance present in an article has been substituted by a safer alternative)

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Keep SCIP notification up to date

How?

Using IUCLID:

- 1. Update the information included in your dataset.
- 2. Validate the updated dataset.
- 3. Create a new IUCLID dossier. The primary article identifier (type and value) in the dossier needs to remain the same.

How?

Using system-to-system (S2S):

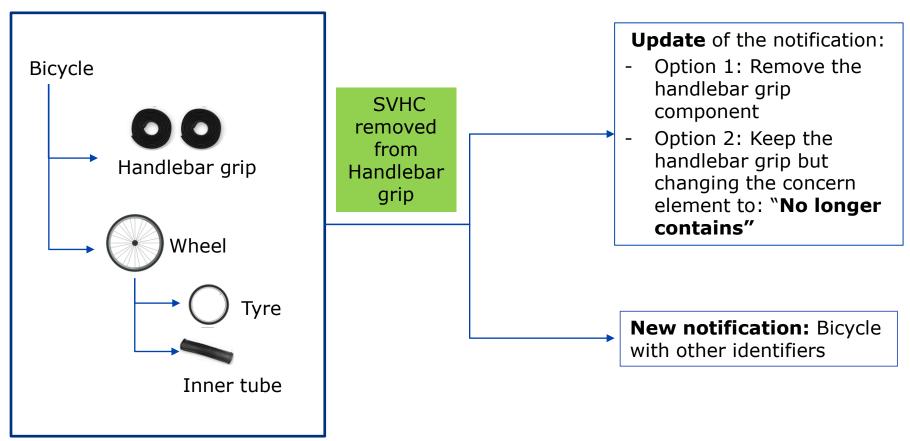
1. Create a new dossier following the SCIP format with the up-to-date information. The primary article identifier (type and value) in the dossier needs to remain the same.

The submission of this dossier will be considered automatically as an update if:

- a. The submission is made using the same ECHA account
- b. The **same primary article identifier (type and value**) is part of your dossier.



Example, Candidate List substance substitution



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Tips and recommendations for successful S2S integration

Ferran Villar Garcia European Chemicals Agency

January 2021





S2S Recommendations and messages

- Reviewing the recommendations provided late Dec
 - S2S When requesting access
 - S2S When submitting dossiers
 - S2S When tracking submission status
- Improvements coming to facilitate integration



S2S – When requesting access

- Try to define a strategy of submission in advance, this will help you to understand how many accounts you need within your organisation. In case of doubts, please contact ECHA.
- You do not need test accounts. The test environments are guaranteed with the current S2S offering. Same Production accounts can be used for testing when setting the right HTTP attributes and headers.
- Once you receive the confirmation that the S2S Keys are configured the assignment of the role and S2S key generation should be possible. In case of trouble please contact ECHA (ECHA Website (europa.eu)).



S2S – When submitting dossiers

- Avoid the submission of big volumes in peak hours which are between 10.00 and 17.00 Helsinki time. We are expecting high levels of activity in our IT-systems due to concurrent regulatory processes. This may lead to some slowness in our tools and systems.
- Wait until you get a response from the ECHA Submission portal and do not abort the connection. Set a sufficiently long timeout in your requests (e.g. 30 seconds or 1 minute), allowing the ECHA Submission portal to respond when the system is busy.
- Do not set an unlimited number of retries when submitting, instead set a small and configurable number of retries (e.g. two retries.



S2S - Submitting dossiers

- Avoid consecutive submission retries without allowing sufficient time to receive a response, instead retry after one hour and if that fails, try the next day.
- Reduce the number of retries. If you reached your limit, contact ECHA.
- Avoid submitting everything in one go. It is preferable to send in batches and verify the status of submissions before moving on with the next batch. In this way, you can avoid having a large amount of submissions failing for the same reason, while the issue could have been spotted since the first one.
- Avoid unattended submissions, monitor your systems and block the automated submissions when a threshold of failed submissions is reached.



S2S Tips – Submitting dossiers

- Avoid the resubmission (e.g. recreating a dossier) when the reason for failure of previous submissions pertaining to the same entity has not been identified. It is possible that the new dossier will fail once more.
- Differentiate between technical and business errors (business rule failures).
 - For additional information please see support documentation available at https://echa.europa.eu/en/manuals?panel=s2s#s2s (on the format tab you can access the validation rules defined for each regulatory context).
 - Classify the response codes differently and retry when the status code indicates a recoverable situation, e.g. HTTP 500 indicates a server error, so need to retry in such cases, while HTTP 400 indicates a Bad request that will also fail in subsequent retries.
 - Failed submissions indicate a final status and requires human intervention in most of the cases to correct the data. Do not automatically retry in such cases.



S2S Tips – Submitting dossiers

- Avoid unnecessary submissions, ensure the quality of the data before submitting your notification (e.g. by validating 'representative' dossiers) and avoid submitting updates to correct minor mistakes.
- The tools to refer to data already successfully submitted to SCIP, Simplified SCIP notification (SSN) and 'Referencing' can also be used via S2S. See the support documentation available at https://echa.europa.eu/en/manuals?panel=s2s#s2s

Note: To safeguard that only articles containing substances of very high concern (SVHCs) on the Candidate List are submitted, ECHA will FAIL the processing of dossiers containing more than 1 200 components. At this stage, ECHA will not prevent their submission (you will still get a submission number), but where needed, dossier submitters will be invited to improve the notification.



Automating the submission status check

- Avoid polling to get the submission report to identify the status of each submission. Instead, get the events related to your submissions.
- Get the submission report when the status is final (either successful or failed) in order to fetch the information related to this submission.
- Polling for events should have an incremental configuration to the submission service. Polling may be continuously performed (no upper limit), while each request is performed each configurable time. The value will depend on the number of submissions, could be 1 min, 1 hour, 6 hours, 1 day.
- In general, we suggest that fetching information can be done in batches, to avoid high numbers of requests for individual checks.

Note: The processing time depends on the volumes that we are receiving. During periods of high levels of activity, you may experience longer processing times, when your submissions will appear with a pending status.



Improvements to facilitate integration

- User Interface UX improvements and facilities
- Multiple S2S keys per LE linking to the user during H1 2021
- API improvements by summer 2021
 - Get submission report: Include the submission history, i.e. all submissions having the same SCIP number
 - Get list of events:
 - Include the SCIP number (PSSI): Allowing the correlation a failed submission, for which the PSSI is reported back, with the initial successful one (in case of duplicates)
 - Include the Dossier UUID: Allowing the correlation of a failed submission, for which the dossier UUID is reported back, with the initial successful one (in case of duplicates) – same case as (a) but different correlation identifier
 - Include a period, define dates in the request (List of events related to the LE's submissions) or provide alternative way of performing such operation



Thank you for you attention!

Limit set for complex SCIP dossiers

Telmo Vieira Prazeres





Dossiers containing more than 1 000 components (1)

ECHA is pausing the processing of IUCLID dossiers containing more than 1 000 components.

ECHA has set this limit to ensure optimised processing and usability of the data for the waste operators and consumers.



Dossiers containing more than 1 000 components (2)

Information in the submission report:

- Submission status: pending
- Submission number is issued
- No SCIP number is issued

Current analysis on how to proceed with submitted dossiers.

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Drawbacks of complex dossiers (1)

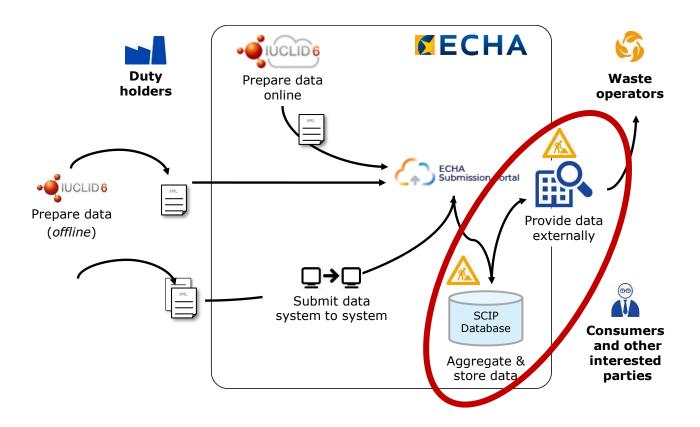
- Large dossier sizes
- Big volumes of data and complex data (potentially not relevant to achieve the objectives of the SCIP database)
- Not easily understandable for waste operators and consumers

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Drawbacks of complex dossiers (2)

Potentially, it transfers to ECHA an disproportionate burden to handle and process irrelevant data.



scip database is
not a 'full'
repository of data
contained in
Companies IT
tracking systems
(to comply with
several legislations
and potentially for
other purposes)



Simplify your dossiers!

ECHA strongly discourages the creation of SCIP notifications for complex objects with more than 1 000 documents in the dossier

- Only submit relevant data to achieve the objectives of the SCIP database, by following ECHA's recommendations.
- Use 'grouping' or 'referencing' to reduce the complexity of your dossiers and create a clear and simple 'hierarchy'.
- For very complex objects consider adding disassembly instructions (illustrative scheme), instead of having a very lengthy hierarchy, which brings difficulties in navigating through the complex object 'hierarchy'

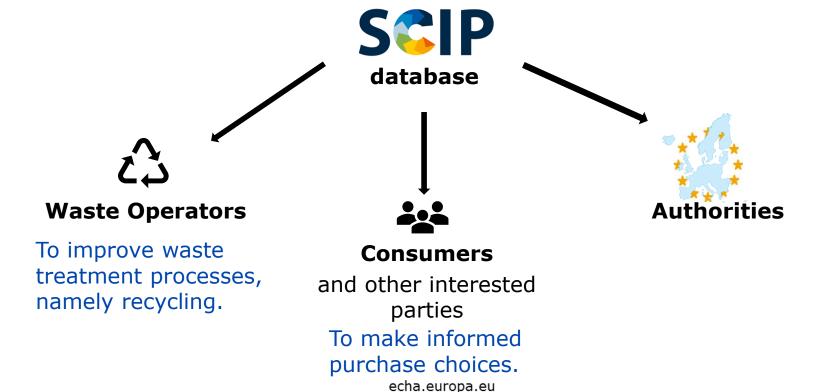
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SCIP database improves transparency on articles with (severely) hazardous substances

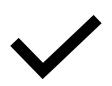
Information to be clearly understandable to target audiences.

It is the <u>responsibility of companies</u> to submit their data in a clear and understandable way.





'Hierarchy' in a complex object – Only the sufficient number of layers



Include <u>only</u> he **lowest number of layers** of components and subcomponents of a complex object ('hierarchy' length) necessary to allow the identification and 'location' of the article containing a Candidate List substance within the complex object by a SCIP database user

The hierarchy for a complex object must be constructed based on practical considerations to include the lowest number of layers that reflect the incorporation of the articles in subcomponents, as well as the incorporation of the subcomponents and components in that complex object at each assembling stage.

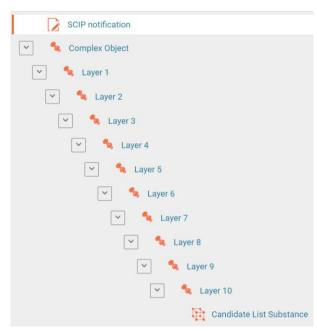


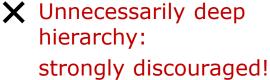
Appropriate hierarchy depth

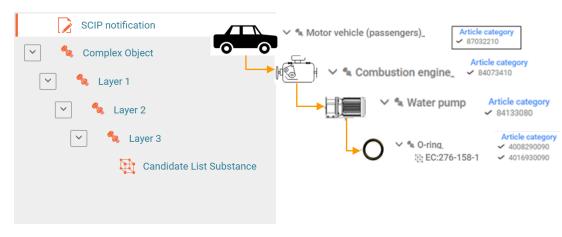
Target a good balance between 'granularity' and key information!

Too many layers may not provide useful information. Focus on providing clarity concerning the 'location' of the article containing the Candidate List substance.

 Create a clear and simple structure: a very complex hierarchy does not necessarily bring any benefit to the users of the database and for the purposes of the SCIP Database







Clear and simple structure: highly recommended



Only submit notifications for articles containing SVHCs on the Candidate List

- The SCIP notification only applies to articles containing SVHCs on the Candidate List.
 - For example: Boron (e.g. diboron trioxide, boric acid and disodium tetraborate) and lead (e.g. lead oxide) substances in the Candidate List used in the production of a glass article may not be present as such in that final glass article. In such cases, there is no obligation to submit a SCIP notification for that article, nor to communicate information down the supply chain under Art. 33 of REACH.
 - It remains the responsibility of companies to assess for their specific use of the Candidate List boron and lead substances whether these are completely transformed into glass in the manufacture of the glass substance and are not present as such in the final glass article.

We invite you to consult the Q&A 1218 (Do I need to notify and communicate information down the supply chain for certain boron substances included in the Candidate List, which are involved in the production of boron glass articles but not present as such in these articles?) which has been developed when certain boron substances are involved in the production of boron glass articles. Similarly to the case covered by that Q&A, certain lead substances (e.g. lead oxide) included in the Candidate List may be involved in processes leading to the production of articles containing a 'glass' substance. In these processes, the lead substances may be first chemically transformed into a manufactured glass substance. The glass substance is subsequently processed into articles. In many cases, the lead substances are completely transformed and are not present as such in the final glass article.





Work in a collaborative way within your supply chain together with your suppliers and customers.

- Use 'referencing' when preparing your notification.
- Facilitate the work of distributors placing your products on the market by allowing them to use the 'Simplified SCIP Notification' (SSN).



You are responsible for your own information!



Be transparent! While ensuring compliance, make efforts to submit and structure your information in a clear and understandable way that is useful for the intended users of the SCIP Database.



Keep in mind your company's image and reputation! The publicly available information in the SCIP database will potentially be subject to scrutiny by the users of the database, namely waste operators, consumers, NGOs representing the interests of consumers, and Member States Authorities.

Please, refer to the document 'Requirements for SCIP notifications', Chapter 2.4



SCIP notifications without complete information in addition to the mandatory fields are potentially not compliant and may not fulfil the SCIP objectives

(e.g. articles or complex objects placed on the market for consumers)

Please, refer to the document 'Requirements for SCIP notifications', Chapter 2.1.1

Candidate List Package





The authentic Candidate List (1)

(https://echa.europa.eu/candidate-list-table)

Candidate List of substances of very high concern for Authorisation

(published in accordance with Article 59(10) of the REACH Regulation)

Notes:

- Authentic version: Only the Candidate List published on this website is deemed authentic. Companies may have immediate
 legal obligations following the inclusion of a substance in the Candidate List on this website including in particular Articles 7, 31
 and 33 of the REACH Regulation.
- Numerical identifiers: Each candidate list entry covers both anhydrous and hydrated forms of a substance. The CAS number shown in an entry is typically for the anhydrous form. Hydrated forms of the substance identified by other CAS numbers are still within the scope of the entry.
- Other numerical identifiers: For those entries with "-" in the EC number and CAS number columns, a non-exhaustive
 inventory of EC and/or CAS Registry numbers describing substances or groups of substances considered to fall within the scope
 of the Candidate List entry is included, where practicably possible. This information can be accessed through the "Details"
 button of the selected entry.

FURTHER INFORMATION

- More information about Candidate list of Substances of Very High Concern for Authorisation
- Data on Candidate List substances in articles
- Reason for inclusion
 by cs da de el es et fi fr hr hu it
 it iv mt ni pl pt ro sk sl sv

See a problem or have feedback?

> Filter the list





The authentic Candidate List (2)

(https://echa.europa.eu/candidate-list-table)



Doc: D(2020)9139-DC Public 1(3)

Helsinki, 11.01.2021

Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV

(Decision of the European Chemic

I HAVE DECIDED THE FOLLOWING:

1. The following substances are identified as substances of very high concern meeting the criteria under Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Bis(2-(2-methoxyethoxy)ethyl)ether	205-594-7	143-24-8	Toxic for reproduction (Article 57c)
Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	-	-	Toxic for reproduction (Article 57c)

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The authentic Candidate List (3)

- ECHA considers it justified not to include EC or CAS numbers for certain entries on the Candidate List.
- It is not always possible to rely on EC and CAS numbers only to identify the substance(s) that may be covered by an entry in the Candidate List.
- ECHA is committed to support industry to comply with their obligations and whenever needed to confirm that some specific substances are covered by a group entry and include them as members in the published Candidate List.

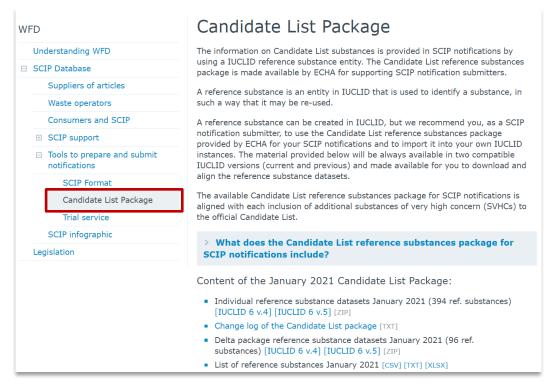
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Identification of substances in SCIP

Communicating and providing the substance identity information as given on each entry of the Candidate List is sufficient

ECHA provides the Candidate List package to support industry and is working continuously to meet their needs.



Share your experience





Your experience.....

- Have you started? Initial lessons learn?
 - Creating dossiers (collecting data and Technical challenges)
 - With ECHA submission portal
 - S2S experience
 - Using SSN
 - Using referencing
 - Using grouping and screening the existing data

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Your experience.....

- What is pending to be submitted?
 - Why?
 - When are you planning to submit?

Other experiences/Challenges to share?

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Trial service

- Are you using it?
- Experience?
- Impact on deleting information submitted and information about those submissions monthly?

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SCIP Next phase





- 1st Feb: IUCLID Cloud release
 - Will include the updated Candidate List
 - Non selectable values not accepted (article category)
- Next months
 - High focus on making the data available
 - Monitoring the data coming, supporting industry
 - Working on further developments

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Next SCIP events







Next SCIP IT user group meeting

25 March 2021 (15-16.30 Helsinki time)

Please follow our website for updates:

https://echa.europa.eu/scip



19 January 2021

chemicals in products
22 December 2020

SCIP duty kicks in: 5 million notifications received for harmful



Thank you for your participation!

scip@echa.europa.eu

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