Introduction

Consultation on proposed restriction of PFHxA

23 April 2020

Peter Simpson

What you can expect from today

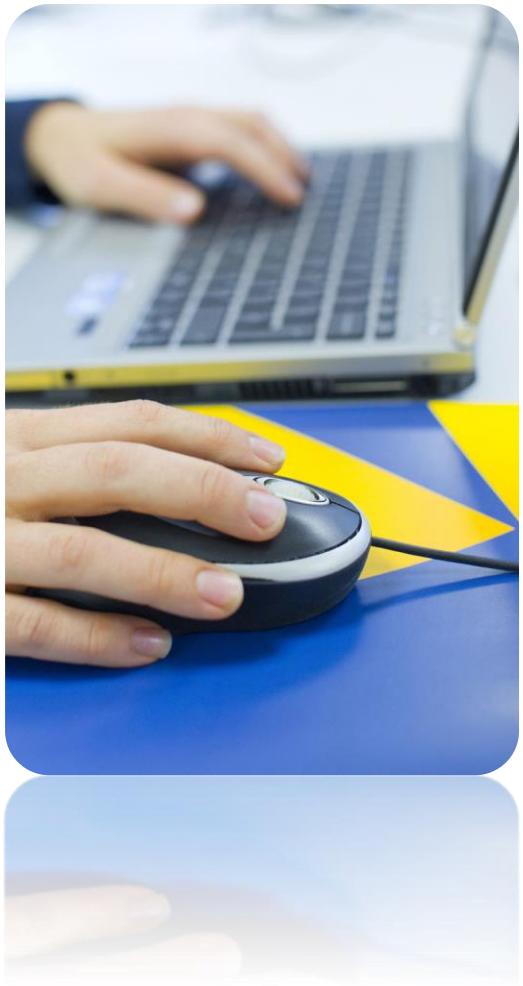
- Scope of proposed restriction for placing PFHxA on the market
- Clarify your questions on the consultation
- Help you decide if and what information to submit

Agenda

- Introduction to REACH restriction
- Overview of work on PFAS
- Proposed restriction
- Specific information requests
- How to give input

Q&A

- Send questions to echa-events@echa.europa.eu until 29 April
- All questions compiled to a Q&A document and published in May
- You will be notified by email



Material published

Video recording, presentations, Q&A:

echa.europa.eu/support/training-material/webinars

Introduction to REACH restriction

Consultation on the proposed restriction of PFHxA

23 April 2020

Peter Simpson

REACH restriction

- Restriction is a tool for protecting our health and the environment from the risks posed by chemicals
  - Address a risk that is not adequately controlled
  - Where action is required at Union level
  - Safety net for other REACH and EU processes
- Restrictions usually limit or ban manufacture, placing on the market or use of a substance(also in a mixture/article)
- A restriction can also set out specific conditions such as technical measures or labelling requirements
- Dossier submitter can be a Member State or ECHA

echa.europa.eu/registry-of-restriction-intentions

Restriction process

I Phase

Preparation and submission of a restriction proposal

- Starting the restriction process
- Notification of intention to submit a restriction proposal
- Registry of Intentions
- Preparing the restriction dossier
- Submission and conformity check

II-A Phase

(Public)consultations

- (Public)consultation on the restriction report
- (Public)consultation on SEAC's draft opinion

II-B Phase

Opinion development

- Advice from the Forum
- RAC's opinion
- SEAC's opinion

III Phase

Decision and follow-up

- Commission decision on restriction
- Complying with restriction
- Enforcing the restriction

echa.europa.eu/restriction-process

Starting the process

- If Member States, Commission or ECHA have a concern that a substance poses a risk to our health or the environment, preparatory work starts to investigate the problem through risk management option analysis (RMOA)
- If they conclude that a restriction is the best way forward, they have to notify their intention to prepare a restriction 12 months before it is submitted
- Germany notified its intention to submit a restriction on PFHxA, its salts and related substances on 21 December 2018

Registry of intentions

- Indicates when a new restriction dossier is planned to be submitted to ECHA for a particular substance
- Enables interested parties: citizens, organisations, companies and authorities to plan for and contribute to consultations in the restriction process

echa.europa.eu/registry-of-restriction-intentions

Restriction proposal
Annex XV report

- Restriction dossier:
  - Information on hazards, exposures and risk
  - Justification for action at EU-wide level
  - Available information on alternatives
- Proposal has to show that a restriction is the most appropriate risk management measure to address identified risk
- Proposal may also include socio-economic impact analysis

Evaluation

After submission by ECHA

- Risk Assessment Committee (RAC)
- Socio-Economic Analysis Committee (SEAC)
- 'Effectiveness' of a proposed restriction
  - key criteria for justifying restriction
- Restriction must be:
  - Targeted to effects or exposures resulting in the risk
  - Capable of reducing these risks within a reasonable time period (proportionate to the risk)
- Socio-economic analysis
  - Net benefits (human heath and environment)
  - Net costs (manufacturers, importers, consumers)

Timeline after submission

- Restriction dossier publicly available after submission (circa 2 weeks)
- Opinion-making process (typically 12 months)
  - Conformity check prior to 6 month public consultation
  - Evaluation of proposal set out in an ‘opinion’
- Opinions published and sent to Commission for decision with background documents

Steps in RAC and SEAC

Committee plenary meeting (timing)	Committee for Risk Assessment (RAC)	Committee for Socio-Economic Analysis (SEAC)
1. (2.5 months after consultation starts)	Verify proposed scope. Conclude on hazard and hold preliminary discussion on exposure and risk	Verify proposed scope. Conclude on costs of proposed restriction. Hold preliminary discussions on benefits
2. (5.5 months after consultation starts)	Conclude on exposure and risk. Hold preliminary discussion on derogations	Conclude on benefits and hold preliminary discussions on proportionality and derogations
3. (8.5 months after consultation starts)	Finalise derogations. Finalise opinion and justification text before adopting final opinion	Conclude on proportionality and derogations. Finalise opinion and justification text. Agree draft opinion
4.	Not relevant	Conclude on issues raised during SEAC draft opinion consultation. Adopt final opinion

Overview of work on PFAS

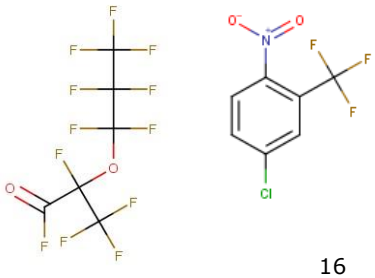
Consultation on the proposed restriction of PFHxA

23 April 2020

Peter Simpson

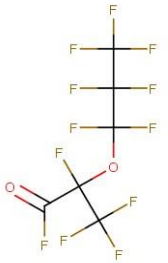
Our experience and on-going work

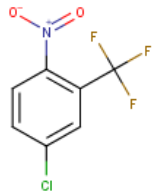
- Since 2014: subgroup-by-subgroup approach to assessment and risk management of PFAS in ECHA processes
- Due to shift from long-chain PFAS to other PFAS within industry, regulatory assessments need to target increasing number of PFAS subgroups – increase in assessment efforts in the EU over last 5 years
- Exploration on-going among Member States, Commission and ECHA whether after PFHxA restriction process a sector/use specific restriction covering various PFAS necessary/possible/more efficient than addressing PFAS subgroup by subgroup



Our experience and on-going work

- Mass screening of our databases in 2019: ~2400 PFAS manufactured/imported to EU as substance or in mixture (volume in most cases < 1 tpa)
- Small fraction has fluorinated carbon chain with 3 carbons or more
- Mass screening for PFHxA restriction in 2020: **45** REACH registered substances, **73** CLP notified substances found that belong to scope of restriction proposal
  - Non-exhaustive substance list available on the consultation page
- No regulatory tools in place to track PFAS in imported articles -> reliable exposure estimation dependent on measured exposure data





Overview of PFAS in ECHA

CLH regulation Harmonised classification & labelling opinions	REACH Identification as Substance of Very High Concern	REACH Restriction opinions
PFOA, PFNA, PFDA (i.a., toxic to reproduction) PFHpA (on-going process)	PFOA, C_9-C_{14}-PFCAs PFHxS, PFBS HPFO-DA (a PFECA)	PFOA and related substances (restricted in the EU from mid-2020)
PFBA (preparation ongoing)	PFHpA (preparation of PBT assessment ongoing) Several additional PFASs currently subject to testing and evaluation due to suspected SVHC properties	C_9-C_{14}-PFCAs and related substances (opinion available, finalisation ongoing in Commission) PFHxA and related substances (restriction proposal submitted) Preliminary preparation of restriction proposals ongoing for any PFAS in AFFF and textiles (COM, ECHA)

Specific information requests

Consultation on proposed restriction of PFHxA

23 April 2020

Maria Ottati

What to submit?

- Any information you consider relevant
- Some topics on which Committees and dossier submitter particularly welcome information. Covered in ‘Specific Information Requests’
- Remember to give evidence to support any claims you make in your responses

Question 1
Additional uses

In addition to uses described in Annex XV dossier, are you aware of any other present or future intentional uses, or uses where impurities are above the proposed concentration limit? The question concerns both uses in and outside the EU involving imports to the EU. If such uses exist, provide:

- Description of use
- Quantities used and information on potential risks to the environment (e.g. quantified release estimates)

Questions 2-6

Specific sectors and uses

Question 2

Emissions of PFHxA from polymers

PFHxA, its salts and its related substances are emitted from side chain fluorinated polymers. Such emission may also take place from fluoropolymers. The available data describing these emissions is, however, limited. Provide any additional data you may have on the extent of these emissions.

Question 3
Textile sector

Majority of clothing used in the EU is imported from outside the EU. Provide any additional data on:

- Share of imported clothing (outdoor and occupational clothing) treated with:
  A. Side-chain fluorinated polymers
  B. Fluoropolymers
  C. PFHxA, salts or related substances directly
  - Provide, if available, share of imported clothing treated with PFHxA, its salts and/or related substances
- Content of extractable perfluorinated substances and applied fluoropolymers in treated textiles.
  - Provide, if available, share of imported clothing treated with PFHxA, its salts and/or related substances

Question 4
Coatings

Provide data on tonnages used in coatings and for release of PFHxA, its salts and/or related substances from coated building and construction materials.

Question 5

Fire-fighting foams (all relevant sectors, including defense sector)

a) Have you already shifted from PFHxA, its salts and/or related substances to fluorine-free foams or are you planning to shift to those alternative foams?

If yes:

- In which area did you or are you planning to shift to fluorine-free foams (e.g.: seagoing units, storage of fuel)?
- How long did the transition to fluorine-free foams take you or how long will it approximately take to perform the transition?
- What are/were the challenges when performing such a transition? E.g., when using the same equipment, are the residues of PFHxA, its salts and/or related substances in the equipment posing a technical challenge in relation to the proposed concentration limit?

If no:

- Specify whether you have moved from PFHxA, its salts and/or related substances to a foam containing other fluorinated substances
- Provide information on volumes and value of stocks you may have on fluorinated foams in general and more specifically on foams containing PFHxA, its salts and/or related substances
- Provide information on volumes of fire-fighting foams containing PFHxA, its salts and/or related substances currently in use in your equipment
- Provide information on handling, release mitigation and waste management instructions relevant for estimating releases and evaluating socio-economic impacts

If no:

- Why did you decide not to shift to fluorine-free foams or, more specifically, to foams free of PFHxA, its salts and/or related substances?
- What changes are necessary to allow transition to fluorine-free foams from PFHxA, its salts/related substances? Are you already taking measures to achieve such changes? How long will it take until respective measures are in place to allow a transition to fluorine-free foams?

b) Hand-held fire extinguishers:

- Provide information on volumes and concentrations of PFHxA, its salts or related substances you use in the extinguishers, the use sectors using extinguishers containing these substances, current handling, release mitigation and waste management instructions
- Any other information relevant for estimating exposures and socio-economic impacts of proposed restriction

c) Are you using aqueous film-forming foams (AFFF) containing PFHxA, its salts and/or related substances for training purposes?

If yes, specify why

d) Are you using AFFF containing PFHxA, its salts and/or related substances for testing purposes?

If yes, specify why

Question 6
Other uses

Cleaning, cosmetics, waterproofing agents, polishing products, floor waxes, food contact materials, etc., including uses in consumer products

- Provide information on tonnages used for these mixtures and the identity of the substances (within the scope of this restriction and/or any fluorinated substance)

Questions 7-11

Substitution and alternatives

Question 7

Are you aware of any alternative fluorine-free substances or technologies for uses of PFHxA, its salts and related substances?

Question 8

Uses where substitution impossible

- What is the use?
- What are the main obstacles to substitution?
- Describe consequences resulting from the proposed restriction and provide information about costs associated to these consequences

Question 9

Uses where substitution is or is not possible now but is expected to become possible within short to medium timeframe

- What is the use?
- What transitional period would be needed?
- Describe technical and economic consequences from the proposed restriction and provide information about costs associated to these consequences
- What would be the consequences of a shorter transitional period? What would be the costs?
- Would investments to enable new processes etc. be needed? If so, provide information about costs of these investments

Question 10

Uses where substitution would be possible but is expected to lead to a lower quality of products or lower performance

- What is the use?
- Describe impacts on quality/performance of products
- If possible, provide estimate of economic impacts expected on an annual basis

Uses where we need above information in relation to substitution:

- Performance of fluorinated polymers and fluoropolymers within the scope of the proposal, compared to fluorine-free alternatives in various uses of these polymers. What are the cost implications if substitution is required?
- Performance loss of textiles or membranes in case of substitution to fluorine-free alternatives. What would be the impacts of substitution in non-woven textiles used in the automotive and aerospace sectors, medical textiles, textiles for worker protection and membranes for treatment of effluents?

Question 11
PFAS-based alternatives

Previously, PFOA restriction led to replacement of 8:2 FTOH technology by 6:2 FTOH. Are you aware of the usability of alternative fluorotelomer substances (e.g. 4:2 FTOH, etc.) or other fluorinated substances (e.g. perfluoroalkyl ether carboxylic acids) in the different processes that now rely on 6:2 FTOH?

Question 12
Costs

- If for your use/sector the dossier submitter provided a concrete cost assessment, do you agree with the assumptions and costs used? If not, provide additional data and evidence to support it
- Dossier submitter proposes annual reporting on use of PFHxA, its salts and PFHxA-related substances in the production of personal protective equipment (PPE), non-woven medical textiles and impregnation agents (see paragraph 10 of proposal entry) and the quantities and substitution efforts for fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances (paragraph 12 of proposal entry). Are there costs associated with that reporting?

Question 13
Analytical methods

Are you aware of a method for chemical analysis of PFHxA present in a matrix relevant for the restriction proposal? Do you develop or intend to develop such a method?

What happens to your comments?

- Published on our website (circa monthly).
- Scrutinised by dossier submitter (Germany), RAC and/or SEAC and – if considered significant, addressed in the background document and/or in the opinion
- Dossier submitter and RAC and/or SEAC provide a response to all comments and submitted information
  - Responses published on our website at the end of the process

How to give input?

Consultation on proposed restriction of PFHxA

23 April 2020

Anna-Lena Rehrl

ECHA website

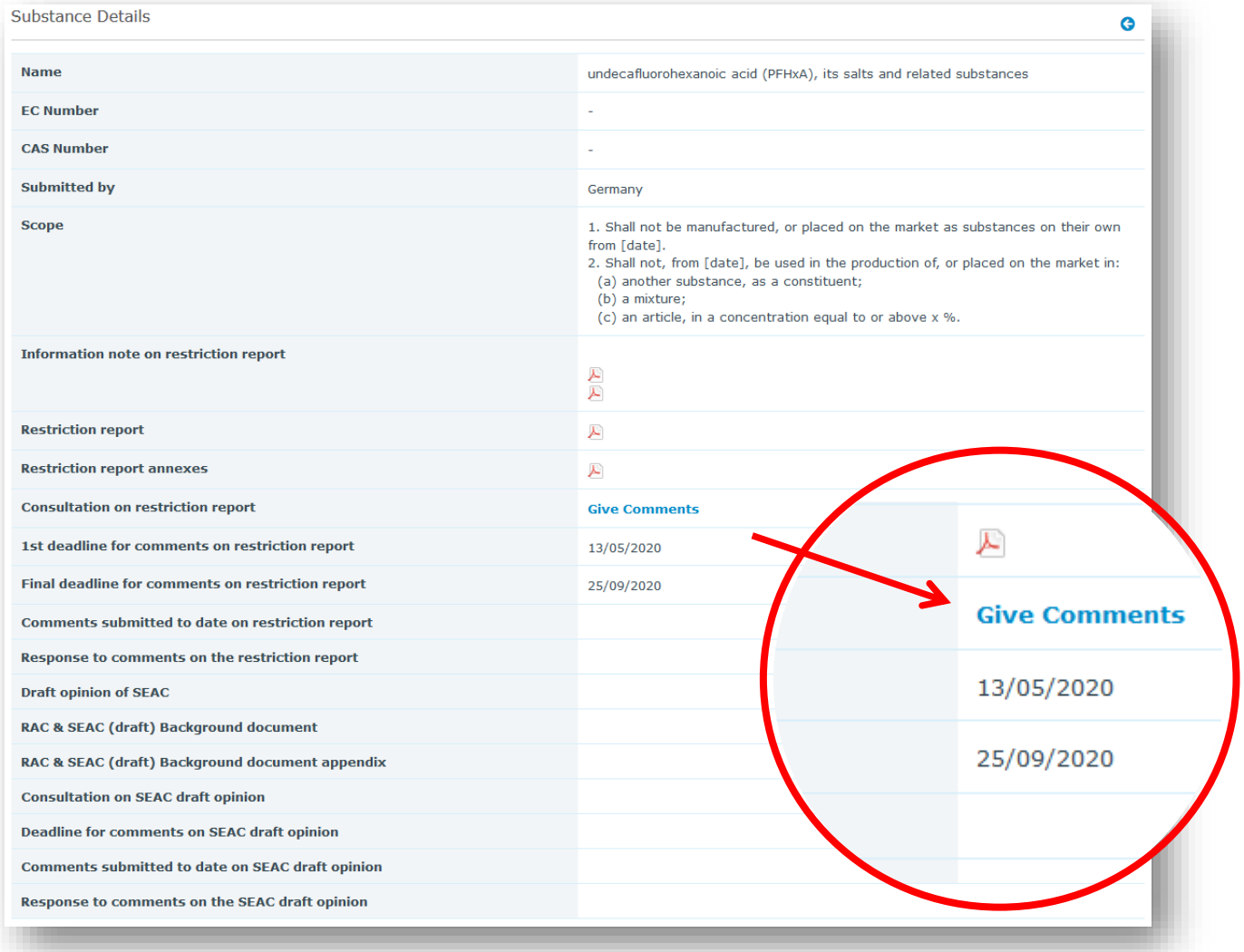
ECHA > Consultations > Submitted restriction under consideration

echa.europa.eu/restrictions-under-consideration

Submitted restrictions under consideration

Name	EC Number	CAS Number	1st deadline for comments on restriction report	Final deadline for comments on restriction report	Deadline for comments on SEAC draft opinion	
undecafluorohexanoic acid (PFHxA), its salts and related substances	-	-	13/05/2020	25/09/2020		Details

Substance details

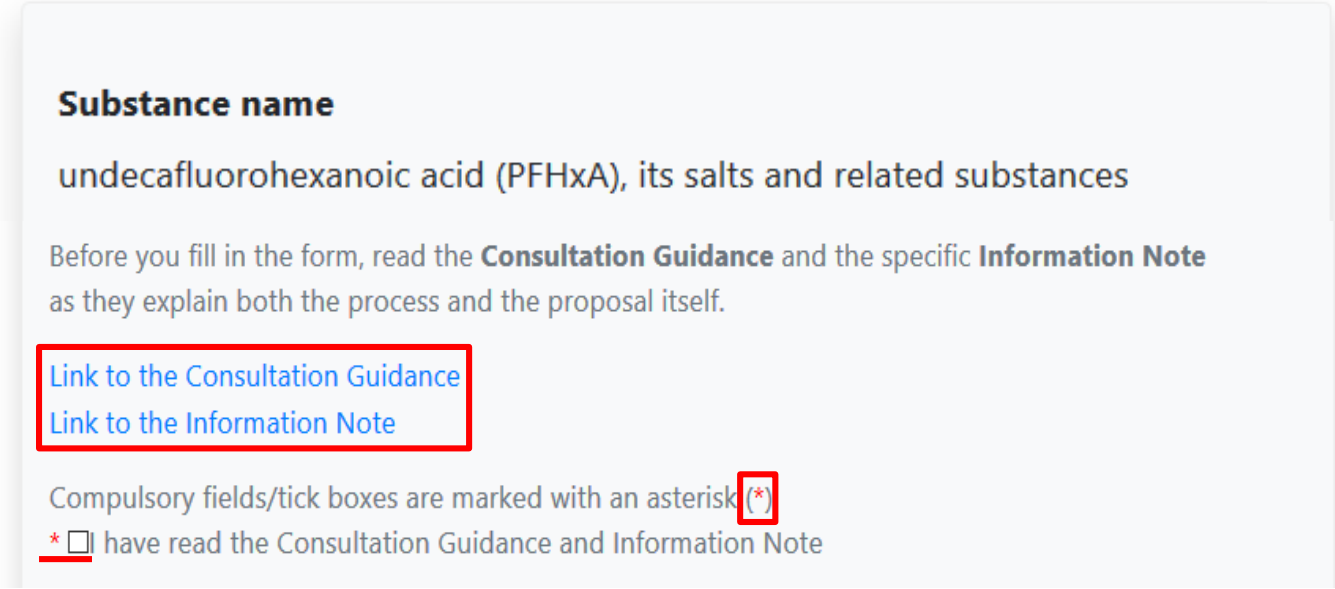


Substance Details

Name	undecafluorohexanoic acid (PFHxA), its salts and related substances
EC Number	-
CAS Number	-
Submitted by	Germany
Scope	1. Shall not be manufactured, or placed on the market as substances on their own from [date]. 2. Shall not, from [date], be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, in a concentration equal to or above x %.
Information note on restriction report	
Restriction report	
Restriction report annexes	
Consultation on restriction report	Give Comments
1st deadline for comments on restriction report	13/05/2020
Final deadline for comments on restriction report	25/09/2020
Comments submitted to date on restriction report	
Response to comments on the restriction report	
Draft opinion of SEAC	
RAC & SEAC (draft) Background document	
RAC & SEAC (draft) Background document appendix	
Consultation on SEAC draft opinion	
Deadline for comments on SEAC draft opinion	
Comments submitted to date on SEAC draft opinion	
Response to comments on the SEAC draft opinion	

Give Comments
13/05/2020
25/09/2020

Comments for Annex XV restriction report



Substance name

undecafluorohexanoic acid (PFHxA), its salts and related substances

Before you fill in the form, read the **Consultation Guidance** and the specific **Information Note** as they explain both the process and the proposal itself.

Link to the Consultation Guidance
Link to the Information Note

Compulsory fields/tick boxes are marked with an asterisk (*)
* ☐ I have read the Consultation Guidance and Information Note

Consultation guidance

- What information can be submitted and the level of information needed
  Public consultation (6 months) on Annex XV restriction report
- Is it your first public consultation?

Information note

- Summary of proposed restriction
- Timeline of (public) consultation
- How to submit a comment

Filling in the form

SECTION I. Personal information

SECTION II. Organisation

SECTION III. Non-confidential comments

- General comments

  (General comments can be on any aspect of the Annex XV restriction proposal, including issues related to socio-economic analysis)

- Specific information requests

  (These are several specific questions for which we would like to have your input where possible)

Responses can be entered directly into the form or through section IV or V as attachments

SECTION IV. Non-confidential attachment

SECTION V. Confidential Attachment

Submission of comments

! It is **not possible to save your submission** and come back to it. Prepare your comments in an attachment or saved in another format in advance

- Once finished, press submit and your comments will be sent to us. You will receive a **submission number** via e-mail. **Refer to it in any communication with us** on this topic
- It is not possible to retrieve your submission. You can take a screen shot, or printed copy for your reference

Once you are ready

Submit to ECHA

Thank you!

echa.europa.eu/contact

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
@EU_ECHA

Follow us on Facebook
Facebook.com/EUECHA