CTACSUB AUTHORISATION OF CHROMIUM TRIOXIDE (CrO_3)

HOW TO COMPLY
AN OVERVIEW FOR DOWNSTREAM USERS

15 JANUARY 2021

RAMBOLL Bright ideas. Sustainable change.

JONES DAY

MacDermid Enthone
INDUSTRIAL SOLUTIONS

AGENDA

1. BACKGROUND (*JONES DAY – MANAGER CTACSUB*)
2. AUTHORISATION CONDITIONS – GENERAL OVERVIEW (*RAMBOLL – TECHNICAL CONSULTANT*)
3. AUTHORISATION CONDITIONS – TOPICS (*RAMBOLL*)
   - NOTIFICATION – HOW TO INFORM ECHA
   - EXTENDED SAFETY DATA SHEETS
   - WORKPLACE EXPOSURE MEASUREMENTS
   - AIR AND WASTE WATER EMISSION MEASUREMENTS
   - EVALUATION AND REPORTING
4. HELPFUL LINKS
5. SETTING THE SCENE FOR THE NEXT 4 YEARS (*MACDERMID ENTHONE*)

CTACSUB – History – Part 1

- In 2010, LANXESS (REACH lead registrant CrO_3) brought together interested co-registrants to discuss authorisation of CrO_3 under REACH. A pre-consortium was built to map uses.
- In March 2012, the CTAC Consortium consisting of 154 companies was founded to collect information for REACH application for authorisation (AfA).
- The collection of information in CTAC was voluntary (sub-optimal exposure data; very broad scope), but it was completed with an enormous effort at the end of 2014.
- In January 2015, 7 upstream applicants organised a new Consortium (CTACSUB) and volunteered to file joint upstream applications with the AfAs developed by CTAC.
- The CTAC Members were free to also file their own DU authorisation using CTAC data – which some of them did.
- Non-CTAC Members could buy licenses to the data, which 13 companies did.

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CTACSUB – History – Part 2

- CTACSUB sent the draft AfA to ECHA for comments. ECHA had none but urged applicants to submit quickly („ice breaker application").
- In May 2015, CTACSUB filed the AfA with ECHA.
- After substantial RAC & SEAC ECHA Committee questioning, ECHA issued positive opinions in September 2016.
- The European Commission took more than 4 years to issue the authorisation and there was intense scrutiny (Resolution) in the European Parliament.
- On December 18, 2020, the European Commission finally adopted the authorisation decision.
- The total cost for the authorisation between 2012 and 2020 was 4 Mill. EUR (if 3000 companies benefit from September 2017 until September 2024, this makes EUR 1,333 per company).
- CTAC was closed on December 31, 2020.
- CTACSUB will continue its work – as discussed in next slides.

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AUTHORISATION OVERVIEW

CTACSUB AUTHORISATION

- This webinar is (only) relevant for downstream users in relation to CrO_3 supplied (on its own or in a mixture) by a CTACSub authorisation holder.
- The authorisation holders will update their labels on impacted products to include an authorisation number. Check your supply is via an authorisation holder and your use is consistent with the scope and description in the CTACSub Decision.
- The substance and the use of the substance by the downstream user must be consistent with CTACSub Authorisation decision.

Authorisation holders

Chemservice GmbH

Atotech Deutschland GmbH

Boeing Distribution Inc.

Prospere Chemical Logistic OÜ

CROMITAL S.P.A.

Elementis Chromium LLP

MacDermid Enthone GmbH

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CTACSUB – DECISION OF THE EUROPEAN COMMISSION DOWNSTREAM USERS INCLUDE FORMULATORS AND SURFACE TREATMENT FACILITIES

Use	Use Description	Review Deadline
Use 1	Formulation of Uses 2, 4, 5 and 6	21st September 2024
Use 2	Functional (hard chrome) plating	
Use 4	Surface treatment other than Use 2 or Use 3 – Aeronautics and aerospace industry specific	
Use 5	Surface treatment other than passivation of tin-plated steel – Other industries	
Use 6	Passivation of tin-plated steel (ETP)	

Important! The authorisation decision does not include Use 3 – Functional plating with decorative character. This use is not discussed in the webinar; there has been extensive separate discussion with supply chain.

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CTACSUB – DECISION OF THE EUROPEAN COMMISSION

- **Important!** Key functionalities of the substance for the intended use are integral parts of the authorisation decision.
- You **must ensure** your use is consistent with the key functionalities for authorisation decision for the relevant use. You **must notify** the functionality relevant for your use and provide appropriate justification.
- Key functionalities and justification are provided in the updated CTACSub Q&A

  https://jonesdayreach.com/news/

Example: Use 2

"Functional chrome plating where any of the following key functionalities is necessary for the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, or effect on surface morphology"

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CHECK!

- Your supply is via an authorisation holder
- Your use is consistent with the scope and description in the CTACSub decision, and associated key functionalities set out in the CTACSub decision
- You comply with the risk management measures (RMM) and operational conditions (OC) described in the chemical safety reports and the conditions laid down in the decision

In case of non-compliance, you are not covered by the authorisation!

AUTHORISATION CONDITIONS - GENERAL

CTACSUB CONDITIONS OF AUTHORISATION AUTHORISATION HOLDERS MUST

1. Update Exposure Scenarios (ES) and provide to DUs via extended SDS	2. Provide detailed guidance to DUs on how to select and apply RMM and carry out monitoring programs and develop templates for the reporting of monitoring results	3. Validate ES and communicate validated ES to DUs immediately	
• Describe OC and RMM • Within 3 months of the date of adoption of the decision (18 March 2021)	• Good Practice Sheets (GPS) available at Jones Day website https://jonesdayreach.com/substances/	• 18 months after adoption of the decision (18 June 2022)	• In case the authorisation holder is a formulator, all authorisation conditions for DUs apply also

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CTACSUB CONDITIONS OF AUTHORISATION DOWNSTREAM USERS IN THE CTACSUB SUPPLY CHAIN MUST

1. Notify ECHA that an authorised substance is used	2. Comply with Exposure Scenarios provided by authorisation holder in extended SDS	3. Carry out workplace exposure measurements

• Within 3 months after first supply after publication of the authorisation decision in the Official Journal	• Fully implement all relevant OC and RMM	• Within 6 months of adoption of the decision (18th June 2021), then anually
		• Use information to regularly assess OC and RMM
		  • Introduce measures to further reduce exposure and emissions
		• Document and submit report to ECHA
		  • Keep documentation available for possible inspections

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CTACSUB CONDITIONS OF AUTHORISATION
DOWNSTREAM USERS IN THE CTACSUB SUPPLY CHAIN MUST

4. Implement air emission and wastewater measurement programs	5. Communicate measurement results (points 3 and 4 above) to ECHA	6. Comply with specific requirements for spraying applications
• Annually • Assess OC and RMM, submit report to ECHA and keep available for possible inspections	• Within 12 months from the adoption of the decision (18th Dec 2021), then annually • Include all parameters/conditions	• Annex to the Authorisation Conditions includes more stringent operational conditions and risk management measures than AfA

In case of non-compliance you are not covered by the authorisation!

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AUTHORISATION CONDITIONS - TOPICS

AUTHORISATION CONDITIONS

Notification: How to inform ECHA

1

- You need a REACH-IT account
- Procedure
  1. Login via: REACH-IT (reach-it.echa.europa.eu/reach/)
  2. Go to menu: 'Downstream user notification of authorised uses'
  3. Start filing via: 'Prepare and submit online in REACH-IT'

Instruction video available in English with sub-titles in other languages:
www.youtube.com/watch?v=N-IGhimWBKs&feature=youtu.be

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AUTHORISATION CONDITIONS

Notification: How to inform ECHA

1

- The Downstream User prepares a notification 'dossier' for submission to ECHA
- Dossier compilation is performed via the authorisation number
  - Name dossier (substance name, trade name, *e.g.*)
  - Search for authorisation number (REACH /xx/xx/xxxx)
  - Obligatory information are marked in red (filing of measurement data, information on key functionalities of the respective products, *etc.*)
  - Additional voluntary information (tonnage range, short description, substitution activities, *etc.*)
- More authorisation numbers can be added to a substance dossier (in case of several suppliers or different products)

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AUTHORISATION CONDITIONS

Notification: How to inform ECHA

1

- Further steps
  - Indication of sites of your authorised uses
  - Administrative tasks
  - Requesting CBI, including justification (company name, sites, name of uses, tonnage)

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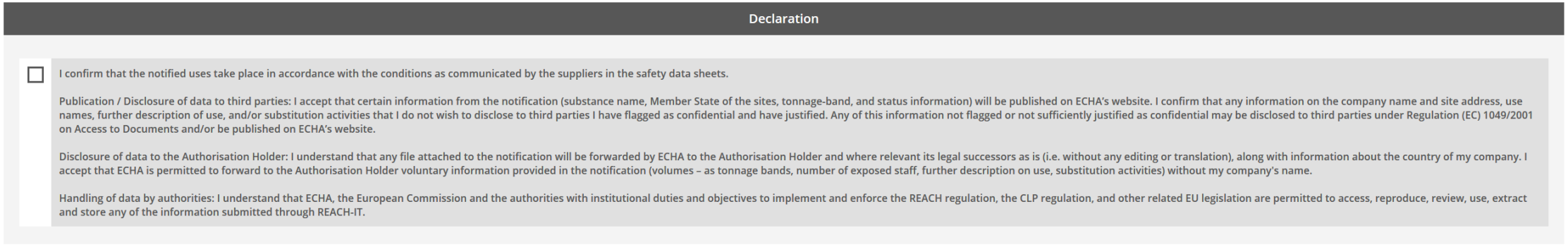
AUTHORISATION CONDITIONS

Notification: How to inform ECHA

1

- Final steps
  - ‘Preview dossier’: Summary of the data entered and confirmation that uses are performed according to the conditions of authorisation
  - Submission to REACH IT
  - Name a person of contact for the notification
  - With the submission you will receive a confirmation and a ‘preliminary submission number’



Declaration

☐ I confirm that the notified uses take place in accordance with the conditions as communicated by the suppliers in the safety data sheets.

Publication / Disclosure of data to third parties: I accept that certain information from the notification (substance name, Member State of the sites, tonnage-band, and status information) will be published on ECHA’s website. I confirm that any information on the company name and site address, use names, further description of use, and/or substitution activities that I do not wish to disclose to third parties I have flagged as confidential and have justified. Any of this information not flagged or not sufficiently justified as confidential may be disclosed to third parties under Regulation (EC) 1049/2001 on Access to Documents and/or be published on ECHA’s website.

Disclosure of data to the Authorisation Holder: I understand that any file attached to the notification will be forwarded by ECHA to the Authorisation Holder and where relevant its legal successors as is (i.e. without any editing or translation), along with information about the country of my company. I accept that ECHA is permitted to forward to the Authorisation Holder voluntary information provided in the notification (volumes – as tonnage bands, number of exposed staff, further description on use, substitution activities) without my company’s name.

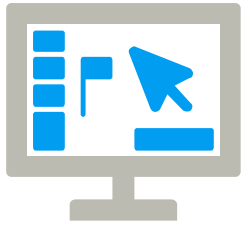
Handling of data by authorities: I understand that ECHA, the European Commission and the authorities with institutional duties and objectives to implement and enforce the REACH regulation, the CLP regulation, and other related EU legislation are permitted to access, reproduce, review, use, extract and store any of the information submitted through REACH-IT.

AUTHORISATION CONDITIONS

Notification: How to inform ECHA

1

- Further management via REACH IT
  - Update of the dossiers
  - Creation of PDFs (as templates if necessary)
- Update notification with monitoring data in due course (before December deadline)



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AUTHORISATION CONDITIONS

Comply with Extended Safety Data Sheets **2**

- Exposure Scenarios annexed to Extended Safety Data Sheets are consistent with the CTACSub Good Practice Sheets (GPS) www.jonesdayreach.com/SitePages/Home.aspx
  - Include information from the Chemical Safety Report (CSR) in the AfA
  - Include additional information submitted to ECHA during evaluation of AfA (as relevant)
  - Include authorisation conditions (e.g. spray applications) specified in the decision
  - Describe OC and RMM that must be in place

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AUTHORISATION CONDITIONS

Comply with Extended Safety Data Sheets **2**

- Each Exposure Scenario includes:
  - Introduction to the activity covered by the Exposure Scenario
  - Information on Equipment Design and Access that must be in place
  - Risk Management Measures that must be implemented
  - PPE that must be used
  - Requirements for training and supervision
  - Monitoring requirements (conditions)
  - Exposure and risk assessment

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AUTHORISATION CONDITIONS
2. EXTENDED SAFETY DATA SHEETS (2)

Comply with Extended Safety Data Sheets **2**

- Will be delivered to the DUs via their supplier within 3 months of the adoption of the authorisation (18th March, 2021)
- CTACSUB currently translating into several languages

You must comply with the Exposure Scenarios in the extended SDS

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AUTHORISATION CONDITIONS
WORKPLACE AND ENVIRONMENTAL MEASUREMENTS

- Downstream Users must monitor worker and environmental exposure to Cr(VI).
  - Monitoring data is required to validate the Exposure Scenarios.
  - The authorities want to check that exposure to workers and the environment is minimised when requisite Operational Conditions (OC) and Risk Management Measures (RMM) are in place.
- The results must be submitted to ECHA and, on request, made available to the relevant national enforcement authority.
- Monitoring involves sampling workers and/or environment and analyzing samples to quantify Cr(VI) exposure associated with a well-defined activity.

Important! Your existing worker and environmental monitoring programs are unlikely to meet specific authorisation requirements

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AUTHORISATION CONDITIONS

Workplace Exposure Measurements

3

- First worker exposure measurement within 6 months of adoption of the authorisation (**June 18th, 2021**)
- Submission of the measurement results to ECHA within one year of adoption of the authorisation decision **(December 18th, 2021)**
- Repeat measurements annually

The authorisation requires the measurements must be:

- Based on relevant standard methodologies or protocols; and
- Representative of:
  - the range of tasks undertaken where exposure to chromium is possible, including tasks involving process and maintenance workers
  - the operational conditions and risk management measures typical for each of these tasks
  - the number of workers potentially exposed

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AUTHORISATION CONDITIONS

Workplace Exposure Measurements

3

WHERE	HOW
Chemical storage	*(Static measurement)*
Loading and unloading area	Static measurement
Automatic/manual baths	Personal and/or static measurement
Sampling at bath	Personal measurement
Re-filling/adjustment of the bath	Personal measurement
Maintenance (!)	Personal measurement
Waste-water treatment	Static measurement

AUTHORISATION CONDITIONS

Air and Wastewater Emission Measurements 4

- Emission measurements must be performed at least annually
- The authorisation requires the measurements must be:
  - Based on relevant standard methodologies or protocols; and
  - Representative of:
    - Operational conditions
    - Risk management measures (such as waste water treatment systems, gaseous emission abatement techniques)
- Similar to workplace exposure measurements, results must be submitted to ECHA within one year of adoption of the authorisation decision

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AUTHORISATION CONDITIONS

Evaluation and Reporting

5/6

- Internal documentation system (for potential inspections)
  - Results of workplace and emission measurements
  - Contextual informaton including RMM
    - Exhaust ventilation and its maintenance
  - Assessment of appropriateness and effectiveness of OC and RMM
- Annual reporting to ECHA via REACH-IT, notification tool
  - Include the contextual information associated to each set of measurements
  - GPS E2bis Implementing and Reporting Worker Exposure Monitoring https://jonesdayreach.com/substances/
  - GPS E3bis Implementing and Reporting Environmental Monitoring https://jonesdayreach.com/substances/
- Results are forwarded from ECHA to the authorisation holders for use in the review report

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AUTHORISATION CONDITIONS MONITORING

- There are no detailed ECHA guidance or standards for monitoring.
- It is up to each DU to design worker and environmental monitoring programmes that meet requirements. This presents some challenges:
  - Because each facility is unique (use, layout, equipment, processes and procedures), a one-size-fits-all approach is impossible. Use and site-specific considerations also have to be considered.
- CTACSUB has prepared general guidance to support worker and environmental monitoring as part of the Good Practice Sheets (GPS) available at the Jones Day website.
  - GPS E2bis Implementing and Reporting Worker Exposure Monitoring
    Includes reporting template
  - GPS E3bis Implementing and Reporting Environmental Monitoring
    Includes reporting template

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HELPFUL LINKS

Instruction video for the notification

www.youtube.com/watch?v=N-IGhimWBKs&feature=youtu.be

Further information about the notification of DUs and download of the upload-form for specific information: *Format for reporting of occupational exposure data by downstream users*

https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use

ECHA template for reporting of monitoring data

https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use

CTACSUB Q&A

News | Jones Day Reach

Good Practice Sheets (GPS)

jonesdayreach.com/substances/

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FINAL NOTES

- The Authorisation decision for Use 1, 2, 4, 5 and 6 extends until 21st September 2024.
- As the Authorisation decision was adopted before 1 January 2021, it has effect in Great Britain (GB), meaning existing downstream users in GB that obtain CrO_3 from a CTACSub Authorisation holder can continue to rely on that authorisation.
- CTACSub will apply for an extension of the authorisation and prepare and submit a review report by March 2023.

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SETTING THE SCENE FOR THE NEXT 4 YEARS

Authorisation granted! What is next?

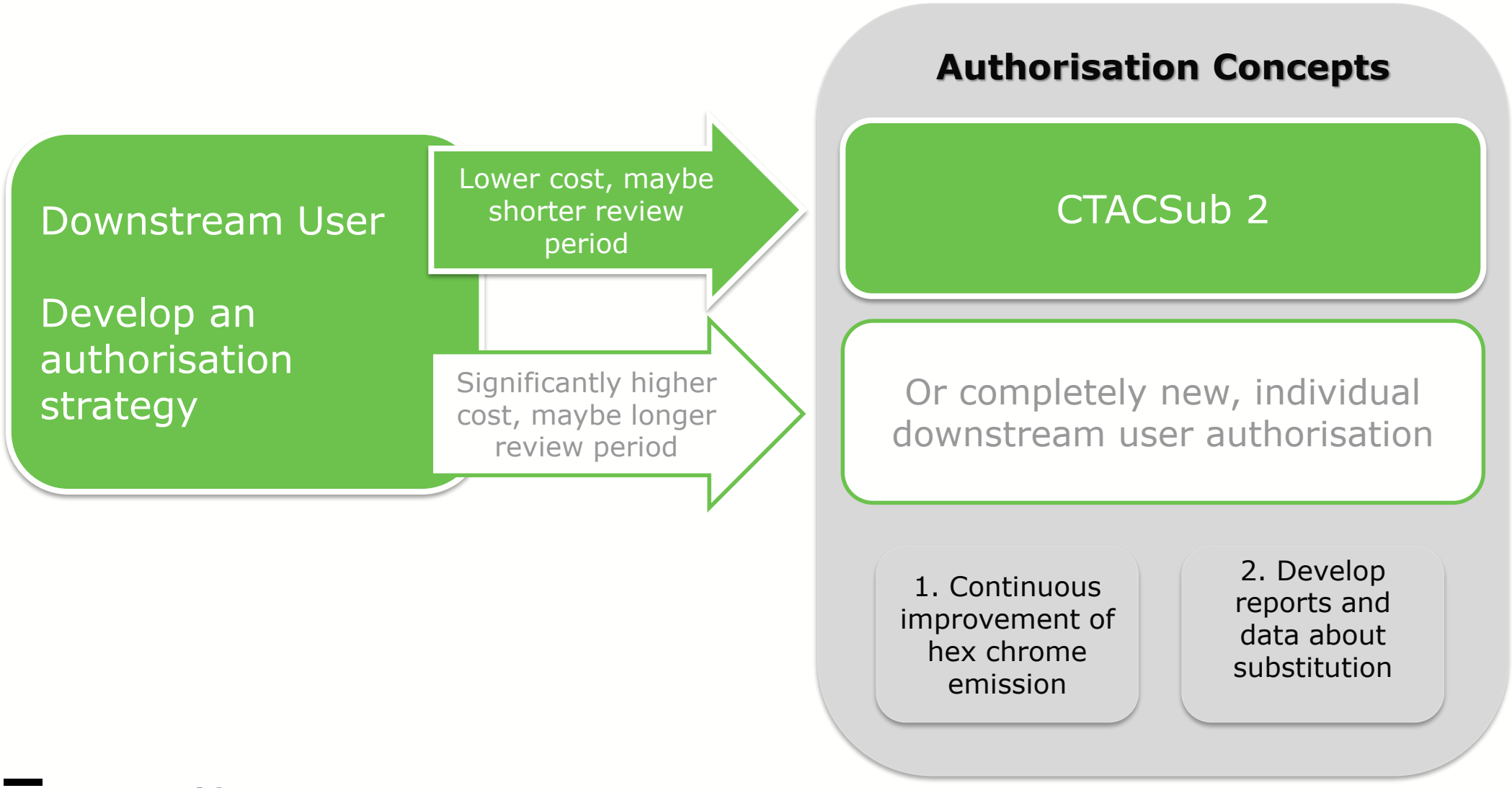
!

Some facts UG 2, 4, 5 equivalent use groups

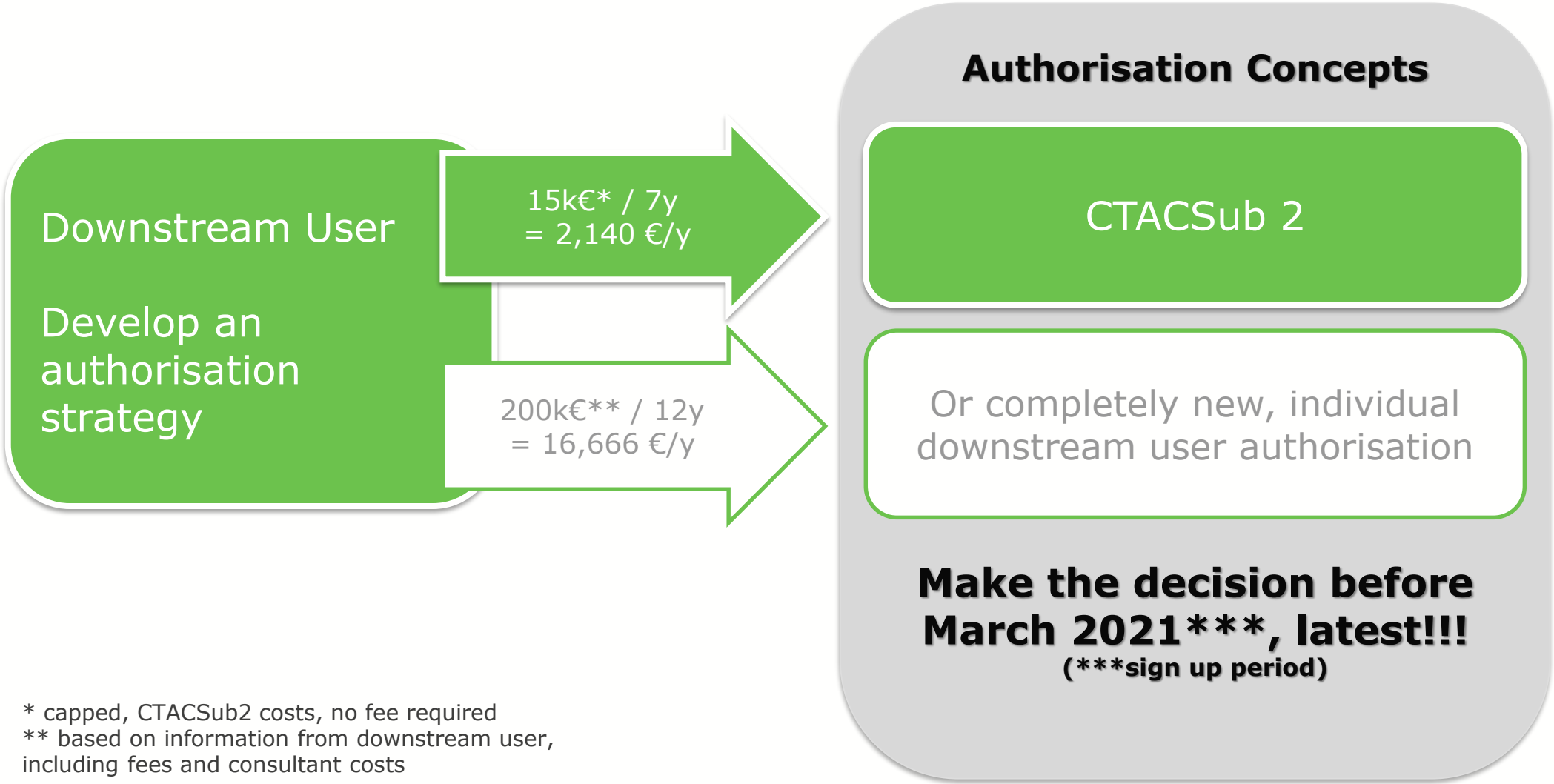
- Approximately 1000 downstream users (DU) benefit from the upstream authorisation!!!
- 42 EU DUs filed individual applications for authorisation for Hard Chrome (34 EU DUs received approval with 10 years average review period)
- 25 EU DUs filed individual applications for authorisation for Anti Corrosion (24 DUs received approval with 9 years average review period)
- 58 DUs received the approval in total
- Approximately 94% DUs are covered by CTACSub upstream authorisation
- Approximately 6% of DUs have own approval

The majority of the market is covered by the umbrella authorisation of CTACSub !!!

Demand for authorisation beyond 2024



Demand for authorisation beyond 2024



* capped, CTACSub2 costs, no fee required
** based on information from downstream user, including fees and consultant costs

Demand for authorisation beyond 2024

Downstream User

Develop an authorisation strategy

Authorisation Concepts

CTACSub 2

Commitment to active participation, to conditions of authorisation and continuous HSE improvement

"No data, no product"

…or hard stop at 21st September 2024

or, develop an exit strategy

Downstream User:

Develop an exit strategy

Phase out hex chrome by substitution or cease manufacturing

In case **you do not** want to continue hard chrome plating or anti corrosion surface treatment, you need to complete the phase out by September 21st 2024!

Make the decision before September 2021, latest*!!!

(*18month response time + preparation time, depending on capacity of authorities and EU Commission)

Summary

THE TIME IS NOW TO MAKE A DECISION

- If you do not have the capacity to make your own organization, CTACSub2 offers you a solution which is cost effective and covers your individual needs.
- CTACSub2 has an established structure with experienced teams and members – Authorisation Holders already committed to join CTACSub2
- Sign up before March 31st, 2021, consider enough lead time for decision making
- If you miss the deadline, you need to kick off preparation of an individual authorisation by September 2021, latest
- EU Commission/authorities may not have enough capacity to process AfA in time

Q&A

THANK YOU

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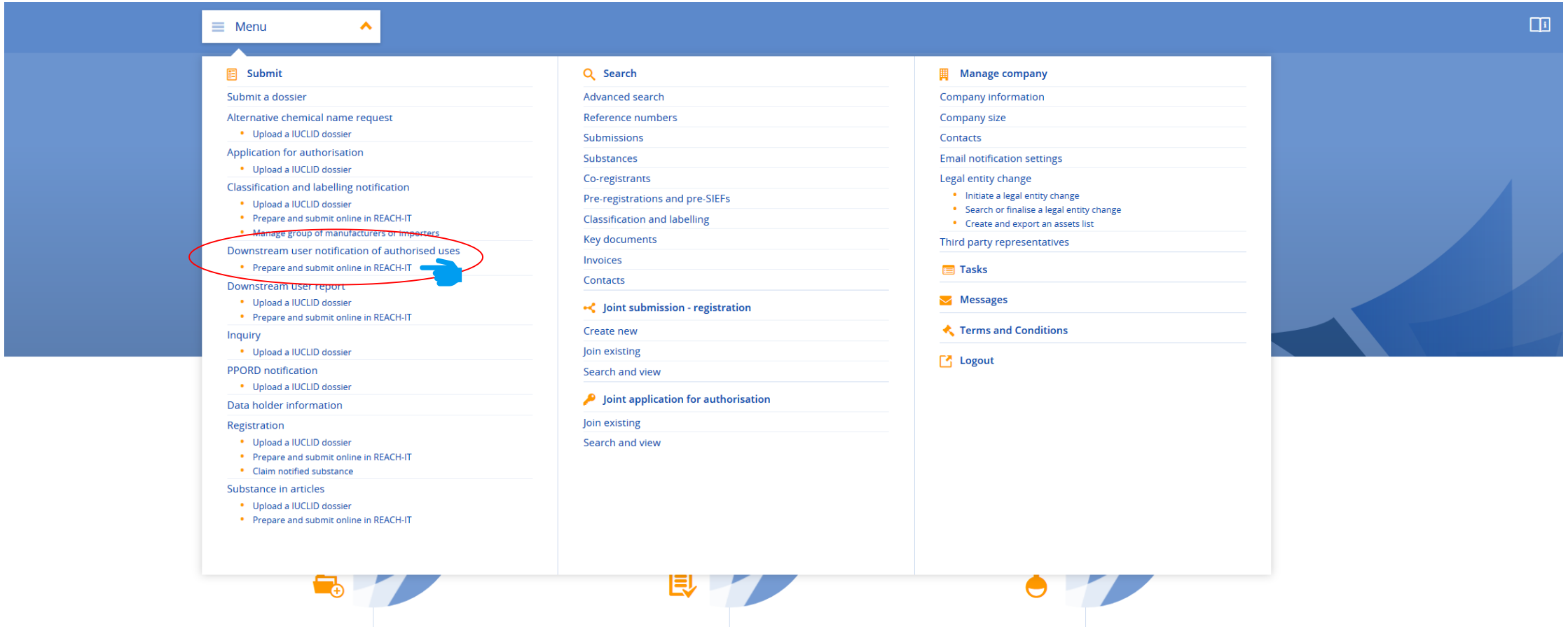
ANNEX

ANNEX - AUTHORISATION CONDITIONS NOTIFICATION – HOW TO INFORM ECHA



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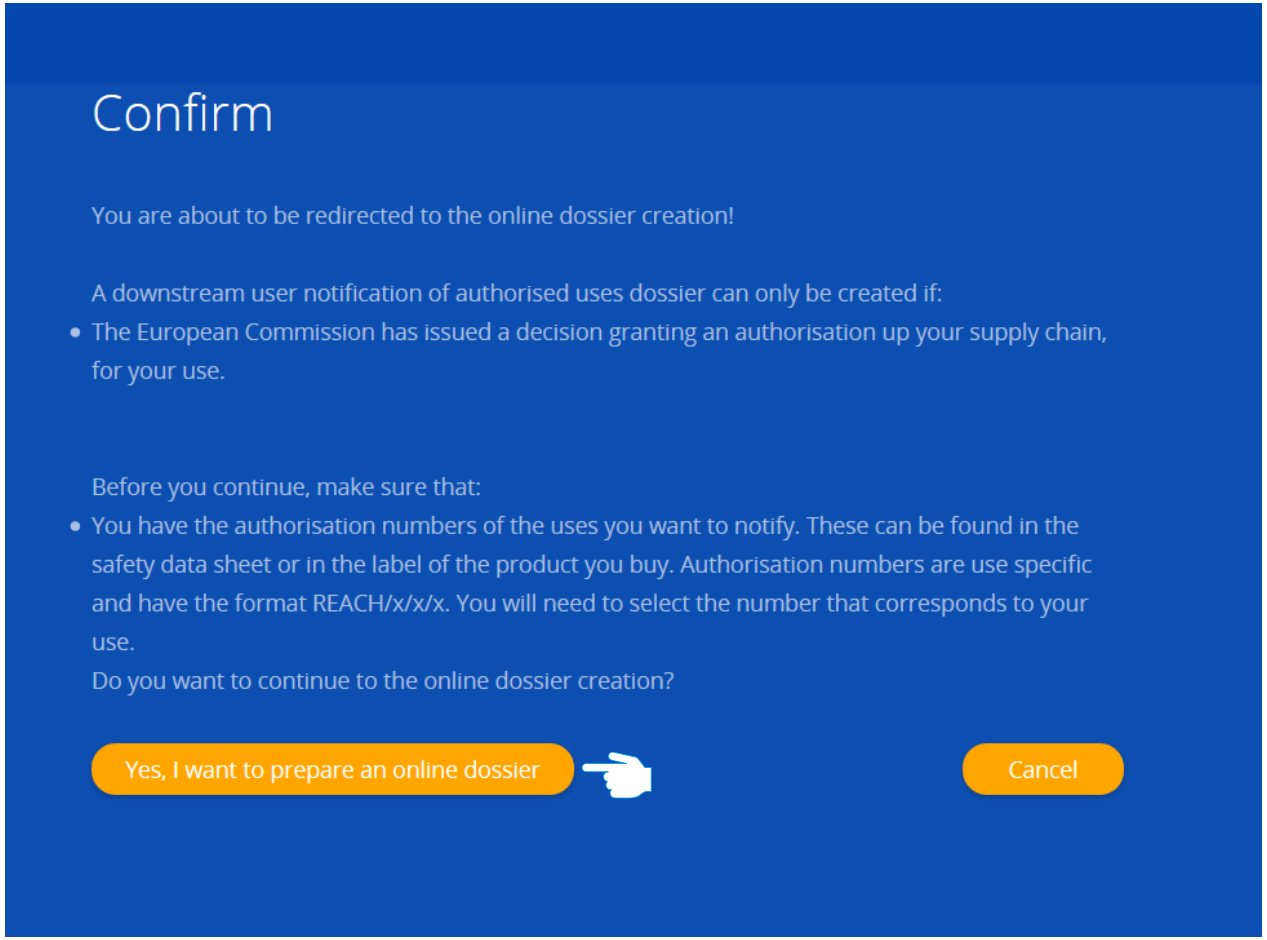

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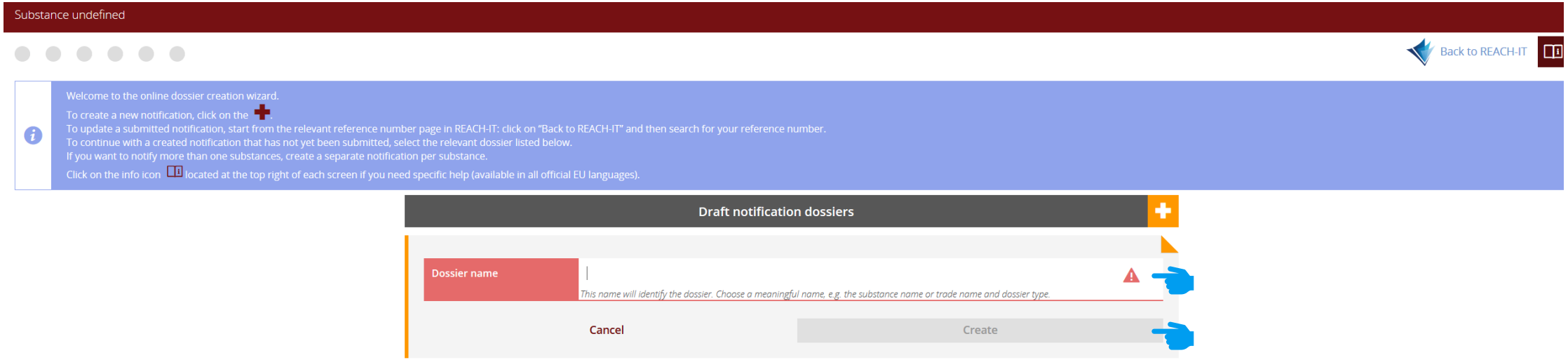

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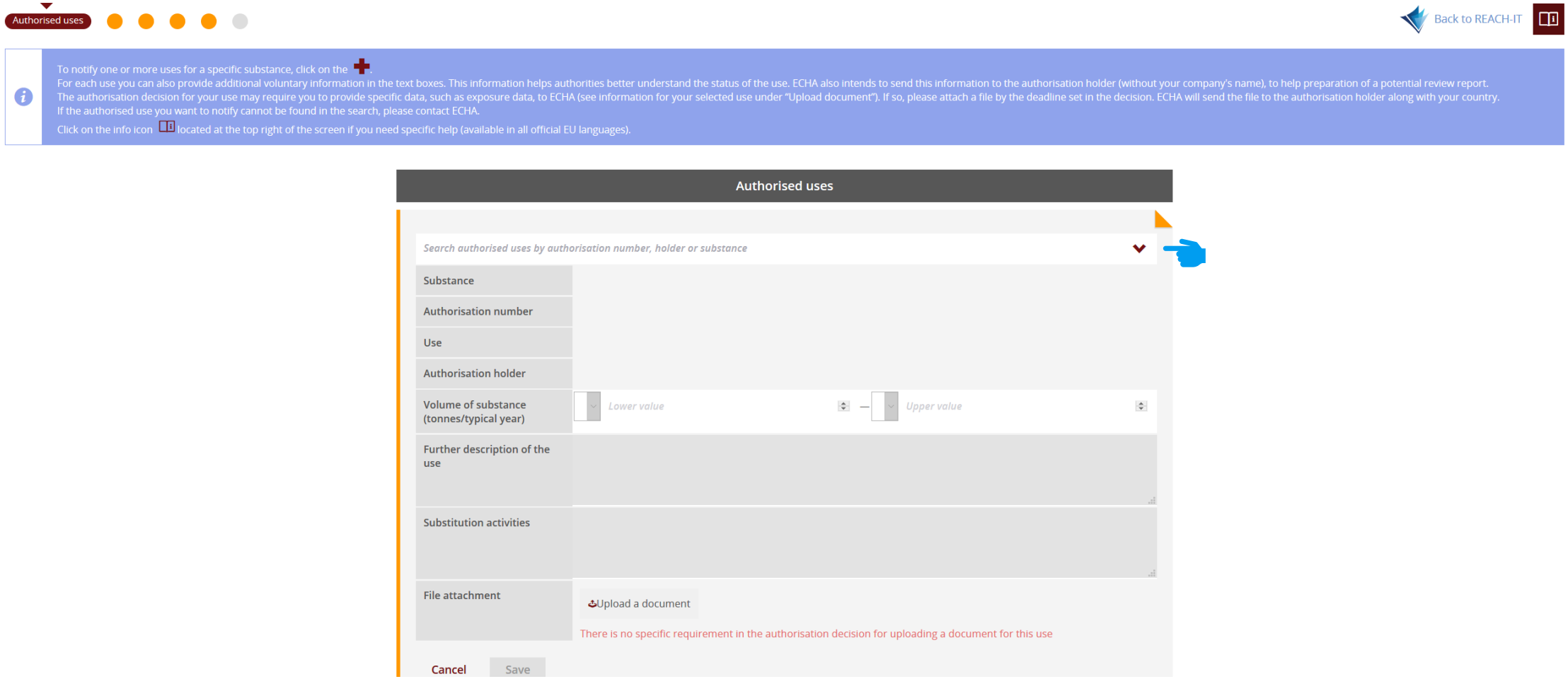
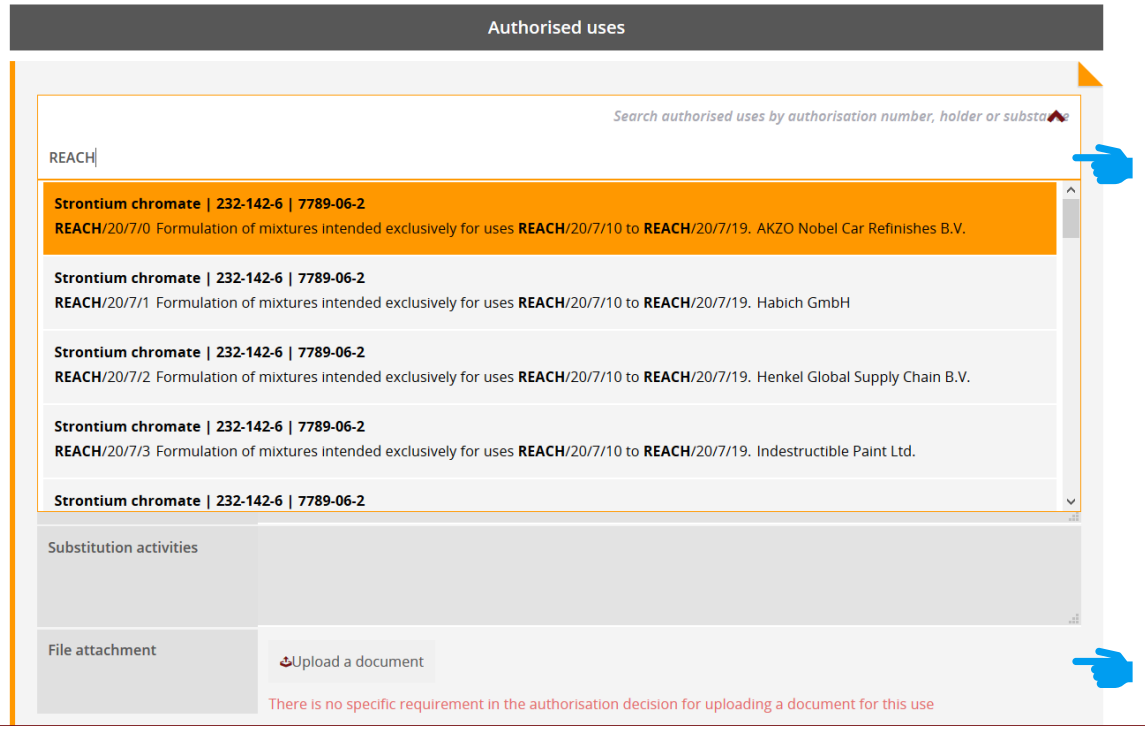


ANNEX - AUTHORISATION CONDITIONS NOTIFICATION – HOW TO INFORM ECHA

To notify one or more uses for a specific substance, click on the ✚.
For each use you can also provide additional voluntary information in the text boxes. This information helps authorities better understand the status of the use. ECHA also intends to send this information to the authorisation holder (without your company's name), to help preparation of a potential review report.
The authorisation decision for your use may require you to provide specific data, such as exposure data, to ECHA (see information for your selected use under "Upload document"). If so, please attach a file by the deadline set in the decision. ECHA will send the file to the authorisation holder along with your country.
If the authorised use you want to notify cannot be found in the search, please contact ECHA.
Click on the info icon located at the top right of the screen if you need specific help (available in all official EU languages).



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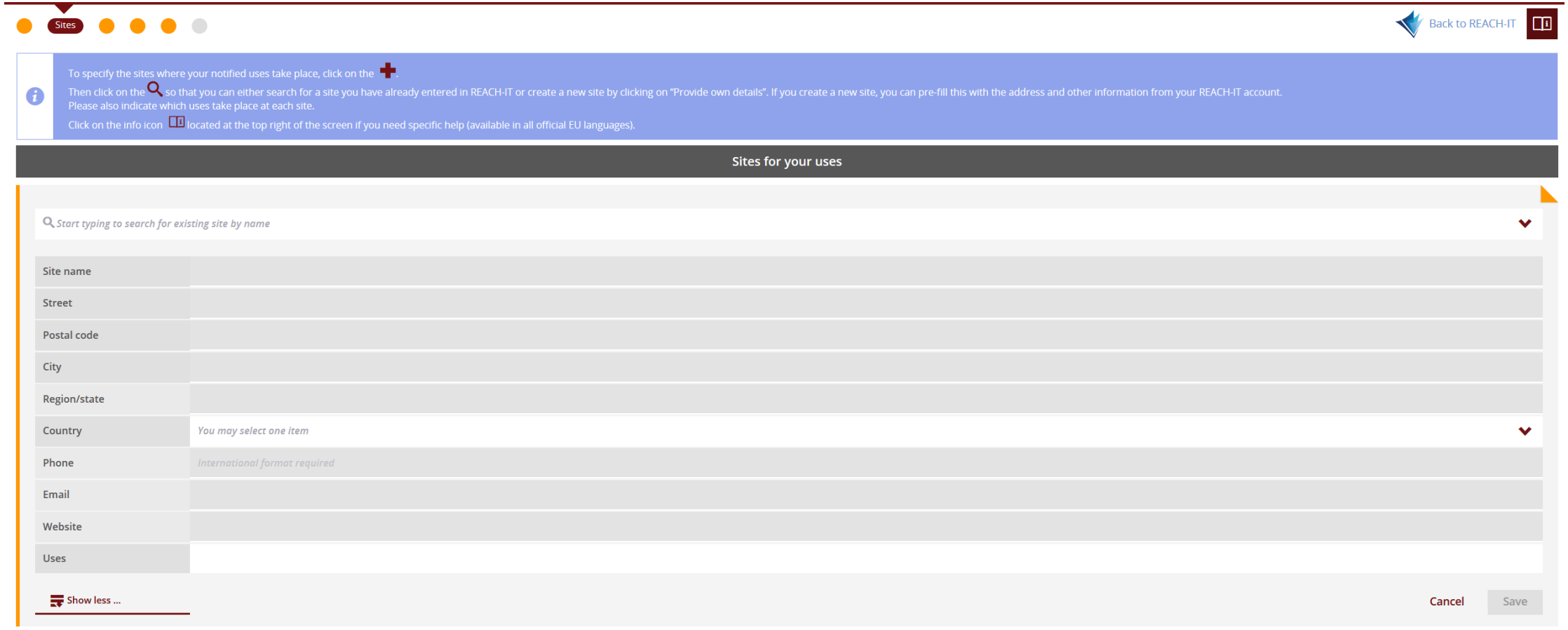

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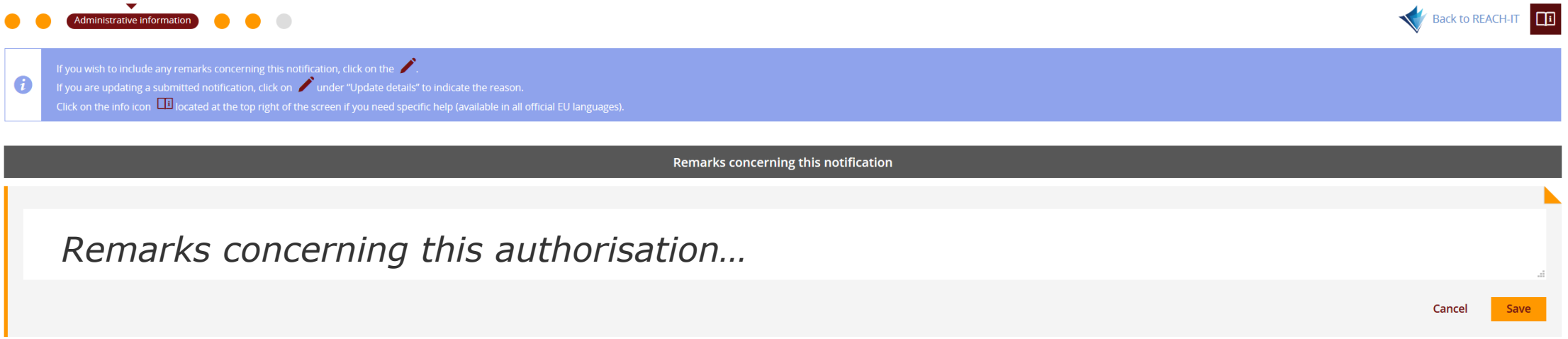

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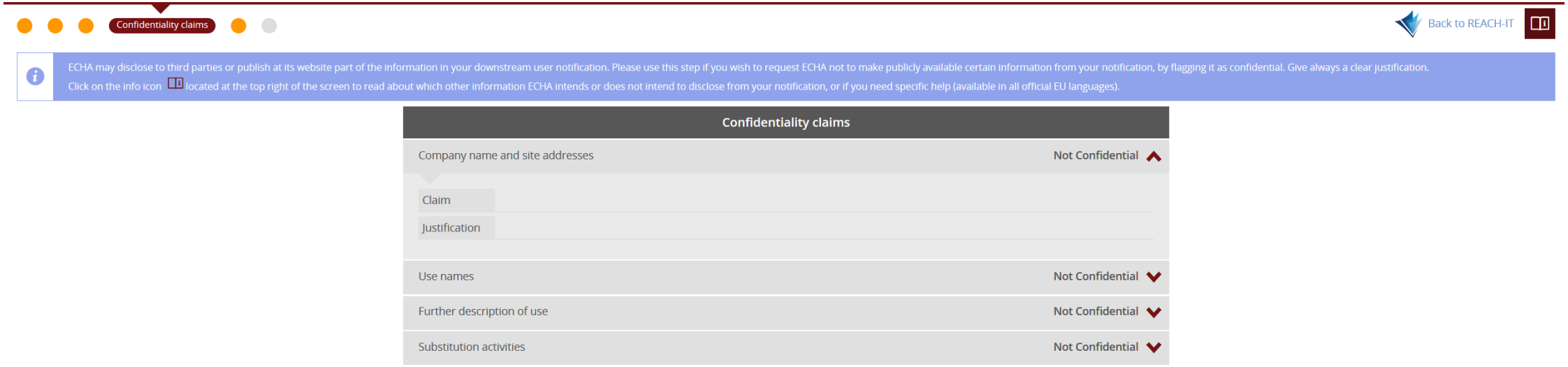

ANNEX - AUTHORISATION CONDITIONS NOTIFICATION – HOW TO INFORM ECHA

- Obligatory information to hand in:
  - Name of the company
  - Authorisation number (REACH Authorisation number 'REACH/xx/xx/x`)
  - Contact information
  - Specific information (e.g., measurement results)

- Volunatary information to hand in:
  - Annual tonnage of the substance
  - Number of employees working with the substance
  - Short description of your uses and your contribution to potential substitution activities

What will happen to your data?

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