



Workshop on REF-9 project results and recommendations with ECHA Accredited Stakeholders Organisations and industry representatives

12 May 2023



Workshop prepared by the Forum Working Group

The Forum coordinated enforcement project REACH-EN-FORCE-9
'Enforcement of compliance with REACH authorisation obligations'

The final REF-9 project report was published on the ECHA website on the 8th of March 2023
(links: [news release](#) and REF-9 [project report](#)).



2.0. REF-9 project on REACH authorisation - results

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12 May 2023

Eugen Anwander

Chair Forum Working Group REF-9



Information on inspections

- In 2021 and Q1 2022 **28** countries participated with inspections in the REF-9 project
- A total of **690** inspections of substances were reported, while **502** inspections actually have covered an Annex XIV substance with the sunset date already passed
- In this way **404** companies were inspected
- **79%** of the inspections were on-site inspections (focus on control of use)

REACH Authorisation obligations & inspections

Inspections along the **full value chain**

Duty holder	Art. 56, not Art. 56(2)	Art. 56(2)	Art. 60	Art. 65	Art. 66(1)	Art. 31	Art. 37(5)
	Autor. is in place	DU and Autor.	Safe use	Label	Notifi-cation	SDS	Imple-ment RMM
I / M	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
Supplier	(<input checked="" type="checkbox"/>)			(<input checked="" type="checkbox"/>)			
Formulator (DU)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Supplier	(<input checked="" type="checkbox"/>)			(<input checked="" type="checkbox"/>)			
End user (DU)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>

REACH Authorisation obligations & inspections

6 years of inspections

Duty holder	Pilot Authorisation 1	Pilot Authorisation 2	REF-9
year of inspections	2014/2015	2016	2021
special focus	exemptions	authorisations	uses
I / M	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Supplier	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)
Formulator (DU)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Supplier	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)
End user (DU)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Substances inspected in REF-9

- The **most frequent substances** checked were chromium trioxide (**47%**) and strontium chromate (**12%**) out of 31 different substances
- **73 different uses** defined in applications for authorisations or in granted authorisations were inspected
- In addition, **63 different uses primarily linked to exemptions** from authorisation (e.g., intermediate use) were also inspected

Companies inspected in REF-9

- 90% of companies had the role of a **downstream user**

Situations identified during inspections

Situation for the Annex XIV substance is covered by	p.o.m.	use
Companies own authorisation	16	44
Authorisation granted to a supplier	48	324
Pending application for Authorisation	5	29
Exemption from Authorisation	23	55
In „full“ breach with Authorisation obligation	6 (1%)	11 (2%)
Number of inspections	98	463

p.o.m. - placing on the market

Some key inspection results

- **35%** of DU inspections identified an **absent supply chain communication** on OC/RMM/PPE and on monitoring arrangements
- Once the **critical information in the supply chain** is available to DU:
 - **10%** of cases lack the information on OC/RMM/PPE
 - **20%** of cases lack the information on monitoring arrangement
- When **DU use** the authorised substance non-compliance is about
 - **20%** related to applying the OC/RMM/PPE or additional conditions
 - **30%** related to monitoring conditions
 - **19%** related to the Article 66 notification duty to ECHA

Non-compliances

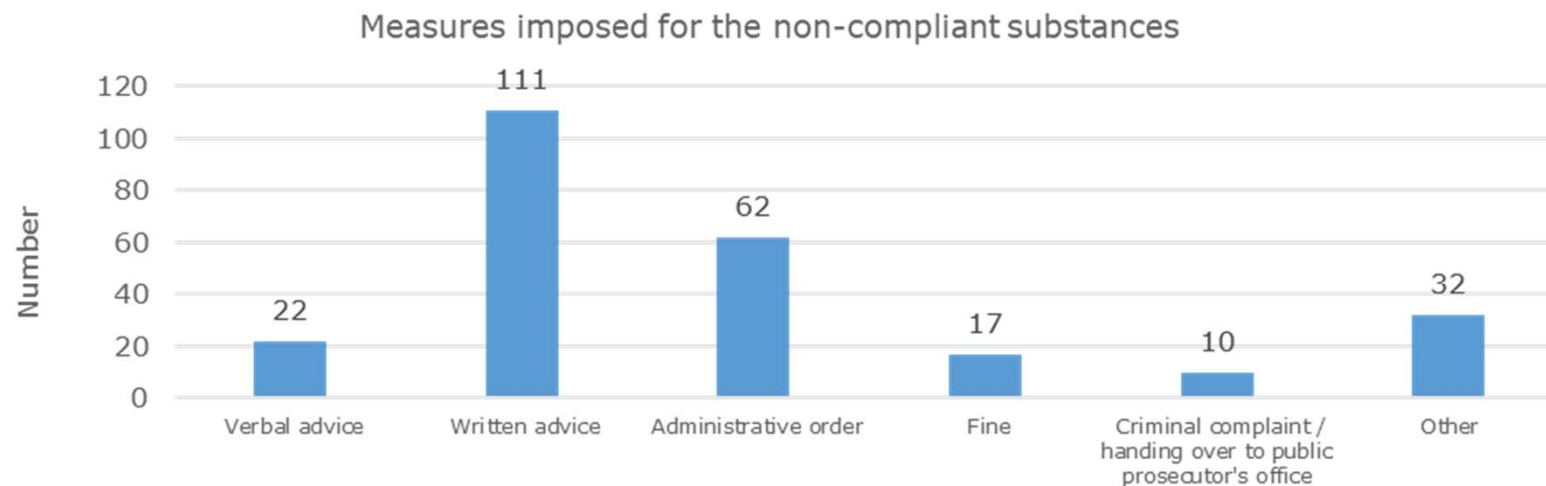
- **203** out of 502 substances inspected were found non-compliant with REACH obligations, that were in the scope of the REF-9 project - **40%** non-compliance rate
- Non-compliances were as follows (multiple non-compliances were detected):

REACH Articles	Number (non-compliant inspection)	Frequency (% of related inspections)
Art. 56 (1)	23	7%
Art. 56 (2)	97	26%
Art. 65	31	19%
Art. 66 (1)	73	20%
Art. 37 (5)	99	26%
Art. 31	41	18%

- Cases being fundamentally in breach with the REACH authorisation provisions under Article 56: **3% of inspections** have identified such cases (both, related to use and to placing on the market) – “free riders”

Measures

→ **254** enforcement measures for 203 cases of non-compliance



→ **72%** of cases covered by ongoing follow-up activities by the enforcement authorities

Conclusions

- **90%** of inspections focused on uses by downstream users
- The overall non-compliance rate of **40%** is quite alarming
- "Downstream user obligations" are the most frequently reported non-compliances (up to **26%** non-compliance for obligations of Articles **37(5)**, **56(2)** and **66(1)** of REACH); supplier duties are less affected (20%)
- Problems in the supply chain communication contribute to DU's non-compliance (e.g. 35% cases with absent supply chain communication)
- REACH authorisation obligations are generally observed by duty holders, however, the support by suppliers to downstream users (supply chain communication) requires considerable improvements

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2.0. REF-9 project recommendations

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12 May 2023

Majella Lowe
IE WG REF-9 member



Recommendations to Industry

Improve the quality of extended SDS's

1. In relation to conditions of use with the OC/RMM/monitoring arrangements clearly set out.
2. Relevant information communicated down the supply chain in clear and concise language easily understood by DU.
3. SDS in Language of MS.
4. Prompt update SDS when Authorisation granted.

Recommendations to Industry

Active communication in supply chain:

1. Suppliers to implement Systems/Procedures for DU to request additional information, seek clarification in relation to OC/RMM/monitoring arrangements for their specific uses.
2. Downstream users (DU)
 - Ensure that the substance is used in accordance with the Authorisation decision for the specific use, in accordance OC/RMM.
 - Seek clarification from supplier if the OC/RMM for their specific use is unclear from extended SDS.
 - Ensure Art 66 notification is maintained up to date.

Recommendations to Commission

Commission to ensure:

1. Authorisation decisions are clear enough for implementation by the duty holders and to enable effective enforcement.
2. Most up to date information, succinct summaries/CSR's/Authorisation decisions are available on one dedicated website.
3. Improve information flow and control of authorised substance in the supply chain.

Recommendations to ECHA Secretariat/Inspectors

1. ECHA Secretariat to develop guidance for suppliers and users of authorised substances in relation to their duties to improve compliance.
2. Inspectors encouraged to continue to raise awareness of specific duties of suppliers and actors in supply chain including DU of authorised substances.

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3.0 NL NEA experience

Workshop with ECHA Accredited Stakeholders Organisations and industry representatives

12 May 2023

Mirjam van der Meer

NL WG REF-9 member
Coordinator REACH
Human Environment and Transport
Inspectorate
the Netherlands



Forum Project REF-9 - the Netherlands

Participating NL REACH inspection partners:

-  • Consumer products safety (NVWA)
-  • REACH/OSH (NL Netherlands Labour Authority)
-  • Industrial and professional products (ILT)
-  • Customs



Reinforcement REACH Autorisation

Compliance check of complex Autorisation uses in the supply chain requires capacity, experience and expertise.

A collaboration of the REACH inspectors with expertise of occupational safety and health (OSH), environment, consumers product safety, customs.

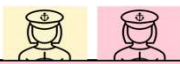
REACH inspectors from different inspectorates reinforced our information position with:

Sharing expertise on monitoring, exposure, implementing RMMS and information requirements

Reality check on the compliance with:

- Information requirements upstream > downstream and vice versa
- Import volume, trade and downstream use/customers

Sharing results and reflection on findings



ILT Customs



ILT professional NVWA consumers



ILT (REACH)

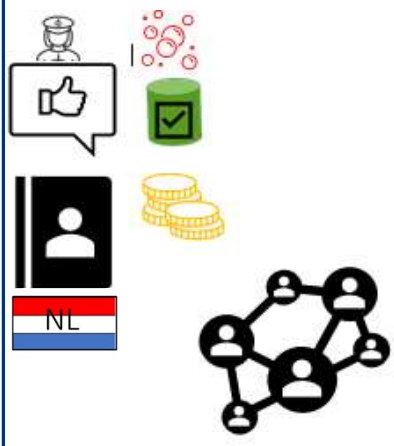


Netherlands Labour Authority (OSH/REACH)

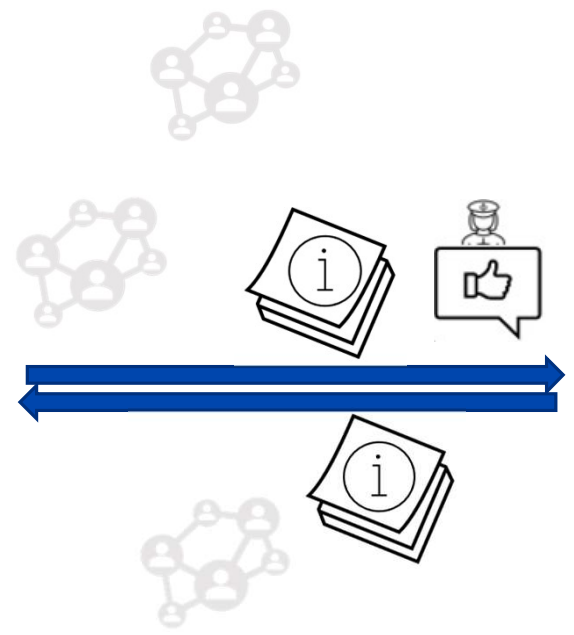
Import control



Producer/Importer/OR
Authorisation holder

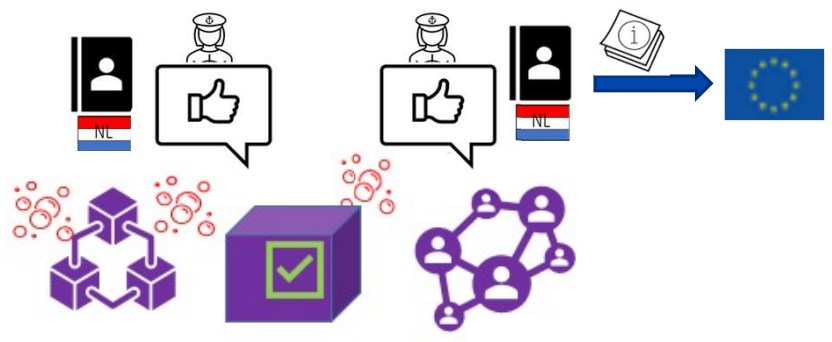


Distributors

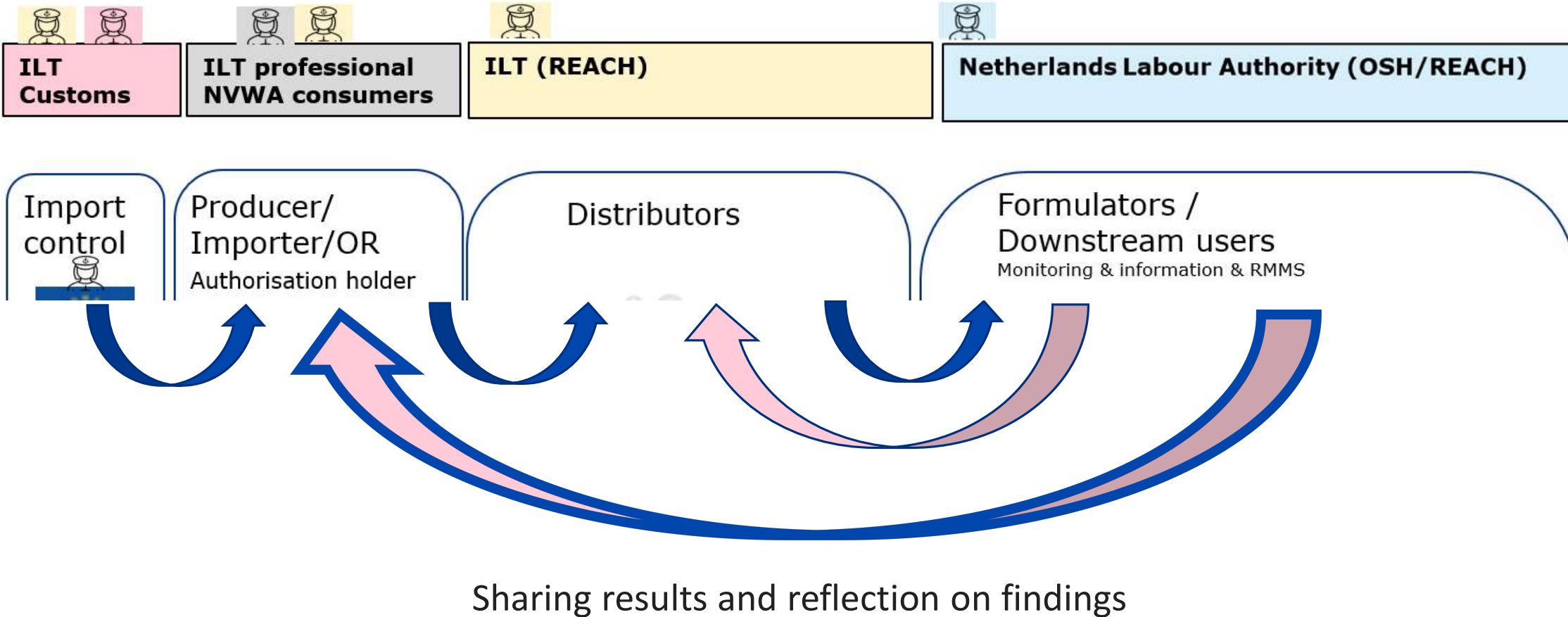


Formulators / Downstream users

Monitoring & information & RMMS



Control and reflection – Reality check at customers



Reality check
upstream and downstream

Reinforce the inspectors
experts by sharing and
reflection on complex cases

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3.0. Authorisation – NO experiences from inspections 2021-22

Workshop with ECHA Accredited Stakeholders Organisations and industry representatives

12 May 2023

Tore Alfheim
Senior Engineer
Norwegian Labour Inspection Authority



Number of inspections 2021 - 2022

The Norwegian Labour Inspection Authority investigated the use of hexavalent chromium compounds in 2021 and 2022.

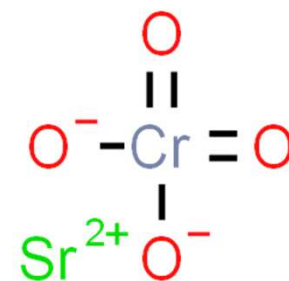
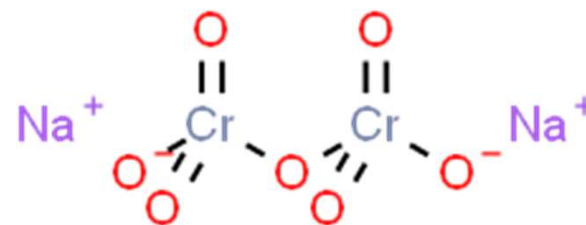
We carried out inspections with:

Downstream Users

17 inspections

Suppliers

6 inspections



Authorised use and substances

Example use:

- Surface treatment for applications in the aeronautics and aerospace industries
- Functional chrome plating – e.g., corrosion resistance, chemical resistance....

Substances, used alone or in mixtures:

- Chromium trioxide
- Strontium chromate
- Sodium dichromate
- Potassium dichromate
- Dichromium tris(chromate)
- Pentazinc chromate octahydroxide
- Potassium hydroxy octa oxo dizincate dichromate

Different kind of use, defence, aircraft/helicopter, engine



Different kind of use, aluminium profiles, offshore



Different kind of applications....



Findings – downstream users



Monitoring programmes for chromium (VI)

No one had performed monitoring according to terms of authorisation, for

- Occupational exposure
- Emissions (air from local exhaust ventilation and/or waste water)
- Inhalation exposure in combination with post-shift biomonitoring, where relevant (spraying)

Personal protection

- Wrong type of filter in respiratory protective equipment (RPE)
- Lacking procedures for fit testing of RPE
- Wrong kind of glove materials
- Glove material was not assessed on the basis of combination exposure

Findings – downstream users

Ventilation

- All have ventilation / process extraction. Difficult to assess whether appropriate and effective enough
- Subsequent responses to orders given, showed high exposure values (much over the Norwegian OEL, 0,001 mg/m³)

Risk assessment

- Not well enough specified; risk management measures and operational conditions, ventilation conditions, personal protective equipment
- Does not appear that the substance is subject to authorisation
- No information about Norwegian exposure limit value
- Not in accordance with the Norwegian regulation relating to the Performance of Work

Findings – downstream users

Work instructions

- Lack of work instructions
- Not good enough work instructions – not sufficiently specified protective measures

First aid

- Lack of easily accessible emergency shower and eye-wash equipment
- Substance in hydrofluoric acid mixture – lack of readily available antidote in case of skin contact (calcium gluconate gel)

Findings – downstream users

- Insufficient knowledge of authorisation
- Nearly no one had sent notification – some done after we had informed about the inspection
- Not updated SDS
- Not familiar with current authorisation decisions
- Not familiar with the conditions for being allowed to use the substances
- Many conditions are not met
- Insufficient information from suppliers about authorisation and terms of use

Something positive

Substitution – some users have replaced chromate and several are considering replacing

Findings – suppliers

Insufficient knowledge of authorisation

Not updated SDS. Example missing in SDS;

- Sections 2.2 and 15. - information about authorisation
- Specified protective equipment
- Norwegian OEL value (0,001 mg/m³)

Not familiar with the responsibilities of the authorisation holder or the downstream users

Not good enough information to downstream user

Not good enough routines for fulfilling obligations in accordance with REACH and the Norwegian Working Environment Act

Our conclusion

Really bad!



A lot of guidance during inspections and follow up proceedings

A lot of administrative orders given

We have given long deadlines for conducting measurements

The Norwegian Labour Inspection Authority posted information about the REF project on authorisation, on the website February 2021

The Norwegian Environment Agency had similar information, and also has comprehensive information on authorisation on its website.

NOT READ???

The way forward?

Consider inspections of other substances

Considering to be stricter in imposing violation fines

Challenges

- Norway has many small companies with no or little expertise in the chemical field
- DU receives poor guidance from the Norwegian suppliers
- The role of distributors not good enough defined in REACH – We have also used legal basis from Norwegian regulations (administrative orders)
- Norwegian distributors receives poor information from their suppliers/producers
 - Poor information in SDS (In regulation 2020/878 there must be info in section 15 about conditions of use)
 - Poor translation to Norwegian in SDS. ES not in Norwegian
 - Large suppliers outside Norway are poorly acquainted with Norwegian special rules. They have their professional expertise outside Norway. (No knowledge of Norwegian exposure limits, Norwegian relevant regulations.....)
 - Some suppliers/manufacturers in Europe believe that since Norway are not members of the EU, they do not need to meet obligations under REACH, such as SDS in Norwegian...

Thank you for your attention

Contact:

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3.0. IE NEA experience.
Limited use/costly implications

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12 May 2023

Majella Lowe
IE WG REF-9 member



Authorised use in Aerospace Industry



Authorised use in Aerospace Industry

Material used to carry out the repair contains Dichromium tris(chromate), CAS No 24613-89-6 used for surface treatment in aerospace industry corrosive resistance.

Original Equipment Manufacturer Manual (OEM) specifies chemicals/process to be used to carry out repairs.

The aerospace industry is very regulated and the company cannot deviate / use alternatives to those specified.

Authorised use in Aerospace Industry

Company carry out task very infrequently (1/year). Usage is miniscule (<100mls), with very controlled usage in pen format (concentration authorised substance is <1% in the material being used). Extremely low risk from an OSH point of view but still user must comply with authorisation decision.

Authorisation Decision requires monitoring to be carried out annually.

Downstream user notification

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4.0. Impact of REACH authorisation on the use and exposure of SVHCs

Workshop with ECHA Accredited Stakeholders Organisations and industry representatives

12 May 2023

Matti Vainio

Head of Risk Management Unit II
European Chemicals Agency



Authorisation under REACH



Aim is to ensure that:

- the risks from Substances of Very High Concern (SVHC) are **properly controlled** and
- that these substances are **progressively replaced by suitable alternative substances or technologies**
- where these are economically and technically viable and whilst
- ensuring the good functioning of the EU internal market.

Are SVHCs progressively
replaced by suitable
alternative substances or
technologies?

Authorisation list

59 entries (substance or group)

30 no application for authorisation received

29 entries for which:

➤ **285** Applications for authorisations received

➤ **438** Uses applied for

248 Authorisations granted

August 2022

Substance name	EC No.	CAS No.	Entry No.	Latest application date	Sunset Date	Intrinsic property
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	01	21-Feb-2013	21-Aug-2014	vPvB (Article 57e)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	02	21-Feb-2013	21-Aug-2014	Carcinogenic (Article 57a)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified	-	-	03	21-Feb-2014	21-Aug-2015	PBT (Article 57d)
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	04	21-Aug-2013	21-Feb-2015	<ul style="list-style-type: none"> Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - environment) Endocrine disrupting properties (Article 57(f) - human health)
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	05	21-Aug-2013	21-Feb-2015	<ul style="list-style-type: none"> Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health)
Dibutyl phthalate (DBP)	201-557-4	84-74-2	06	21-Aug-2013	21-Feb-2015	<ul style="list-style-type: none"> Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health)
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	07	21-Aug-2013	21-Feb-2015	<ul style="list-style-type: none"> Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health)
Diarsenic trioxide	215-481-4	1327-53-3	08	21-Nov-2013	21-May-2015	Carcinogenic (Article 57a)
Diarsenic pentoxide	215-116-9	1303-28-2	09	21-Nov-2013	21-May-2015	Carcinogenic (Article 57a)
Lead chromate	231-846-0	7758-97-6	10	21-Nov-2013	21-May-2015	<ul style="list-style-type: none"> Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)
Lead sulfochromate yellow	215-693-7	1344-37-2	11	21-Nov-2013	21-May-2015	<ul style="list-style-type: none"> Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)
Lead chromate molybdate sulfate red	235-759-9	12656-85-8	12	21-Nov-2013	21-May-2015	<ul style="list-style-type: none"> Carcinogenic (Article 57a) Toxic for reproduction (Article 57c)
Tris(2-chloroethyl) phosphate	204-118-5	115-96-8	13	21-Feb-2014	21-Aug-2015	Toxic for reproduction (Article 57c)
2,4-dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	14	21-Feb-2014	21-Aug-2015	Carcinogenic (Article 57a)

[Source: Authorisation List](#)

Approach

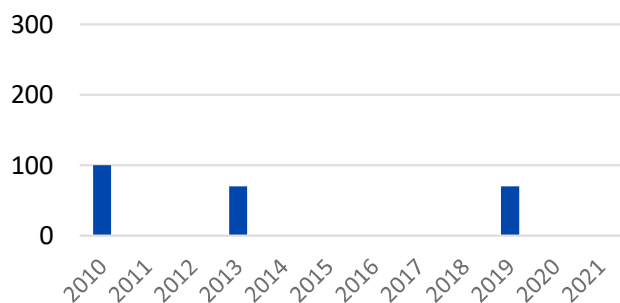
- Several data sources used
 - Applications, Eurostat (Cr(VI)), reported tonnages as part of registration (incl. cease of manufacture), information from companies
 - Tonnage for intermediate uses removed especially relevant for EDC (over 99% for PVC manufacture)
- Ensure tonnage information is representative

Filling data gaps

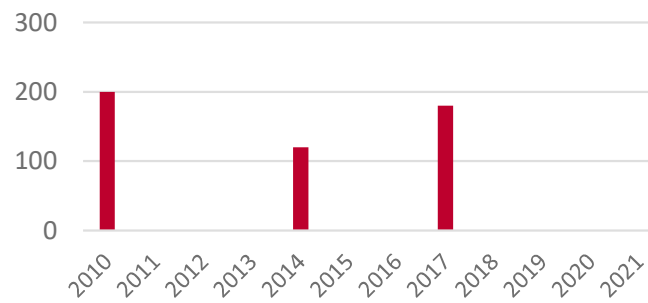
- Linear interpolation between two consecutive records.
- Gaps at the end of the reporting period extrapolated using last available record (“forward propagation of last record”)
- Cease of manufacture recorded when information was provided

Filling data gaps

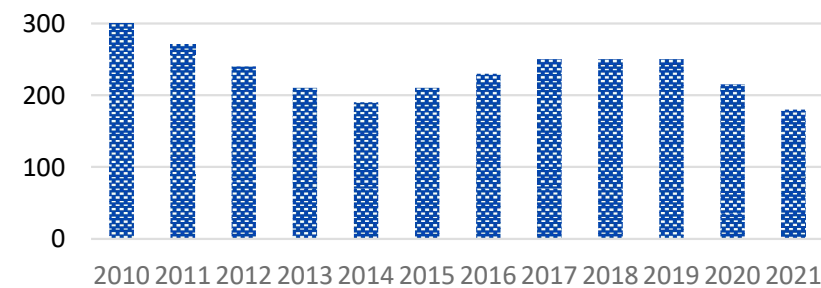
Registered data: Registrant 1



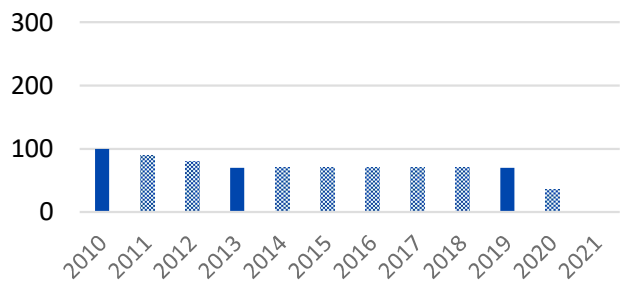
Registered data: Registrant 2



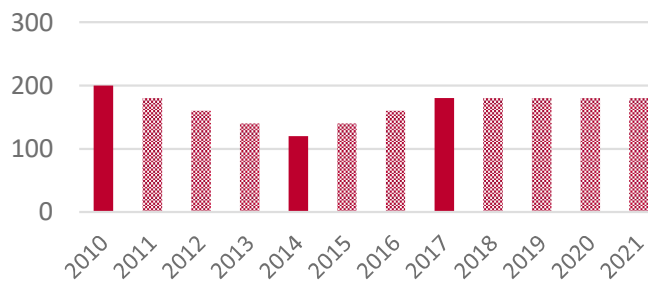
Estimations published in the special report



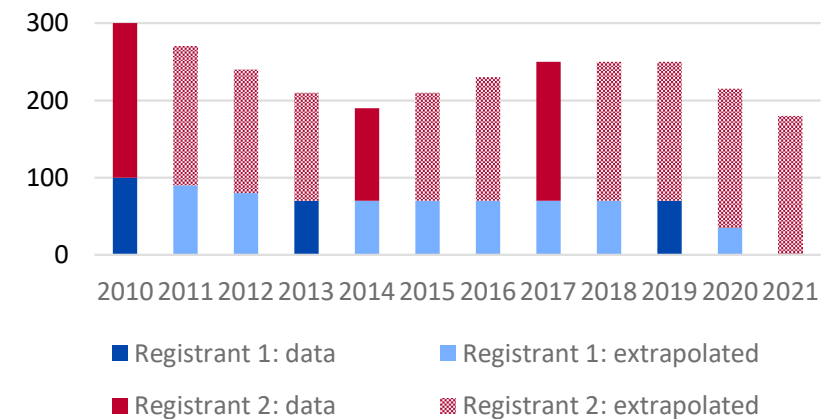
Extrapolated data: Registrant 1



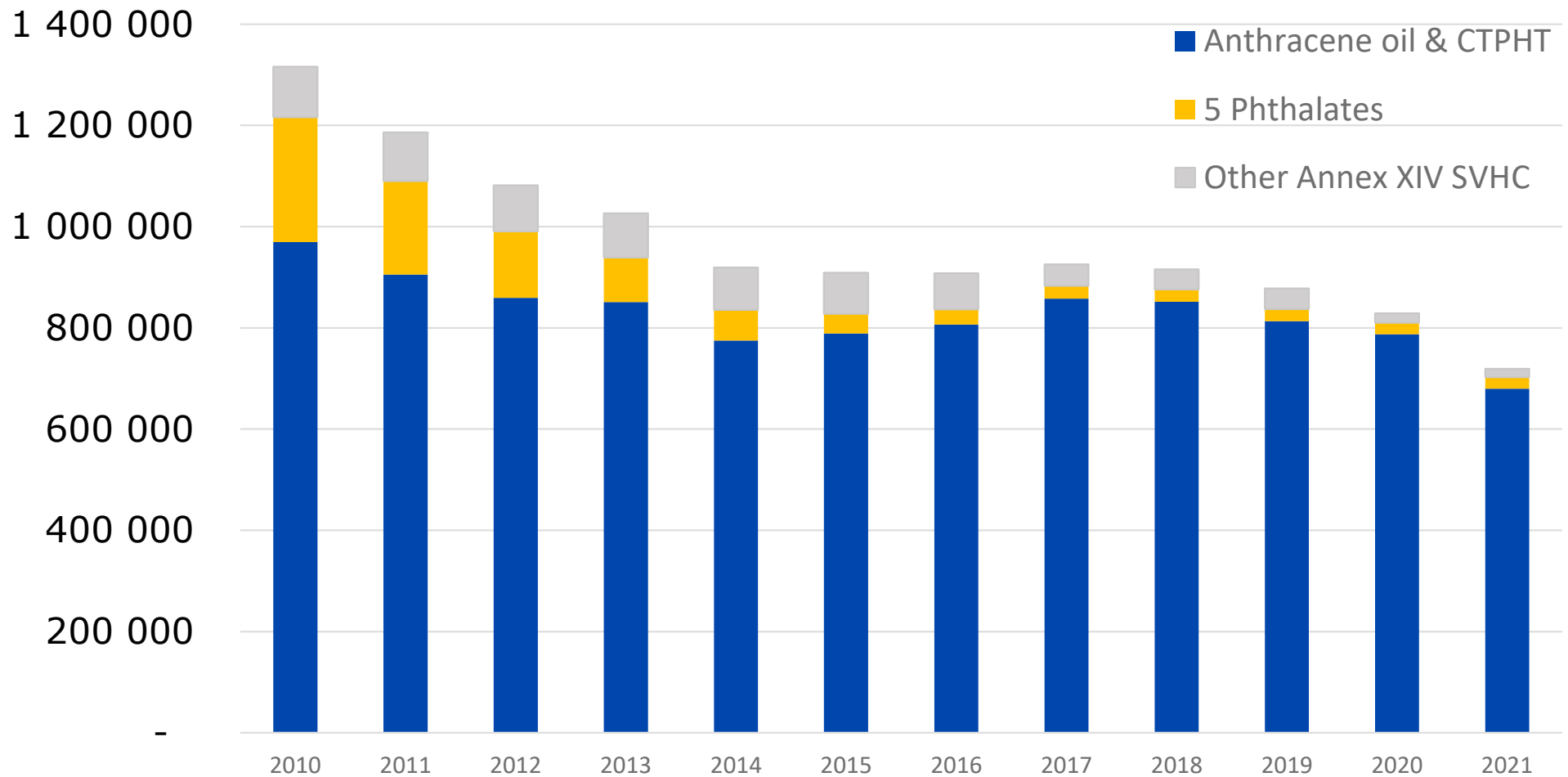
Extrapolated data: Registrant 2



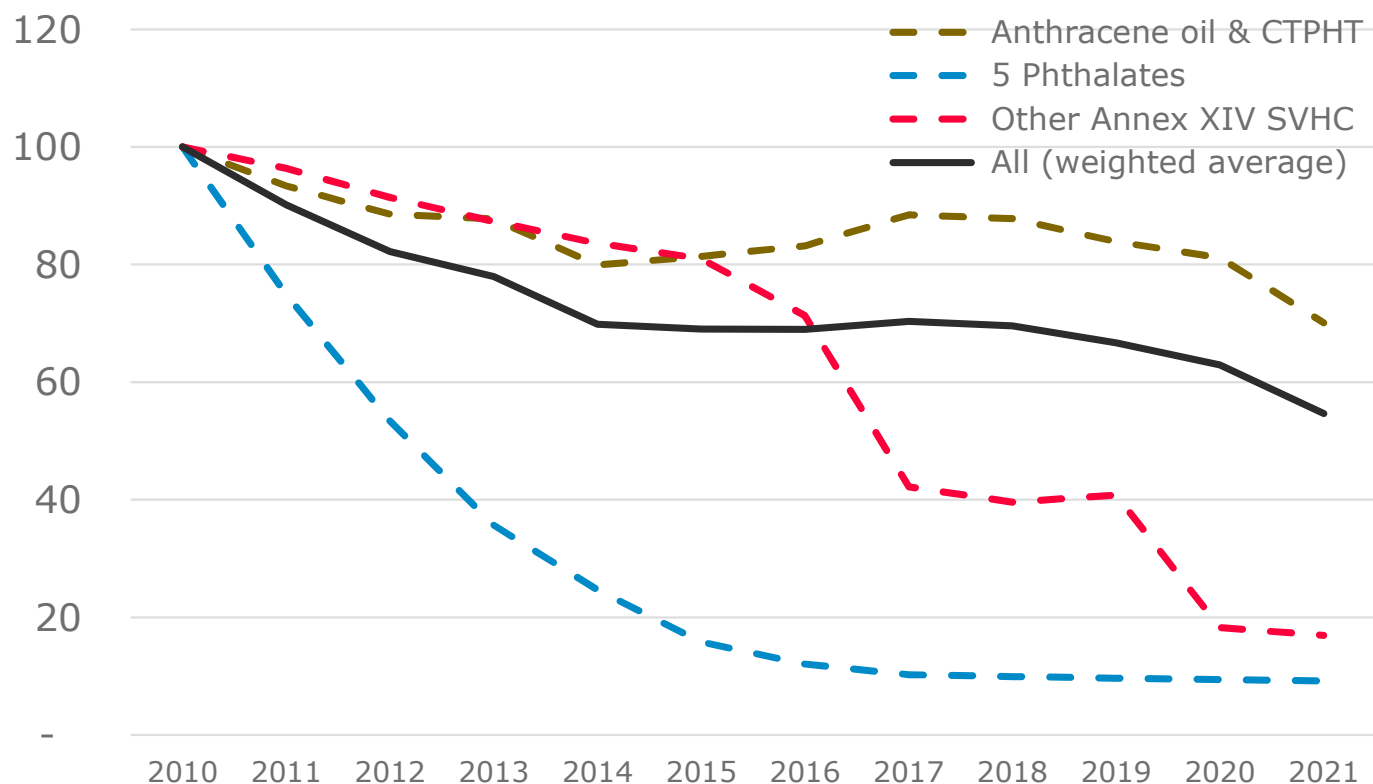
Combining data and extrapolations



Observations (tonnes 2010-21)



Observations (relative to 2010)



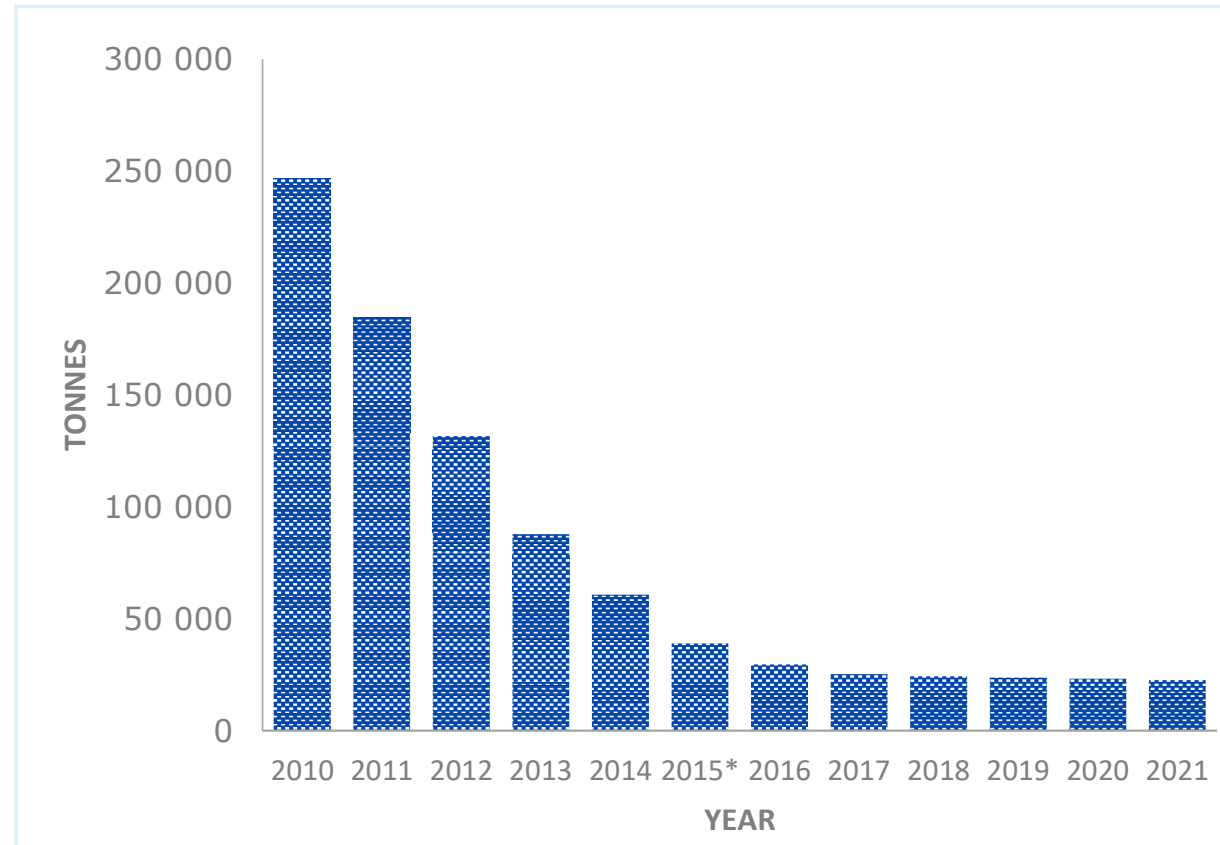
Overall tonnage reduction $\sim 45\%$

Differences:

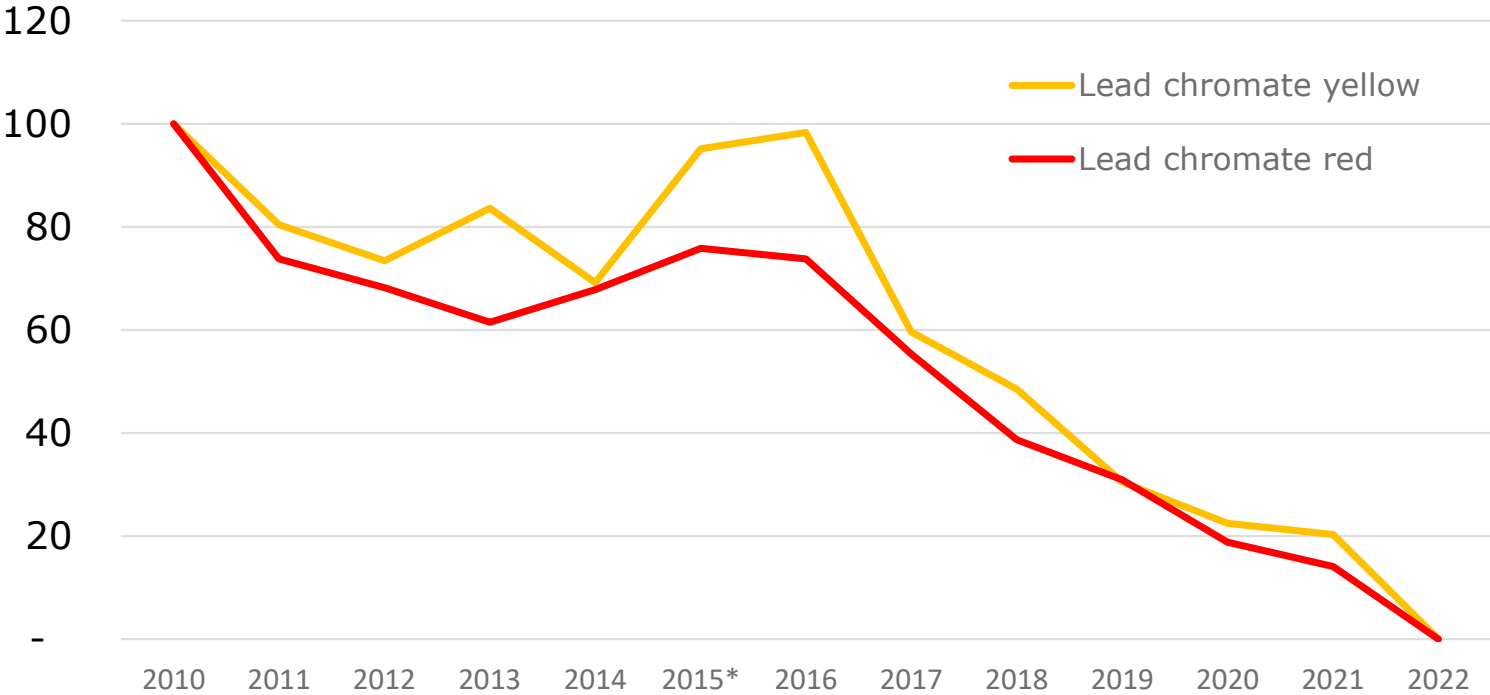
- Anthracene oil & CTPHT show smaller reduction ($\sim 25\%$) but correspond to lion share of use
- 5 Phthalates total reduction $\sim 90\%$
- Other Annex XIV SVHC total reduction $\sim 80\%$

DEHP and 4 other phthalates -90% (-100% in 2023)

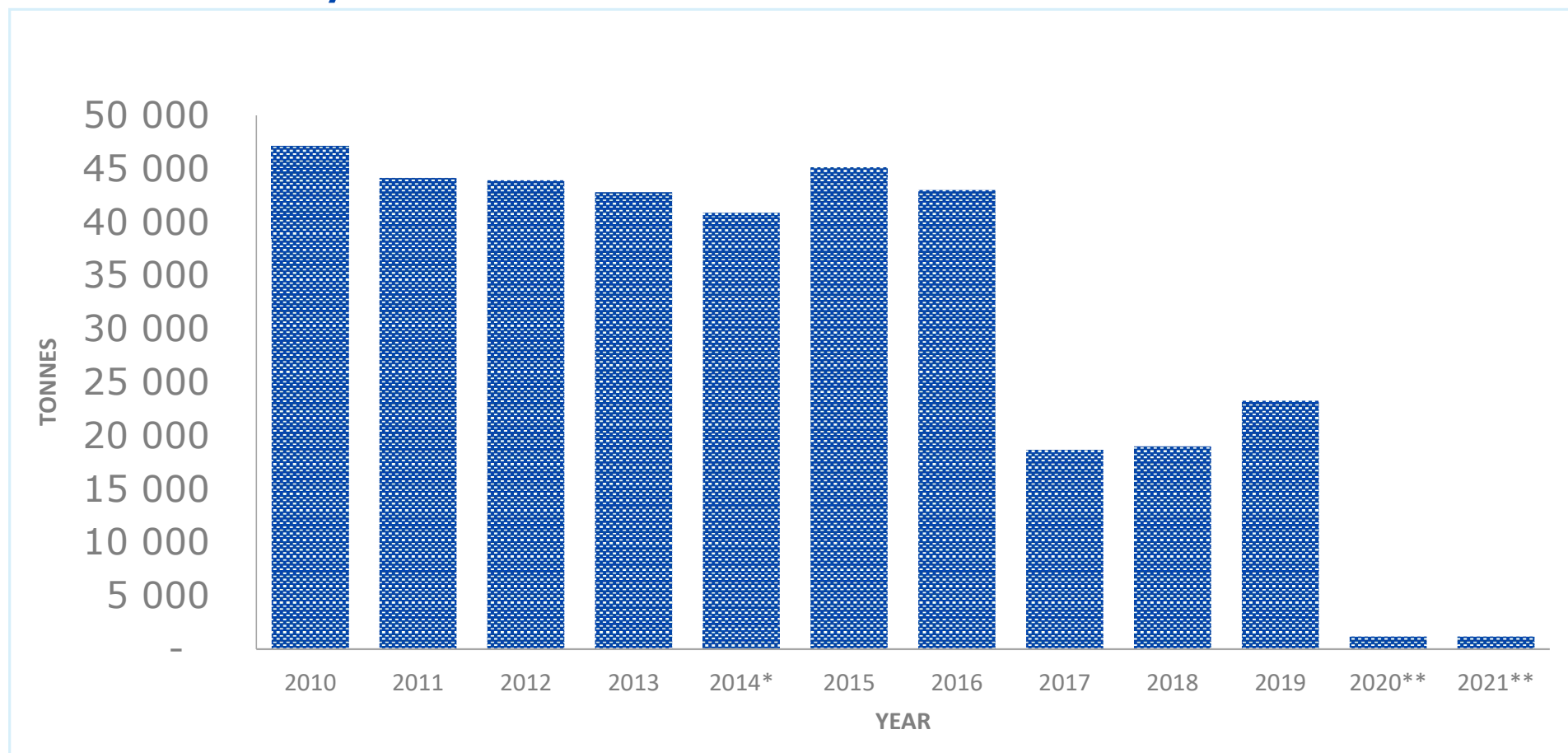
- Included in Annex XIV in 2011
 - Latest application date 2013
 - Sunset date in 2015
- Restriction of the use of DEHP, BBP, DBP, DIBP in articles entered into effect in July 2020
- Alternatives exist
 - other phthalates (DIDP and DINP) and DINCH
- In March 2023, last manufacturer (Deza) withdrew its application



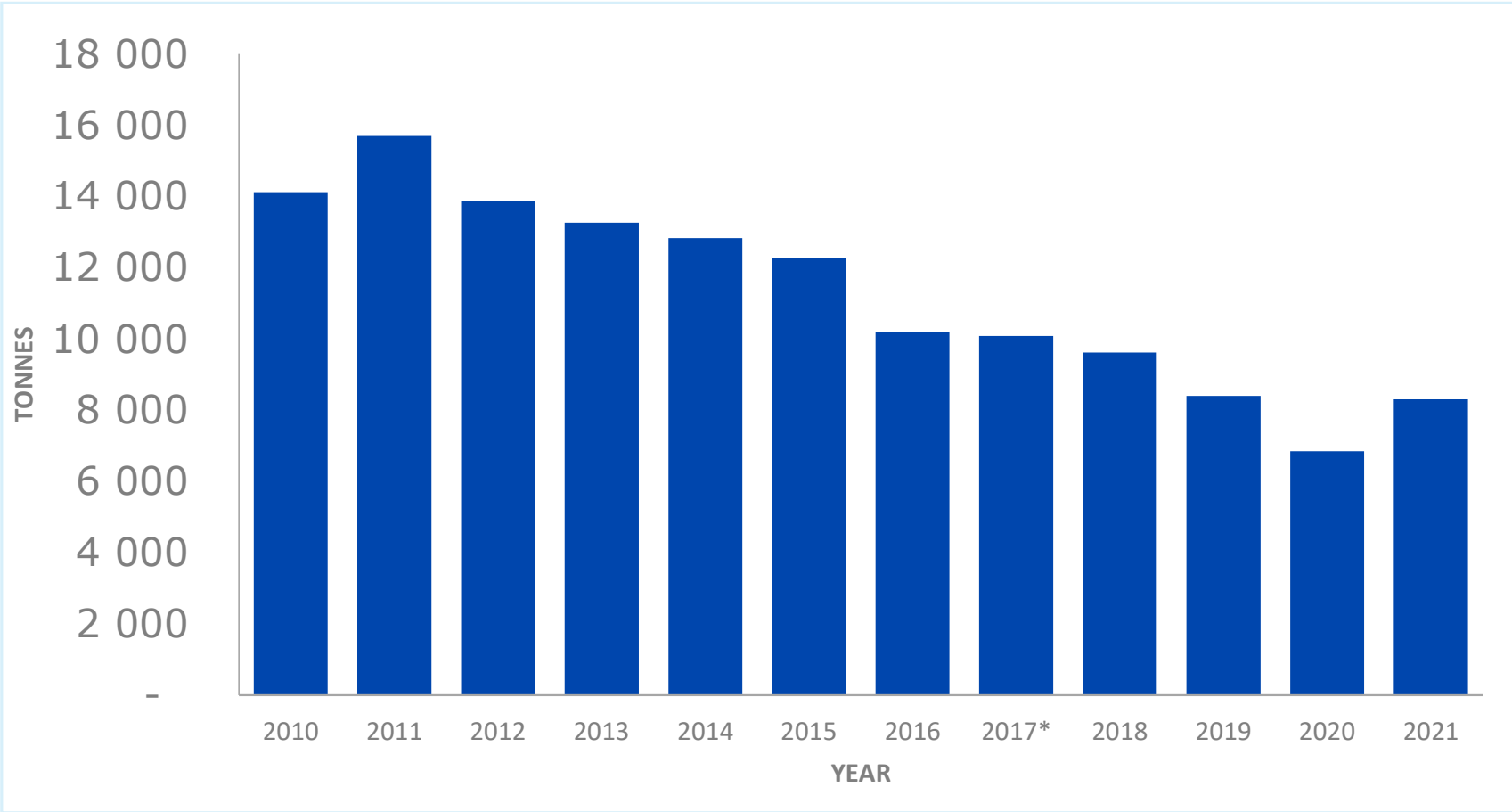
Lead chromates -100%



Trichloroethylene -95%

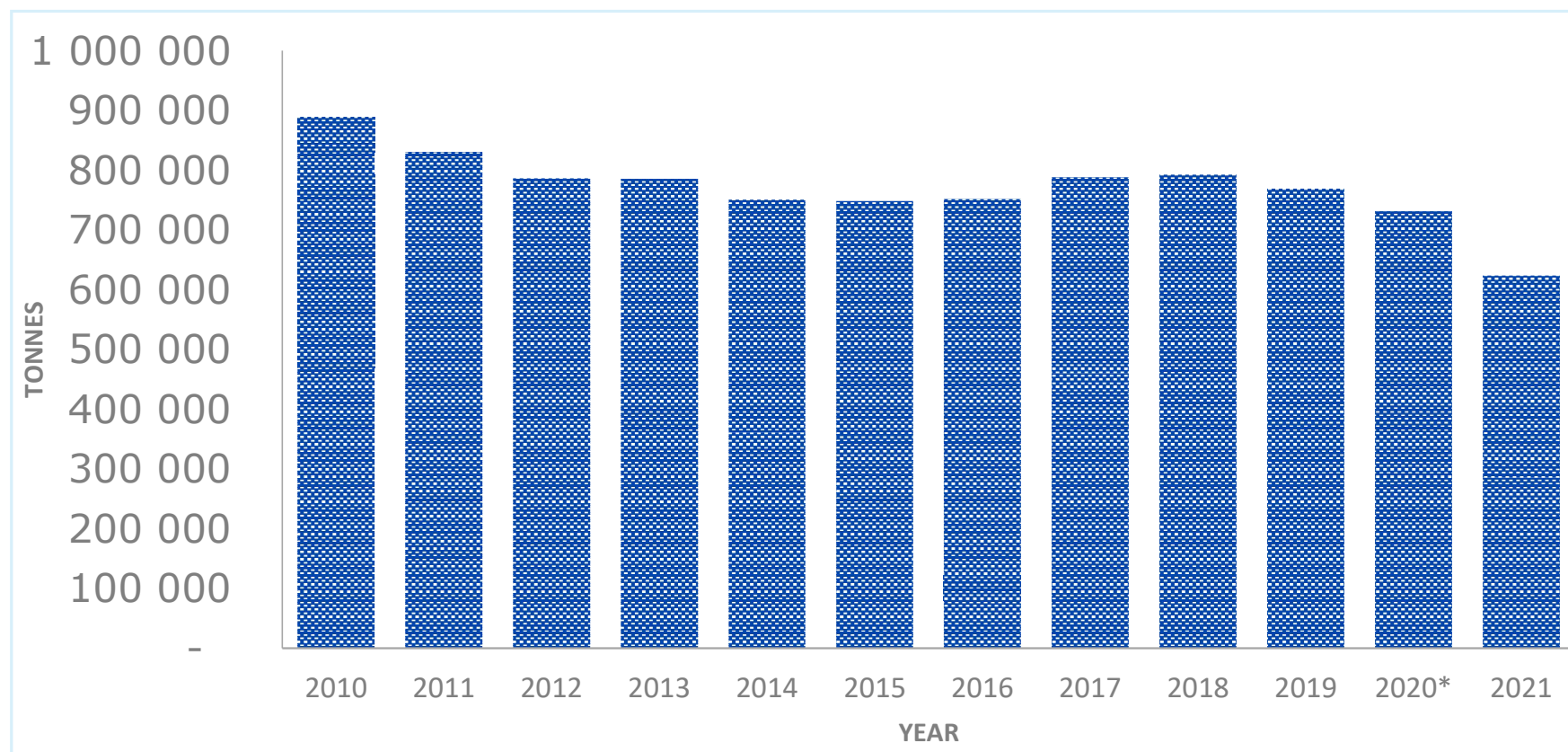


Chromium trioxide -40%

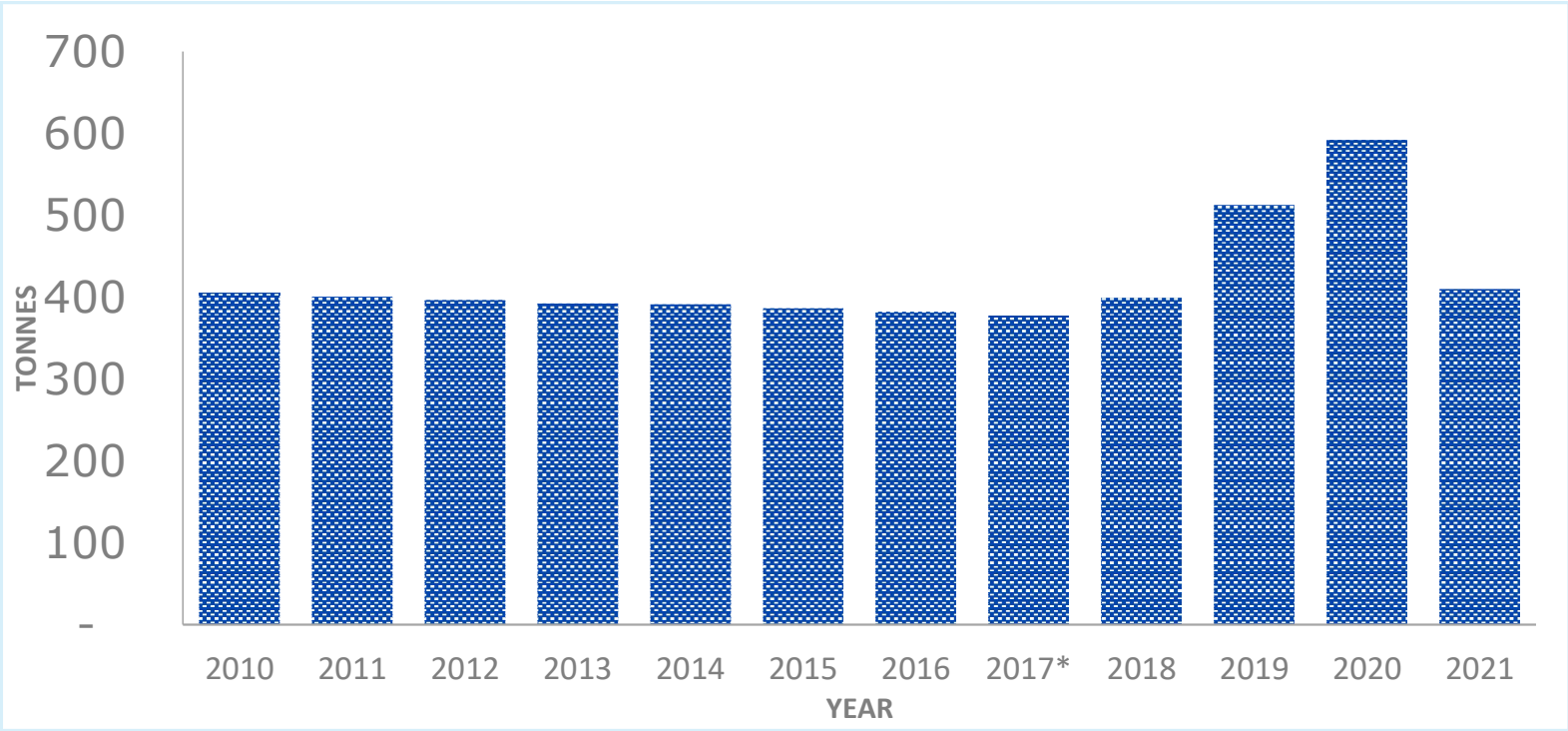


Source: Comext

Coal tar pitch, high temperature -30%



Diglyme +9%

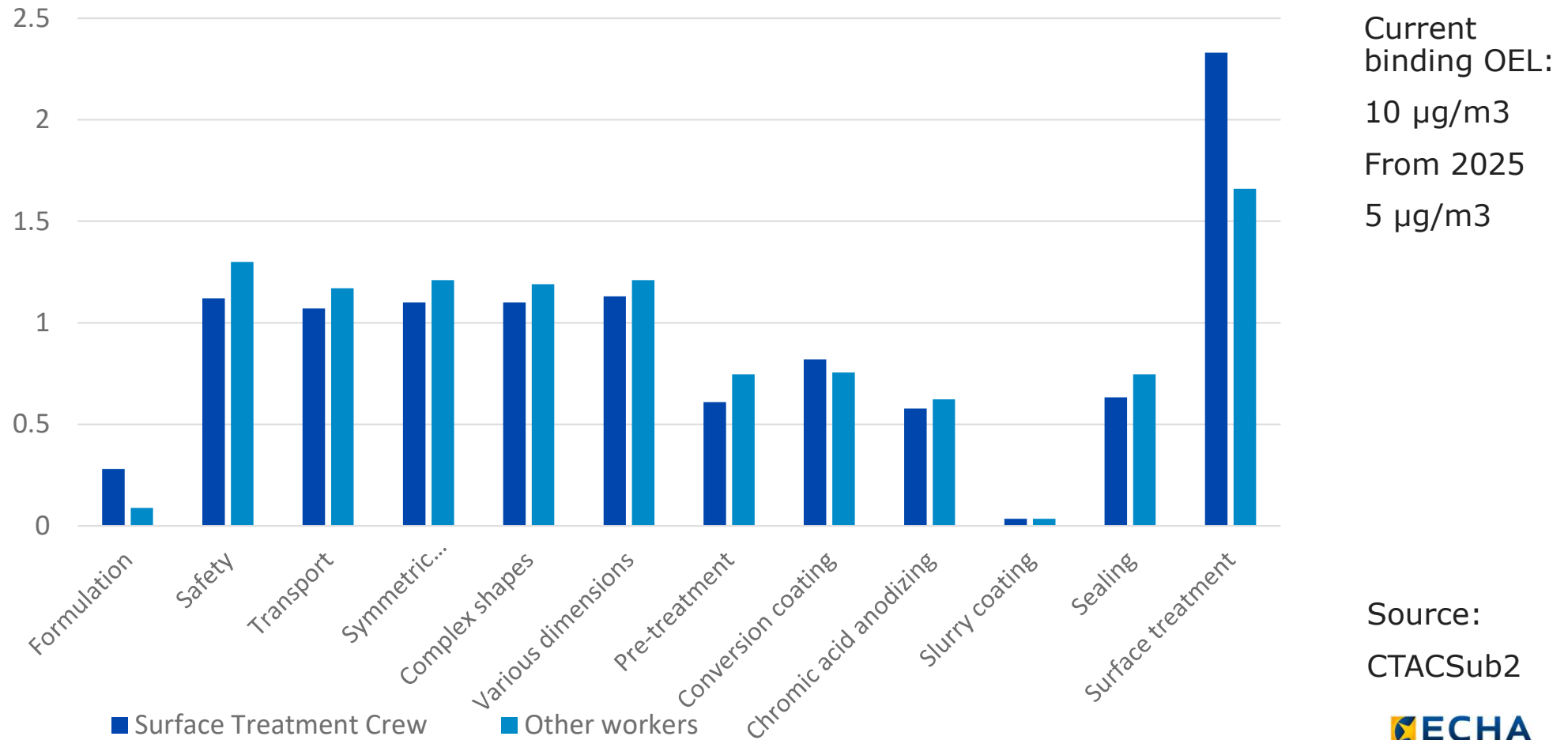


Are risks properly controlled?

Anecdotal evidence of exposure reduction

- Applicants and authorisation holders have focused on reducing exposures
- They have informed to have reduced exposures
- Commission added operating conditions & risk mgmt measures
- Tonnage used has reduced by 45% (25%-100%) in 10 years
- No time series data of exposures
- CTACSub2 application gives a overview of current status of Cr(VI)

Median exposures in 2021-22 (8h TWA $\mu\text{g}/\text{m}^3$)



Source:
CTACSub2

Conclusions

Observations

- Tonnage reduced for most substances
- Possible explanations for reductions

Substitution

Companies found ways to substitute the SVHC used
Clear indications it has happened

Efficiency

Companies found ways to reduce the quantity of SVHC used
plausible

Withdrawal/relocation

Companies ceased using SVHC or relocated to third countries)
Withdrawals known

Over-reporting

Registrants exaggerated initial volumes (2010)
Possible but no particular advantage

Conclusions

- Seems that REACH Authorisation is important driver for substitution (reduction of 45 % from 2010 to 2021)
 - In many cases reductions of 80 – 100 %
- Not possible to demonstrate a causal effect between authorisation and the reduction of the uses of the substances.
- Corroborates an earlier causal finding in Sweden (40 % reduction from baseline five years after entry to to Annex XIV)
- No time series of changes related to risks
- Anecdotal evidence and CTACSub2 point towards reduced risks

Reflections on REF-9

My reflections

- Substitution and exposure reduction are not visible in REF-9
- 80% in full compliance to operating conditions and risk management measures
- 98% were operating under authorisation
- Is the cup half full or half empty?
- Did compliance rates differ -> source for benchmarking?

Thank you

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REACH AUTHORISATION EXPERIENCES

KOVA-KROMI OY

ANTTI VÄHÄMAA

REACH AUTHORIZATION PROCESS: POSITIVE

Determines uniform rules for companies in EU

Positive effect on worker's contribution to follow safety regulations

REACH regulation improves competition equality

AUTHORIZATION DETERMINES UNIFORM RULES FOR COMPANIES IN EU

- Determines the company obligations for taking care of the occupational hygiene, health, protection of employee's safety and protection of the environment and waste disposal.
- Ensures the same rules for all operators and thereby increases equality between companies.

FURTHER IMPROVES THE ATTITUDE OF WORKERS

- When the requirements are at EU level, it improves the attitude of employees towards the use and maintenance of personal protective equipment and other safety equipment and clothing
- After all, individuals are the only ones who really protect oneself and take care of occupational hygiene.
- The more positive the attitude the better the result in occupational hygiene

REACH REGULATION IMPROVES COMPETITION EQUALITY WITHIN EU

- When the authorization requirements are same at EU level, it improves the equality among companies within EU.
- Not a single company can “save money” by not taking care of workers occupational hygiene nor ignoring environmental care or other conditions regulated in authorization documents

REACH AUTHORIZATION PROCESS: NEGATIVES



Numerous rumors are circulating



Uncertainty



Lack of resources related to length of authorization periods

NUMEROUS RUMORS ARE CIRCULATING

- No-one really knows for sure about the future use of chrome trioxide
- Too many people suggest their opinions as facts
- None of the tested alternatives have anywhere near the versatility of traditional hard chrome plating.
- SME's haven't got enough resources for simultaneously running daily production, improving occupational health, finding and testing alternative coatings and being prepared in closing and cleaning their premises after sun set date.
- The alternatives are not ready in industrial scale, nor tested enough and have no standards to manufacture. For example, one of our customer owns partially company which develops trivalent chrome process. Not even this customer allows us to use "their own" trivalent process in plating their process industry parts!
- Why would anyone want to switch away from today's well regulated processes to nonregulated, not tested in industrial scale and non standardized alternatives which do contain hazardous chemicals like Nickel chloride, Nickel sulfamate, boric acid?
- We believe in higher requirements in using traditional chrome trioxide-based process until required necessary tests for alternatives are completed in industrial scale

ALTERNATIVES TO CHROME TRIOXIDE BASED PLATINGS

- Yes, there are alternatives suitable for some applications
- No, there are no equally versatile alternatives
- It's not possible to use existing process and set up industrial scale alternative. What happens if you bet the wrong horse?
- Subcontractors do not have vote in switching to alternative coating, not to mention which alternative could be used
- This leads to a situation where we reserve cash float and working power to factory closing plan. Shut down/Sun set date may be as soon as 2024. All that money should use in improving occupational health and environmental security.



THANK YOU!

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RPA survey of ADCR members on findings and recommendations of REF-9

Presentation to

ECHA Forum workshop

12 May 2023

Richard Roy

Aerospace & Defence Chromates Reauthorisation (ADCR) Consortium

- Launched in September 2019
- Aim to ensure the continued use of 8 chromates in the A&D industry, where no suitable alternatives have been certified, beyond the end of the current review periods
- Over 40 member companies including:
 - Largest Original Equipment Manufacturers (OEMs)
 - Majority of existing authorisation holders for relevant uses of the chromates
 - A number of smaller build-to-print (BtP), design-to-build (DtB) and maintenance, repair & overhaul (MRO) companies
- Completed submission of review reports for 5 soluble chromates in February 2023. Currently preparing dossiers for 3 further chromates for submission in 2024



Risk & Policy Analysts Ltd

- ADCR are working with a team of consultants led by Risk & Policy Analysts Ltd supported by Fieldfisher, FoBiG and Bureau Veritas
- RPA are Market leader in application of SEA to chemical risk management
- Worked with European Commission on development and implementation of REACH Regulation
- Working with industry clients since 2001
 - Implications of EU regime for chemical risk management
 - Preparation of applications for authorisation of SVHC under REACH
- Richard Roy is a principal consultant at RPA and the ADCR Consortium manager



Topics for discussion

- ADCR response to REF-9 report
- Result of RPA survey of ADCR members
- Comment on results in context of recommendations



ADCR response to REF-9 report

- Publication of the report discussed in monthly meeting with members in March 2023
- RPA subsequently surveyed members to assess views in 3 areas:
 - Experience gained during inspections
 - On the findings and recommendations of the report
 - On any approach taken to improve supply chain communication

Results of RPA survey of ADCR members

- 70% of members who responded were only aware of the report via the discussion in the ADCR monthly meeting
 - Other 30% primarily aware via ECHA bulletins or trade associations
- For almost all downstream users who responded to the RPA survey, the eSDS is the primary source of information on OC/RMMs relating to the Annex XIV substance
 - Despite this 37.5% of respondents had not received an eSDS for the Annex XIV substance; and
 - 60% who did receive an eSDS reported that it did not adequately communicate all the relevant information from the Commission Decision in relation to uses/OCs/RMM/PPE/monitoring arrangements



Results of RPA survey of ADCR members

- In both REF-5 and REF-9, it was identified that information on safety measures provided in SDS can be complex and difficult to understand
 - Majority of respondents reported that information on safety measures had been clearly communicated
- Issues reported by respondents included:
 - SDS were only sent on request
 - Exposure scenarios were only accessible via web portal
 - Exposure scenarios were available only in English language
 - Updated exposure scenarios were not distributed
 - Protection factors were not communicated

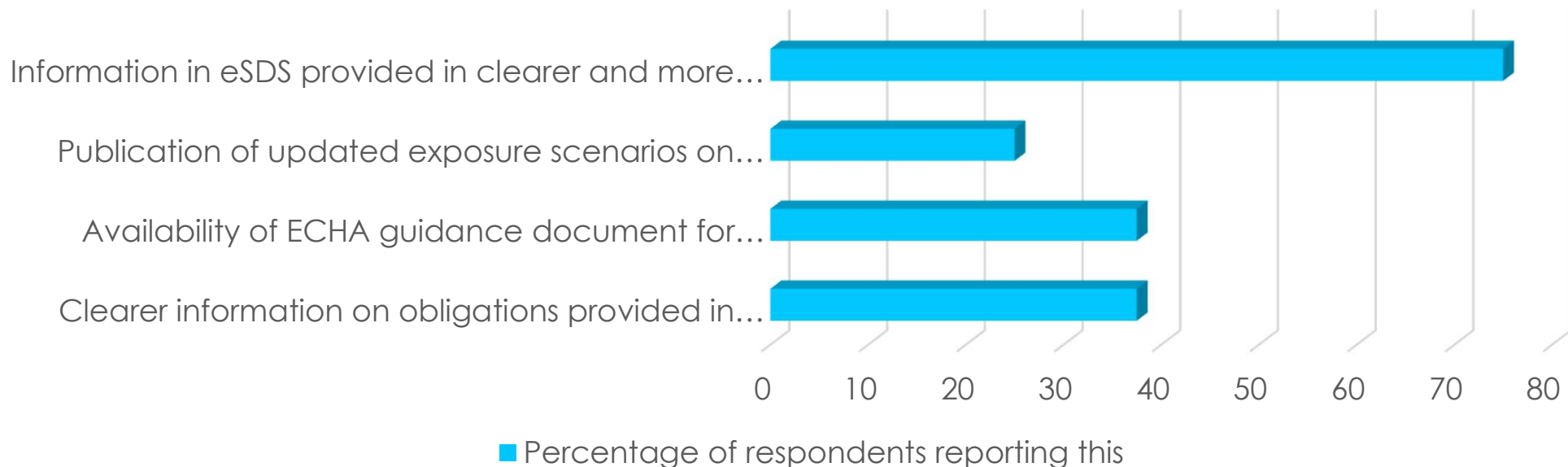


Results of RPA survey of ADCR members

- Only 25% of respondents reported that section 15 of SDS had been updated following implementation of Regulation (EU) 2020/878
- It was a recommendation of the report that suppliers actively communicate to downstream users the procedures to be followed in relation to requests for further clarification of information:
 - 75% of downstream users who responded to the survey reported that this was not done by their suppliers of Annex XIV substances
 - Only one authorisation holder responded to the survey, however reported that they did actively communicate this information

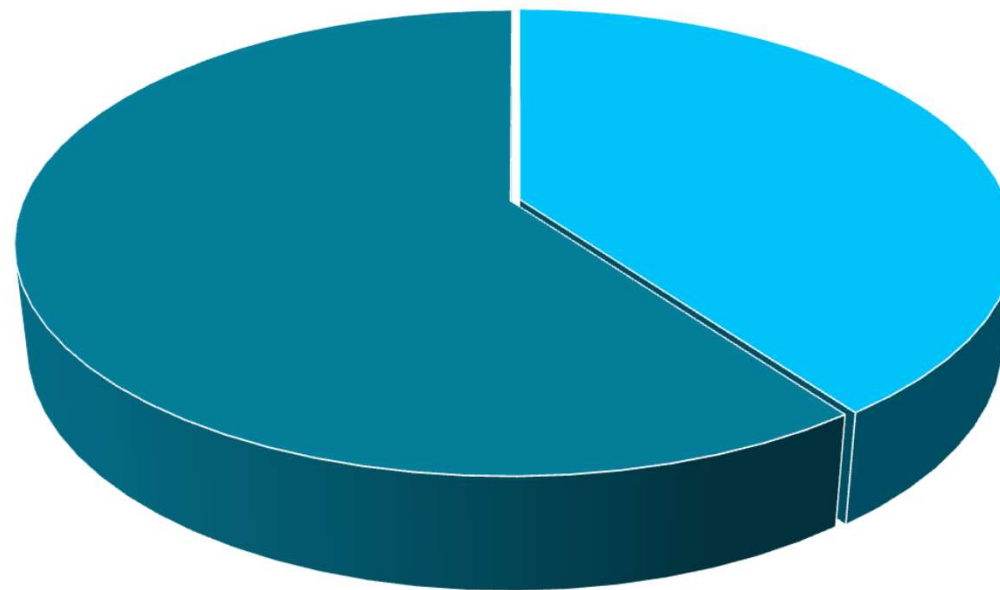
Results of RPA survey of ADCR members

Would any of the below enable your organisation to better ensure use of an Annex XIV was in accordance with the conditions of use of the decision?



Results of RPA survey of ADCR members

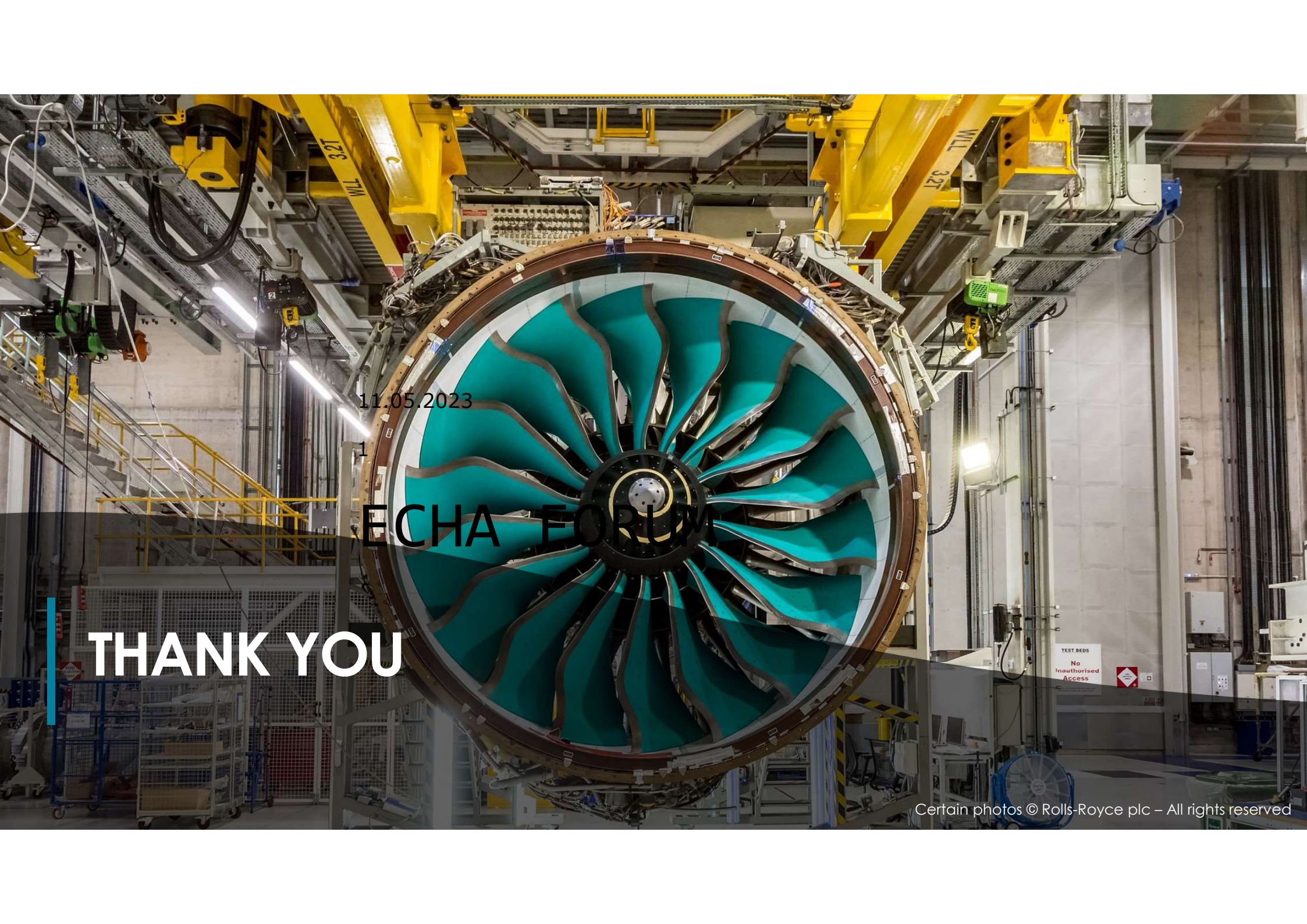
Have you taken any actions, or do you intend to take any actions, since the publication of the report, to improve supply chain communication?



■ Yes ■ No

Comment on results in context of recommendations

- Development of comprehensive and consistent guidance by ECHA secretariat would be welcomed
- Dedicated website for up-to-date succinct summaries/chemical safety reports would be helpful – would be important to ensure information required by decision (e.g., updated exposure scenarios) were published
- Suppliers generally responsive to requests for more information:
 - Publication of report has empowered downstream users to seek clarification
 - Important that procedures to follow are clearly communicated by suppliers
- Update to Annex II via Regulation (EU) 2020/878 is a welcome step towards improving communication of information



11.05.2023

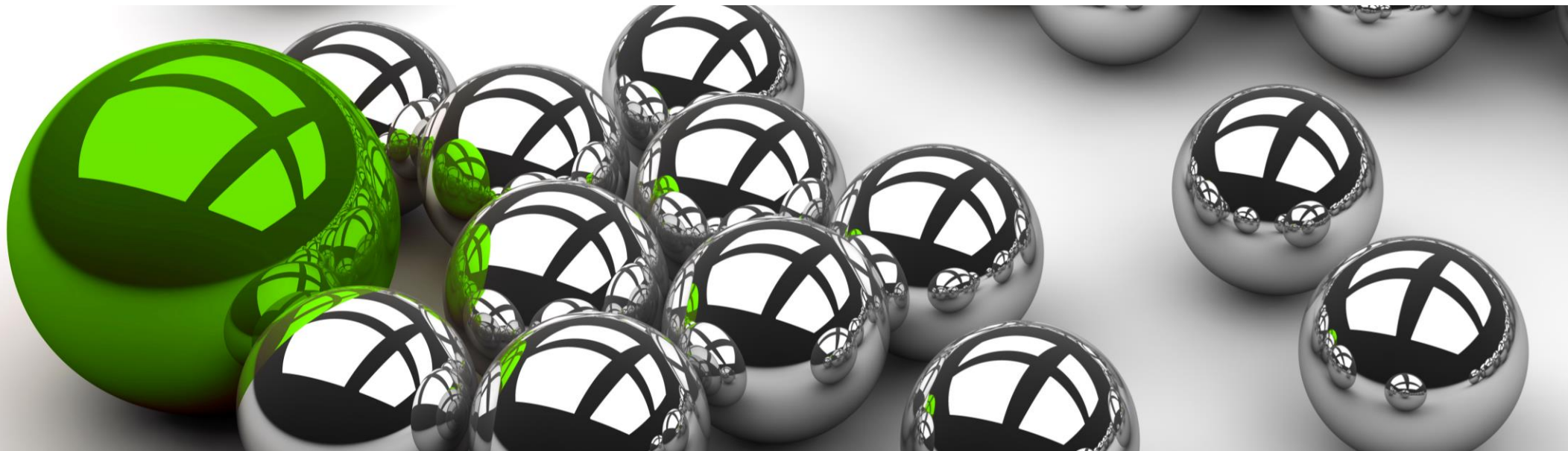
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ECHA FORUM

THANK YOU

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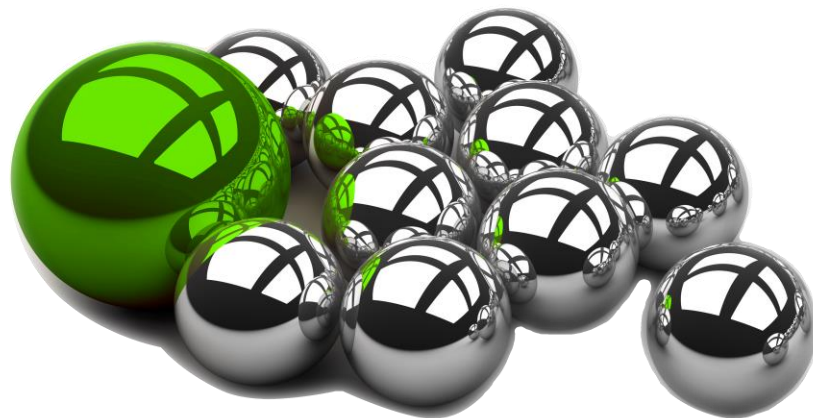


Presentation

Matthias Enseling

Board of Directors VECCO e.V.

Managing Director Eupoc GmbH & HAPOC GmbH & Co KG



Keyfacts Vecco e.V.:

Foundation: 09.05.2012 in Seligenstadt

Members: >120

Membership structure: majority SMEs

Size of members: small enterprises to corporate groups

➤ **Comments from ...**

... the perspective of downstream users

... the perspective of a supplier

... the perspective of an authorisation holder



Compliance with REACH authorisation obligations

- Forum REF-9 project report on enforcement
- 690 substance inspections in 516 companies
- 40% non-compliant / 35% chromium-trioxide
- This is more than the average for other inspections

➤ ***Why is that?***

What are the deviations ?

- **Article 31(9): Safety data sheet**

Full information, admission requirements, WCS, comprehensibility, language, access staff

- Recommended guidance is very much appreciated

- **Article 37(5): Implementation of risk management measures**

Knowledge of the specific conditions of authorization, defined risk measures, etc.

- Job platers have a high safety level and a lot of inspections. But Knowledge of specific conditions is key.

- **Article 56(2): Compliance Scope of Authorization**

Scope Use, Conditions, Annual Measurements, Compliance with Substitution Plan

- Requires sound expert knowledge in all areas of authorization

What are the deviations ?

- **Article 66(1): Notification ECHA**

REACH-IT, Account, Procedure, Upload measurement data (Excel spreadsheet), Regular processing

- Complex procedure, SME downstream users are sometimes overwhelmed here

Problems from our point of view:

- Quality and quantity of information
 - Complexity of the issues
 - Constant updating and frequency of information needed
 - Expert know-how in very different fields of competence
 - Expert know-how in all areas of the system
- ***How we want to do this in the future: Hapoc IT Tool***

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HERZLICH WILLKOMMEN

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- Data collection Measured values
- Evaluation and benchmarking
- Compliance check
- Communication with DU
- Automatic generation:
Excel spreadsheet ECHA

Thank you for your attention