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23–27 October
Vienna, Austria

Workshop:

Enforcement; best practices, focus areas and industry perspectives

Organiser:

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Handbook Manual

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Organiser's Message

Dear ChemCon family,

Vienna was the host city of our 31st ChemCon Conference, ChemCon Europe 2023. Another successful conference in the global series of ChemCon Conferences, which took place from 23 - 27 October 2023 in Austria.

With thanks to the enthusiastic support of the distinguished speakers and partners of ChemCon Europe 2023, we were able to set up a great event in the music city. Almost 250 experts from 26 countries representing over 120 companies, authorities and associations attended our conference sessions and exhibition. Together, they contributed to an inspiring exchange of experiences and discussions about regulatory affairs around the globe.

This hands-on workshop '*Enforcement*' provided best practices, focus areas and industry perspectives on enforcement.

For this electronic handbook, we might have slightly adapted papers and presentations in order to provide an easily accessible overview of the content presented during the conference sessions.

We would like to express our gratitude to our partners and supporters - thank you for the joined efforts in making this conference a success. To all speakers and chairpersons - thank you for the wonderful job in preparing and presenting valuable information and insights. And of course, thanks to all the delegates who have participated in ChemCon Europe 2023. The experiences and views shared by you, allow this platform to continue being the leading international regulatory affairs meeting point for the chemical sector.

If you want to learn more about upcoming events in the series of ChemCon Conferences, please visit our website: www.chemcon.net.

From 3 - 7 June 2024, Bangkok, Thailand will be the host city for ChemCon Asia 2024. In 2025 we expect the next ChemCon The Americas (spring) and ChemCon Europe (fall) to take place.

Thank you for your continued interest in ChemCon Conferences. We are looking forward to meeting you at one of our future conferences.

Yours faithfully,
Tjeerd Bokhout
Conference Director

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Interview on Turkish REACH implementation and preparation experiences by industry >>

Interview on how technological developments can enhance transparency and sustainability >>

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Chemicals Strategy for Sustainability – Zero Tolerance for Non-Compliance Best Practices and Key Priorities of Enforcement

Henrik Hedlund, The Forum for Exchange of Information on Enforcement

Best practices and key priorities of enforcement

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Enforcement in the EU (1)

Forum = Forum for Exchange of Information on Enforcement

- Formal network of authorities responsible for enforcement of the REACH, CLP, PIC, BPR & POPs Regulations
- Key tasks identified in REACH
- Members: representatives of National Enforcement Authorities, some from competent authorities, many are inspectors

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Best practices and key priorities of enforcement

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Enforcement in the EU (2)

Scope of work

- Develop and harmonise enforcement

Way of work

- Main vehicle for Forum work = enforcement projects
- Outputs: project manuals, reports, methodologies, training for inspectors, advices on enforceability of restrictions etc.

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Key enforcement priorities

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New Forum Work Programme

Purpose

- Provide steer to the Forum and update priorities
- Communicate and explain actions of the Forum

Perspective

- Two years (2024-2025) to allow accurate and specific plan

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New Forum Work Programme

Concise and concrete

- Focus on priorities
- List specific planned actions

Alignment

- ECHA strategy 2024-2028 & ECHA Programming Document 2024-2027

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Best practices and key priorities of enforcement

Horizontal enforcement priorities

- Imports & cooperation with customs
- Online sales
- Integrated enforcement

Priorities for ways of work

- Focus on enforcement projects
- Prepare for potential changes in Forum mandate

Specific enforcement priorities

- Regulatory Risk Management Measures
- Classification and labelling
- Information in the supply chain
- New provisions

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Best practices and key priorities of enforcement

Action on the enforcement priorities

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Best practices and key priorities of enforcement

Control of imports and cooperation with customs

Pilot project on cooperation with customs (2018-2020)

- Scope: REACH restrictions (jewellery) & CLP labelling
- Results:
  - ~1400 products checked in 16 countries
  - 23% of checked imported products non-compliant

REF-12 project on import controls (2023-2025)

- Scope: REACH Registration, Authorisation & Restrictions
- Status: manual in preparation by end of 2023. Inspections in 2024

"Training for trainers" in 2023 will focus on control of imports and cooperation with customs

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Online sales

REF-8 project on online sales of chemicals (2019-2021)

- Scope: REACH restrictions and SDS and CLP provision on advertising, BPR duties related to authorisation of products and advertising:
  - over 5700 products checked in 29 EU / EEA countries
  - 78% non-compliance with REACH restrictions
  - 77% non-compliance with BPR duties checked
  - 75% non-compliance with CLP duties checked

REF-13 new project on online sales of chemicals (2024-2026)

- Scope: REACH and POPS restrictions, CLP duties, Market Surveillance Regulation, new horizontal laws
- Makes use of new horizontal legislation that regulates online sales

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Integrated enforcement

REF-10 Project on integrated control of products (2021-2023)

- Scope: REACH Restrictions, POP restrictions, REACH duties for Substances in Articles
- Over 2400 consumer products checked in 26 countries
- Results still in preparation
- Report publication in December 2023

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Integrated enforcement

Pilot project on control of substances restricted under POP and REACH focusing on cosmetics

- Scope: Control of cosmetics for REACH and POP Restrictions (e.g. PFCAs and PFOA)
- Status: manual was adopted, inspections to start in Nov 2023

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Regulatory risk management measures

Restrictions

- Delivered advice on enforceability of all new restriction proposals
- Ongoing review and improvement of the advice delivery process
- Forum decided to publish new advices to make them more impactful and improve transparency of the legislative process https://echa.europa.eu/sv/-/advice-on-enforceability-on-restricting-creosote-now-available

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Regulatory risk management measures

Restrictions

- Advice on restriction for CMR in childcare articles proposed by the Commission under Art 68(2)
- Stronger focus on Restrictions in Forum work: three projects and exchange of enforcement experience on new restriction entries
- With new restrictions proposals having broad and detailed scopes this work is even more important to make them enforceable

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Regulatory risk management measures

Authorisation

REF-9 on REACH Authorisation obligations project

- project report published in March 2023
- Workshop with accredited stakeholder organisations & industry
- Guide for inspectors

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Regulatory risk management measures

Biocidal Products

BEF-2: biocidal products & active substances (2021-2023)

- Scope: product authorisation, approved substances + optional checks
- ~3700 inspected biocidal products in 29 countries
  - ~2900 “transitional” biocides and 800 “EU” biocides
  - 63 % of all biocides (and 92% disinfectants) found to be fully compliant
  - 18 % found with major compliance deficiencies
  - 19 % found with minor compliance deficiencies
- Report will be published in Q4 2023
- Workshop with stakeholders planned for 2024

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Information in the supply chain

REF-11 project on Safety Data Sheets (SDS) 2022-2024

- Scope: Quality of information in the SDS as required by Annex II of REACH
- Status: inspections carried out in the EU in 2023

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Best practices and key priorities of enforcement

Classification and labelling

Pilot project on classification of mixtures (2022-2023)

- Scope: use of bridging principles, expert judgement and weight of evidence approaches in classification of mixtures
- Deliver guide for inspectors to clarify conditions for the bridging to be applied and data requirements for weight of evidence and expert judgement
- Informal input provided to COM for revision of CLP

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Best practices and key priorities of enforcement

Preparing for potential changes in the Forum mandate

- REACH Revision and ECHA Basic Regulation may bring changes to the mandate of the Forum – new, expanded or changed tasks
- Once the legislative proposals are published the Forum will:
  - identify their impact on the Forum and enforcement
  - propose a roadmap for adjusting its priorities and practices to align with potential changes in the mandate
  - collect the views of the NEAs about the enforcement-impacts
- Dedicated Working Group was established to assess these impact and deliver the Forum roadmap

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Best practices and key priorities of enforcement

Best enforcement practices

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Best practices and key priorities of enforcement

Zero tolerance

- Purpose of enforcement: compliance
- Enforcement resources are limited, prioritisation is essential
- Non-priority areas are checked less frequently
- Serious non-compliance, where identified is always enforced

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Risk-based enforcement

- Focus on duties where breach implies risk for human health & environment
- Target products and companies where risk of non-compliance is highest
- Other aspects to considered are volume and level playing field

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Coordination through practical action

- Focus on enforcement projects “in the field”
- Joint actions among the Member States
- Exchange of information and experience
- Cooperation between authorities (in EU and MS)

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Integrated enforcement

- Multiple legislations can apply to one product, or even to the same material
- Controls aim to check several legislations for the same product at the same time

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Harmonisation at EU level

- Guides for inspectors after every project
- Manual of Conclusions with common approaches
- Compendium of Analytical Methods for enforcement for REACH restrictions

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Harmonisation at EU level

Annual trainings for inspectors and trainers

REACH inspector training 2022

- Topic: Control of SDS
- 239 inspectors and trainers trained
- expected outreach: ~1000 inspectors

BPR inspector training 2022

- Topic: CLP for biocides, in situ generation systems and BPR borderline issues
- 439 inspectors trained

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Conclusions

The Forum

- will continue to deliver on its enforcement priorities and improving enforcement through coordination projects and exchanging views and methods of working
- will continue to harmonise enforcement by developing best practices through guides, manuals and trainings for inspectors
- is ready to adapt to new tasks and challenges resulting from the REACH Revision and CSS

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Best practices and key priorities of enforcement

Thank you

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Enforcement - Inspector Focus on Key Priorities: Online Sale & Cooperation with Customs

Eugen Anwander, Chemical Inspectorates Austria

Enforcement – Inspector's Focus

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- Inspector's Focus "Online Sales"
- Inspector's Focus "Imports/Cooperation with Customs"
- Conclusions

Enforcement – Inspector's Focus

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General Focus – compliance/enforcement bodies in the EU

- General competence of formal enforcement by National Enforcement Authorities (NEAs) in the Member States (Title XIV of REACH, Title VI of CLP)
- REACH Evaluation is a competence of ECHA together with Member State Competent Authorities (Title VI of REACH)
- ECHA Forum is competent for "coordination" of enforcement (Title X of REACH, Title VI of CLP)
- ECHA/NEAs share a borderline of control competences – a further coordination role covered by ECHA Forum

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of NEA enforcement of CLP

- National Enforcement Authorities (NEA) **main tasks** for CLP control/enforcement:
  - proper classification and labelling (C&L) and packaging of substance/mixtures when placed on the market (including labels and SDS)
  - notification to the C&L inventory
  - notification of mixture information to national poison centres
  - online sale provisions (advertising, online offers)

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of NEA enforcement of CLP

- National Enforcement Authorities (NEA) **main tasks** for CLP control/enforcement:
  - duty to provide data required for classification along the supply chain (mainly data in the SDS, e.g. a LD50)
  - enforce ECHA evaluation decisions (can be related to CLP)
- NEA address **all suppliers** in the supply chain with a main focus on manufacturers, importers and formulators & online sales

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of NEA enforcement of CLP

- **Prepare yourself** for NEA's enforcement actions:
  - keep the required documentation according to Article 49 of the CLP Regulation !!!
  - keep detailed information on composition, impurities and substance identities of substances and mixtures
  - keep information on/from the suppliers (e.g. SDS)
  - keep data relevant for classification (e.g. SDS of components in mixtures, M-factors, ATE, test results, …)

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of NEA enforcement of CLP

- **Prepare yourself** for NEA's enforcement actions:
  - document the rational for classification and for the design of the label
  - keep a copy of the label and of the SDS (language versions)
  - document your compliance with online sale provisions (offers, advertisements)

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of joint ECHA/ NEA enforcement of CLP

- **ECHA compliance checks of registration dossiers:**
  - harmonised C&L in REACH registration dossiers (hazardous substances like CMR, skin sensitisers)
  - duty to apply harmonised C&L according to Article 4 (3) of the CLP Regulation
  - substance C&L often triggered by constituents/impurities identified in Annex VI of the CLP Regulation

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Enforcement – Inspector's Focus

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General Focus – EXAMPLE of joint ECHA/ NEA enforcement of CLP

- **ECHA compliance checks of registration dossiers:**
  - joint ECHA/NEA activity in 2016 and in 2022/2023
  - initial indication for non-compliance established from registration data screening by ECHA (composition, C&L)
  - for not respondent registrants: follow-up enforcement action initiated by NEAs based on the information on-site and in the registration dossier

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Online Sale

- Proportion of sales in the online format is high
- (Very) high non-compliance rates for products sold online due to the nature of how online business/trade is done
- High dynamic in the evolution of new online sale formats
- Regulators, policy authorities and enforcers specifically address this situation

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Enforcement – Inspector's Focus

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Online Sale – enforcement procedure

- **Focused actions** addressing sales in the online format
- Division of task in enforcement authorities
  (avoid duplications, use specialization):
  task1: checks and investigation of identified irregularities
  task2: follow-up enforcement at responsible duty holders
- Checks cover compliance of:
  - products
  - offers (presentation, obligatory information)
  - advertising (information)

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Online Sale – enforcement procedure

- **Routine actions** addressing sales in the online format by any duty holder
- Checks and enforcement do not differ from the approach taken with physical trade
- Checks include also a focus on specific online sale provisions

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Online Sale – enforcement procedure

- **High relevance of online sales via marketplaces** require a "permanent focused action"
- Specific liability duties of marketplaces exist
- Specific liability duties of fulfilment services exist
- The principles of the general duties stipulated in the Market Surveillance Regulation (EU) 2019/1020 apply

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Online Sale – new elements for enforcement procedures

- **New details on the liability/obligation of marketplaces** are defined in the Digital Service Act (EU) 2022/2065
- Further details on liability/obligations of marketplaces are defined in the General Product Safety Regulation (EU) 2023/988
- CLP Revision: obligation for inclusion of an EU-based supplier in each supply (including supply to consumers)

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Imports & Cooperation with Customs

- Proportion of import trade with products required to comply with EU chemicals legislation is high
- Need to cover a high number of EU legislation: REACH, CLP, POP, PIC, RoHS, Biocides, toys, F-gas, ozone depleting gases, …
- Customs procedures are geared to taxation, efficiency of product compliance checks is now in a new focus

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Imports & Cooperation with Customs

- Specific challenge for checks of imports of products sold online (non EU marketplaces)
- EU Market Surveillance Regulation defines a clear cooperation between national enforcement authorities (NEAs) and customs authorities on a national level
- Focus on checks before products are released into free circulation in the internal market (EEA market) – "import"

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Imports & Cooperation with Customs - PROCEDURES

Different procedures are in place:

- Customs request NEA to assess compliance for shipments where non-compliance is suspected
- Customs request NEA to assess compliance for shipments identified based on a (NEA's) risk profile
- Customs asses compliance in cases of suspicion by sending samples to a laboratory and taking a compliance decision based on the laboratory results

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Imports & Cooperation with Customs - PROCEDURES

Different procedures are in place:

- Joint action: customs and NEA inspectors together do physical checks of consignments. Joint selection of shipments, NEAs check the product compliance.
- NEA assesses compliance based on import data provided by customs on NEA request
- On a case by case basis customs provide import data to NEAs. NEAs assess compliance based on this data and subject to their priorities

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Imports & Cooperation with Customs - PROCEDURES

Plans for more efficient procedures:

- Reform of the EU customs code – enhanced focus on product compliance
- Exchange of data between customs and NEAs
- Additional obligations to document evidence for product compliance with the customs declaration ("TARIC")
- Full digitalisation of customs declarations/documents and the procedures ("Digital Product Passport")

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Conclusions …

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Conclusions

- Member State enforcement actions are much more than the part of EU coordinated enforcement, however, the portion of EU coordinated enforcement is raising
- With finalisation of the ECHA Forum enforcement project REF-9 on "REACH Authorisation" enforcement of all provisions of REACH and CLP is now harmonised and part of the routine of Member State enforcement
- Compliance with other provisions are under the spotlight of routine integrated enforcement by the Member States

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Conclusions

- Rules assuring a level playing field for product safety in online sales are permanently updated and provide an effective basis for enforcement
- While the import control procedures for cooperation with customs are in place, an enhanced efficiency of import controls is on the radar of regulators and policy authorities and is being implemented
- New EU rules on online sale and import control will require enforcers to seek for intensified EU-wide cooperation and for additional coordinated actions

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Enforcement – Inspector's Focus

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Thank you

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Lessons Learned from a Targeted Screening Exercise on Registration Dossiers

Dunja Drmač, Cefic

Lessons learned from a targeted screening exercise on registration dossiers

Dunja Drmač

Source: Putting more Union in the European customs, 2022

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How can enforcement/customs spot (potential) free-riders?

Lessons learned from a targeted screening exercise on registration dossiers

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Analytical methods

e.g. Project planned to map analytical methods for PFAS

Providing sector expertise

e.g. Sectors can give guidance to enforcement authorities about “high risk profiles” and analytical methods

Giving guidance to companies to stay up to speed with legislation

e.g. Practical advice for companies to keep their dossiers up to date/follow Art 22 in REACH

Dunja Drmač

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Lessons learned from a targeted screening exercise on registration dossiers

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What is in Article 22 under REACH:

- obliges registrants to keep their registration dossiers up to date with new info
- Commission Implementing Regulation clarified the deadline for these updates

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Lessons learned from a targeted screening exercise on registration dossiers

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ECHA screening campaign: scope

- Two campaigns during 2021-2023 to check whether companies are following their duties under Article 22:

1) Checking if uses are up to date for SVHCs subject to authorisation **148**
2) Checking substances that have harmonised classification under CLP **541**

689 screened registrations

Dunja Drmač

Source: ECHA news

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Lessons learned from a targeted screening exercise on registration dossiers

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ECHA screening campaign: outcome

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ECHA screening campaign: zooming in on the outcome

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Analysis based on internal assumption

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Lessons learned from a targeted screening exercise on registration dossiers

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Common reoccurring issues:

Not informing about bankruptcy

Outdated contact info

Missing portfolio data

Transferring of assets

Inactive dossiers

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Lessons learned from a targeted screening exercise on registration dossiers

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What can companies do to improve:

- Have up-to-date contact details; process in place not to miss emails from REACH-IT
- De-activate registration No when ceasing manufacture ("on/off" button)
- Changes of companies' business need to be updated in REACH-IT
- Check your "inbox"; REACH-IT tool connects companies and ECHA
- SOS
- No chemicals "lost" in assets transactions, update in REACH-IT
- Be clear on reasons for dossier update in IUCLID → avoid selecting "others"
- Regularly review your chemical portfolio, update with new CLH, prioritise updating dossiers
- Ask ECHA to revoke registration No in case of bankruptcy

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Lessons learned from a targeted screening exercise on registration dossiers

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"Zero tolerance approach to non-compliance"

REACH Dossier Improvement Action Plan

Cefic takes the quality and accuracy of the information provided in REACH dossiers very seriously

Cefic to continue communicating the learnings from this exercise to the companies

Dunja Drmač

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Lessons learned from a targeted screening exercise on registration dossiers

Thank you

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Dunja Drmač

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Curriculum Vitae

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Eugen Anwander is chemist and working as a chemical inspector for the Federal State Government Service Vorarlberg in Austria for more than 30 years. As the Austrian member in the ECHA Enforcement Forum he is engaged in this ECHA body and it's Biocide Subgroup since 2011 as a chair and a vice chair.

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Strategic Advisor

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Henrik Hedlund is a strategic advisor at the Swedish Chemicals Agency where he has been working with enforcement since 2011. Since 2016, he has been the Swedish Forum member. He was the chair for several working groups and vice chair for 3 years. Starting June 2023, he is the chair of the Enforcement Forum - ECHA (https://europa.eu).

Curriculum Vitae

Mercedes Viñas

European Chemicals Agency (ECHA)

Director of Submissions and Interaction

Ms Mercedes Viñas was appointed as the Director of Submissions and Interaction in May 2022, including ECHA's communication and stakeholder engagement activities, enforcement and support to industry, and the Registration process under REACH. In addition, she is coordinating the international activities of the agency.

Ms Viñas joined ECHA in 2013 and was appointed Head of Unit in 2017 leading different units and cross-organisational goals. She has more than 18 years of experience in the field of chemicals legislation. Prior to joining the Agency, she worked in Brussels on the adoption and implementation of REACH as well as on other EU and international chemicals management topics in different positions in the European Commission and chemical industry associations.

She is Spanish and holds a chemical engineer degree and a Master's degree in European Studies.