

# New compliance check strategy – what changes and how you can prepare

## Tenth Stakeholders' Day

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## Outline

1. Key elements of the new strategy
2. Our priorities for selecting dossiers
3. Testing on vertebrate animals as last resort
4. Learn how to help yourself
5. How to respond to a (draft) decision
6. What's coming next?



## **It is the E in REACH**

- Compliance check – the tool in REACH to ensure compliance and instil confidence
- Target set in law: 5% per tonnage band checked for compliance by ECHA

# What is changing in the new Compliance Check Strategy

1. Focus on substances and endpoints that matter the most
2. Compliance check integrated better with other REACH and CLP processes
3. Streamlined process
4. Other tools in our toolbox
5. More transparency on the process and outcomes
6. Enforcement by national authorities

Active registrants with up-to-date dossiers will have the most successful CCH experience

ECHA's compliance check strategy:

[http://echa.europa.eu/documents/10162/13608/echa\\_cch\\_strategy\\_en.pdf](http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf)

# ECHA's priorities – is your dossier on our radar?

Focus on:

- > 100 tonnes, lead and individual standard dossiers
- Substances with potential for high exposure of humans or environment
  - Consumer uses, poorly controlled professional uses, wide spread uses, substances in articles
- Dossiers with important data gaps in the higher tier human health and environment endpoints

**However: RANDOM checks will also be performed**

# Animal testing

Testing on vertebrates animals can be undertaken only as a last resort:

- Follow Annex VI guidance note
- Make use of alternative methods and integrated testing strategies
- Make use of endpoint-specific or general adaptations which you can justify and document
- Submit a testing proposal when required

Compliance with these requirements can also be addressed under compliance check





## You can help yourself

1. Keep your dossier up-to-date
2. Keep your knowledge up-to-date
3. Apply all the guidance, advice and recommendations
4. Attend our events
5. Search and use ECHA's evaluation decisions
6. If you get a letter from ECHA – consider it and take prompt action
7. Keep an eye on:
  - The Community rolling action plan updates
  - The indicative list of substances planned for compliance check

## If you do receive a draft decision on CCH

- 1. Do not waste time – respond in 30 days**
- 2. Take up the offer of a phone call with ECHA**
- 3. Inform SIEF members as need be**

- **Take note:** now, no more dossier updates are taken into account
- ECHA will address your comments before proceeding to the decision making
- If there are proposals for amendments made by Member States, you will have an opportunity to comment on these proposals (30 days)







## After decision is taken

- A non-confidential version will be published on ECHA's website
  - Check no confidential information is published and respond to ECHA's request (21 days)
- If you are requested to do a test:
  - You can still make an adaptation provided that you justify it
  - If a vertebrate test is requested, your obligation and responsibility is to consider all alternative methods before initiating the testing
- You have the possibility to appeal

## After the deadline set in the decision has passed



- ECHA follows up by evaluating your updated dossier to see whether it complies with the decision
  - In most cases, within six months after the deadline
- If all information requests addressed adequately:
  - ECHA notifies Member States and the Commission - the case is concluded
- If one or more issues remain non-compliant:
  - Statement of non-compliance sent to the national enforcement authority
  - Remaining issues explained
  - You will be informed - start communication with the national enforcement authorities (not with ECHA)

# New developments to look for in 2016

1. You will receive a copy of notification concluding the dossier evaluation process
  - Take good note of ECHA's observations
  - Consider that possible further action may be planned (substance evaluation, risk management measures)
2. More information will be disseminated
  - See which dossiers (substances) ECHA has checked, for which elements and what was the outcome
  - You will see whether your dossier was checked and the evaluation was closed with no action – the happiest place to be in, hence:

**Improve your dossier now**



# Thank you

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