What are the scientific challenges for ECHA?

ECHA’s new tasks on Biocides
Technical Media Briefing

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ECHA Strategic Aim III

Address scientific challenges by serving as a hub for building scientific and regulatory capacity
Address scientific challenges by serving as a hub for building scientific and regulatory capacity - why this aim?

- ECHA aspires to become the world’s leading regulatory authority on the safety of chemicals
- ECHA continuously facing new scientific challenges that attract (regulatory) attention
- Increasing scientific capacity is vital to enable the Agency to meet these challenges
- Cooperation with other actors in the chemicals management landscape in Europe and elsewhere is essential
- Transparency and credibility reliant on proper cooperation with stakeholders and partners
What will it involve?

• Address new challenges related to e.g. endocrine disruptors, test methods (including alternative methods), mixture toxicity and other scientifically complex areas
• Use this new knowledge to improve implementation of chemicals legislation
• Orient training programme of scientists towards competencies that support scientific capacity of ECHA
• Contribute to steering science to better serve regulatory needs of chemicals management
Main activities today (1)

- Nanomaterials
  - REACH Guidance on information requirements and chemicals safety report has been updated regarding NM’s
  - First cases of examination of dossier and substance evaluation for substances in nano form ongoing
  - Specific cooperation structures with Member States and stakeholders established
  - Contributing to international cooperation – OECD

- Test methods and non-testing approaches
  - Development and promotion of non-testing approaches
  - Guidance and advice to industry
  - Contribute to new test methods on priority areas
Main activities today (2)

• Mixture toxicity
  • Follow scientific & regulatory developments (e.g. EC, OECD, WHO)
  • Guidance for cumulative and synergistic effects under preparation (biocides)
  • First case of combination effects (restriction proposal from DK) addressed by RAC & SEAC

• Endocrine disrupting chemicals
  • Follow scientific & regulatory developments (incl. COM wg’s)
  • Contribute to development of identification, testing, and assessment methods
  • First endocrine disruptor added to the Candidate List in 2011
  • First substance evaluation cases ongoing for suspected EDC’s
Scientific capacity building – elements for implementation

- Knowledge management
  - Systematic gap analysis – competence mapping
  - Filling the current or future gaps with training and development activities (part of the training already open for MS’s)
  - Ensure direct regulatory relevance
- ECHA serving as a hub for capacity building
  - Platform and network for expertise, involving MS’s, COM, other Agencies, international partners, academia
  - Topical scientific workshop(s) annually
- ECHA’s regulatory science strategy
  - Ensure a good two-way interaction with research
ECHA’s new tasks on Biocides
What are biocides?

• Biocidal products are used against harmful organisms (e.g. pests, bacteria). For example:
  • Household products: disinfectants, rodenticides, repellents, etc.
  • Industrial applications: wood and material preservatives, etc.

• Estimated around 20,000 biocidal products on market

Biocidal products contain active substance(s)
  • A substance or a micro-organism having an action on or against harmful organisms
  • Around 275 allowed on the EU market

• May also be contained in treated articles
  • E.g. textiles, refrigerators, floor coatings, shower curtains, etc. ("anti-bacterial, anti-odour")
New EU legislation now in place

- Biocidal Products Regulation EC No 528/2012
  - entry into force 17 July 2012
  - application from 1 September 2013

- Ongoing work with the Commission on secondary legislation and a Fee Regulation for biocides

- Replaces Biocidal Products Directive 98/8/EC
Core processes in BPR - two step approach

1. Approval of active substances

2. Product Authorisation – applicant can choose
   a. National Authorisation,
   b. Mutual recognition (of national authorisations), OR
   c. EU Authorisation (new procedure)

- For active substances and EU authorisation
  Commission decision based on ECHA opinion
- New Biocidal Products Committee (BPC)
ECHA’s new tasks for biocides (1)

- Centralised IT system
  - Increase efficiency of information flow (R4BP & IUCLID).
  - Monitor time lines

- Biocidal Products Committee and Coordination Group
  - Central bodies for an EU-wide approach
  - Scientific and administrative support to members
  - Assure quality, consistency and transparency

- Support to applicants and Member States
  - Provide guidance
  - ECHA Helpdesk and network of national helpdesks
  - Promote a consistent approach between Member States
ECHA’s new tasks for biocides (2)

- Technical equivalence assessment
- Data sharing (facilitation)
- Dissemination
- Communication
  - Awareness raising with key actors and stakeholders
- Consistency / Synergy with REACH and CLP
Biocides – Revenue and staff

![Graph showing revenue and staff over years]

- **Staff**
  - **Forseen staff**
  - **Subsidy**
  - **Forseen fees income**
  - **TOTAL**

- **Revenues (m€)**
  - 2012: 19
  - 2013: 48
  - 2014: 59
  - 2015: 59
  - 2016: 59
  - 2017: 69
  - 2018: 72
  - 2019: 87
  - 2020: 110
  - 2021: 110

- **Legend**
  - Blue bar: Forseen staff
  - Red line: Subsidy
  - Green line: Forseen fees income
  - Black line: TOTAL

**Note:** Data points for 2012 to 2021 are shown on the graph.
Thank you.

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