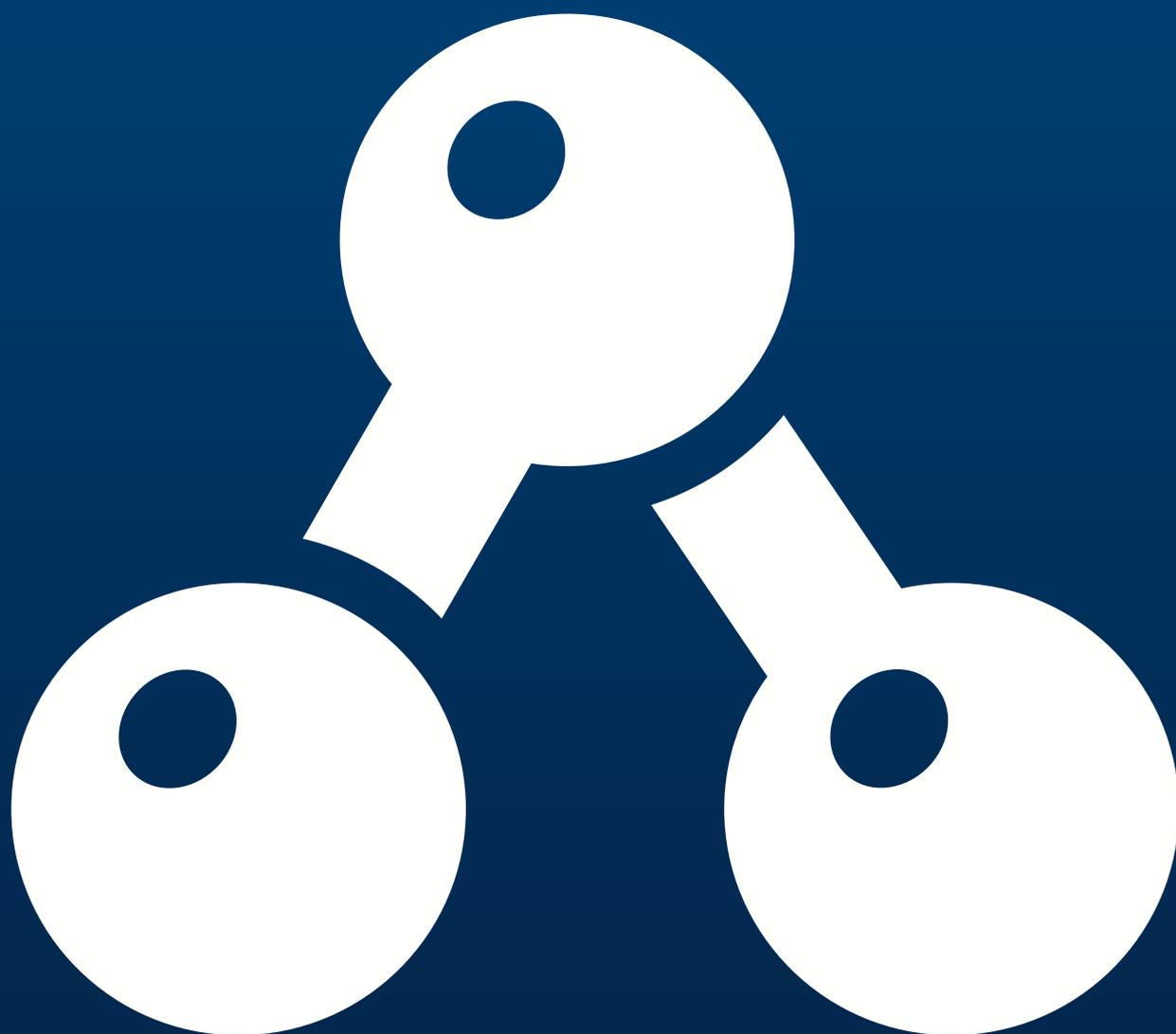


ECHA's Regulatory Science Strategy



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1. Introduction

The Regulatory Science Strategy gives a framework for how ECHA approaches the scientific content and context of its work, taking into account its current tasks and priorities, and how they are likely to evolve over the coming years, as well as considering the changing constraints of its working environment.

Science is at the heart of ECHA, although we do not conduct scientific research, and we rely on the expertise of our staff and our Committees and expert groups. Our key deliverables – opinions, decisions, guidance, advice – are based on scientific arguments in various regulatory contexts, i.e. the REACH, CLP and Biocides Regulations. It is essential therefore that ECHA's scientists are highly knowledgeable, up-to-date and proficient in scientific developments and that, where possible, ECHA can influence research to be of most benefit and relevance. This strategy is therefore to provide

focus on regulatory science as an integral part of ECHA's activities.

ECHA has four strategic objectives for 2014-2018 (set out in its Multi-Annual Work Programme)¹, the third of which is to:

- Address the scientific challenges by serving as a hub for scientific and regulatory capacity building of the Member States, European institutions and other actors.

The Regulatory Science Strategy is one of the Action Areas of this strategic objective by serving as a high level plan to orientate and prioritise our regulatory science activities and to steer the other Action Areas under strategic objective 3 of (a) expertise and capacity building and (b) serving as a hub for excellence in regulatory science.

2. Intention of the Regulatory Science Strategy

The strategy provides focus and direction to:

- communicate ECHA's regulatory science objectives and needs;
- identify priority areas of high practical relevance for ECHA;
- facilitate integration of generally-accepted mature scientific developments into ECHA's regulatory activities;
- optimise cooperation and scientific capacity building amongst key stakeholders, avoiding gaps and overlaps, leading to more focused scientific cooperation and consensus;
- communicate R&D needs to the scientific community and those funding research with a view to steering work to be of most benefit to the regulatory needs of REACH, CLP and the BPR;
- help bring together common themes affecting

chemicals and biocides and, where relevant, plant protection products and medicines. In particular, a specific case is to facilitate a systematic improvement of risk assessment methodologies ultimately leading to appropriate updates of Guidance or other advisory documents; and thereby

- steer ECHA's own capacity building activities.

The Regulatory Science Strategy identifies current needs and priorities but will also contain an element of foresight to enable ECHA to respond to emerging scientific challenges, including the development of new or additional scientific or technical capabilities, and to be proactive rather than reactive in this.

It will be kept under active review and will be revised as necessary – at least every three years. Earlier revisions may be prompted by changes in the field of regulatory science; changes in ECHA's activity; changes in ECHA's stakeholder management strategy; and scientific developments in general.

¹ http://echa.europa.eu/documents/10162/13608/final_mb_38_2013_mawp_2014-2018_en.pdf

3. Priority regulatory science areas

The selection of areas of regulatory science of importance to ECHA is primarily driven by their relevance to ECHA's work, taking into account the current and emerging scientific needs within REACH, CLP and BPR implementation. In addition, the following elements are considered:

- Important developing areas of regulatory science
- EU-wide policy needs
- New and emerging scientific issues that have potential regulatory relevance.
- New areas of focus which emerge during ECHA's operational work.

Based on the above, the following list outlines the current priority areas for ECHA's regulatory science activities:

- Improved methodologies for risk assessment:
 - For 'difficult' scenarios: e.g. substances with complex composition, substances that undergo transformation and naturally-occurring entities.
 - For 'difficult' types of substance: e.g. metals, petroleum chemicals.
 - Release from articles.
- Non-animal alternative methods and new approaches to hazard assessment, in particular rational integration of different lines of evidence (ITSs², IATAs³, AOPs⁴; with links to the QSAR Toolbox, omics and high-throughput screening methodologies) and

other means of reduction or refinement when non-animal approaches are not yet available.

- Exposure assessment, in particular, quality and interpretation of exposure models, and the assessment of the presence and release of chemicals from articles.
- Tools and methods for identifying and assessing endocrine disrupting substances, and effects of exposure during sensitive life stages.
- Improved tools and methods for assessing persistence and bioaccumulation.
- Characterisation, hazard and exposure assessment, risk assessment and risk management of nanomaterials.
- Approaches to screening and priority setting of substances
- Methods for combining evidence and integrating assessment methods, such as Weight-of-Evidence approaches.
- Assessing, describing and communicating uncertainty and incomplete knowledge (both classical randomness, i.e. statistical, and unforeseeable chaotic 'unknown unknowns'), including the impact on the conclusions. This should include qualitative and preparatory examination of the a priori, explicit or implicit hypotheses used in the assessment.
- Health and environmental impact, socio-economic analysis and risk-benefit approaches (including social science approaches).

² ITS = Integrated Testing Strategy

³ IATA = Integrated Approach for Testing and Assessment

⁴ AOP = Adverse Outcome Pathway

4. Expertise and capacity building

An essential aspect of the strategy is to steer expertise and capacity building within ECHA.

ECHA is committed to developing a more systematic approach for managing its scientific competences. This will support ECHA in ensuring that the scientific capacity and expertise of its staff corresponds to the evolving needs of the organisation, thus

creating a win-win approach combining individual professional development with the interests of the Agency.

Developing capacity in the necessary areas will be done through a 'project approach', i.e. through time-limited projects with well-defined objectives and ex-post assessment of effectiveness.

5. Serving as a hub for excellence in regulatory science

The concept of the 'hub' means that ECHA can act as a centre of networks for regulatory science to catalyse dialogue and consensus-building in the areas of priority interest. This also involves linking with and encouraging other organisations that may be better placed to do this for the mutual benefit of various actors.

In practice, this means:

1. Organising Topical Scientific Workshops.
2. Active participation in the regulatory science community, with academia and scientific societies.
3. Influencing R&D in regulatory science.

5.1 TOPICAL SCIENTIFIC WORKSHOPS

ECHA's Topical Scientific Workshops foster discussions among academia, regulators, industry and other stakeholders on the possible regulatory impacts that the latest scientific developments may have. This is done in partnership with other organisations, such as other EU Agencies or EU-funded research projects.

An outcome of these workshops is the emergence of new or improved approaches which may be applied in the implementation of the REACH, CLP and Biocides Regulations, e.g. through:

- Updated or improved regulatory practice.
- Updated or improved ECHA Guidance or other

advisory documents.

The foreseen topics for the Topical Scientific Workshops for the next two years are the following:

- 2015 – Soil Risk Assessment (in cooperation with EFSA).
- 2016 – New approach methodologies for human health hazard assessment.

5.2 INTERACTION WITH REGULATORY PARTNERS AND OTHER ACTORS

The Regulatory Science Strategy will enable ECHA to benefit by harnessing the external capacity of other scientists and regulators. Key groups of organisations to work with include international organisations, other EU Agencies, the Joint Research Centre of the European Commission, Member State authorities and research institutes, non-EU regulatory agencies, industry research organisations, and scientific societies.

The cooperation programme between ECHA and the Institute for Health and Consumer Protection of the Joint Research Centre (IHCP/JRC) is fruitful in focusing certain aspects of the IHCP work to be of most use for regulators and in helping ECHA with regulatory science issues. The strategy strengthens this cooperation, thus enhancing the mutually beneficial regulatory science partnership by consolidating the existing activities.

ECHA has Memoranda of Understanding in place with EFSA, EU OSHA and EMA to ensure coherence

and consistency in scientific opinions. These also facilitate cooperation in areas of mutual interest in regulatory science. In particular, there are commonalities in technical and organisational issues between ECHA, EFSA and EMA.

The cooperation agreements that ECHA has with the United States of America's Environmental Protection Agency, Health and Environment Canada, Australian NICNAS⁵ and Japanese authorities enhance technical cooperation to share knowledge, and exchange experience and best practice on matters of mutual interest.

ECHA engages with scientific societies by encouraging staff to join and by actively participating by lecturing at meetings.

The most active scientific society engagement by ECHA takes place with SETAC⁶ Europe and Eurotox.

5.3 ECHA'S INTERFACE WITH R&D IN REGULATORY SCIENCE

It is important to communicate regulatory needs to scientists. Establishing and maintaining a dynamic dialogue between academic science and science-based regulations is both necessary and challenging. ECHA wants to increase the awareness of the scientific community about the regulatory relevance of various research activities. This can be done by formulating problems precisely and communicating regulatory needs clearly in order to steer R&D with a view to producing concerted action.

One way for ECHA to communicate with scientific R&D is by participating in the scientific projects under the EU Framework Programme for Research and Innovation (FP7 and Horizon 2020). Although it is not appropriate to contribute at the 'bid' stage, ECHA may on a case-by-case basis contribute to relevant research projects, e.g. by being represented in the project steering board.

⁵ National Industrial Chemicals Notification and Assessment Scheme

⁶ Society of Environmental Toxicology and Chemistry



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