

European Chemicals Agency Role and governance

SUMMARY

The European Chemicals Agency (ECHA) is a decentralised agency of the European Union. Established in 2007, it is based in Helsinki. Its main mission is to contribute to the implementation of European chemicals legislation for the benefit of human health and the environment, as well as improving innovation and competitiveness.

ECHA carries out technical, scientific and administrative tasks under four EU regulations: the regulation on registration, evaluation, authorisation and restriction of chemicals (REACH); the Classification, Labelling and Packaging (CLP) Regulation; the Biocidal Products Regulation; and the regulation on export and import of hazardous chemicals. It may also initiate regulatory processes and take limited regulatory decisions under these regulations.

ECHA comprises a number of bodies active on specific aspects. These include the Member State Committee which is involved in key processes under REACH, three advisory scientific bodies (Committee for Risk Assessment, Committee for Socio-economic analysis and Biocidal Products Committee), a Forum aimed at strengthening enforcement, a Board of Appeal deciding on appeals against decisions taken by the ECHA, and a Management Board, which acts as the Agency's governing body.

These bodies are supported by a secretariat employing 564 staff at the end of 2016. ECHA's annual budget, which is about €110 million, has two main sources: a subsidy from the EU budget, and fees levied on companies for services carried out under the four relevant regulations. In 2016, fees and charges accounted for 46 % of expenditure.

An evaluation carried out for the European Commission in 2017 found that the ECHA carries out its work effectively and efficiently, is relevant to societal needs and brings EU added value, although the evaluation also highlighted some areas where there is room for improvement, for instance regarding IT and communication.



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Background

The European Union's (EU) chemicals policy falls within the wider scope of environmental policy, which aims to establish, under the Treaty on the Functioning of the European Union, a 'high level of protection'. In 2002, the EU and its Member States subscribed to the goal set at the [World Summit on Sustainable Development](#) to 'achieve, by 2020, the objective that chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment'. In 2013, the European Parliament and Council set as an objective in the [7th Environment Action Programme](#) 'to ensure a high level of protection for human health and the environment as well as the free circulation of chemicals within the internal market while enhancing competitiveness and innovation, while being mindful of the specific needs of SMEs'.

Role

The European Chemicals Agency ([ECHA](#)) is a decentralised agency of the European Union. It was established by the regulation on the registration, evaluation, authorisation and restriction of chemicals (widely known as the REACH Regulation) and founded in 2007. The ECHA is based in Helsinki, Finland.

Mission

The ECHA describes its [mission](#) as being 'the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human

Figure 1 – Overview of EU legislation under which ECHA plays a role

REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)

The 2006 [REACH Regulation](#) is the cornerstone of EU chemicals legislation. It applies in principle to all uses of all substances throughout their whole life cycle (from manufacturing to disposal) and imposes obligations on all actors in the supply chain, although it provides for a series of partial or complete exemptions.

REACH contains four regulatory regimes:

- **registration**
requiring manufacturers and importers of chemicals to analyse and submit information on substances;
- **evaluation**
checking the quality of registration dossiers and whether a given substance constitutes a risk to human health or the environment;
- **authorisation**
classifying certain substances as hazardous, possibly banning them with a view to encouraging their substitution for safer ones, and authorising certain uses of banned substances;
- **restriction**
restricting the manufacture, placing on the market and/or use of certain chemicals.

CLASSIFICATION, LABELLING AND PACKAGING (CLP)

The 2008 [CLP Regulation](#) aims to ensure that hazards from chemicals are clearly communicated to consumers and workers. It requires a company placing a substance on the market to identify its hazards and to classify the substance among pre-defined categories (based on a United Nations classification system). Some substances may also be subject to 'harmonised classification and labelling' at EU level to ensure adequate risk management.

BIOCIDAL PRODUCTS

The 2012 [regulation on biocidal products](#) covers chemicals used against pests and bacteria, such as disinfectants or preservatives, except for products used on plants. It lays down the applicable dual authorisation process whereby active substances are authorised at EU level, and biocidal products are subsequently authorised at EU or national level.

TRADE OF HAZARDOUS CHEMICALS

The 2012 regulation on export and import of hazardous chemicals (also known as [Prior Informed Consent Regulation](#)) requires all exported chemicals to comply with the CLP Regulation and places obligations on companies wishing to export certain hazardous chemicals to non-EU countries.

Source: European Parliamentary Research Service.

health and the environment as well as for innovation and competitiveness'. It also helps companies to comply with the legislation, promotes the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. It defines its [values](#) as transparency, independence, trustworthiness, efficiency and commitment to well-being.

Tasks

The ECHA was created in order to 'ensure effective management of the technical, scientific and administrative aspects' of the REACH regulation at EU level. Administrative tasks include managing the centralised processing and storage of large quantities of data. However, ECHA also has limited regulatory decision-making powers: it can issue decisions which are binding on third parties¹ and initiate regulatory procedures, for instance in the evaluation, authorisation and restriction regimes under REACH.² In addition, the ECHA issues guidance on specific aspects. Its tasks relate to four EU regulations outlined in Figure 1.

ECHA's main tasks under the four relevant EU regulations include:

- **REACH Regulation:**
 - under the **registration** regime, the ECHA checks information on substances provided by registrants, stores them in a central IT system ([REACH-IT](#)), and publishes some information from registration dossiers;
 - under the **evaluation** regime, the ECHA examines the quality of registration dossiers (so-called 'compliance check' carried out on at least 5 % of registration dossiers); approves or rejects proposals for tests on vertebrate animals; and lists in the 'Community rolling action plan' ([CoRAP](#)), together with Member States, substances to be evaluated;
 - under the **authorisation** regime, the ECHA may initiate the procedure for identifying a substance as a 'substance of very high concern' (by including it in the 'candidate list') and concludes the procedure with a formal decision; recommends the Commission to ban a 'substance of very high concern' (by including it in the 'authorisation list'); and evaluates requests for authorising specific uses of otherwise banned substances;
 - under the **restriction** regime, the ECHA may initiate the procedure and evaluates the proposed restriction;
- **CLP Regulation:** The ECHA maintains a database containing all classification and labelling information from manufacturers ([C&L inventory](#)) and assesses proposals for 'harmonised classification and labelling';
- **Regulation on biocidal products:** The ECHA receives requests for approval of active substances and drafts conclusions on these requests, on the basis of an evaluation carried out by a Member State. It also evaluates requests for 'Union authorisation' of biocidal products and granting such authorisations;
- **Regulation on export and import of hazardous chemicals:** The ECHA processes export notifications and sends them to importing countries outside the EU. It keeps records of the notifications and the explicit consents given by importing countries.

As some processes may overlap (in particular between the REACH and CLP regulations), the ECHA pursues an 'integrated regulatory strategy' to create synergies focusing on substances of potential concern.

In addition, on all four regulations, the ECHA provides technical and scientific [guidance](#) to relevant actors such as industry, national authorities or the European Commission. The ECHA also issues other [publications](#) to inform stakeholders about specific aspects of its operations.

Governance

ECHA bodies

Pursuant to relevant EU legislation, the European Chemicals Agency includes a number of bodies:

- **Member State Committee (MSC)**: composed of one representative appointed by each Member State and up to five co-opted members, it participates in several evaluation and authorisation processes under REACH. In particular, it resolves possible divergences of views among Member States, proposes substances to be identified as 'substances of very high concern', and reviews draft decisions on the inclusion of a substance in the 'Community rolling action plan' and in the 'authorisation list'. It usually takes decisions unanimously; if it cannot reach an agreement, the matter is referred to the European Commission for a decision.
- **Committee for Risk Assessment (RAC)**: composed of experts appointed by ECHA's Management Board from candidates nominated by Member States and up to five co-opted members, it is an advisory scientific body. It drafts opinions on the risks of substances to human health and the environment under REACH (authorisation and restriction) and the CLP Regulation (harmonised classification and labelling). The final decisions are taken by the European Commission.
- **Committee for Socio-economic analysis (SEAC)**: composed of experts appointed by ECHA's Management Board from candidates nominated by Member States and up to five co-opted members, it is an advisory scientific body. It drafts opinions on the socio-economic impact of possible regulatory actions on chemicals under REACH (authorisation and restriction). The final decisions are taken by the European Commission.
- **Biocidal Products Committee (BPC)**: composed of experts appointed by Member States, it is an advisory scientific body. It drafts opinions in particular on the approval of active substances and on the authorisation of biocidal products at EU level. The final decisions are taken by the European Commission.
- **Enforcement Forum** (officially known as '[Forum for exchange of information on enforcement](#)'): composed of one representative appointed by each Member State and up to five co-opted members, it aims to strengthen enforcement by disseminating good practices and by solving problems. Most of its work is done in [working groups](#).
- **Board of Appeal (BoA)**: composed of one chair and two members (as well as alternate chairs and members) appointed by the Management Board, it decides on appeals lodged against certain decisions taken by the ECHA under REACH (mainly relating to registration and evaluation) and the Biocidal Products Regulation (mainly relating to approval of active substances and authorisation of biocidal products). Decisions of the Board of Appeal can be appealed before the General Court of the European Union.
- **Management Board**: composed of one representative from each Member State appointed by the Council, six representatives appointed by the Commission (including three stakeholders' representatives without voting rights) and two independent persons appointed by the European Parliament, the [Management Board](#) is the ECHA's governing body. It appoints the Executive Director as well as members of the Board of

Appeal, of the Committee for Risk Assessment and of the Committee for Socio-economic analysis. It adopts the ECHA's annual and multiannual work programmes, its budget and its annual reports.

ECHA secretariat

The secretariat supports the four committees and the Enforcement Forum, works on registration and evaluation processes, prepares guidance, maintains databases and provides information. It is headed by the [Executive Director](#), who is in charge of the daily management and administration of the Agency (except for the Board of Appeal and its registry). The Executive Director is appointed by the Management Board upon a proposal from the Commission for a five-year term renewable once. Since the ECHA's creation, the position has been occupied by Geert Dancet, whose second term expires at the end of 2017.

The secretariat is [structured](#) in four operational services (registration; evaluation; regulatory affairs; risk management) and three support services (cooperation; information systems; resources). It also comprises an office supporting the work of the Executive Director and an internal audit service. The Agency also has a [Conflicts of Interest Advisory Committee](#).

Resources

The ECHA's **budget** has two main sources: a subsidy from the EU budget and fees levied on companies for services carried out under the four relevant EU regulations. In past years, ECHA's total budget has been around €110 million. ECHA's [general report 2016](#) shows that in 2016, fees and charges collected accounted for €51 million, or 46 % of expenditure, while €56.6 million came from the EU budget. It also notes that the amount and timing of fees has been difficult to predict, particularly for operations relating to REACH and biocides.

At the end of 2016, ECHA employed 564 **staff**, among whom 454 were temporary agents and 108 were contract agents. Staffing levels authorised under the EU budget are to decrease by 10 % between 2014 and 2018 in line with the Commission's staffing [policy](#) for decentralised agencies. Meanwhile, ECHA's remit is somewhat expanding: the Agency now hosts the [EU Nanomaterials Observatory](#) and could be requested to carry out new tasks under the [regulation on persistent organic pollutants](#). In addition, the ECHA expects a significant peak in its activities related to REACH registration as a result of the latest REACH [registration deadline](#) in May 2018.

Plans and reports

The ECHA's work is based on a five-yearly **multiannual work programme** adopted by the Management Board. The [Multiannual Work Programme 2014-2018](#) sets out four strategic objectives: improving the quality of information on chemicals; making best use of that information to identify and address chemicals of concern; addressing scientific challenges by serving as a hub for capacity building in the EU; and ensuring its tasks are carried out efficiently and effectively. The multiannual work programme is implemented through **annual work programmes**, while **general reports** describe the work carried out.³

Stakeholders and networks

The ECHA engages in dialogue with **stakeholders**, in particular [accredited stakeholder organisations](#) (from industry, non-governmental organisations and academia), and is involved in [international cooperation](#). The ECHA also runs several **networks** related to specific aspects of its work. These include [HelpNet](#), a network bringing together the ECHA

and the national helpdesks for the REACH, CLP and Biocidal Products regulations; the [Security Officers Network](#), made up of experts appointed by Member States, the European Commission and industry working on the secure access to the ECHA's IT systems; the [Risk Communication Network](#), bringing together national experts on communicating information about safe use and risk to the general public; the [Exchange Network on Exposure Scenarios](#), bringing together industry representatives on cooperation and communication between supply chain actors; and the [Directors' Contact Group](#), an informal platform for the exchange of views between the European Commission, ECHA and industry associations.

Evaluation of the European Chemicals Agency

In a 2017 [evaluation](#) of the Agency, consultants for the European Commission found that the ECHA 'has been performing effectively and efficiently', brings 'EU added value' and carries out work which 'is relevant to the social needs in Europe and even beyond'. However, the evaluation underlines areas where there is room for improvement, including the lack of managerial experience among Management Board members, high levels of expenditure in some areas such as IT and communications (in part due to the rules applicable to the Agency), the functionalities of certain IT tools, and communication to SMEs.

European Parliament's views

In its discharge decision of 27 April 2017 on the [implementation of the ECHA's budget for 2015](#), Parliament noted the ECHA's robust conflict of interest policy and anti-fraud strategy, welcomed the improved communication of information on chemicals to companies and consumers, and recommended the development of impact indicators.

Main references

Bourguignon, D., [EU policy and legislation on chemicals: Overview, with a focus on REACH](#), EPRS, European Parliament, 2016.

Bourguignon, D., [EU policy and legislation on pesticides: Plant protection products and biocides](#), EPRS, European Parliament, 2017.

Endnotes

- ¹ These include performing a 'completeness check' and a 'compliance check' of registered data, setting conditions on exemptions for research purposes, issuing decisions regarding proposals for testing on animals, handling data and cost sharing conflicts, and setting appropriate standards for registration information requirements.
- ² An EPRS In-Depth Analysis on [EU policy and legislation on chemicals](#) provides an overview of these processes.
- ³ These documents are accessible on ECHA's [Plans and reports](#) webpage.

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