Overview of the scientific processes of the EU Agencies Network on Scientific Advice (EU-ANSA) 2017

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Contents

Introduction

The European Parliament and the Council of the European Union (EU) have set up a number of decentralised Agencies to carry out specific legal, technical or scientific tasks within the European Union (*EU agencies — The way ahead*, European Union, 2011).

The Heads of EU Agencies Network (HOA) has set up various sub-networks to provide it with support on specialised issues that are common to EU agencies. These sub-networks have often been active for many years. In 2013, the HOA decided to set up a specialised sub-network for EU agencies tasked to provide scientific and technical advice to EU institutions, Member States and other relevant EU policymakers. It is called the EU Agencies Network on Scientific Advice (EU-ANSA).

Its mission (Annex I) is to promote cooperation between these agencies on issues of common interest related to the provision of scientific and technical advice. It provides a forum for the exchange of good practices and experience, mutual advice and sharing of information with the aim of facilitating the work and enhancing the quality of the scientific and technical advice provided by each participating agency.

This initiative is in line with the Interinstitutional Working Group (IIWG), which stressed in a joint statement of the European Parliament, the Council of the European Union and the European Commission the need for a more coordinated common approach (§20) on decentralised agencies with regard to the provision of scientific and technical advice.

The sub-network became operational in May 2013. In order to carry out the shared objectives it was decided that it would be useful to create a document that presents, in a standardised format, a high-level description of the nature of the scientific advice and the processes in place to carry it out in the different agencies. Thus the aim of this document is to provide a concise overview that can serve as a general first reference to the scientific work conducted by the different agencies. Consequently, this document is not exhaustive and does not contain all the details necessary to obtain a complete understanding of an agency's scientific processes. Nor does it have the status of a legal reference, as this would be beyond the scope of the responsibility of this sub-network. Further information on the EU agencies is available at https://euagencies.eu

The result of this compilation is presented consecutively by individual agency. The document is to be considered a living paper which is updated on a regular basis. The current version of this report is a first update of the original produced in 2015. It now includes overviews of all 13 member agencies of EU-ANSA, reflecting the status as of the end of 2016.

It is hoped that this report will foster an improved comparative understanding of the scope of scientific work across the agencies.

European Centre for Disease Prevention and Control (ECDC)

1. Nature of the scientific work

Domain in society covered

According to Article 3 of its founding regulation, ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases.

In order to achieve this mission, ECDC works in partnership with national health protection bodies across Europe to strengthen and develop continent-wide disease surveillance and early warning systems. By working with experts throughout Europe, ECDC pools Europe's health knowledge so as to develop authoritative scientific opinions about the risks posed by current and emerging infectious diseases.

Aspects assessed

The core activities of ECDC include:

- surveillance,
- epidemic intelligence and response,
- preparedness,
- scientific advice,
- microbiology support,
- training,
- health communication.

In all of the above functions the focus is clearly on the European dimension. Combining information, resources and competences enables the delivery of a series of products, services and means of support that complement and augment national efforts.

Many of these activities are coordinated within seven disease programmes:

- antimicrobial resistance and healthcare-associated infections (ARHAI),
- emerging and vector-borne diseases (EVD),
- food and waterborne diseases (FWD),
- STIs, including HIV/AIDS and blood-borne infections (HASH),
- influenza and other respiratory viruses (IRV),
- vaccine-preventable diseases (VPD),
- tuberculosis (TB).

The balance of core activities differs between the disease programmes, but for all disease programmes scientific outputs encompass evidence and expertise drawn from experts in Surveillance, microbiology and (risk) communication. However, the determinants for the prevention and control of the various diseases and conditions differ widely. Thus, although (core) functions are represented in all disease programmes, the relative importance varies. Scientific advice on prevention and control activities are a substantial element of the ARHAI programme, whereas scientific activities related to health inequalities and climate change are more significant elements of the TB and EVD programmes respectively. In the present cultural climate, vaccine-preventable diseases require substantial scientific work in support of health communication and knowledge on behaviour change. Similarly, while preparedness is important to all programmes, scientific advice related to pandemic preparedness is accorded more emphasis for influenza. So the 'programmatic nature' of infectious disease control differs over the various programmes.

2. Scientific work programme

Programme

ECDC adopts a work programme on an annual basis within the context of a strategic framework that is set out in a strategic multiannual plan (SMAP) and annually updated 3-year single programming documents. The work programme comprises specific projects that correspond to one or more of the centre's thematic areas of work.

The content of the work plan is developed through internal and external processes of consultation, involving input from all ECDC staff and the members of the Management Board and Advisory Forum, and Member State representatives in its disease networks. The proposals from internal management units and disease programmes are reviewed by the senior management team to ensure consistency with

the overall strategic priorities of the centre. Other EU institutions also guide and review ECDC work plans: the European Commission gives direct input into the annual and multiannual work programmes and the European Parliament offers oversight and guidance on ECDC activities.

The planning process complies with the recommendation of the Internal Audit Service of the Commission. Written consultations of the Management Board and Advisory Forum members are carried out. The Management Board approves the final version of the annual work programme, including the list of activities and their operational budget, the allocation of staff by strategies and a detailed activity-based budget.

The propensity of infectious diseases to cause epidemics and pandemics and the constant threat of emerging infection can result in substantial in-year changes to priorities and consequent changes to the scientific work programme

Monitoring programme execution

ECDC's objectives are clearly defined and updated when necessary. They are formulated in a way that makes it possible to monitor their achievement. Key performance indicators are established to help management evaluate and report on progress made in relation to their objectives. The ECDC Management Board adopts the general report on the centre's activities on an annual basis.

Funding

The funding for all ECDC activities comes from the internal budget of the agency. No additional funding sources are used.

3. Approaches used to conduct the scientific work

Scientific collaborations

ECDC collaborates with different partners with respect to individual projects.

ECDC works closely with the European Commission, but it also advises and reports to the European Parliament and the Council of the European Union.

European Commission

ECDC has daily contact with staff of the European Commission. The closest links are with the Directorate-General for Health and Food Safety, in particular Directorate C (Public Health, Country Knowledge and Crisis Management) and its Crisis Management and Preparedness in Health Unit (C3), but also with Directorate G (Crisis Management in Food, Animals and Plants) on the issue of zoonoses.

European Parliament

Within the European Parliament, the Committee for Environment, Public Health and Food Safety deals with all issues concerning ECDC (together with the Budgets Committee on budgetary issues).

The Council of the European Union and the presidency

Health ministers from the EU Member States meet regularly in the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO). In recent years the threat to human health posed by infectious diseases, such as influenza, HIV/AIDS and healthcare-associated infections, has been an important topic at these meetings.

Other EU agencies

The remits of ECDC are complementary to those of some other EU agencies, for example the European Food Safety Authority (EFSA), the European Medicines Agency (EMEA), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Environment Agency (EEA). Close links have been established with EMA and EFSA in relation to antimicrobial resistance monitoring, and with EFSA on issues concerning reporting under the zoonoses directive (Directive 2003/99/EC) and avian influenza.

Member States, European Economic Area/European Free Trade Association, candidate countries and potential candidates

ECDC will work closely with the 28 EU Member States, but also with the European Economic Area/European Free Trade Association countries (Iceland, Liechtenstein, Norway and Switzerland), candidate countries (Montenegro, the former Yugoslav Republic of Macedonia, Albania, Serbia and Turkey) and potential candidates (Bosnia and Herzegovina and Kosovo (the latter under UN Security Council Resolution 1244)). The main contact points in the Member States are the members of the ECDC Advisory Forum and Management Board, in their respective roles,

the competent bodies identified by the Management Board and Member State members of its disease networks.

World Health Organisation (WHO)

ECDC experts regularly contribute to the technical work of WHO on infectious diseases, and ECDC participates in WHO's Global Outbreak Alert and Response Network (GOARN). The WHO Regional Office for Europe (WHO/EURO), in particular, has tasks and responsibilities that interlink with those of ECDC.

Evidence and analysis

Collection of surveillance data is done through the European Surveillance System (TESSy), which includes a database (also called TESSy). The goal of TESSy is to provide comparable information on infectious diseases and surveillance systems across the Member States. The system provides an overview of the current status of infectious diseases in the EU and monitors changing trends over time.

The centre also undertakes epidemic intelligence scanning activities, and is able to initiate scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States will avoid duplication of effort.

Expertise

Approximately 280 staff members contribute to the work and functioning of the agency. This includes experts in all areas of ECDC´s activities. Internal expertise is complemented by external experts who support ECDC activities. External experts are commonly members of formal disease networks and competent bodies linked to ECDC, or other independent experts from participating EU Member States and non-EU countries who register their interest to work with ECDC through a dedicated expert database. Typical profiles include epidemiologists, data managers/IT experts, microbiologists, statisticians, health professionals reporting diseases, laboratories and other expert profiles involved in the surveillance of communicable diseases at the EU level.

Methods

For all scientific advice outputs, ECDC applies evidence-based methodologies and practices. However, as most evidence-based methodologies have been designed for the purpose of clinical medicine and are not easily applicable to public health topics, ECDC has initiated a project that aims to develop a more appropriate methodology, based on the principles of the GRADE consortium.

This project (Precept) will deliver a framework on how to apply evidence-based methodologies in the field of public health.

4. Outputs

Review of draft outputs

In ECDC the review processes are related to the specific output format. For scientific advice there are the following three main output formats.

Expert opinion: a scientific view/comment based on a review of the scientific evidence and/or on an expert opinion.

Systematic review: systematic review of the scientific evidence with regard to a specific question or a set of questions.

Guidance: based upon a systematic review of scientific evidence and on a scientific expert panel appraising the evidence and providing a list of options with regard to the potential benefits, costs and harms of measures, areas and level of uncertainty, along with recommendations for future research. ECDC also produces rapid risk assessments, which follow a more rapid timeline than other output types as they focus on emerging health threats and offer commentary and options for mitigation to support rapid action. Although they are produced quickly they also follow principles of good scientific practice, including consultation with internal and external experts, review of published evidence and a full review process. All scientific advice outputs are finally reviewed and approved by the chief scientist of ECDC, who may also decide to seek additional approval by the director in certain cases. Beforehand, the outputs are reviewed by the head of the specific disease programme, or by the head of section where the output has been produced.

Authorship

All reports go out under the name of the agency. In-house staff who draft scientific advice documents are mentioned as authors/coordinators.

Responsibility for issuing scientific documents

Responsibility resides with the director of the agency.

Communication

The main channel for the agency's research results is its website, although staff are also encouraged to publish ECDC scientific work in peer-reviewed journals to enhance the scientific credibility and visibility of the agency. ECDC adheres to the policy that peer-reviewed publications should be published as open-access papers.

Use and follow-up

ECDC outputs are provided as evidence, opinion or options for action for the consideration of stakeholders in the Member States and at the EU level. All areas of infectious disease prevention and control are covered. The impact of activities is followed up via direct contact with partners at the EU level and national risk managers.

European Centre for the Development of Vocational Training

European Centre for the Development of Vocational Training (Cedefop)

1. Nature of the scientific work

Domain in society covered

Cedefop's mission reflects the aim and tasks outlined in its founding regulation, and those that the agency has been entrusted with over time ([1]). As laid out in its founding regulation, Cedefop's mission is to support the development of European vocational education and training (VET) policies and to contribute to their implementation. The agency provides evidence for VET policy and contributes to developing VET and matching skills with labour market needs. Cedefop has three key functions, namely to: provide new knowledge and evidence; monitor policy trends and provide policy analysis; and act as a knowledge broker.

Aspects assessed

Since its foundation in 1975 Cedefop has traditionally given high priority to providing VET-relevant research. In recent years the agency has also become a recognised centre of policy-relevant research on skills needs, supply and mismatch in the EU labour markets. This strand of work has reinforced the agency's role at the interface between education and training and the labour market. Key aspects covered by Cedefop work are:

- research and (comparative) analyses on VET, covering the whole spectrum from initial to continuing training at all qualification levels;
- identification and anticipation of skill needs and skill mismatches;
- monitoring and analysis of the implementation of national and European VET policies in line with the objectives commonly agreed by the Member States, the Commission and European social partners for 2020 (the Copenhagen process);
- analysing and supporting the use and further development of European tools and principles for VET and lifelong learning, such as the European Qualifications Framework.

2. Scientific work programme

Programme

From 2017 Cedefop will shift from annual work programmes to multiannual programming, in line with the requirements set by the so-called common approach to EU decentralised agencies. Cedefop's multiannual objectives for 2017-2020 reflect the renewed priorities of 'Education and training 2020' (ET2020), European cooperation in VET as agreed in the Bruges Communiqué and the Riga conclusions (Copenhagen process), the renewed European agenda for adult learning and the European Commission's 'New skills agenda for Europe'. The programming document sets out the main strategic areas of operation, reflecting the key thematic areas of work identified for the period. They are selected taking due account of the context and key challenges for VET, as well as EU policy objectives. For each strategic area of operation, key activities with concrete objectives, expected outputs, outcomes, indicators and targets are defined annually. The programme development process is managed by Cedefop's management. It is an iterative process with various rounds of consultations of all relevant stakeholders and parties involved (in particular the European Commission, the Cedefop Bureau and Enlarged Bureau and the Governing Board), as well as Cedefop staff. The programme is adopted by the Cedefop Governing Board in its role as the agency's supervisory body.

Monitoring programme execution

Programme execution is monitored though a variety of activities and procedures. Since 2009 Cedefop has had a comprehensive performance measurement system (PMS) which assesses performance on an ongoing basis by using an evaluative approach based on external evaluation and the analysis of a set of outcome indicators, complemented by a qualitative approach — focus groups, usefulness surveys, etc. The PMS measures project-, activity- and organisational-level performance. Progress towards achieving the objectives set out in the programming document is assessed by using a battery of indicators from Cedefop's performance management system.

([1]) Council Regulation (EEC) No 337/75 of 10 February 1975, as last amended by Council Regulation (EC) No 2051/2004 of 25 October 2004. As part of its common approach to regulatory agencies, Cedefop's founding regulation is to be revised in 2018.

Cedefop project managers use standard templates and other tools to report on activities/project implementation and progress on a regular basis to management.

Cedefop's management provides regular progress reporting to its Governing Board. The agency closely follows-up evaluations and external audits recommendations and keeps its Bureau and Governing Board informed on the follow-up. Follow-up action plans give a comprehensive view of recommendations, actions envisaged, responsibilities, deadlines and status of implementation.

Risk assessment and management is an integral part of Cedefop's planning and reporting processes. Cedefop's risk assessment is a form of *ex ante* evaluation of activities/projects and also considers generic risks at organisational level. Risks are evaluated based on their potential impact on the organisation and the likelihood that risks will materialise.

Funding

All activities are fully funded by Cedefop's budget. Cedefop's funding is essentially made up of its subsidy from the European Union budget (and therefore of the contribution from Member States) and a contribution from the EFTA states of Iceland and Norway. The agency's financial rules clearly state the possible sources of funding, which are limited essentially to eliminate the possibility of any conflict of interest in the agency's activities.

3. Approaches used to conduct the scientific work

Scientific collaborations

Cedefop collaborates with scientists through contracts (via public procurement procedures) and networks. In 2004 the agency established Skillsnet, a network on anticipation of skill needs which brings together highly qualified researchers and other experts from across the world to discuss outcomes and methods of research and analysis on new and changing skill needs. In addition, Cedefop cooperates with other international institutions, such as the Organisation for Economic Cooperation and Development (OECD), the International Labour Organisation or Unesco. At European level Cedefop cooperates with other EU agencies, especially Eurofound and the ETF.

It also works closely with Eurostat. The agency is engaged in several working groups and networks to improve the availability and analysis of data and statistics, including the European Commission Standing Group on Indicators and Benchmarks (SGIB), an expert group in the field of development and validating of educational indicators and the OECD-led Network on Labour Market, Economic and Social Outcomes of Learning (LSO).

Evidence

Evidence is collected by a combination of in-house research staff and external contractors.

Cedefop collects and uses primary and secondary data, applying quantitative and qualitative methods.

Analysis

Analyses are carried out by combinations of in-house research staff and external contractors.

Expertise

Research staff are recruited through Cedefop's recruitment processes, derived from the EU Staff Regulations. Staff include experts from different fields, such as social sciences, economics and statistics, allowing also for interdisciplinary work. The majority have strong research backgrounds and hold PhDs. Cedefop has a comprehensive learning and development strategy that promotes the personal and professional growth of staff and organisational effectiveness based on an annual learning and development plan. Scientific expertise is also contracted through public procurement via calls for tenders.

In addition to contracted external expertise Cedefop receives input from external experts in various forms and stages during the research process, for example expert meetings or consultations on research methodology during the inception phase and validation of data during the interim and final phases of projects. To procure external expertise Cedefop can also make use of its two networks: Skillsnet, a network which brings together highly qualified researchers in the field of research on skills; and ReferNet, a network of institutions created by Cedefop in 2002 to provide information on national VET systems and policies in the EU Member States, Iceland and Norway. Each ReferNet national partner is a key organisation involved in VET in the country it represents.

Cedefop has an in-house 'research support centre' to support scientific work. This service includes various activities in support of Cedefop experts, for example a discovery tool enabling staff to search concurrently all electronic sources subscribed to and other open-access databases; subscription, acquisition and articles delivered on request; impact analysis of Cedefop publications in scientific literature; and a limited reference collection including the most recent and important publications in the library. As an authoritative source of information on VET Cedefop's research support centre also provides information to externals organisations.

Methods

Cedefop develops quantitative research (e.g. surveys, forecast modelling), qualitative research (e.g. policy analysis, case studies, interviews, literature reviews) and combinations of the two. Standard methods are used and adapted to the particular needs. Some methods and tools (e.g. surveys) are developed in-house.

4. Outputs

Peer review and support for scientific process

Peer review and support at Cedefop aim at ensuring the quality and adequacy of research methodologies and content, the appropriate external communication of research outputs and the ethical nature of the process. In line with Cedefop's publication policy all publications undergo internal peer review by staff (external to the research teams) and the head of department responsible prior to final approval by the director.

While all studies leading to a publication benefit from peer review, this is adjusted depending on their nature and complexity. Depending on the type of research activity (explorative research, comparative analysis, etc.), peer review ranges from mere checks of quality assurance of the final output, to peer support, to the definition of scope, methodology and to main research-project milestones. Peer reviewers are selected taking into account the nature of the research and the specific expertise required, with the ad hoc possibility of employing external reviewers.

Peer review and support is an automated process supported by a workflow, and is formally considered for management and evaluation purposes. Various other strategies are also used to verify research outcomes by externals, for example validation workshops with external experts/organisations, validation of country-specific information by Cedefop's ReferNet members and so forth.

Authorship

Authorship resides with Cedefop.

Responsibility for issuing scientific documents

The final responsibility for issuing scientific documents resides with Cedefop.

Communication

Cedefop has a comprehensive, integrated communication strategy, including publications, briefing notes, press, social media, web news, newsletters and video clips. The web portal (http://www.cedefop.europa.eu) is the agency's principal channel for the distribution of research outcomes.

Further, Cedefop also organises and participates in conferences, workshops and seminars to disseminate results and share expertise. Several data inventories, as well as source data for many studies, are available online and Cedefop is currently working on establishing an open-access repository.

Use and follow-up

The purpose of Cedefop's work is to support better informed, evidence-based policymaking at European and national levels. Cedefop's research outputs provide information to different stakeholders such as governments, social partners, researchers, practitioners and international organisations, and contribute to developing and implementing VET in Europe and matching skills with labour market needs. To ensure that Cedefop's work is used in the best manner the agency organises different types of activities, for example policy-learning and capacity-building activities.

Cedefop's performance measurement system follows up the use of the agency's work. Indicators measure, for example, citations of Cedefop's work in EU and international policy documents and academic literature, Cedefop's participation in policy relevant meetings of senior stakeholders, publication downloads and media coverage.

European Chemicals Agency (ECHA)

1. Nature of the scientific work

Domain in society covered

ECHA operates in a complex environment: it is responsible for four regulations, the REACH regulation, the classification, labelling and packaging regulation (CLP), the biocides regulation (BPR) and the prior informed consent regulation (PIC). The implementation of the legislation is a shared responsibility with many partners, and REACH, CLP, BPR and PIC are not the only pieces of legislation which impact on industry in the chemicals area. The range of companies impacted by EU chemicals legislation is vast and reaches all companies, many of whom are unaware that it affects them.

ECHA is responsible for managing the core processes of REACH and CLP, which are registration, evaluation, classification and labelling, authorisation and restrictions. In addition, ECHA is required to provide free and easy access to data on substances collected, including information on properties (hazards), classification and labelling, authorised uses and risk management measures.

With regard to the BPR, ECHA is responsible for coordinating the evaluation of active substances and EU-wide authorisations for biocidal products. A Union authorisation (granted by the European Commission) is valid in all EU Member States, as well as in the European Economic Area countries.

With regard to the PIC regulation, which applies to banned or severely restricted chemicals and provides for information-exchange mechanisms regarding the export and import of those chemicals, ECHA is responsible for managing the practical functioning of the PIC mechanisms.

Aspects assessed

The focus is on the scientific evaluation of hazard identification (including classification), exposure and risk assessment of chemical substances and their subsequent uses with respect to the different regulations (i.e. REACH, CLP and BPR). These regulations also include an assessment of the PBT/vPvB properties and whether the substances have endocrine disruptor properties. In addition, there is an examination of risk impact and socioeconomic analysis (SEA) to assess the impact of possible legislative actions on chemicals in certain REACH processes. Within the context of the BPR the efficacy of the active substance/biocidal product is considered.

2. Scientific work programme

Programme

A multiannual work plan (MAWP), which allocates resources and is a 5-year strategy broken down into action areas is adopted by the ECHA Management Board. Annual work programmes provide details of the individual actions planned year by year.

Four strategic aims have been developed to support prioritisation and guide ECHA on how it approaches its activities, allocates resources and motivates its staff. Strategic aim 3, 'Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors' is an enabler for strategic aim 1, 'maximising the availability of high quality information to enable the safe manufacture and use of chemicals' and strategic aim 2, 'mobilising authorities to use information intelligently to identify and address chemicals of concern'. It also contributes to strategic aim 4, 'embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints'.

The regulatory science strategy (RSS) gives a high-level picture of how ECHA should approach the scientific content and context of its work. It is the foundation for implementing strategic aim 3, and it steers the strategic aim 3 action areas of (a) expertise and capacity building and (b) serving as a hub for excellence in regulatory science.

Monitoring programme execution

The ECHA Management Board reviews the progress of the MAWP in the action areas and milestones on an annual basis, and corrective action is taken where necessary. The management team reviews the annual work programmes on a regular basis using a system of key performance indicators to identify areas of concern. In addition, ECHA operates an integrated quality management system (IQMS).

Funding

ECHA's budget comes primarily from industry fees and is subsidised through EU subsidies.

3. Approaches used to conduct the scientific work

Scientific collaborations

ECHA coordinates the scientific work with the Member States competent authorities (MSCAs) and its committee, the Member State Committee (MSC), is responsible for resolving divergences of opinions between Member States. The MSC provides opinions on ECHA's draft recommendations, and absence of agreement is referred to the European Commission for decision-making.

ECHA committees — the Committee for Risk Assessment (RAC), the Committee for Socio-Economic Analysis (SEAC) and the Biocidal Products Committee (BPC) — prepare the opinions of ECHA related to the evaluation and assessment and the socioeconomic impact of possible legislative actions, respectively.

ECHA collaborates and has cooperation agreements with other EU agencies, i.e. EFSA, EU-OSHA and EMA, and with the Joint Research Centre. ECHA also has cooperation agreements with non-EU chemical regulators (in Australia, Canada, Japan and the United States) and contributes to international Organisation for Economic Cooperation and Development and World Health Organisation activities.

Evidence

Evidence comes mostly from the dossiers submitted by registrants containing summaries of reports of scientific studies, including published scientific literature. In addition, the dossiers include an interpretation of the hazard information to characterise the classification and for use in exposure assessments and risk assessments. In some cases, risk impact assessments, SEAs and recommendations for risk management measures are included.

Analysis

Analysis (evaluation and assessment) of the evidence is conducted by ECHA scientific staff, ECHA committees and MSCAs.

Expertise

ECHA staff are recruited as temporary or contract agents through the usual EU agency procedures, as is the case for seconded national experts. ECHA committee members are nominated by Member States. ECHA scientific staff provide scientific, technical and administrative support. ECHA committee members assess and evaluate evidence and prepare opinions.

Training and capacity building is provided by ECHA to its staff. In addition, ECHA supports professional development for its staff.

A competence mapping study is part of the 'Expertise and capacity building' action area of strategic aim 3. Firstly, the in-house capacity will be assessed in the areas of regulatory science of importance to ECHA, then a gap analysis will be undertaken to decide upon areas of expertise that require strengthening to meet expectations. The areas of regulatory science of importance to ECHA, which can be revised and updated as necessary, reflect the principles from the RSS of: (a) relevance to ECHA's regulatory work on REACH, CLP and the BPR; (b) important areas of regulatory science with an EU policy aspect; (c) new and emerging scientific issues and matters of high societal concern of potential regulatory relevance; and (d) to be of added value to ECHA's stakeholders.

Methods

Key methodological issues include assessing the validity and quality of experimental data, determining the acceptability of uncertainty and evaluating alternative and new test methods and predictive techniques, such as the use of grouping and read-across, computational tools and integrated testing strategies.

The methods used are described in ECHA guidance documents and are mostly based on international or EU guidelines.

4. Outputs

Review of draft outputs

There is a review of the draft scientific output through internal peer review for nearly all documents, either within the ECHA committees or with ECHA staff. There is a consultation process with stakeholders for scientific guidance, and there is public consultation for many processes, such as testing proposals, authorisation, restrictions, harmonised classification and labelling.

Authorship

Authorship resides with ECHA or ECHA committees, depending on the type of document.

Responsibility for issuing scientific documents

Scientific documents are issued by ECHA on its website.

Communication

All scientific outputs are published on the ECHA website. Their publication may be accompanied by a web or press release.

Use and follow-up

Industry uses the information on their chemicals to ensure safe manufacture and use and to recommend risk management measures throughout the supply chain, right down to consumers.

Decisions on the evaluation of dossiers and substances are binding on registrants, who are obliged to provide the missing information or conduct the requested studies. The follow-up on the work is conducted by ECHA.

Opinions of ECHA committees on risk management dossiers are used by the Commission in legislative decision-making.

European Environment Agency (EEA)

1. Nature of the scientific work

Domain in society covered

The EEA/Eionet founding regulation ([1]) setting up the European Environment Agency and the European Environment Information and Observation Network (Eionet) came into force in 1993 with the aim of providing the then European Community and the Member States, and in particular the European Commission, with the objective information necessary for framing, implementing and evaluating sound and effective environmental policies and for keeping the public properly informed on the state of the environment.

Aspects assessed

The key areas covered by the work are defined by the founding regulation as follows.

'1. The principal areas of activity of the Agency shall, as far as possible, include all elements enabling it to gather the information making it possible to describe the present and foreseeable state of the environment from the following points of view: (a) the quality of the environment; (b) the pressures on the environment; (c) the sensitivity of the environment; including placing these in the context of sustainable development.

2. The Agency shall furnish information which can be directly used in the implementation of EU environmental policy. Priority shall be given to the following areas of work: (a) air quality and atmospheric emissions; (b) water quality, pollutants and water resources; (c) the state of the soil, of the fauna and flora, and of biotopes; (d) land use and natural resources; (e) waste management; (f) noise emissions; (g) chemical substances which are hazardous for the environment; (h) coastal and marine protection. In particular, transfrontier, plurinational and global phenomena shall be covered. The socioeconomic dimension shall also be taken into account.'

2. Scientific work programme

Programme

The EEA's multiannual work programme (MAWP) for 2014-2020 sets out the framework, objectives and priorities for an initial 5-year period, extended in 2016 to a 7-year period. The EEA's management has the overall responsibility for the programming, monitoring and reporting of the work of the EEA. The MAWP is adopted by the EEA Management Board after consultation with the EEA Scientific Committee and the European Commission. Consultations are also carried out with all EEA member countries and the Environment Committee of the European Parliament. Within the framework of the MAWP, the EEA Management Board adopts annual work programmes (AWPs) following a similar procedure.

The current MAWP identifies three domains of work: (1) Informing policy implementation; (2) Assessing systemic challenges; and (3) Knowledge co-creation, sharing and use. This work is carried out in the context of the overall policy framework of the EU covering: environmental thematic policies, with their own timelines and deadlines for implementation, reporting and revision; more comprehensive policies (Europe 2020, seventh environment action programme), including specific 2020/2030 targets for the environment and climate; and long-term visions and targets, mostly with a 2050 societal transition perspective.

Thus, through its work programmes, the EEA provides the necessary input on the environment and climate to follow up on EU policies and report on progress towards related objectives, contributing, among other things, indicators on environment and climate-related matters, especially in the context of the Europe 2020 strategy's regular monitoring process. These indicators measure the overall progress towards a resource-efficient European economy and society, and the long-term implications for prosperity, natural capital maintenance, health and well-being.

The EEA's 5-yearly state and outlook reports on the European environment (SOERs), mandated by the founding regulation, collate and assess the evidence base needed to both inform the implementation of existing polices (many related to existing 2020/30 policy targets) and facilitate longer-term transitions (towards 2050 ambitions). The latest SOER was published in March 2015.

Monitoring programme execution

Progress on the EEA's objectives and performance indicators embedded in the AWPs are assessed by management quarterly. Key performance indicators are

([1]) http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0401

set to help management evaluate and report on progress made in relation to the objectives and make adjustments and improvements as necessary. The EEA Management Board and Scientific Committee are regularly kept informed about the progress of the work programme throughout the year.

Funding

The funding for all EEA activities comes from the internal budget of the agency. Apart from the core subsidy from the EU and membership fees from EEA member countries outside the EU (Iceland, Norway, Liechtenstein, Switzerland and Turkey), the EEA receives additional funding from the Instrument for Pre-Accession Assistance (IPA) to support the integration of the six western Balkan countries (Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo (under UN Security Council Resolution 1244/99), Montenegro and Serbia) into Eionet as EEA cooperating countries. Furthermore, additional EU resources are made available to the EEA from the European Neighbourhood Partnership Instrument to support specific project work in the East and South (Mediterranean countries). Funding under the Copernicus programme for the implementation of the land monitoring service and *in situ* component was approved at the end of 2014.

3. Approaches used to conduct the scientific work

Scientific collaborations

The EEA is required by its founding regulation to collaborate with a large variety of European and international partners in carrying out its work. This includes the member countries and nominated bodies in these countries through the Eionet, the EEA Scientific Committee, the European Parliament, the Council of the European Union, the European Commission and other EU agencies. Beyond this there are a number of bodies with which the EEA works regionally and internationally, in particular UN bodies, several of which are explicitly mentioned in the founding regulation.

Member States, European Economic Area/European Free Trade Association, candidate countries and potential candidates

The EEA has 33 member countries: the 28 European Union Member States together with Iceland, Liechtenstein, Norway, Switzerland and Turkey. The six western Balkan countries (Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo (under UN Security Council Resolution 1244/99), Montenegro and Serbia) are not EEA members but, due to their long-standing and ongoing collaboration with the agency (supported by EU IPA funding), they are embraced in the work as 'EEA cooperating countries'.

All these countries cooperate as members of Eionet. The EEA is charged by the founding regulation to coordinate and develop Eionet. Eionet is a partnership network comprising the main component elements of the national information networks, the national focal points (NFPs – typically key persons in the national environment agencies or environment ministries in the member countries) and the European topic centres (ETCs – institutions, or groups of bodies, in the countries that have concluded an agreement with the EEA to carry out specific tasks). In this manner the relevant bodies and experts in the member countries cooperate with the EEA, contributing directly to the agency's work programme by collecting, collating and analysing data nationwide.

The NFPs are responsible for coordinating networks of the national reference centres (NRCs), which are identified by the countries as the main component elements of the national information networks. This brings together around 1 500 experts from up to 400, mostly national, institutions and other bodies dealing with environmental information. Eionet currently covers six ETCs in the areas of: air pollution and climate change mitigation; biological diversity; climate change impacts, vulnerability and adaptation; inland, coastal and marine waters; urban, land and soil systems; and waste and materials in a green economy. ETC partner organisations also participate in EU research projects, enhancing know-how and knowledge sharing.

EEA Scientific Committee

The Scientific Committee is composed of independent and leading scientists in their field from the EEA member countries. It has three major tasks: (1) to deliver an opinion on the EEA's MAWP and AWP; (2) to give an opinion to the executive director for the purpose of recruitment of the agency's scientific staff; and (3) to provide advice and/or opinions on any scientific matter concerning the agency's activity which the Management Board or the executive director may submit to the committee.

European Commission

The EEA has regular contacts with the European Commission. The closest links are with DG Environment and DG Climate Action, along with the Joint Research Centre (JRC), Eurostat and, as it is referred to in the founding regulation, 'the Community's environmental research and development programmes'. The latter three are explicitly mentioned in the EEA/Eionet founding

regulation, with a specific annex dedicated to Eurostat and JRC cooperation. In addition, the EEA has regular interactions with many other directorates-general acting in some cases as partners in projects. These include the Secretariat-General; DG Internal Market, Industry, Entrepreneurship and SMEs; DG Agriculture and Rural Development; DG Energy; DG Mobility and Transport; DG Research and Innovation; DG Maritime Affairs and Fisheries; DG Regional and Urban Policy; DG Health and Food Safety; DG Trade; DG Neighbourhood and Enlargement Negotiations; and DG International Cooperation and Development.

European Parliament

The EEA provides information and briefings on request for the European Parliament. The Parliamentary Committee for Environment, Public Health and Food Safety deals with all issues concerning EEA, and the Budgets Committee with financial and budgetary issues.

The Council of the European Union and the presidency

The EEA contributes to the work of the Council of the European Union in several ways. The EEA's executive director is regularly invited to the informal Environment Council meetings and makes specific presentations on topical issues. Over the past years, environment ministers have appreciated receiving up-to-date information on the environment to underpin political decisions. The EEA also assists each Member State during their Council presidency, coordinating and programming as far as possible particular events to address their priorities.

Other EU agencies

The EEA liaises with other EU agencies where there are important links in remits, in particular: the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the European Maritime Safety Agency (EMSA).

International and regional cooperation

The EEA is mandated by its founding regulation to cooperate actively with other bodies 'such as the European Space Agency, the Organisation for Economic Cooperation and Development (OECD), the Council of Europe and the International Energy Agency as well as the United Nations and its specialised agencies, particularly the United Nations Environment Programme, the World Meteorological Organisation and the International Atomic Energy Authority …' It is specified that such cooperation must in particular take account of the need to avoid any duplication of effort.

Actual international and regional cooperation in fact goes beyond these organisations directly mentioned in the founding regulation to cover collaboration with numerous international and regional organisations to support the EU and Eionet partners in the implementation of international processes and conventions and related thematic activities, and in ensuring national and EU contributions to regional and global processes and assessments to support policy- and decision-making. The EEA also seeks to influence the way these organisations frame and conduct their information and assessment processes, encouraging improved coherency and accessibility of information to support the strengthening of the science/knowledge-policy interface and of global environmental governance in general. To these ends, the agency specifically promotes EU and EEA/Eionet approaches and experiences, including the EEA/Eionet networking model and the concept and principles of the Shared Environmental Information System (SEIS). All such collaboration provides a basis for European inputs to a wide range of international, regional and subregional policy processes where EEA also ensures European data and information are available at the global level.

Evidence

Given the EEA's goal of contributing to the knowledge base on environmental and climate policies in light of the policies and ambitions of the EU, this means that excellence in data provision, indicator development and reporting on the comprehensive set of thematic policies constitute the core of the agency's activities. To this end the EEA has established a set of priority data flows from member countries, a core set of indicators and sets of indicators for its different areas of work. EEA monitoring, data, indicators, assessments and knowledge (MDIAK) provides a basis on which to assess the state and outlook of Europe's environment and conduct other types of integrated assessments and policy effectiveness analyses. Other sources of information used come from institutional bodies such as the JRC and Eurostat, from the scientific community and to a small extent, in specific areas of need, from non-traditional sources of information including lay, local and traditional knowledge, businesses and citizen science. The EEA also promotes the use of new analytical methods and technologies to increase the value of the knowledge base for the EU and member countries.

Analysis

Analyses (assessment and evaluation) are carried out by in-house staff and the ETCs. The information (evidence) received from the countries and other bodies is submitted to quality assurance procedures before being included in the information base.

Expertise

Approximately 200 staff members contribute to the work and functioning of the agency, including experts in all areas of the EEA's activities. In addition, Eionet brings together around 1 500 experts from up to 400 national institutions and other bodies dealing with environmental information, complemented by six ETCs, which constitute at any point in time the best European expertise available.

Methods

The EEA develops and delivers a wide range of knowledge products, including reports and assessments, data and indicators, maps and web services. Much, but not all, of this is specifically required under EU legislation and international conventions. At the heart of this work is the development of a comprehensive range of integrated environmental and thematic assessments. These include the 5-yearly SOER, along with indicator reports (mandated by the founding regulation), thematic and sectoral assessments, forward studies and megatrends, policy evaluations and studies on the impacts of globalisation on Europe's environment and resources.

The EEA is an important source and custodian of environment-related data and indicators, and a key provider of environmental knowledge and information services. In this context, EEA's 5-yearly SOERs (supplemented by more regular indicator reports) are a primary 'method' for transmitting evidence across the science/ knowledge-policy interface. This is evidenced by the SOER being mentioned explicitly in the seventh Environment Action Programme as a basis for the evaluation of progress.

To support its work the EEA has developed a number of typologies, concepts and approaches that help frame and guide its work and that of the Eionet. These include: the MDIAK chain ([2]); the DPSIR framework ([3]); the SEIS; and approaches to integrated assessment indicator development and foresight studies.

4. Outputs

Review of the draft outputs

For all EEA reports a thorough consultation and review process is held with all EEA member countries and, as appropriate, with other experts. In some specific cases consultations are public, and in other cases the relevant NRCs are consulted.

The exact design of each process depends on the type of output and can be different depending on whether the output in question concerns updating key data sets, indicators, technical reports, thematic reports, indicator-based assessments or the EEA's main 5-year SOER.

Authorship

All reports go out under the name of the agency. EEA staff and ETC personnel are usually named as leading authors and contributors. Other Eionet partners, Scientific Committee members and ETC staff can also be authors and contributors to the production process.

Responsibility for issuing scientific documents

Responsibility resides with the executive director of the EEA.

Communication

The main dissemination channel for the agency's research results is its website where newly produced reports are published in up to 28 languages. The agency also has a subscription service where users sign up to be notified of new reports and other outputs, works actively with media relations and has an enquiry service dealing with and responding to public requests. Furthermore, the agency uses social media extensively for disseminating new information and engaging with the public on topics related to the environment, and makes an effort to be present and visible at key environmental conferences and events. Finally, the EEA actively promotes the reuse of its data and information, and follows the same policy in this respect as the European Commission ([4]) responding to public requests.

Use and follow-up

The EEA delivers reports specifically required under EU legislation and international conventions and undertakes a comprehensive range of integrated environmental and thematic assessments. These include 5-yearly SOERs, thematic and sectoral assessments, analyses of the effectiveness of policy measures, forward studies

([2]) MDIAK = from **m**onitoring (in the broadest sense), through **d**ata, **i**nformation and **a**ssessments to **k**nowledge.
([3]) DPSIR = driving forces — pressures — state (of the environment) — impacts — responses.
([4]) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:330:0039:0042:EN:PDF

and studies on the impacts of globalisation on Europe's environment and resources. The EEA is an important source and custodian of environment-related data and indicators, and a key provider of environmental knowledge and information services. The EEA takes part in many EU policy working groups adding specific environment expertise. One indicator of the EEA's added value is the use of its data, information and knowledge by EU institutions in the preparation of new legislation.

Between 1999 and June 2014 more than 100 references were made to the EEA in this context. Moreover, in the same period, over 40 references to the EEA were made in secondary legislation (regulations, directives, and decisions) and more than 60 references in 'soft' legislation (opinions, communication, etc.). In more general terms, the last 5-year evaluation of the efficiency and effectiveness of the EEA carried out in 2013 concluded that: '… the EEA and Eionet are well-established and well-functioning structures, delivering comprehensive and reliable outputs which, to a large extent, satisfy stakeholders' needs. The qualitative assessment inherent in this evaluation indicates that the EEA continues to be the most effective and efficient solution to providing credible information on the state of the European environment.'

European Food Safety Authority (EFSA)

1. Nature of the scientific work

Domain in society covered

EFSA provides scientific advice in the form of scientific assessments on nutrition, food and feed safety, animal health and welfare, plant health and environmental health, where it concerns the food chain. Much of this work relates to the evaluation of regulated products, which must be assessed prior to the granting of a market authorisation in the European Union. The other part concerns scientific assessments on more general public health issues regarding chemical or biological contaminants in food and feed, along with plant and animal health and animal welfare.

Another major activity concerns scientific reports issued by EFSA, most often regarding data collected by Member State organisations on food consumption, composition and the presence of residues (such as from pesticides and veterinary drugs) and chemical or microbiological contaminants.

Aspects assessed

The focus is on the scientific evaluation of health risks, although in specific areas benefits are also considered. The scientific reports mostly concern the monitoring of occurrence and exposure assessments. The remit does not cover socioeconomic aspects or ethical considerations (though animal welfare is within EFSA's mandate). Control or mitigation options may also be addressed.

2. Scientific work programme

Programme

Most of the advice issued by EFSA is upon the request of the European Commission. Member State competent authorities and the European Parliament can also ask EFSA for scientific advice. EFSA may also self-task. With the input of the European Commission, EFSA has developed a multiannual work programme to try and better align the distribution of workload with resources.

The precise annual work programme is difficult to predict as it depends very much on the number and nature of the dossiers being submitted by industry. Also, the European Commission may launch regulatory review programmes for an entire sector, resulting in work that may take several years to complete. Here the workload also depends on what industry decides is worth keeping on the market.

In the area of general public health issues, the complexity of the question posed may impact the workload substantially. There are also regularly urgent requests for scientific advice, including on food-borne disease outbreaks.

The (multi-) annual programme is adopted by the EFSA Management Board, which allocates the human and financial resources. During the year, as requests for specific tasks come in, the management team of EFSA is responsible for reviewing these requests and making sure that the resources are available and the timeline for delivery of the opinion is consistent with the annual work plan.

In 2014 and 2015, for example, EFSA produced over 650 and 600 scientific outputs, respectively, contributing to evidence-based decisions and improved consumer protection.

The array of subjects covered during these 2 years ranged from work on the potential risks of antimicrobial-resistant pathogens to providing emergency responses, alone or with other agencies, for example during the Ebola crisis and outbreaks of hepatitis A in humans, *Xylella fastidiosa* in olive trees, African swine fever in pigs and small hive beetle in honey bee colonies. Also, among the assessments related to the market authorisation of regulated products or claims, EFSA produced annually some 70 scientific opinions on proposed uses of feed materials, 35-40 peer reviews of assessments of active substances intended for use in pesticides and 80 reasoned opinions on maximum residue levels of pesticides in food.

Monitoring programme execution

The Management Board reviews completion of the work programme on a regular basis. Using a system of key performance indicators it identifies areas of (potential) concern.

Funding

There is very little funding outside the normal budget provided to EFSA through the EU budget. Some separate funding has been given to EFSA in the framework of activities to support candidate countries and for the European Neighbourhood Policy.

EFSA could charge for some work, for example when organising workshops for the benefit of industry. This has not been done thus far.

3. Approaches used to conduct the scientific work

Scientific collaborations

EFSA scientific opinions are issued by its 10 scientific panels and the Scientific Committee. The experts in these panels and this committee are employed by (or retired from) public organisations, principally in Member States. In addition, the Member State organisations that have a similar remit to that of EFSA cooperate with the authority via the Advisory Forum, in which all Member State competent authorities are represented and which advises the EFSA executive director on its scientific work programme. EFSA also cooperates with many scientific institutions in Member States on various aspects of its work, which are financially supported through grants or procurements.

EFSA liaises closely with other EU agencies (ECDC, ECHA, EMA), international organisations and organisations in non-EU countries. This allows the exchange of work programmes and other information.

ESFA has signed confidentiality arrangements with organisations in non-EU countries, including the US Food and Drug Administration, the US Environmental Protection Agency, parts of the US Department of Agriculture, Health Canada, Japanese authorities and Food Standards Australia New Zealand. EFSA exchanges information as part of these arrangements.

Evidence

The sources of information used concern any combination of the following:

- dossiers submitted by the market authorisation;
- the EFSA's scientific colloquia and its scientific conferences;
- data collected and submitted by Member State competent authorities, most often as surveys on food consumption, the occurrence of contaminants or residues (which are issued regularly by EFSA as scientific reports);
- data received through open calls;
- studies that are shared with EFSA by Member State organisations, DG Research and Innovation, the Joint Research Centre, Eurostat or other stakeholders;
- applicants primarily submitting reports of scientific studies carried out or sponsored by industry;
- peer-reviewed literature reviews conducted by EFSA or submitted by industry;
- own-initiative studies supported through grants or procurements;
- expert elicitation to address data gaps.

From 2015 many of the datasets provided to EFSA for its assessments and those generated by EFSA-funded projects will progressively be made available to interested parties following the launch of the EFSA Data Warehouse.

Analysis

The evidence submitted by industry has to be shown to meet quality standards (e.g. good laboratory practice) in order to demonstrate a lack of bias.

The analysis of survey data collected by Member States resides with EFSA, which issues scientific reports, often on an annual basis. For biological hazards this is done jointly with the ECDC, and for antimicrobial resistance with both the ECDC and the EMA.

The review and analysis of literature may utilise systematic review and possibly a subsequent statistical meta-analysis.

Preparatory work to support the panels is carried out by working groups or by EFSA staff, or it can be outsourced to organisations in Member States. The experts in a panel's working group(s) support the preparation of a draft opinion.

Expertise

The scientific panels and committee are appointed for a 3-year renewal period, following a public call. The latest renewal was in July 2015. They are selected based on their scientific competence to meet the needs of the panel and their lack of any interests that may pose a conflict. They are appointed by the Management Board of EFSA.

Potential members of working groups are selected based on their ability to meet the needs of the working group, their availability and the lack of a conflict of interest.

Staff are recruited as temporary or contract agents in a manner consistent with the regulations for staff working in the EU institutions, as is the case for seconded national experts.

EFSA offers training in scientific risk assessment to its staff and the panel members. This work is outsourced to organisations in Member States.

EFSA runs a training programme and an exchange programme for national experts, and recently started a fellowship programme.

In addition, EFSA collaborates with the European Commission's programme on better training for safer foods (BTSF), which has a module on basic training in risk assessment.

Methods

The methods used are described in EFSA guidance documents. Depending on the area the European Commission may also adopt guidelines which are regulatory requirements. External sources of guidance, such as those developed by the Food and Agriculture Organisation of the United Nations and the World Health Organisation on food safety risk assessment, or Organisation for Economic Cooperation and Development test guidelines, are also considered.

4. Outputs

Review of draft outputs

For a scientific opinion, the preparatory work is reviewed and eventually adopted by the panel concerned. Prior to its adoption the panel may carry out a public consultation. Draft scientific reports are submitted for peer review and may also be the subject of a consultation.

Authorship

The authorship of scientific opinions resides with the panel concerned. EFSA may also author scientific and technical reports. The accountability resides with EFSA, i.e. its executive director.

Responsibility for issuing scientific documents

Outputs are issued by EFSA on its website (https://www.efsa.europa.eu/en/publications) and in the *EFSA Journal*, an online scientific journal (http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1831-4732).

EFSA aims to evolve towards an open-science organisation, making supporting information (e.g. related datasets, statistical models, assessment methodologies etc.) available as much as possible.

Communication

Publication of the scientific outputs may be accompanied by communication support (e.g. press releases, frequently asked questions, briefings, videos, infographics, data visualisation, etc.) designed to raise awareness among EFSA's different target audiences.

Use and follow-up

The follow-up of the work carried out by EFSA is in the hands of the European Commission and the Member State risk management bodies. The scientific opinions and reports on regulated products provide the basis for a decision by the European Commission and the Member States to issue a market authorisation and under what conditions. Similarly, the outcome of other scientific opinions is taken on board when new legislation is being drafted or existing legislation is being revised.

European Institute for Gender Equality (EIGE)

1. Nature of the scientific work

Domain in society covered

The European Institute for Gender Equality (EIGE) has been given a mandate to strengthen the promotion of gender equality, including gender mainstreaming in all EU policies and the resulting national policies, to fight against discrimination based on sex and to raise EU citizens' awareness of gender equality. The institute supports the EU and the Member States by providing gender equality expertise in the implementation of the Council conclusions on the European pact for gender equality 2011-2020, the follow-up to the Beijing Platform for Action (BPfA) and the Commission strategy for equality between women and men 2010-2015, including the implementation of the gender equality dimension in the Europe 2020 strategy.

Aspects assessed

The key areas covered by the work are defined by the founding regulation as follows:

- collect, analyse and disseminate relevant objective, comparable and reliable information as regards gender equality and suggest areas for further research;
- develop methods to improve the objectivity, comparability and reliability of data at European level and take into account gender issues when collecting data;
- develop, analyse, evaluate and disseminate gender mainstreaming methods and tools in order to support the integration of gender equality into all EU policies and the resulting national policies;
- set up and coordinate a European Network on Gender Equality of organisations and experts dealing with gender equality and gender mainstreaming;
- disseminate information regarding positive examples of non-stereotypical roles of women and men;
- set up documentation resources accessible to the public.

2. Scientific work programme

Programme

The agency has a 3-year single programming document that defines the broad scope of its work with respect to gender equality in the EU. For the 2016-2018 period the five main focal areas for the agency's work are:

- monitoring the BPfA and supporting the presidencies of the Council;
- the Gender Equality Index;
- the Gender Statistics Database;
- violence against women;
- gender mainstreaming tools and methods.

In accordance with its mandate, EIGE occasionally initiates innovative research on gender equality to inform policymakers and other key stakeholders. Two such initiatives will be completed and disseminated during this programming period: a study on the benefits of gender equality and a new thesaurus on gender equality.

EIGE also develops a work programme on an annual basis, in which activities correspond to the thematic priorities (as listed above). Specific activities for multiannual and annual work programmes are proposed by EIGE on the basis of its expert knowledge and consultations with stakeholders, such as the European Parliament, the Commission, governmental equality bodies of the Member States, the Council of Europe, European civil-society organisations (through the Social Platform) and social partners, national statistics institutes and other data providers, the European Women's Lobby, MenEngage and other experts working on gender equality. In addition, EIGE's Experts' Forum, composed of members from competent bodies specialising in gender equality from all Member States and representatives from EU-level civil-society organisations and social partners, constitutes a mechanism for the exchange of information in relation to gender equality issues and the pooling of knowledge.

EIGE's Management Board adopts, after consultation with the Commission, the annual and multiannual work programmes.

Monitoring programme execution

Programme execution is monitored through a variety of quality control procedures, which oversee the quality of project deliverables. EIGE's operational activities are organised in two units — Operations, and Knowledge Management and Communications. The Operations Unit has three programme areas — Gender-based Violence, Gender Mainstreaming, and Research and Statistics — each with a programme coordinator leading the staff there. The staff work across programmes and units on specific projects as EIGE has moved towards a project-led organisational structure. A tailor-made project management tool was built to support EIGE in this regard. The project teams implement projects in line with EIGE's annual work programme, regularly monitor the quality of deliverables, including those from external contractors, and monitor implementation of the budget. In addition to the support from EIGE's Experts Forum members, a call for external experts was launched, and this pool is engaged regularly to assist with the quality control process of research and studies, according to their area of expertise. EIGE's reports on the follow-up of the BPfA are reviewed by the Commission's High Level Group on Gender Mainstreaming, composed of the members of the governmental gender equality bodies of Member States.

EIGE's work on good practices involves gender equality experts and practitioners from the Member States, who assess practices according to established frameworks and criteria. EIGE seeks support for its research work from diverse groups of its stakeholders, which are usually engaged in EIGE's work at the earliest stage of the research projects (through experts' meetings, EuroGender online discussions, working groups or thematic networks).

Funding

Activities are fully funded by EIGE's budget. No additional funding sources are used.

3. Approaches used to conduct the scientific work

Scientific collaborations

Scientific experts' inputs are mostly provided through contracts (for example, EIGE's framework contract: Collection of information and provision of research related services — a network of national experts who provide research related services). In addition, EIGE collaborates with a broad range of institutions.

At the international level EIGE collaborates with the following.

- The Council of Europe, mostly in the area of gender-based violence. EIGE has observer status in the Council's Gender Equality Commission.
- The United Nations Economic Commission for Europe (UNECE), mostly in the area of gender statistics.

In its research work EIGE has also greatly benefited from cooperation with UN Women, the Organisation for Economic Cooperation and Development, the International Labour Organisation, the World Health Organisation (WHO) and the World Economic Forum.

At the EU level EIGE works closely with the following.

- Eurostat, mostly in the areas of labour force, earnings, social inclusion, living conditions, time use and crime statistics. EIGE is engaged in a number of Eurostat's working groups; the representatives of Eurostat support EIGE in its Working Group on the Gender Equality Index, research work on gender-based violence and follow-up of the BPfA.
- The Commission's High Level Group on Gender Mainstreaming, which provides input to EIGE's reports on implementation of the BPfA in the EU.
- The FEMM Committee of the European Parliament. EIGE regularly informs the committee about its annual and multiannual work programmes and the main findings of its studies and other activities.
- Social partners (ETUC, BusinessEurope, Ueapme, CEEP).
- The European Women's lobby, Social Platform and MenEngage, a network dedicated to promoting gender equality from a male perspective.

At the Member State level EIGE is engaged with the following.

- Governmental bodies for gender equality, independent bodies on equal treatment of women and men and other organisations promoting gender equality. For example, EIGE provides support to the presidencies of the Council of the European Union by developing reports on the progress of implementation of the BPfA in the areas selected by the presidency, and participates in other presidency events and debates.

- National statistics institutes, especially in EIGE's work on the Gender Equality Index, Gender Statistics Database and gender-based violence.
- EIGE arranges meetings of experts from Member States concerning specific areas of work, for example good practices, gender mainstreaming tools and methods, gender-based violence, men and gender equality, monitoring of the BPfA, etc.

Through the Instrument for Pre-Accession Assistance (IPA) , EIGE is engaged with candidate and potential candidate countries in their efforts to strengthen national gender equality policies and practices.

EIGE also collaborates closely with several EU agencies (Eurofound, FRA, EASO).

Evidence

Evidence is collected by EIGE's internal research staff and external contractors. EIGE undertakes both primary and secondary data collection for its research and conducts both qualitative (e.g. policy analysis, face-to-face interviews, good-practice case studies) and quantitative (e.g. surveys) research. Extensive reviews of literature (policies, legal provisions, research findings) inform all of EIGE's studies and reports. For its research work EIGE most frequently uses EU-wide sex-disaggregated data and gender statistics.

In 2013 EIGE developed a unique gender equality monitoring tool, the Gender Equality Index, which includes data and indicators in six core domains (work, money, knowledge, power, time and health) and two satellite domains (intersection inequalities and violence against women). The index includes data from Eurostat, Eurofound, the Commission's DG Justice database on women and men in decision-making and FRA. The data cover all 28 EU Member States. The Gender Equality Index will be updated every second year.

In its work on the follow-up of the BPfA, EIGE most frequently uses EU-wide data from Eurostat. Occasionally EIGE undertakes research and data collection in areas where there is a lack of EU-wide data on certain gender equality issues; hence EIGE has to undertake its own primary data collection (e.g. women in decision-making in media institutions, gender equality and climate change, institutional mechanisms for gender equality).

In the area of gender-based violence EIGE also collects evidence from existing administrative data sources at the national and EU levels.

Analysis

Analysis is usually carried out by EIGE's research staff and external contractors. For most of EIGE's studies the external contractors deliver research material to EIGE. However, EIGE undertakes further analysis and develops the final report. The Gender Equality Index is developed by EIGE's research staff members only.

Expertise

Research staff are recruited through EIGE's recruitment processes. Research staff include social scientists and statisticians.

Scientific expertise is also contracted through public procurement, usually using open calls for tender.

Experts required for EIGE's working groups and thematic networks are nominated by EIGE's Management Board or Experts Forum, also selected by EIGE, as required, avoiding any conflict of interests.

Training/capacity building is provided by EIGE for internal staff only. It includes general and specialised training, internal capacity-building seminars, knowledge management (through EIGE's Resource and Documentation Centre), etc. EIGE has also provided training on the Gender Equality Index to the national statistical institutes of several pre-accession countries (under the IPA).

EIGE also receives input from external academics/experts in various forms and at various stages of the research process. This can involve consultations on the research methodology at the inception phase, the reviewing of interim reports, the validation of data and information and the peer reviewing of the final report.

Methods

EIGE's reports on the BPfA, gender-based violence and the Gender Equality Index specifically identify gender gaps (i.e. the difference in outcomes for women and for men) and provide recommendations on the availability and quality of data.

4. Outputs

Review of draft outputs

All publications are reviewed internally by the project manager, team members and the head of the respective unit prior to approval by the director. Country-specific information may be consulted with/verified by members of EIGE's Management Board or Experts' Forum. If

a working group has been established to work on a specific topic, the publication will also be reviewed by members of the working group. The institute's work on good practices always involves gender equality experts and practitioners from Member States, who use EIGE's specific criteria in their assessments. The Commission and its High Level Group on Gender Mainstreaming are involved in the review of EIGE's reports on the implementation of the BPfA in the EU.

As of 2015, with the adoption of a new quality assurance policy at EIGE, major research-based reports are reviewed by external experts prior to publication.

Authorship

All reports go out under the name of the agency. The research staff of EIGE who draft reports are acknowledged as authors and contributors. Where external contractors have contributed material for a report they and/or their institutions are also acknowledged.

Responsibility for issuing scientific documents

The final responsibility for issuing the scientific documents resides with EIGE, in line with the internal review of all products as described above. EIGE's Management Board adopts the institute's consolidated annual activity report (CAAR), which presents results achieved within the objectives of the annual work programme.

Communication

EIGE has communication, stakeholder and networking teams that support the dissemination of research material. Websites and social media are the main channels for the dissemination of EIGE's research results. EIGE's publications (electronic and printed) are also delivered to key stakeholders (the European Parliament, the European Commission and Member States' governmental gender equality bodies) and other actors on key distribution lists (adjusted to the topic), which are provided by EIGE to the Publications Office. EIGE regularly organises EU-wide international conferences on its flagship initiatives (e.g. launch of the Gender Equality Index), sometimes jointly with the presidencies of the Council of the European Union or international organisations (e.g. a conference on gender-based violence together with WHO and the Council of Vienna).

In the context of EIGE's support for the presidencies of the Council on the follow-up of the BPfA in the EU, EIGE is making efforts to mainstream a gender equality perspective into various events and debates within the presidencies' agendas.

Use and follow-up

EIGE has set out its mission to become the European knowledge centre on gender equality issues. Its impact-level objectives are to support better-informed policymaking at the EU and Member State levels and to increase awareness among decision-makers and the public of progress and challenges in implementing the EU's gender equality policies. EIGE collects evidence on how the results of its work are used or referred to by the European Parliament, the Council, the Commission or other stakeholders at the EU and Member State levels (e.g. EIGE's reports on the BPfA serve as a basis for EPSCO Council conclusions).

EIGE monitors web-based downloads and its social media accounts, and its publications are widely disseminated by the Publications Office. For specific initiatives, such as the Gender Equality Index, EIGE requests that its contractors report on media coverage.

European Medicines Agency (EMA)

1. Nature of the scientific work

Domain in society covered

EMA is responsible for the scientific evaluation of applications for EU market authorisations for human and veterinary medicines (small molecules and biologics) in the centralised procedure. Under the centralised procedure, pharmaceutical companies submit a single market authorisation application to the agency. Once granted by the European Commission, a centralised market authorisation is valid in all EU Member States and in the European Economic Area countries.

The agency is also responsible for coordinating the EU's safety-monitoring or 'pharmacovigilance' system for medicines and for coordinating inspections.

Aspects assessed

Quality, safety, and efficacy (QSE) of medicinal products — on the basis of QSE data the agency evaluates whether the benefits of a medicine outweigh its risks (the benefit–risk balance).

2. Scientific work programme

Programme

Long-term plans (usually 'road maps' for a 5-year period) and short-term (annual) plans.

Bodies/persons responsible for defining programme elements include agency staff and national competent authorities, with adoption by the EMA management board.

Monitoring programme execution

The agency operates an integrated quality management system and has stringent reporting timelines in place. In addition, the agency contributes to a benchmarking exercise comprising all European medicines agencies (national competent authorities).

Funding

On average, 83 % of the agency's budget derives from fees and charges (from the bio-pharmaceutical industry) and 17 % from the EU contribution for public health issues.

3. Approaches used to conduct the scientific work

Scientific collaborations

The agency coordinates the scientific evaluation of applications and related work with the national medicines regulatory authorities in the EU Member States. The agency's committees are responsible for the scientific evaluation of market authorisation application dossiers submitted by pharmaceutical companies and for providing opinions on referrals and other issues impacting on public health at the request of the Member States, the European Parliament or the European Commission.

The agency cooperates with other EU agencies such as EFSA, ECDC and EMCDDA.

The agency has also signed confidentiality arrangements with non-EU-country agencies, such as the US Food and Drug Administration, Health Canada and Japanese authorities. The agency exchanges information on medicinal products as part of these arrangements. Extensive international collaboration takes place in the area of international inspections.

Collaboration takes place with the World Health Organisation (WHO) in various areas, including giving opinions, in cooperation with WHO, on medicinal products for human use that are intended exclusively for markets outside of the European Union.

Evidence

Evidence comes most often from studies and clinical trials conducted by the market authorisation applicant/holder; sometimes from scientific literature; and occasionally from other sources.

Analysis

Analysis (assessment and evaluation) of evidence is conducted by assessors (usually) in Member States' national competent authorities, most often based on international or EU guidelines.

Expertise

Committee members are nominated by Member States or the European Commission. EMA scientific staff are recruited through the usual EU agency procedures.

Committee members assess and evaluate evidence and prepare opinions with help from national experts. EMA scientific staff coordinate and provide scientific, technical and administrative support.

The training/capacity building model is mixed: some training is provided by individual Member States and some by EMA.

Methods

Key methodological issues include: assessing the validity of experimental and clinical trial data; determining the acceptability of uncertainty around benefits and risks and the possibility of bias; weighting different health outcomes when balancing benefits and risks; and communicating uncertainty and risks to the scientific community and the general public.

Many guidance documents, along with evidence and analysis standards, are international; some are EMA guidelines and standards; and occasionally some guidelines are developed by other organisations (e.g. learned societies).

4. Outputs

Review of draft outputs

The draft output resulting from the rapporteur and co-rapporteur assessment system is reviewed through an internal peer-review process that is in place for nearly all documents, either within the committees or with agency staff. A public consultation is conducted, for example, for scientific guidelines and policies.

Authorship

Authorship resides with the agency or the agency's committees, depending on the type of document.

Responsibility for issuing scientific documents

The final responsibility for issuing the scientific documents depends on the type of document: the committee chair signs on behalf of the committee; the executive director signs with respect to certain paediatric opinions.

Communication

For product-related activities the initial opinions are communicated to the European Commission. If/when an opinion becomes a legally binding decision it is posted on the agency's website. Other documents (e.g. scientific guidelines) are also posted on the agency's website. Agency positions or the views of agency staff or committee members are occasionally published in peer-reviewed journals.

Use and follow-up

For individual medicinal products the follow-up of the work carried out by EMA is in the hands of the European Commission. The scientific opinions and reports on regulated products provide the basis for a decision by the European Commission to issue a market authorisation and its conditions. Similarly, the outcome of other scientific opinions is taken on board when new legislation is being drafted or existing legislation is being revised, both by the EU and, sometimes, in other jurisdictions.

European Monitoring Centre for Drugs and Drug Addiction

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

1. Nature of the scientific work

Domain in society covered

'The Centre's objective is to provide, in the areas referred to in Article 4, the Community and its Member States with objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences.' (EMCDDA recast regulation, 2006.)

Aspects assessed

The priorities in the recast regulation are: (a) monitoring the state of the drugs problem, in particular using epidemiological indicators, and monitoring emerging trends; (b) monitoring the solutions applied to drug-related problems; (c) providing information on best practices in the Member States and facilitating information exchange among them; (d) assessing the risks of new psychoactive substances and maintaining a rapid information system; (e) developing tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate EU policies.

2. Scientific work programme

Programme

The EMCDDA has a multiannual programming document, which includes the objectives and programme of the agency for a 3-year period, and a more detailed annual programme to implement the activities and commitments set out in the multiannual programme. This single programming document is updated every year on a rolling basis and is developed from a detailed planning exercise completed by each of the agency's units. A core planning team is responsible for the coordination of the planning work.

The programming document is aligned with the EMCDDA Strategy 2025 in terms of structure (with three main areas: health, security and business drivers) and content (expected results defined in line with the Strategy's roadmap 2020).

The EMCDDA's draft single programming document is sent for consultation and input to the EMCDDA Management Board and Scientific Committee, to the European Commission and to the 30 national focal points of the Reitox network (see Section 3) in each Member State, along with Norway and Turkey.

Monitoring programme execution

Specific objectives and priority interventions are defined for each of the areas of work in the annual work programmes, mirroring the structure of the multiannual work programme. Priority interventions are accompanied by their related activities and expected outputs or results, which will help achieve the key expected results defined in the work programme.

Monitoring of the annual work programmes is conducted in the context of the general report of activities. The general report of activities is an annual publication providing a detailed progress report of the EMCDDA's activities over a 12-month period. An annual mid-year monitoring exercise is conducted. During this exercise all the units are required to report on the status of implementation of the annual work programme. The outcome is submitted to the director and supports the detection of deviations from the initial planning, the implementation of any corrective measures and the preparation of the upcoming work programme.

In addition, different mechanisms and tools are in place to monitor programme execution and ensure that the agency achieves the objectives set out in the work programme (management plan, products database, etc.).

Funding

The agency has a (limited) budget for funding scientific studies. No other funding of scientific work outside the normal agency budget is undertaken.

3. Approaches used to conduct the scientific work

Scientific collaborations

Cooperation with EU institutions, the Reitox network (30 national drug monitoring centres) and regional and international organisations has been an important part of the EMCDDA's work since its creation.

- The EMCDDA coordinates and relies on a network of some 30 national monitoring centres (the Reitox network) to gather and analyse country data according to common data-collection standards and tools.

- The EMCDDA has cooperation agreements with agencies (Europol, ECDC and EMA) and works closely with the EU institutions and other agencies (Eurojust and CEPOL). The cooperation with other agencies resulted, among other things, in a number of joint publications (including the EU drug markets report with Europol, and ECDC and EMCDDA guidance on prevention and control of infectious diseases among people who inject drugs).

- The EMCDDA collaborates with numerous international partners, often within the framework of formal cooperation agreements supplemented by practical joint work programmes. The cooperation with ESPAD, for example, has resulted in several joint publications since 2009.

The EMCDDA cooperates with candidate and potential candidate countries as part of their process of accession to the EU, with neighbouring countries under the European Neighbourhood Policy and with other non-EU countries on the basis of bilateral agreements.

The EMCDDA works very closely with the scientific community, and EMCDDA activities both utilise research findings and act as a catalyst for new research questions. The centre assists where possible with scientific networking and an active link with the scientific community is kept through collaboration with all major European and international projects and stakeholders.

Evidence and analysis

A key priority for the EMCDDA is to identify effective practices in the area of interventions and to encourage the sharing of information on what works. Ongoing dialogue with the scientific and practice community, including the Cochrane group, ensures that the EMCDDA has an understanding of the very latest available evidence for effectiveness. This collaboration also provides a channel for disseminating results.

Expertise

EMCDDA's scientific staff are recruited through the usual EU agency procedures.

The nomination, selection and role of experts vary for the different types of experts involved in the agency's work. Experts are mainly nominated by the countries (management board or national focal points). Expert meetings in the different areas of work have a central role in maintaining, coordinating and supporting the European networks of data collection, and thereby the EMCDDA's core monitoring role, through promoting and discussing standards for harmonised data collection, interpreting the collected data and developing capacity in the countries.

Training and capacity-building activities developed at the EMCDDA cover a broad area of initiatives, from academic-oriented training (the European drugs summer school) and capacity-building projects to in-house traineeship opportunities. The training and capacity building is given mainly by internal EMCDDA staff, in-house or in the Member States.

Methods

Considerable methodological progress has been attained in previous years and the agency is shifting emphasis from developmental activities to more analytical ones (while keeping the key indicators fit for purpose).

Key methodological issues are the development of a trend-spotting and rapid-reporting methodology to provide immediate dissemination of critical information relevant to the safeguarding of public health and safety. Quality assurance is relevant to all aspects of the data management process and the analysis of data; the EMCDDA has an internal statistics code of practice, developed on the basis of the Eurostat statistics code of practice, and a data coherence group to oversee the coherence and efficiency of the reporting system.

Methodological guidelines and tools developed for the Member States to report data annually to the EMCDDA are developed in-house in collaboration with the Reitox network.

4. Outputs

Review of draft outputs

Ensuring the quality of its outputs based on an overall quality framework for scientific publications has been an ongoing commitment for the agency. EMCDDA scientific publications are discussed, monitored, reviewed and approved through many different mechanisms.

After the formal approval of the single programming document, the publications are entered into a products database. This database was set up in 2012 to facilitate follow-up on EMCDDA publications in preparation; monitor progress on products; and plan and allocate resources more efficiently. While primarily developed as a planning and monitoring tool, the products database contributes to the quality control in the production process of EMCDDA publications by, among other things, formalising key control and sign-off points in the workflow.

Key quality control during the preparation of the product is ensured by internal and external checks and reviews.

Internal checks and reviews are done by the head of unit, internal peer review by colleagues, the head of the statistics sector and the scientific director. External checks and reviews are done by the members of the EMCDDA's Scientific Committee, the national focal points or other external experts.

Authorship

All EMCDDA publications, except joint publications and submissions to scientific journals, go out under the name of the agency. For most publications the authors are acknowledged in the publication as the 'EMCDDA project group: … ' or 'Prepared by …' Some of the major publications will have an editorial group listed or contain authored chapters.

Responsibility for issuing scientific documents

Final responsibility resides with the EMCDDA director, after approval by the scientific director.

Communication

In line with the EMCDDA communication strategy, the EMCDDA stakeholders are the Management Board, the Scientific Committee, the Reitox network, the EU institutions and international partners. The EMCDDA target groups are policymakers, scientists and researchers, practitioners and EU citizens. To engage with the stakeholders and target groups, the EMCDDA has a well-established set of communication channels and tools: the website, publications (the principle means for communicating scientific content), scientific publishing, media relations, social media, audiovisual, events (conferences, seminars and expert meetings), networks, marketing and promotions.

Use and follow-up

The outputs related to the implementation of the Council Decision 2005/387/JHA have been resulting in legislative changes. The EMCDDA is working on an overall evaluation plan and communication impact system (including satisfaction surveys and user testing, download statistics, distribution figures, media coverage, etc.).

European Union Agency for Network and Information Security (ENISA)

1. Nature of the scientific work

Domain in society covered

ENISA provides scientific and technical advice on improving information security to various stakeholder groups in the public and private sectors. Although the agency also exchanges information on threats and mitigation measures with other communities, its mandate places strict limitations on what it can undertake in terms of collaborative efforts. At the time of writing, ENISA is represented, for example, on the Programme Board of the EU Cyber Crime Centre and the CERT EU, but has no formal communication with the intelligence or military sectors.

The advice the agency provides is produced in a variety of formats and depends strongly on the needs of the particular stakeholder community that is being addressed. Advice to EU and Member State policymakers tends to be qualitative, although it is based on studies that ENISA has carried out with the operational communities. Such studies often have a quantitative component. ENISA also produces a number of very technical reports which are based on quantitative methods.

ENISA's core mission is to create an effective EU-wide network and information security community and, as a result, the vast majority of its projects are carried out together with representatives from the public and private sector. The agency also tries to leverage national results wherever possible and provide guidance for how such results may be interpreted in a pan-EU context.

Aspects assessed

The agency has the mandate to address all aspects of information security and is only limited by its geographical scope (it does have the mandate to undertake projects outside the EU in certain domains) and the communities it can address.

Because the scope of activities is so wide, ENISA spends a lot of time ensuring that its work is highly focused and is not being done elsewhere. One of the main roles of ENISA is to provide high-quality data and analysis to policymakers; the agency is therefore planning to develop its potential for collecting, storing and analysing data over the next few years.

2. Scientific work programme

Programme

Up until 2010, ENISA was working to a multiannual work programme while still respecting a yearly budget cycle. This changed between 2011 and 2013 due to the fact that the mandate of the agency was only until 2012, which rendered multiannual planning impossible. The agency now has a new, extended mandate and will resume multiannual planning as from 2015.

The ENISA work programme is strongly stakeholder driven, the role of the agency being one of guidance throughout the process. The initial proposal for the ENISA work programme for year *n*+2 is generated in year *n* by the Permanent Stakeholder Group, a group of high-level industry representatives. This initial proposal is then modified by the Management Board to generate a stable version reflecting the views of both communities. The document is then subject to a stepwise review process of continual refinement, which terminates in acceptance by written procedure at the end of November of year *n*+1.

In the future the existing stepwise process will be gradually transformed into a continuous process based on the same methodology but making increased use of modern technology to control the different interactions that are inherent in the process.

Monitoring programme execution

The agency uses activity-based budgeting to support the development of the annual work programme. As such, each work programme is supported by a schema relating resources and budget to each of the planned deliverables. Responsibilities are assigned to project managers via terms of reference, and there is a line-management structure composed of heads of unit (HoU), heads of department (HoD) and the executive director supporting the delivery mechanism.

Projects are tracked using a software tool that provides standard project-management functionality together with timesheets and a link to ABAC, the financial system. This allows schedules and resources to be tracked in a consistent manner across the agency.

Project management is based on key performance indicators (KPIs), whereas impact measurement is based on key impact indicators (KIIs). These are defined as follows.

KPIs are quantifiable metrics used to evaluate objectives to reflect the performance of an organisation. They measure the agency's performance during the budgetary/fiscal year. KPIs differ depending on the nature of the organisation. Different layers and dimensions should be taken into consideration. KPIs can constitute both quantitative and qualitative measures, however the most useful and common types are quantitative based. These include, among other things, a focus on metrics such as the number of Member States targeted, the number of hits on the website, etc.

KIIs are indicators used to evaluate long-term performance and are eventually linked to the strategic foundation stone of an organisation.

ENISA's experience to date shows that stakeholders often change their priorities before sufficient time has elapsed to measure the impact. The result is that, although the agency does measure such impacts, they are not as useful as they could be for decision-making.

Funding

ENISA is mainly funded through the EU budget. The agency also receives additional funds from the EFTA countries. There are no obligations linked to this extra funding.

ENISA is not able to charge for its services, nor is it able to receive funding through other EU schemes (e.g. the seventh framework programme, Horizon 2020).

3. Approaches used to conduct the scientific work

Scientific collaborations

ENISA collaborates extensively with its stakeholder groups. The agency uses expert groups extensively in order to ensure that it has the right operational experience contributing to its reports. ENISA also has more structural collaborations at the institutional level (such as a memorandum of understanding with the European Telecommunications Standards Institute, the International Telecommunication Union, the European Committee for Standardisation/European Committee for Electrotechnical Standardisation and the EU Cyber Crime Centre). ENISA aims to be represented on industry boards wherever appropriate.

Evidence

The sources of information used by the agency include the following.

- Similar studies carried out by Member States and other international institutions. ENISA occasionally also uses commercial studies.
- Data provided directly to ENISA from the operational communities. The agency collects these data through a variety of techniques including questionnaires and face-to-face interviews.
- Data that are provided to ENISA as a result of legal obligations, such as data on significant incidents provided by telecommunications providers in accordance with Article 13a of the Telecommunications Framework Directive of 2009 ([1]).

Analysis

Wherever possible ENISA uses standard mathematical techniques for analysing data, but the agency is often confronted with the problem of sparse data due to a general reticence in the industry to speak about security matters. This makes it difficult on occasion to achieve representative samples and requires ENISA to make more qualitative judgements based on expertise.

An interesting question in the field of information security is: which data enable predictions to be made? The industry has been dominated by a number of low-probability, high-impact events (so-called black-swan events) in the past decade, which have had a very significant impact on the way in which the industry has developed. ENISA is also faced with the problem of analysing data that is affected by many variables, not all of which are known (e.g. an increase in the number of incidents per year can only be sensibly interpreted if the agency knows how the number of systems, number of people using them, etc. have evolved).

Analyses are verified by peers as part of the review process and are subsequently checked by the HoU and HoD for correlation with data and/or recommendations from other studies.

([1]) Telecommunications regulatory package (Article 13a, amended Framework Directive 2002/21/EC).

ENISA always has the final say on conclusions and recommendations and does not outsource this.

Expertise

ENISA's core expertise is in its staff. The emphasis in ENISA's recruitment policy is placed on core information-security skills as opposed to related skills (such as economics, social sciences, etc.). The general level of academic achievement is very high, but the agency puts even more emphasis on operational experience.

Potential members of working groups are selected based on their ability to meet the needs of the working group, their availability and the lack of a conflict of interest.

Methods

Given that ENISA is asked to provide guidance on a wide range of issues and for different stakeholder groups, the agency does not standardise on any particular method but aims to use the methods that are most accepted by the target community.

4. Outputs

Review of draft outputs

The agency has developed a highly structured approach to reviewing core deliverables based on the following multistage process.

- Initial peer review.
- Review by the HoU for consistency across the area of expertise of the unit.
- Review by the HoD for strategic and agency-wide issues.
- Review by the executive director for political issues.

This is an automated process that is supported by a web interface showing target dates for the different steps and the status of any particular deliverable.

Authorship

Authorship is exclusively with ENISA, although contributors are mentioned.

Responsibility for issuing scientific documents

The head of the Core Operation Department has full responsibility for issuing scientific or technical documents, although the final approval of the executive director is required before a document is published.

Communication

All outputs are published on the ENISA website, except for those documents that are deemed confidential by the Member States (in practice this is extremely rare). Their publication may be accompanied by a news item or a press release.

ENISA experts travel a lot and present the agency's results at key international conferences.

Use and follow-up

ENISA is just beginning a process to follow up on its recommendations in a more structured manner. This will involve placing all past recommendations (post-2010) into a database and assigning an expert to follow up on what has been achieved.

The work of ENISA is also reported on in the agency's general report and annual activity report.

European Agency for Safety and Health at Work (EU-OSHA)

1. Nature of the scientific work

Domain in society covered

EU-OSHA's purpose is described in its founding regulation as follows.

'In order to improve the working environment, as regards the protection of the safety and health of workers as provided for in the Treaty and successive Community strategies and action programmes concerning health and safety at the workplace, the aim of the Agency shall be to provide the Community bodies, the Member States, the social partners and those involved in the field with the technical, scientific and economic information of use in the field of safety and health at work.'

The agency collects and analyses this information to identify risks and good practices, along with national priorities and programmes. It passes this information to the EU bodies, Member States and interested parties, also as input to the priorities and programmes of the EU. In addition, it collects, analyses and disseminates scientific and economic information on research related to safety and health at work.

2. Scientific work programme

Programme

EU-OSHA has two key programming documents: the multiannual strategic programme (MSP) and the programming document (PD). The MSP defines the mission, vision, strategic objectives, priority areas and groups of activities. It runs for seven years, from 2014 to 2020, and replaces the EU-OSHA strategy 2009-2013. The PD defines the activities to be carried out for 1 year in detail and in less detail for the following 2 years. The detail includes defining objectives, deliverables and indicators for individual activities.

Scientific work is covered by the following six priority areas defined in the MSP and developed in each PD.

Anticipating change. The identification of new and emerging risks in order to improve the timeliness and effectiveness of preventive measures.

Facts and figures. The provision of an accurate and comprehensive picture of occupational safety and health (OSH) risks, their effects and how they are prevented and managed.

Tools for OSH management. The provision of tools for smaller workplaces to manage health and safety and consequently improve implementation of the core elements of EU OSH legislation.

Raising awareness. Get the OSH message across to the multiple intermediaries and beneficiaries by raising awareness about workplace risks and how to prevent them.

Networking knowledge. The mobilisation of the OSH community through new tools to promote and facilitate the generation and maintenance of a body of knowledge.

Networking and communication. Ensure that the agency's activities meet the needs of its key stakeholders, enable networks to participate actively and ensure that the information reaches the intended beneficiaries.

The MSP is based on the external evaluation of the agency's previous strategy and reflects priorities on OSH at EU level (e.g. as expressed in the Community strategy 2007-2012 on health and safety at work and the EU OSH strategic framework 2014-2020). The final draft is based on in-depth discussions with the bureau and Governing Board, which are tripartite and have representation from the Commission.

Activities are specified in the PD, which draws on the multiannual planning set out in the MSP. The proposals are drafted by research staff and then discussed in an internal seminar with the participation of staff representing all units. The management group takes a final decision on which proposals to approve and these are then worked up in more detail for consultation with the agency's advisory groups (tripartite — composed of members of the board). Proposals for new activities are also discussed with the focal points (see below), particularly as regards information gathering from the national level and the approach to dissemination.

Following the approval of the draft MSP or PD by the Governing Board, the consultations provided for in the agency regulation are initiated (European Commission, Advisory Committee and Eurofound).

Monitoring

Programme execution is monitored through activity-level reporting at unit level to the head of unit and at agency level to the director, and externally to the advisory groups, the bureau and the board. A number of tools are used, based either on Excel sheets or written reports.

Funding

All activities are fully funded by the EU-OSHA budget, including a relatively small amount for earmarked activities such as the Instrument for Pre-Accession Assistance (IPA) and the the European Neighbourhood Partnership (ENP).

3. Approaches used to conduct the scientific work

Scientific collaborations

The main scientific collaboration, which is described in the founding regulation and represents a key resource for the agency, is its network of focal points in the Member States and in IPA/ENP and EFTA countries. Focal points are nominated by each government as the official representative and are usually the national authorities for safety and health at work. They support EU-OSHA activities with information and feedback, and work with national networks, including government, workers' and employers' representatives.

For specific projects the focal points may be asked to nominate members to an expert group also comprising social partners and Commission representatives.

Expertise

Scientific expertise is contracted through public procurement, usually using open calls for tender. These services are used to collect data (often in collaboration with the focal points), analyse them and report.

EU-OSHA also collaborates with various other bodies, institutes, agencies, etc., such as Eurostat, the International Labour Organisation, the Pan American Health Organisation, the National Institute for Occupational Safety and Health, the Senior Labour Inspectors' Committee, the Scientific Committee on Occupational Exposure Limits, the Advisory Committee for Safety, Hygiene and Health Protection at Work, Eurofound, ECHA and EIGE.

Evidence

EU-OSHA draws on national-level data covering administrative sources — such as occupational accident statistics, occupational disease registers and survey sources — as well as national-level research — for example case studies on interventions. This evidence is provided either through the network of national focal points or by contracted researchers operating at the national level.

Data from Eurostat are also frequently used, in particular European Statistics on Accidents at Work, results from the Labour Force Survey ad hoc module on health and safety and, to a lesser extent, data from the European occupational diseases statistics.

EU-OSHA runs its own establishment-level survey (Esener), the second edition of which was completed in 2014. It provides comprehensive comparable data on how OSH is managed in practice in European workplaces, based on around 50 000 telephone interviews.

Data are also gathered through face-to-face interviews at workplaces and through structured interviews with experts as part of the 'OSH overview' activities.

Methods

Various methods are used in the scientific work, including literature surveys, policy and practice reviews, case studies, telephone surveys, expert interviews, focus groups, etc. The evidence or data is normally collected and analysed by the contracted experts or provided by the focal points. Information directly relating to a Member State may be collected through the focal point, but will always be checked by the focal point prior to completion of the work or publication.

Scientific training for staff covers social science research methods and also participation in conferences, usually combined with an active role. EU-OSHA promotes the sharing of experience and best practice through the various meetings, workshops and seminars it organises. The recruitment process for staff working in the Prevention and Research Unit puts a strong emphasis on social science qualifications and experience.

The principal methodological issues centre on the presentation of information covering all Member States in such a way that valid comparisons can be made between countries. In general there is a lack of clear, reliable data from which to present the OSH situation in Europe and on which to try and base forecasts of new and emerging risks. Methods are mostly developed in-house, drawing on examples from similar exercises carried out else-

where. In the case of the establishment survey there has been very close collaboration with Eurofound.

4. Outputs

Review of draft outputs

All publications are reviewed internally by a member of the scientific staff (other than the project manager) and the head of unit, prior to approval by the director. Where information relating to a particular Member State is presented the respective focal point is consulted as part of the process. If there is an expert group on the topic the publication will also be sent to its members for consultation.

Authorship

Authorship is retained by EU-OSHA, which is also responsible for issuing the scientific documents. A disclaimer is included in some publications explaining that the views expressed are not necessarily those of EU-OSHA.

Responsibility for issuing scientific documents

The main channel of communication is the agency's website, from which all publications are available for download. Publications are also available for purchase from EU Bookshop and are promoted using the agency's newsletter and, if appropriate, through a press release. Conferences, workshops and seminars organised by the agency or to which members of staff are invited are also used to communicate outputs.

Use and follow-up

EU-OSHA has developed an intervention model on which it bases its impact assessments. The main purpose of the agency's outputs is to support policymaking at the EU and national levels by providing information to governments, social partners, researchers, etc. In addition, EU-OSHA also targets intermediaries, such as practitioners, to increase their awareness and knowledge about tools that can be used at the workplace to manage health and safety.

European Foundation for the Improvement of Living and Working Conditions (Eurofound)

1. Nature of the scientific work

Domain in society covered

As defined in Eurofound's founding regulation: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1975R1365:20050804:EN:HTML

'The aim of the Foundation shall be to contribute to the planning and establishment of better living and working conditions through action designed to increase and disseminate knowledge likely to assist this development. With this aim in view, the tasks of the Foundation shall be to develop and to pursue ideas on the medium- and long-term improvement of living and working conditions in the light of practical experience and to identify factors leading to change. The Foundation shall take the relevant Community policies into account when carrying out its tasks. It shall advise the Community institutions on foreseeable objectives and guidelines by forwarding in particular scientific information and technical data.'

Aspects assessed

Again as defined in the founding regulation:

'As regards the improvement of living and working conditions, it shall deal more specifically with the following issues, determining the priorities to be observed:

- man at work,
- organisation of work and particularly job design,
- problems peculiar to certain categories of workers,
- long-term aspects of improvement of the environment,
- distribution of human activities in space and in time.'

2. Scientific work programme

Programme

The scientific work programme is an integral part of Eurofound's work programmes (4-year and annual programmes), implemented through a range of projects, including research projects.

The annual programme development process is managed by Eurofound's management; overall guidelines are provided through the 4-year programme. Each year, a high-level consultation process with key stakeholders starts off the development process. Standing thematic advisory committees comprised of stakeholder representatives, and sometimes experts, are also consulted. (Research) staff are invited to make relevant proposals for future research proposals (guided by the framework of the 4-year programme); proposals go through a filtering process, according to a number of criteria, by a review board (composed of heads of all thematic research units). This is an iterative process of refinements throughout the programme drafting process: consultations with the Governing Board (GB) on draft 2, refinement of accepted proposals (filtered through Review Board) and eventual sign-off by the GB.

Monitoring programme execution

Activities include: project management reporting; monitoring at management committees; progress reporting to GB Bureau and advisory committees.

Funding

The foundation is 100 % funded through its budget (core operations).

3. Approaches used to conduct the scientific work

Scientific collaborations

Collaborations include scientific expert inputs through contracts (via procurement, for instance a network of correspondents in all EU Member States to provide expert information inputs according to specified needs), and there are also other forms of contractor inputs in place such as calls for expressions of interest and lists of vendors (for a range of subject matter areas covered by the work programmes).

Evidence

Eurofound maintains and manages three EU-wide survey instruments; field work is conducted every 4 years.

- European Working Conditions Survey.
- European Company Survey.

- European Quality of Life Survey.

Observatories:

- European Monitoring Centre on Change (EMCC),
- European Observatory of Working Life (EurWORK).

Thematic research – various research projects, combining range of methodologies as required. For more information, see the description on the web page 'What we do'.

Evidence is collected by contractors for surveys and observatories. For other research evidence is often collected by a combination of in-house research staff and external contractors.

Analysis

Analyses are carried out by combinations of in-house research staff and external contractors.

Expertise

Research staff are recruited through the agency's recruitment processes.

Advisory committee members are nominated through groups represented on the GB. Occasionally, expert members are invited (as relevant). They are selected by the agency, avoiding any conflicts of interest, or suggested by GB groups.

Staff are involved in all key operations relating to research. Contractors perform tasks according to specific contracts only.

Cooperation agreements are in place with five other EU agencies, leading to yearly joint action plans. The foundation has a formal cooperation agreement with the International Labour Organisation, and regular contacts and peer-review agreements with the Organisation for Economic Cooperation and Development and the World Bank.

Training/capacity building is provided by the agency for internal staff only. It includes training courses, internal seminars, internal capacity building, knowledge management, communities of practice, etc.

External academic/expert input: Eurofound's research processes frequently involve input from external independent experts at various stages of the research cycle. This can take various forms, but typically involves expert meetings on specific topical or methodological issues to benefit from external expertise (at relevant stages in the research cycle: inception/conceptualisation, implementation, specific milestones; validation), along with formal external peer reviews of research documents.

No formal policy concerning external expert input is yet in place, but work on it is in progress.

Methods

Both quantitative and qualitative methods are used. The 2011 evaluation on the application of research methodologies provided an inventory of methods and a gap analysis. This 2011 evaluation made various recommendations. For quality research, quality assurance and quality management are considered key issues.

Many standard methods are applied and adapted to the needs; some methods are developed in-house.

4. Outputs

Review of draft outputs

Both externally and internally produced outputs undergo peer review and review by advisory committees (stakeholder feedback). Externally produced outputs also undergo quality assurance performed by the contract manager (usually a research manager).

For surveys there is an extensive quality assurance framework in place and operationalised, based on Eurostat quality criteria. A dedicated survey methodological working group, which works together with other external methodological experts, has been established and staffed with survey methods experts (staff) to further develop and improve survey methodologies and quality management issues for all of Eurofound's surveys.

Authorship

Authorship resides with the researchers concerned (contracted or in-house). The draft reports go through a thorough editing process by Eurofound.

Responsibility for issuing scientific documents

The final responsibility for issuing scientific documents resides with Eurofound. It includes an obligatory (scientific) editing process.

Communication

The agency has a publishing and communication programme, including a website.

Use and follow-up

The whole purpose of Eurofound's outputs is to be taken up by social policymakers, primarily at EU level but also at national level. Data/research from Eurofound is communicated to policymakers, who take it up in their respective proposals and policy papers. Eurofound has a well-established monitoring system in place to track the uptake, outcomes and impacts of its work on social policymaking processes, at both EU and national levels (Eurofound performance monitoring system and EU impact tracking system and analyses).

European Union Agency for Fundamental Rights (FRA)

1. Nature of the scientific work

Domain in society covered

The fundamental rights situation in the European Union and its Member States, within the meaning of Article 6(2) of the Treaty on European Union. The agency's work is situated within the wider context of the Charter of Fundamental Rights of the EU and relevant EU law.

Aspects assessed

The agency has a 5-year multiannual framework (MAF)that defines the broad scope of its work with respect to the fundamental rights situation in the EU. For the 2013-2017 period the nine main themes for the agency's work are:

- access to justice;
- victims of crime, including compensation to victims;
- information society and, in particular, respect for private life and protection of personal data;
- Roma integration;
- judicial cooperation, except in criminal matters;
- rights of the child;
- discrimination based on sex, race, colour, ethnic or social origin, genetic features, language, religion of belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation;
- immigration and integration of migrants, visa and border control, and asylum;
- racism, xenophobia and related intolerance.

In addition, the agency can and does undertake work outside these nine areas at the specific request of EU institutions, such as the Parliament.

2. Scientific work programme

Programme

The agency adopts a work programme on an annual basis (within the framework of a rolling 3-year planning cycle), where projects and activities are set out that correspond to the agency's nine thematic areas of work (as listed above).

Specific projects are proposed by FRA on the basis of in-house expert knowledge and through structured consultation with key stakeholders, including the Commission, the Council of Europe and national human rights bodies, along with experts and practitioners working in fields covered by the agency (among others). The agency also has a structured consultation process with its Fundamental Rights Platform, which brings together several hundred representatives of organisations at the EU and Member State levels that are working in areas covered by the agency, ranging, for example, from NGOs focusing on data protection and privacy to those working on equality and non-discrimination, alongside representatives of business and faith communities and academia.

Project proposals are developed and finalised in-house by FRA staff. The agency's Management Board discusses project proposals before the final list of projects for a future work programme is agreed at a Management Board meeting. As a guarantee of the agency's independence, the Management Board is represented by independent experts in the field of fundamental rights from all Member States, and is not composed of government representatives.

In addition, FRA's Scientific Committee also discusses possible areas of future work that could be undertaken by the agency.

Monitoring programme execution

Programme execution is monitored through a variety of quality control procedures, which oversee the quality of project deliverables, including the following.

- Project teams — which are composed of staff from different departments — closely monitor projects in line with the agency's work programme, which includes regular monitoring of project deliverables and budget oversight. For example, some projects involve the agency's Franet network of national focal points in each Member State (typically universities

and other research institutes) that are contracted by FRA to provide research findings at the individual Member State level for specific projects — the deliverables from Franet are monitored internally by FRA.

- The work programme and its implementation are closely followed by the agency's Planning Sector and Quality Management Sector.
- An internal tool for project oversight and execution is a programme called Matrix, which serves to monitor all projects undertaken by the agency.
- The agency also undertakes *ex post* and *ex ante* evaluations of its project work, which are reported back to project teams.
- The impact of the agency's work is monitored at different levels, for example with respect to the number of times different branches of the European Parliament, the Council and the Commission refer to the agency's work and directly use it; with respect to the take-up of the agency's work at national level; and with respect to distribution of research reports, web and social media 'hits' and media interest.

In addition to the above the agency has a Scientific Committee (composed of 11 leading experts in the field of fundamental rights, from the legal, social sciences and statistics fields) that oversees the quality of FRA research and deliverables in the process of project execution.

Funding

The funding for FRA comes from the agency's internal budget. For some activities the agency receives support from the European Economic Area/Norway grants.

3. Approaches used to conduct the scientific work

Scientific collaborations

FRA collaborates at different levels with respect to specific areas of its work.

Collaboration with international organisations — examples.

- The agency has collaborated with the United Nations Development Programme in its large-scale survey research on the Roma in several Member States.
- FRA collaborates with the Council of Europe at many levels, for example with respect to the production of a series of legal handbooks for judges and lawyers.
- FRA collaborates with the Office for Security and Cooperation in Europe (OSCE), including the Office for Democratic Institutions and Human Rights (ODIHR). For example, FRA contributes to their work in the field of hate-crime data collection and with regard to the replication of FRA surveys in non-EU countries.

Collaboration with Member States — examples.

- In response to the asylum crisis, the agency has a field presence on the ground in the Greek 'hotspots', where it provides technical support and fundamental rights expertise to key actors. This is underpinned by a memorandum of understanding with the Greek authorities.
- FRA works closely with national human rights institutions and equality bodies in the Member States, and also with national parliaments. For example, the agency produced a handbook on the accreditation of national human rights institutions.
- FRA arranges ad hoc working groups with selected Member States concerning specific areas of work, for example on the rights of victims of crime, and in specific technical areas related to EU law, for example on asylum.
- The agency is responsible for working parties that engage directly with Member State administrations, for example the Working Party on Improving Reporting and Recording of Hate Crime.

Collaboration with EU agencies — examples.

- As part of the Justice and Home Affairs Agencies' cluster, during 2016 FRA chaired the Heads of JHA Agencies network.
- FRA works closely with agencies such as eu-LISA and Frontex with respect to specific research projects and forums.

- FRA engages actively with EIGE on a number of levels, for example by supplying data for EIGE's Gender Equality Index.

- Apart from those agencies referred to above, FRA also engages with the following agencies concerning specific projects and/or various exchanges of information (outside the context of EU-ANSA): EASO, Eurojust, Europol, OSHA and Eurofound (among others).

Collaboration with non-EU countries — examples.

- FRA's collaboration with non-EU countries is limited. Some projects address this issue, for example in the asylum field.

- In addition to the above, the agency also collaborates with other actors in its scientific research, for example with DG Research and Innovation, with DG Research and Innovation researchers and research projects and with academic institutions.

Evidence

The agency collects data and develops indicators in key fundamental rights fields (as described above under Section 1, 'Nature of the scientific work'), and provides evidence-based advice on fundamental rights to a range of stakeholders.

The agency undertakes research and data collection in areas where there is often a lack of EU-wide data on certain fundamental rights issues or on certain groups within the population, hence the need for the agency to undertake its own primary data collection in the form of fieldwork research.

Evidence for the agency's qualitative and quantitative research is collected from both duty bearers (such as state representatives) and rights holders (the public, specific groups in society, individuals) with respect to the law, policies and the situation on the ground concerning specific fundamental rights areas, as set out under individual projects.

The agency also collects evidence from existing administrative data sources, at both national and EU level, and analyses case-law and other published material (research and other sources), the results of which feed into its reports.

Evidence from the agency's research informs the development of FRA's 'opinions', which present 'recommendations' on legislation, policy and related actions in key fundamental rights areas. These opinions are published in FRA reports and separately as stand-alone legal opinions, which are typically requested by the European Parliament, alongside other EU institutions.

Analysis

Agency staff are responsible for the development and oversight of all FRA research projects, which includes analysis of project findings and the drafting of reports and other deliverables for publication. The agency's contracted research network (Franet), which is represented in all Member States, is responsible for delivering research material to the agency, however the data analysis and drafting of comparative research reports for publication is the responsibility of FRA. Alongside Franet, other contractors also deliver material to FRA with respect to specific projects, whereupon the agency undertakes further analysis and develops the final research product.

For large-scale surveys the agency has a statistics and surveys sector that is responsible for project development, oversight, data analysis and drafting of reports from survey findings. The fieldwork for large-scale surveys is undertaken by survey companies, with quality assurance being undertaken by FRA staff alongside the contracted company.

Expertise

In the 10 years since the agency's foundation (in 2007) FRA has built up a strong research profile. Research staff are appointed on the basis of job advertisements that are open to anyone to apply for, which specify the field(s) of expertise needed. Staff are typically not selected through the Commission's recruitment competitions. Research staff primarily include lawyers, social scientists and statisticians. Seconded national experts are appointed on the basis of an open call.

Although FRA is not a training institute the agency does provide material for selective training carried out by others that reflects areas of FRA's research work and expertise, for example in the field of fundamental rights and policing (CEPOL) or with respect to the provision of input concerning standard training for border guards (Frontex). FRA has also provided training on fundamental rights to the Council Secretariat.

Methods

The agency undertakes both primary and secondary data collection for its research.

For primary data collection, depending on the research questions and the group(s) being researched, the agency selects the appropriate research methodology/ies for conducting fieldwork — either qualitative fieldwork or large-scale quantitative survey research (involving either

face-to-face interviews or other modes of questionnaire application for surveys).

FRA's projects are typically sociolegal in nature — often carried out over several phases — and involve both desk research (secondary data) and qualitative and quantitative fieldwork by the agency (primary data collection).

Examples of groups covered by FRA's primary data collection in the form of quantitative surveys include, among others: a survey on violence against women (42 000 interviewees); a survey on LGBT persons (93 000 respondents); a survey on selected ethnic minority and immigrant groups (23 500 interviewees); and a Roma survey (11,000 respondents).

Examples of FRA's primary data collection in the form of qualitative research interviews and focus groups include, among other projects: the situation of irregular migrants in the EU; severe forms of labour exploitation in the EU; children as victims and witnesses in the justice systems of selected Member States; and persons with mental health and learning disabilities and their experiences of institutionalisation.

The agency also undertakes in-depth legal analysis and produces comparative legal research for all or selected Member States.

The agency strives to be responsive in real-time to fundamental rights crises, and has developed methodologies for this including weekly and monthly reporting on specific fundamental rights situations.

4. Outputs

Review of draft outputs

An internal FRA committee — which includes the director, senior managers and legal experts — reviews and comments on every report produced by the agency that contains opinions ('recommendations'). This is done to ensure the quality and consistency of approach for agency deliverables. Reports typically go through two internal readings by this committee.

The agency's Scientific Committee — which is composed of 11 independently selected senior experts in fields related to human rights (appointed for a term of 5 years) — oversees all FRA reports for publication. At least one rapporteur from the Scientific Committee is assigned to follow each project and comment on its scientific quality. The Scientific Committee meets four times a year.

Major projects often have expert groups assigned to follow the project's life cycle, which can be over several years.

For many projects, specifically those with a practitioner focus, a peer-review process is set up for deliverables prior to publication.

On occasion, Member States and institutions are asked to check the factual accuracy of FRA material prior to publication, which is particularly important in areas where the law is rapidly changing. However, the final content of all FRA material is decided independently by the agency.

Authorship

All reports go out under the name of the agency without any disclaimer, which is an indicator that the agency stands by its research findings. In-house staff who draft reports are not referred to with respect to any deliverable, as all reports, tool-kits, handbooks, etc. go out as 'FRA products' (having under-gone internal quality controls, as previously described).

Responsibility for issuing scientific documents

Responsibility resides with the director of the agency, in line with the internal oversight of all products (see under 'Review of draft products', above).

The agency's Management Board is responsible for signing off FRA's annual fundamental rights report, which is a substantial report on the situation of fundamental rights in the EU based on the agency's research, alongside other material.

Communication

The agency has a Fundamental Rights Promotion Department which supports the dissemination and communication of research material. The main channel for the agency's research results is its website, alongside the website of the Council of Europe with respect to specific deliverables (such as legal handbooks). Material is distributed to those on key distribution lists, for example through the agency's fundamental rights platform (consisting of several hundred members), the agency's national liaison officers, national parliaments, lawyers' and judges' networks, academic groups, etc.

The agency presents the results of its large-scale surveys in the form of a web-based interactive tool for data use

(alongside traditional reports) and has archived the microdata from its surveys for use by external researchers.

FRA has developed mobile phone apps in specific areas that allow for widespread dissemination of its work.

Certain reports are also launched via 'flagship' conferences, some of which are organised together with Member States and/or international organisations.

The media have proved to be a very useful dissemination tool for the agency, with its most successful research report to date being reported on by over 1 500 media channels (TV, radio, newspapers, etc.) within a few days.

The agency has healthy downloads for its reports, for example individual legal handbooks attain downloads in excess of 250 000.

Use and follow-up

The agency collects evidence about how the results of its work are referred to or otherwise used, for example with regard to references to its findings by the Parliament, the Council and the Commission and also at the Member State level, with respect to key stakeholders such as equality bodies.

At the Member State level FRA requests its national government liaison officers and other actors to report on references to and uses of FRA's findings. The agency also has specific working groups/parties with Member States that follow up its work (as outlined under 'Scientific collaborations' above).

The agency monitors web-based downloads and its social media accounts, and its publications are widely disseminated by the Publications Office (where it is typically among the top three agencies for publication requests).

European Border and Coast Guard Agency (Frontex)

1. Nature of the scientific work

Domain in society covered

The mandate of the European Border and Coast Guard Agency (Frontex) is to promote, coordinate and develop European border management in line with the EU Charter of Fundamental Rights, applying the concept of integrated border management.

Research and development represents one of the core operational areas of Frontex, as defined by Article 6 of the founding regulation (Regulation (EU) 2016/1624) with its subsequent amendments. To fulfil its mission, 'the Agency shall proactively monitor and contribute to the developments in research relevant for the control and surveillance of the external borders and disseminate that information to the Commission and the Member States.'

Aspects assessed

The Agency has a 5-year single programming document, which contains the Frontex strategy and multiannual plan 2016-2019, and the mid- to long-term strategic business plan of the agency that defines the broad scope of its work with respect to the management of the operational coordination at the external borders of the EU Member States. Among the 11 strategic action areas identified the single programme document highlights research and development, and more specifically actions related to:

- harmonisation of EU Member States' border-control capacities by developing/updating best practices/guidelines and by providing technical support and expertise to Member States in applying them, along with identifying capability gaps;
- provision of technical assistance to the European Commission and Member States and (further) development of border-control capacities;
- assessment of border-control technologies to steer their (further) development based on end-user needs

2. Scientific work programme

Programme

To achieve the objectives assumed under the Frontex strategy and multiannual plan 2016-2019 the Frontex Management Board adopts a programme of work on an annual basis in which specific annual objectives are set in relation to each of the strategic areas identified.

Specific projects and activities are proposed by Frontex every year for the implementation of its annual programme of work. The agency uses both its in-house knowledge and the structured dialogue and consultation with its key stakeholders, which include the national border-management authorities of the Member States, the Council of the European Union, the European Commission, the networks of experts and practitioners working in the national administrations in the fields covered by the agency's mandate, industry, academia and international organisations.

Currently the agency develops and suggests projects and activities to its Management Board on the basis of an *n*–2 programming cycle (2 years in advance of the year of execution of an annual programme of work).

Implementation and monitoring of the execution of the programme of work

Together with its 2015 annual programme of work Frontex introduced activity-based budgeting to support the development, implementation and monitoring of its annual work programme. As such, each work programme (2015 on a pilot basis) is to be supported by a schema relating resources and budget to each of the strategic areas identified. Responsibilities are assigned to project managers or activity leaders via specific tasking, which follows a clear line management structure composed of heads of sector (in certain cases), heads of unit, directors of division, deputy executive director and executive director.

Monitoring of the execution of the annual programme of work is based on key performance indicators (KPIs) and other standard reporting templates and tools, which have been developed for activity or project oversight and the implementation of various contracts.

KPIs are quantifiable metrics used to evaluate objectives to reflect the performance of an organisation. KPIs measure the agency's performance during the budgetary year. KPIs differ depending on the nature of the organisation and also in relation to the different kinds of activities undertaken. Different layers and dimensions should be taken into consideration. KPIs can constitute both quantitative and qualitative measures, however the most useful and common types are quantitative. These include, among others, a focus on metrics, such as the number of Member States targeted.

Funding

The funding for all Frontex activities, including research and development, comes from the internal budget of the Agency. No additional funding sources are used.

3. Approaches used to conduct the scientific work

Scientific collaborations

Frontex collaborates extensively with its stakeholder groups at different levels with respect to individual projects or activities.

Among the main contributors and at the same time beneficiaries of the agency's activities are the national border-management authorities of the Member States. In the context of thematic working groups Frontex works closely with national experts from the Member States in order to ensure that the right operational experience is contributing to its products.

More specifically, Frontex proactively monitors and contributes to developments in research relevant to the control and surveillance of the external borders, serving as a platform to bring together Europe's national border-management authorities and the world of research and industry to bridge the gap between technological advancement and the needs of border-control authorities. Frontex facilitates information exchange between border-management authorities, research institutes, universities and industry via the organisation of projects, workshops and conferences. It keeps Member States and the European Commission up to date with developments, provides its expertise in the context of EU border-security-related research and provides input for policy development.

In addition, Frontex is very active in driving the process of harmonisation and development of best practices and soft standards in border control, both operational and technical, in line with existing and future EU measures. Through coordinated intervention, the agency supports and facilitates the work of Member States' experts for the identification of best working practices in border control and surveillance and for the identification of potential gaps at technical and operational level that require further attention and intervention.

To better serve its mission Frontex has more structural collaborations at the institutional level (such as cooperation agreements with other EU agencies and/or memoranda of understanding with various international organisations and/or standardisation bodies).

Evidence

Frontex research and development activities include both desk research and qualitative/quantitative fieldwork for the identification and documentation of the operational border-control practices and standards used by the Member States and of potential related gaps and needs.

The sources of information used by the agency include:

- relevant data and statistics made available by the Member States;
- studies of the relevant legal frameworks for the identification of the technical and operational requirements;
- field tests, demonstrations, observations and studies in the operational environment of different border-management-related technologies;
- similar studies carried out by academia and/or other international institutions — Frontex also carries out different studies on various topics of interest;
- results of the cooperation with other EU bodies, non-EU countries, international organisations and standardisation bodies;
- regular meetings with industry to observe the latest border-management-related technologies;
- monitoring of EU border security research.

Analysis

Analysis of the findings is done together with national experts from the national border-management authorities in the Member States (via the different networks and/or dedicated working groups) and in-house by Frontex experts who have the responsibility for developing and overseeing the activities undertaken, including reporting on deliverables.

Expertise

Professional staff and a set of operational and administrative capabilities enable Frontex to add value to the European Union. Frontex selects its own staff via open calls for recruitment advertised on its website and, whenever necessary, in the *Official Journal of the European Union*.

The human-resources capacity of the agency is complemented by seconded national experts, selected by the agency from the candidates proposed by the national border-management authorities of the Member States based on their proven operational and professional expertise, following dedicated calls communicated by the agency and also advertised on its website.

The experts participating in different working groups and networks established by Frontex are appointed by the national border-guard authorities of the Member States or selected by Frontex based on their proven operational and professional experience following specific requests/calls put forward by the agency.

Frontex, being a knowledge-based organisation, acknowledges the importance of providing training for its staff. Frontex provides general and technical training along with professional development opportunities throughout the annual performance appraisal.

Methods

For primary data collection, depending on the topic, Frontex selects the appropriate methodology/ies and sources for conducting fieldwork and collecting relevant data using, among other things, field missions, quantitative surveys, tests, demonstrations, observation of performance, etc.

4. Outputs

The agency has developed a highly structured approach to reviewing core deliverables based on a multistage process:

- initial peer review by the activity leader responsible;
- review by the head of unit for consistency across the area of expertise of the unit and the agency's legal and policy framework;
- review by the director of division for strategic and agency-wide issues;
- Review by the deputy director and/or by the executive director for policy and strategic issues, whenever necessary.

Authorship

Authorship lies exclusively with Frontex, with contributors being mentioned whenever necessary.

Responsibility for issuing scientific documents

Responsibility resides with the executive director of the agency, in line with his/her general responsibility to oversee all Frontex products.

Communication

All outputs are published on Frontex's website, except those documents that are classified (in practice this is extremely rare). Their publication may be accompanied by a news item or a press release.

Frontex staff attend relevant events organised at European and international levels and use the opportunity to present and disseminate information on the activities, results and products of the agency.

Use and follow-up

Frontex products are used on a regular basis by Member States and are used by the European Commission whenever technical input from the field of border management is required.

Frontex follow up on its products by providing regular updates relevant to the users.

Annex I Mandate and terms of reference of the EU Agencies Network on Scientific Advice (EU-ANSA)

I. Approved mandate

In July 2012 the Interinstitutional Working Group (IIWG) of the three EU institutions adopted a common approach and an annexed joint statement. In this statement the three EU institutions set out certain principles, urging decentralised agencies to streamline their activities and increase their performance within their remit.

These recommendations cover a wide range of issues and do not have a legally binding character. Nevertheless, it is clearly stated that the institutions will take them into account in the context of all their future decisions concerning EU decentralised agencies, following a case-by-case analysis. In particular, in the points set out under paragraph 20 of the joint statement, the IIWG asks for improvements in the areas of exchange of information and coordination between agencies providing scientific advice, focusing mainly — but not only — on selection procedures and independence of scientific experts.

There are already several interagency specialised networks under the aegis of the Heads of the EU Agencies Network, focusing on a range of common activities including, among others, legal, IT, administration and communication. However, there is currently no coordination network with regard to the key role of many EU agencies, namely to provide technical and specialist expertise, advice and analyses based on a scientific methodology, in order to support the EU decision-making process.

Furthermore, due to the current and forthcoming reduction in our agencies' budget and resources, closer collaboration and exchange of tools and best practices between our agencies will be more than necessary.

Therefore, as a follow-up to the IIWG's common approach document and in order to enhance the quality, efficiency and transparency in the provision of scientific advice from our agencies, ECDC has proposed the creation of a specialised EU Agencies Network on Scientific Advice (EU-ANSA).

The proposal was accepted at the meeting of the Heads of EU Agencies (Brussels 14 February 2013), and ECDC will coordinate the network for the year 2013.

II. Terms of reference for EU-ANSA

Scope

This paper describes a proposal for the establishment of a specialised network of EU agencies ([1]) tasked to provide scientific ([2]) and technical advice (including opinions, reports, assessments, guidelines, recommendations and/or other relevant outputs developed with a scientific method) to EU institutions, Member States and other relevant EU policymakers. The network shall hereby be referred to as the 'EU Agencies Network on Scientific Advice' (EU-ANSA). The network operates under the tutelage and in support of the Heads of EU Agencies Network.

Mission statement

The mission of the EU-ANSA specialised network of EU agencies is to promote the cooperation between agencies on issues of common interest related to the provision of scientific and technical advice. EU-ANSA shall be a forum for exchange of good practices and experience, mutual advice and sharing of information with the aim of facilitating the work and enhancing the quality of the scientific and technical advice provided by each participating agency. Common initiatives with regard to the provision of scientific and technical advice shall not replace individual strategies from respective agencies, but shall complement existing activities in a mutually beneficial way.

Objectives

The EU IIWG has stressed in a joint statement and common approach the need for a more coordinated approach with regard to the provision of scientific and technical advice ([3]). Based on these recommendations, it is proposed that the EU-ANSA should have the following objectives.

([1]) For the purpose of these terms of reference, an 'EU agency' shall mean a European Union agency (or similar, like 'authority', 'centre', 'office', 'foundation' or 'institute', etc.) with its own legal personality and which is independently executing the mission assigned to it. EU agencies apply the EU Staff and Financial Regulations and are (usually) subject to discharge by the European Parliament, as well as audits by the European Court of Auditors regarding the legality and regularity of their operations.

([2]) Science is hereby defined as including all areas under the remit of the participating agencies.

([3]) See joint statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies and §20 of the thereto annexed common approach.

1. To enhance the efficiency and effectiveness with regard to the provision of scientific and technical advice given by EU agencies in various regulatory or policy fields in the European Union to the respectively relevant policymaking audiences within their mandate. To fulfil this objective, EU-ANSA members and working groups shall focus on the following aspects.

Independence and transparency

EU-ANSA members shall exchange information and best practices with regard to the independence and transparency of the scientific advice provided. Issues to be addressed include, among others: procedures for selection of experts; procedures ensuring independence and transparency of scientific and technical advice; prevention and handling of conflicts of interest (in collaboration with the interagency legal network).

Collaboration

EU-ANSA members shall collaborate for the common benefit of the EU agencies with regard to general procedures and practices related to the provision of scientific and technical advice, including, among others: finding economical and viable solutions for common problems with regard to the provision of scientific and technical advice; passing on know-how and troubleshooting experiences; exchanging information, tools and best practices; formulating common positions where necessary (under the aegis of the EU Heads of Agencies Network).

2. To foster a more structured dialogue with EU regulators, risk managers and decision-makers with regard to the provision of scientific and technical advice within the remit of each agency.

3. To act as a high-level forum to facilitate the provision of scientific and technical advice to policy and decision-making bodies and to promote EU and international dialogue and activities linked to the provision of scientific and technical advice towards evidence-based decision-making.

Structure of EU-ANSA

Participants

The EU agencies tasked to provide scientific and technical advice ([4]) shall be represented by the chief scientist, or the equivalent member of staff responsible for the scientific output, strategy and coordination of the participating agencies.

The chief scientific adviser to the President of the European Commission shall be invited as a permanent observer to the network, in order to facilitate a link to other scientific advisory structures of the European Commission, such as the Joint Research Centre or other scientific committees and expert groups.

Organisation

Chair
The EU-ANSA network shall be chaired by the chief scientist, or the member of staff with equivalent responsibilities, of one of the participating agencies. This shall be shared between agencies, with a yearly rotation. Efforts should be made in order for the Secretariat of the EU-ANSA network to coincide with the Secretariat of the Head of EU Agencies network, when applicable.

Secretariat
The Secretariat of the EU-ANSA network shall be provided by the agency chairing the network.

The Secretariat shall:

- provide the administrative support to the network;
- organise relevant meetings;
- coordinate the activities of the network, unless agreed otherwise;
- draft meeting minutes and circulate after each meeting — after adoption via a written procedure from participants, the minutes shall be reported to the Heads of EU Agencies Network for their information;
- maintain and update the contact list of the nominated representatives and their back-ups, based upon the names communicated by each agency;
- communicate preferably via an extranet.

EU-ANSA working groups
Apart from the plenary discussions focusing on issues of common interest, there shall be a possibility for an *ad-hoc* creation of working groups within the EU-ANSA network. These working groups shall have a defined mandate, focusing on more specialised issues under the general mandate of EU-ANSA.

Each EU-ANSA participant shall have the opportunity to participate or abstain from a given working group. The members of the working group shall be appointed by

([4]) See the list of EU-ANSA member agencies in Annex II.

their respective agencies. The working groups shall report to the meetings of the EU-ANSA network as required.

Specific guidelines on the creation and function of EU-ANSA working groups shall be set out in a separate document, to be discussed and adopted at the EU-ANSA's first meeting.

Internal decision-making
The EU-ANSA network does not have any formal decision-making capacity and it operates under the tutelage and in support of the Heads of EU Agencies Network. EU-ANSA decides on operational issues with regard to the work of the network. This includes the identification of the EU-ANSA areas of priorities, which shall be submitted for information to the Heads of Agencies. Such decision shall be taken by consensus whenever possible, otherwise by a simple majority of members. Minority opinions shall be recorded in the minutes of the meeting. No agency can be bound by a common position.

If necessary, common positions and conclusions can be adopted by written procedure. In this case, a conclusion shall be considered agreed unless an objection is raised by at least half of the members within 15 working days from the day on which the proposed conclusion has been dispatched to the network by the coordinating agency. At the subsequent meeting of the network, the chairperson shall provide a report on the outcome of the procedure, documenting any minority opinions.

Meetings
EU-ANSA shall in principle hold at least one annual meeting, discussing and adopting the network's activities for the following year. This will be confirmed by the chairing agency given that there are clearly identified issues for which the meeting is expected to add value to the network and the participating agencies' operations. The chairperson and hosting agency will arrange the meeting(s) of the network that will take place during the year of their chairmanship. A draft agenda for the forthcoming meeting(s) will be prepared and circulated to the participants together with an invitation to the EU-ANSA meeting(s).

Work programme and annual report
The timetable for reporting is as follows:

- February (year *n*): presentation of the annual report (year 1) and adoption of work programme (year *n*) by the Heads of Agencies;
- November (year *n*): presentation of draft work programme (year *n*+1).

Annex II EU-ANSA members (as of October 2016)

ECDC	European Centre for Disease Prevention and Control (Stockholm, Sweden)
Cedefop	European Centre for the Development of Vocational Training (Thessaloniki, Greece)
ECHA	European Chemicals Agency (Helsinki, Finland)
EEA	European Environment Agency (Copenhagen, Denmark)
EFSA	European Food Safety Authority (Parma, Italy)
EIGE	European Institute for Gender Equality (Vilnius, Lithuania)
EMA	European Medicines Agency (London, UK)
EMCCDA	European Monitoring Centre for Drugs and Drug Addiction (Lisbon, Portugal)
ENISA	European Union Agency for Network and Information Security (Heraklion, Greece)
EU-OSHA	European Agency for Safety and Health at Work (Bilbao, Spain)
Eurofound	European Foundation for the Improvement of Living and Working Conditions (Dublin, Ireland)
FRA	European Union Agency for Fundamental Rights (Vienna, Austria)
Frontex	European Border and Coast Guard Agency (Warsaw, Poland)

Observers to EU-ANSA

Satcen	European Union Satellite Centre (Torrejón, Spain)
EASA	European Aviation Safety Agency (Cologne, Germany)

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