European and International Affairs Department

Relations between ANSES and the European Union agencies

(EFSA, ECHA, EMA, EEA, EU-OSHA, ECDC) and the JRC

There are currently more than 30 decentralised European agencies, each with their own legal identity, working to implement European Union (EU) policies. ANSES fosters relations with all EU agencies sharing the same areas of competence. These relations vary in their nature and frequency, and are mainly determined by the missions and objectives of each EU agency. In general, ANSES seeks an ongoing collaboration with EU agencies while ensuring the dissemination of consistent information to other French bodies working with these agencies.

For each of the EU agencies in contact with ANSES, there follows a summary of its missions, the area(s) of competence shared with ANSES, and the role of France and ANSES within the agency. The agencies in question are the European Centre for Disease Prevention and Control (**ECDC**), European Chemicals Agency (**ECHA**), European Environment Agency (**EEA**), European Food Safety Authority (**EFSA**), European Medicines Agency (**EMA**) and European Agency for Safety and Health at Work (**EU-OSHA**). Executive agencies created for the purpose of managing one or more EU programmes have not been included[1]. Although not an agency but a Directorate-General of the European Commission, the Joint Research Centre (**JRC**) has also been included.

ANSES's relations with these different agencies and its level of involvement in their work is subject to change, in particular as a result of these agencies' evolving mandates and activities. ANSES's role in the implementation of many regulations on chemicals places it at the heart of the "One substance – One assessment" objective pursued by the European Commission in connection with the EU's Chemicals Strategy for Sustainability. As a result, changes are to be expected in ANSES's relations with the various EU agencies involved in chemical assessment and management (ECHA, EFSA and EMA).

[1] For example, HaDEA (the Health and Digital Executive Agency), which manages various programmes and initiatives on behalf of the European Commission, including the "EU4Health" programme and the "Health" Cluster in Horizon Europe.

A. EFSA: European Food Safety Authority [2] [3]

EFSA is an EU agency set up in 2002 to serve as an impartial source of scientific advice for risk managers and to communicate on risks associated with the food chain. It provides the scientific basis for laws and regulations to protect European consumers from food-related risks: from "farm to fork". The core of its activities is to collect, appraise and integrate scientific evidence to answer questions about risks. The outcome of its work is scientific advice to risk managers, jointly produced by independent experts and EFSA staff.

ANSES and EFSA share many areas of expertise, namely food and feed safety, nutrition, animal health and welfare, and plant health and protection.

In addition to national cooperation with EFSA, for which there is a specific European regulatory framework involving the Member States, with each one having a specific role and contribution – for example for the assessment of plant protection active substances or genetically modified organisms (GMOs) – ANSES has various possible **avenues of cooperation** with EFSA:

— Member of various EFSA bodies and networks:

- the Management Board: France has been represented by the Director General of ANSES (full member) since 1 July 2022.
- the Advisory Forum, an assembly of Member States whose role is to provide scientific guidance and strengthen scientific cooperation between Member States and EFSA. France is represented by ANSES.
- the French Focal Point, whose main task is to act as EFSA's contact for the implementation of its scientific cooperation policy. The Focal Point supports the EFSA Advisory Forum member on behalf of its country, and shares and disseminates information. ANSES fulfils this role for France under a multi-annual agreement specifying the activities required of the focal points. The French Focal Point works on France's behalf to coordinate institutional cooperation under Article 36 (see below).
- thematic scientific networks, which bring together Member State representatives on risk assessment relating to topics such as zoonoses, plant health, microbiological risks, GMOs, etc. The networks facilitate scientific cooperation by coordinating their activities, exchanging information, developing and implementing joint projects, and sharing expertise and practices. France has a representative in each of EFSA's thematic scientific networks, and this is usually an ANSES scientist.
- the Communication Experts Network, which fosters links between the communication departments of national risk assessment stakeholders and EFSA. In particular, it helps promote exchanges and coordination of information in the event of a crisis. This group is informed of the dates of major releases and/or communications planned by EFSA.

— Institutional cooperation with competent organisations under Article 36 of EFSA's founding regulation: more than 300 universities, institutes, governmental, public and

[2] Legal basis: REGULATION (EC) NO 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178
[3] http://www.efsa.europa.eu

other scientific bodies currently form a network of national organisations active in the areas falling within EFSA's remit. They can benefit from grants reserved for them as part of calls for proposals for project funding. To date, 18 competent organisations, including ANSES, have been designated for France.

— Individual cooperation in expert groups such as scientific panels, the Scientific Committee and working groups. Currently, around 20 French experts (including seven from ANSES) are members of EFSA panels, and some 60 (including about 30 from ANSES) are members of working groups. They contribute their scientific expertise in a personal capacity (*intuitu personae*).

There is a wide range of **cooperation arrangements**, which cover the following activities:

- submissions to funded calls for carrying out scientific projects: in May 2022, ANSES was involved in 11 projects following on from calls for tender or calls for proposals, including ANSES's participation in the consortium (led by Italian institutions) tasked with producing the EU's 2020-2024 annual reports on zoonoses, prepared by EFSA and ECDC.
- responses to calls for data, and data transmission, whether in a defined regulatory context (zoonoses, chemical monitoring, food consumption, etc.) or during one-off calls for data;
- responses to public consultations;
- information exchanges;
- participation in or co-organisation of scientific events;
- joint participation in scientific projects, including the European Partnership for the Assessment of Risks from Chemicals (PARC), coordinated by ANSES, or EU inter-agency working groups, for example ECHA's Endocrine Disruptor Expert Group (EDEG) in which EFSA also participates, or international networks involving EFSA, such as the IMFSLG[4], ILMERAC[5], IFCSLG[6] and the IRCLG[7].

B. ECHA: European Chemicals Agency [8] [9]

ECHA's mission is to implement the EU's legislation on chemicals[10], namely:

- the REACH Regulation (Registration, Evaluation, Authorisation and restriction of CHemicals),
- the CLP Regulation (Classification, Labelling and Packaging of hazardous chemicals),
- the PIC Regulation (Prior Informed Consent for certain hazardous chemicals and pesticides in international trade),
- the BPR (Biocidal Products Regulation),

[4] International Microbiological Food Safety Liaison Group
[5] International Liaison Group on Methods for Risk Assessment of Chemicals in Food
[6] International Food Chemical Safety Liaison Group
[7] International Risk Communications Liaison Group
[8] Legal basis: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1565177162369ri=CELEX:32006R1907 and Regulations: https://echa.europa.eu/en/legislation
[9] http://echa.europa.eu/
[10] For more information on the legislation: https://echa.europa.eu/en/legislation

- occupational exposure limits, as part of the Directive on the protection of the health and safety of workers from the risks related to chemical agents at work (98/24/EC) and the Directives on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (2004/37/EC and (EU) 2022/431),
- the revised Drinking Water Directive,
- the Waste Framework Directive, and
- the POP Regulation (Persistent Organic Pollutants).

Like every other EU Member State, France has representation in ECHA's governance bodies and technical committees.

The Directorate General for Risk Prevention (DGPR) of the Ministry of Ecological Transition (MTE) represents France on:

— the Management Board, which is ECHA's governing body;

— the Forum for Exchange of Information on Enforcement (Forum), a network of authorities responsible for enforcement of the REACH, CLP and PIC regulations.

ANSES represents France on:

— the Member State Committee (MSC), which participates in several procedures under REACH, such as evaluation and authorisation.

— the Biocidal Products Committee (BPC): this Committee prepares ECHA's opinions on several procedures for the regulation of biocidal products. Final decisions are taken by the European Commission (EC) through a regulatory committee procedure.

ANSES is involved in hazard and risk assessment work within the framework of these regulations and as a "mandated national institution" when France is the rapporteur Member State. It therefore prepares the assessment dossiers for biocidal active substances and, as part of applications for EU marketing authorisation, for biocidal products. ANSES also assesses substances under REACH and prepares classification, restriction and identification dossiers for substances of very high concern (SVHCs) submitted by France. ANSES then presents and defends these dossiers at the European discussions coordinated by ECHA.

ANSES scientists are members of the two technical committees working on REACH and CLP regulations, namely:

— the Committee for Risk Assessment (RAC), which prepares ECHA's opinions on the risks of substances to human health and the environment under REACH and CLP procedures, and issues the scientific opinions used by the DG EMPL to set occupational exposure limits.

— the Committee for Socio-economic Analysis (SEAC), which prepares ECHA's opinions on the socio-economic impact of potential legislative measures with regard to chemicals as part of REACH procedures (restriction, authorisation). It may also issue opinions in response to other requests.

ANSES scientists also participate in the four permanent technical working groups created under the aegis of the BPC for the assessment of biocidal active substances ("human health", "environment", "efficacy" and "analytical methods and physico-chemical properties") and in the expert groups set up by ECHA to work on certain scientific subjects such as endocrine disruptors (EDEG), or

persistent, bioaccumulative and toxic (PBT) substances. Lastly, ANSES scientists act as technical advisers to the DGPR during the work of the committees in which the Ministry participates.

ANSES participates in European harmonisation work on the provisions relating to assessment of the safety and authorisation of materials in contact with water, especially that of the European Commission's DG ENV, with a view to preparing the implementing acts and delegated acts provided for in Article 11 of Directive (EU) 2021/2184 of 16 December 2020 on the quality of water intended for human consumption. From 2020 to 2025, ANSES scientists are taking part in the two sub-groups of the Working Group on Substances and Materials (WG-SM), including the Sub-Group on Substances (SG-S) led by ECHA.

As part of ECHA's work on occupational exposure limits, ANSES contributes as much as possible, with the support of its experts, to "calls for evidence" consultations (procedures that aim to gather the available scientific data) and to public consultations on limit value recommendations organised by ECHA[11].

C. EMA: European Medicines Agency [12] [13]

EMA is tasked with protecting and promoting public and animal health through the evaluation, supervision and safety monitoring of medicinal products for human and veterinary use.

France is represented on EMA's Management Board by the Director General of the French National Agency for Medicines and Health Products Safety (ANSM), whose alternate is the Director of the French Agency for Veterinary Medicinal Products (ANMV, part of ANSES).

The ANMV, the competent French authority for veterinary medicinal products, is closely involved in EMA's work. ANMV scientists participate in the work of the Committee for Medicinal Products for Veterinary Use (CVMP) and in the technical scientific working groups.

EMA does not itself conduct scientific expert appraisals; it relies on those carried out by the experts of the national agencies.

The CVMP is responsible for preparing EMA's opinions on all matters relating to veterinary medicinal products. The full member and the alternate member representing France on the CVMP are both ANMV scientists. The CVMP plays a crucial role in the procedures for placing veterinary medicinal products on the European market and in setting maximum residue limits (MRLs) for veterinary medicinal products in foodstuffs. For centralised procedures, the CVMP leads the initial expert appraisal by appointing a rapporteur and co-rapporteur from among its members, and issues an opinion to the European Commission for adoption of the marketing authorisation (MA) decision, which is valid throughout Europe. For mutual recognition or decentralised procedures, the CVMP can arbitrate in cases of disagreement between the Member States concerned. The CVMP also issues

[11] https://echa.europa.eu/consultations/current
[12] Legal basis: Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and amending acts
[13] http://www.ema.europa.eu/

opinions following referrals initiated when questions are raised regarding public health protection.

EMA hosts and manages the four European databases set up with the entry into force of the new Veterinary Medicines Regulation (2019/6): (i) the veterinary medicinal product database (UPD), (ii) the veterinary pharmacovigilance database, (iii) the Manufacturers and Wholesale Distributors database (MWD), and (iv) the Collection of Antimicrobials Sales and Use database (ASU) . These databases are interfaced with national databases. The ANMV played an active part in the working groups set up for their development, and now contributes to several groups tasked with database management and governance of EMA IT projects.

D. EEA: European Environment Agency [14] [15]

The EEA's mandate is to provide environmental information for EU and Member State policy-makers, mainly on the state of the environment, economic and social factors affecting the environment, policies and their effectiveness, likely future trends and the problems that may arise from them.

The EEA currently has 32 member countries and six cooperating countries. The General Commission for Sustainable Development (CGDD) of the Ministry of Ecological Transition represents France on the Management Board.

Through the European Environment Information and Observation Network (EIONET[16]), the EEA collects, processes and redistributes environmental information produced by individual countries that has been validated at national level. This knowledge forms the basis for thematic and integrated environmental assessments, and supports environmental management processes, policy-making and environmental assessments, as well as citizen participation. EIONET has about 2500 members, reflecting the diversity of situations and governance approaches in each country. It brings together people responsible for reporting environmental data and experts involved in the EEA's thematic debates. The CGDD acts as the EEA's national focal point, and coordinates and manages the "EIONET France[17]" national network made up of various national partner institutions. Since 2022, technical debates have been held in 13 of the EIONET network's thematic groups, which bring together experts from each country.

ANSES contributes to the EIONET group on environmental health, which includes thematic groups on air pollution and quality, noise and chemicals, and follows the EEA's work in other areas related to its activities.

In addition to the EIONET group's work, ANSES monitors and may be asked to contribute to the EEA's work, or to collaborate with the EEA in European joint projects. For example, the two agencies together contributed to the European project on human biomonitoring of chemical exposure, "HBM4EU" (which came to an end in late April 2022), and have been involved since May 2022 in the European

[14] Legal basis: Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network
[15] https://www.eea.europa.eu/
[16] https://www.eionet.europa.eu/
[17] http://www.eionetfrance.fr/

Partnership for the Assessment of Risks from Chemicals (PARC), which ANSES is coordinating[18].

E. EU-OSHA: European Agency for Safety and Health at Work [19] [20]

EU-OSHA's mission is to collect and share knowledge and information on occupational safety and health issues at European level, particularly on best practice in prevention. It supports the production, analysis and dissemination of information on this topic in Europe, mainly through information campaigns and publications.

The Directorate General for Labour (DGT) sits on the Agency's Management Board and also acts as the French focal point, contributing to its activities and helping to coordinate and disseminate the Agency's information in France.

ANSES is a member of the French focal point network, which includes other French stakeholders in occupational safety and health.

F. ECDC: European Centre for Disease Prevention and Control [21] [22]

The ECDC's mission is to identify, assess and communicate on current and emerging risks to human health from infectious diseases. The ECDC's disease-specific work is organised into seven horizontal programmes, some of which are linked to ANSES's activities: antimicrobial resistance, emerging and vector-borne diseases, water- and foodborne diseases and zoonoses, etc.

Santé publique France is the competent authority for France, which it represents on the Management Board and the Advisory Forum, as well as in other ECDC bodies and networks.

ANSES occasionally contributes to the ECDC's work on specific topics. For example, in food safety, as the European Union Reference Laboratory (EURL) for *Listeria monocytogenes,* it works on rapid investigations of foodborne outbreaks affecting several EU countries, conducted jointly by ECDC and EFSA. In partnership with Italian institutions, ANSES laboratories also contribute to production of the annual EU report on zoonoses prepared by EFSA and ECDC since 2020.

ANSES's interactions with the ECDC are likely to be reinforced with the increasing implementation of "One Health" approaches at European and national level.

G. JRC: Joint Research Centre [23]

The JRC is the internal scientific service of the European Commission, tasked with providing scientific support for EU policies over the entire public policy cycle. Its

[18] https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc
[19] Legal basis: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32019R0126
[20] https://osha.europa.eu/en
[21] Legal basis: Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control
[22] http://www.ecdc.europa.eu
[23] http://ec.europa.eu/dgs/jrc/index.cfm?id=1440

work is mainly funded by the EU's research and innovation budget. It covers a vast range of issues, including environmental challenges, improving public health, natural disaster mitigation and ensuring nuclear safety. The JRC's activities are clustered into ten science areas, some of which are shared with ANSES, such as the "food, nutrition and health" area[24].

ANSES is one of the French scientific organisations that contribute to the JRC's work, in particular through its National Reference Laboratory (NRL) mandates in three fields for which the JRC is EU Reference Laboratory (EURL): food contact materials, feed additives, and genetically modified food and feed. The JRC also hosts the EURL for Alternatives to Animal Testing (EURL ECVAM), which coordinates a network of laboratories that assist in the evaluation (validation) of alternative approaches to the use of animals for scientific purposes.

Through reference laboratory mandates, ANSES scientists take part in JRC expert groups or other scientific work. For example, in 2019, ANSES participated in an inter-laboratory comparative study on the quantification of microplastics, which led in 2022 to the JRC appointing an ANSES scientist as contact point/expert for the identification of a methodology to measure the presence of microplastics in drinking water, in connection with the future implementation of Article 13 (6) of the revised Drinking Water Directive. The ANSES EURLs also cooperate with the JRC on the development of certified reference materials. ANSES and JRC research teams may also work together in the context of European projects (this will be the case with PARC, for example).

With regard to the COVID-19 crisis, in May 2020, the JRC and the European Commission's Directorate-General for the Environment (DG ENV) issued a call for participation in a pan-European feasibility assessment to explore the development of an exercise to monitor the SARS-CoV-2 virus in wastewater and exchange experience in this area. ANSES was appointed as the French Deputy National Contact Point and as such, it participates in the "EU Sewage Sentinel System for SARS-CoV-2" alongside the Directorate General for Health (DGS), the Directorate for Water and Biodiversity (DEB) and *Santé publique France*.

Lastly, ANSES takes part in scientific projects or working groups that mobilise EU agencies and also involve the JRC (e.g. EDEG, ECHA's expert group on endocrine disruptors).

[24] https://joint-research-centre.ec.europa.eu/science-areas/food-nutrition-health_en