Relations between ANSES and the European Union agencies

ANSES fosters relations with all European Union (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 works to maintain its involvement with EU agencies while ensuring the dissemination of consistent information to other French authorities involved in these agencies' work.
For each of the EU agencies in contact with ANSES, a summary is provided below 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 **ECDC** (European Centre for Disease Prevention and Control), **ECHA** (European Chemicals Agency), **EEA** (European Environment Agency), **EFSA** (European Food Safety Authority), **EMA** (European Medicines Agency) and **EU-OSHA** (European Agency for Safety and Health at Work). 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 **JRC** (Joint Research Centre) has also been included.

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

EFSA is responsible for assessing the risks associated with food and feed. Working closely with national authorities, EFSA provides scientific opinions on existing and emerging risks. EFSA's role is therefore to assess and communicate on all risks associated with the food chain.
ANSES and EFSA share many areas of expertise, namely food and feed safety, nutrition, animal health and welfare, and plant health and protection.
Concerning France's position with regard to EFSA, ANSES represents France in the Advisory Forum (assembly of Member States whose role is to provide scientific guidance and strengthen scientific cooperation between Member States and EFSA) and acts as the French focal point (coordination between EFSA and French bodies such as the National Institute for Agricultural Research – INRA, veterinary schools, etc.). EFSA also coordinates several thematic scientific networks (involving Member State representatives on risk assessment relating to topics such as zoonoses, food microbiology, GMOs, etc.). The networks facilitate scientific cooperation by coordinating activities, exchanging information, developing and implementing joint projects, and sharing expertise and best practices. France has a representative in each of EFSA's thematic scientific networks, and many representatives are ANSES scientists.
Besides the institutional relationships mentioned above, many ANSES scientists are members of EFSA's scientific committees and working groups, where they contribute their scientific expertise in a personal capacity (*intuitu personae*). In addition, ANSES plays a part in EFSA's scientific work

[1] For example, CHAFEA (the Consumers, Health, Agriculture and Food Executive Agency), which manages EU programmes on consumers, health, agriculture and food safety, or the Research Executive Agency (REA), which manages the EU's research funding.
[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

through its responses to calls for tenders and proposals published by EFSA on many scientific topics. There are also regular exchanges between the management teams of these two institutions.

B. ECHA: *European Chemicals Agency* [4] [5]

ECHA's mission is to ensure the consistent implementation throughout Europe of the EU's regulations on chemicals, namely REACh (substances), CLP (classification, labelling and packaging) and the Biocidal Products Regulation.
Like any 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 Ecology (MTES) represents France on the:

- Management Board, which is the Agency's governing body.
- Member State Committee (MSC), which participates in several procedures under REACh, such as evaluation and authorisation.

ANSES represents France on the:

- Biocidal Products Committee (BPC), which 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 also involved in hazard and risk assessment work within the framework of these regulations. As a "mandated national institution", ANSES prepares the assessment dossiers for biocidal active substances for which France is the rapporteur Member State, assesses substances under REACh, and prepares classification, restriction and identification dossiers for SVHCs (substances of very high concern) 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 the REACh and CLP procedures.
- Committee for Socio-economic Analysis (SEAC), which prepares ECHA's opinions on the potential socio-economic impact of any legislative actions in REACh procedures.

ANSES scientists also participate in the four permanent technical Working Groups ("human health", "environment", "efficacy" and "analytical methods and physico-chemical properties") created under the aegis of the BPC for the assessment of active biocidal substances. Lastly, ANSES scientists act as technical advisors to the DGPR during the work of the committees in which the Ministry participates.

[4] Legal basis: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1565177162369ri=CELEX:32006R1907 and Regulations: https://echa.europa.eu/en/legislation
[5] http://echa.europa.eu/

C. EMA: *European Medicines Agency* [6] [7]

The EMA is tasked with protecting and promoting public and animal health through the evaluation and supervision of medicinal products for human and veterinary use.
France is represented on the EMA's Management Board by the Director General of the ANSM (French National Agency for Medicines and Health Products Safety), whose alternate is the Director of the ANMV (French Agency for Veterinary Medicinal Products, part of ANSES).
The ANMV, which is the competent French authority for veterinary medicinal products, is closely involved in the work of the EMA. ANMV scientists participate in the EMA's scientific work, on the Committee for Medicinal Products for Veterinary Use (CVMP) and in the technical scientific working groups.
The EMA does not itself conduct scientific expert appraisals, but relies solely on those carried out by the experts of the national agencies.
The CVMP is responsible for preparing the EMA's opinions on all matters relating to veterinary medicinal products. Two scientific experts at the ANMV have been appointed as French representatives to the CVMP: a full member and alternate member. 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 the 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 opinions following referrals initiated when questions are raised regarding public health protection.

D. EEA: *European Environment Agency* [8] [9]

The mandate of the EEA is to provide information on the environment for policy-makers in the EU and Member States. It disseminates a wide variety of information based on the provisions of European regulations, and issues opinions on the state of the environment, environmental trends, economic and social factors affecting the environment, policies and their effectiveness, likely future trends and the problems that will result from them.
Through EIONET (the European Environment Information and Observation Network), the EEA collects, processes and redistributes environmental data received from individual countries and validated at national level.
Each of the 32 member countries has a representative on the Management Board: the French delegate is from the General Commission for Sustainable Development (CGDD) of the Ministry of Ecology. In addition, the CGDD's Observation and Statistics Department (SOeS) acts as a national

[6] 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
[7] http://www.ema.europa.eu/
[8] 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
[9] https://www.eea.europa.eu/

focal point (NFP) for the Agency and therefore participates in EIONET. The French NFP coordinates and manages the EIONET France network[10], which includes the NRCs (National Reference Centre) and PCPs (Principal Contact Point). NRCs are organisations with expertise relevant to the missions of one of the 27 thematic interest groups, while PCPs are NRCs that act as the group's coordinator at the national level. ANSES is the PCP for environmental health and follows the work of the EEA as an NRC in other areas related to its activities.
Besides the work of EIONET, ANSES monitors and may contribute to the work of the EEA, or may collaborate with the EEA in joint European projects (as is the case with the major European project on human biomonitoring and chemical exposure, "HBM4EU").

E. EU-OSHA: *European Agency for Safety and Health at Work* [11] [12]

EU-OSHA's mission is to collect and share knowledge and information on occupational safety and health (OSH) issues at European level, particularly with regard to best practice in prevention. The Agency acts as a catalyst for the production, analysis and dissemination of information to improve OSH in Europe. It launches information campaigns and has implemented a diversified publications programme, ranging from specialised information reports to fact sheets covering a vast range of OSH issues.

The Directorate General for Labour (DGT) of the Ministry of Labour sits on the Agency's Management Board and also acts as the national focal point (NFP), in order to coordinate and disseminate the Agency's information at the national level.

ANSES is a member of the French focal point network, which includes other French stakeholders in occupational safety and health. The network's purpose is to support the DGT in its role as NFP and to contribute to the measures it implements. In particular, ANSES participates in the European Risk Observatory expert group and maintains direct relations with EU-OSHA on specific topics of interest to it.

F. ECDC: *European Centre for Disease Prevention and Control* [13] [14]

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 and represents France on the Management Board and the Advisory Forum.
ANSES has intermittent relations with the ECDC on specific topics, such as food safety through the mandate of its Laboratory for Food Safety as European Union Reference Laboratory (EURL) for *Listeria monocytogenes*.

[10] https://www.eionet.europa.eu/
[11] Legal basis: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32019R0126
[12] https://osha.europa.eu/en
[13] 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
[14] http://www.ecdc.europa.eu

G. JRC: *Joint Research Centre* [15]

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. The JRC has six different sites in five European countries, with unique research facilities and laboratories. The JRC's work is largely funded by the EU budget for research and innovation, and mainly focuses on digital transformation, a fairer and more competitive economy, a sustainable Europe and a Union that protects. Science and technology are essential for formulating good policy. The JRC covers a vast range of issues in its research activities: from environmental challenges to improving public health, natural disaster mitigation and ensuring nuclear safety and security, and includes wide-ranging cross-cutting activities. The JRC's activities are grouped into ten areas, some of which are shared with ANSES, such as agriculture and food security; environment and climate change; health and consumer protection; standards, etc. The JRC also works in partnership with the European Commission's policy services to manage six knowledge centres that bring together expertise and knowledge from different sources, including:

- Knowledge Centre for Food Fraud and Quality
- Knowledge Centre for Bioeconomy
- Knowledge Centre for Global Food and Nutrition Security

These centres inform policy-makers in a transparent, tailored and concise manner to enable them to understand the latest scientific data.

France interacts with the JRC institutes mainly through the French national reference laboratories (NRLs) in each of the fields for which the JRC is European Union Reference Laboratory (EURL). The JRC holds three EURL mandates on food and feed related issues: 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.

ANSES scientists therefore participate in JRC expert groups or other scientific work, mainly within the ANSES laboratories that hold NRL mandates for which EURL mandates are held by the JRC. The ANSES EURLs also cooperate with the JRC, in particular for the development of certified reference materials. ANSES and JRC research teams may also work together in the context of European research projects and joint European actions in the field of public health.

[15] http://ec.europa.eu/dgs/jrc/index.cfm?id=1440