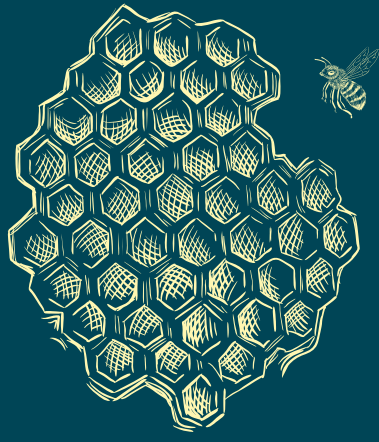


2019 ANNUAL REPORT

ANSES IN ACTION





ANSES KEY FIGURES





2019

Key figures

1,402 employees

838 work in the laboratories

449 men and **953** women

Around **800** independent experts mobilised

66 national reference mandates,

12 European reference mandates and

28 international reference mandates

More than **250** opinions and reports produced in response to formal requests

79 formal requests received **20** of which were urgent

2,052 decisions issued in the field of plant protection products,

300 300 in the field of biocides and

3,848 in the field of veterinary medicinal products

79 news updates published

22,532 mentions in the press

A budget of
€141.1 million ↘

TOTAL EXPENDITURE (€M)

30 scientific
events organised

96.219
Staff



36.342
Operation

8.588
Investments

40 projects
selected as part of
the National Research
Programme for
Environmental and
Occupational Health,
with funding of around

€**6.5** million

BREAKDOWN OF EXPENDITURE BY DESTINATION TYPE – TOTAL – €M

65.462
Scientific activities
of the laboratories



24.878
Support
for Agency
activities

50.810
Expert appraisal,
assessment and
authorisation

INVESTMENTS MADE TOTAL (PAS) – EUROS

394
category A+ and A
scientific publications

3.537
Multi-year
real-estate
operations



1.339
Other

1.859
Scientific
equipment

1.854
IT expenditure



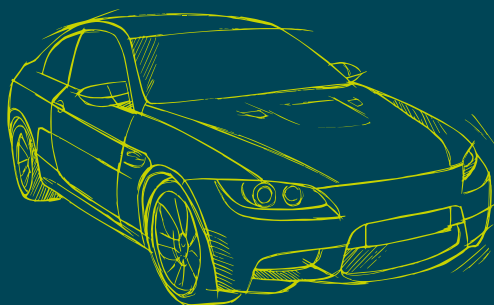
2019

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and openness



ROGER GENET, DIRECTOR GENERAL

On 1 July 2020, ANSES will celebrate its 10th anniversary. How do you approach this milestone given your activity in recent months?

→ Looking back over the past 10 years, we are continually reminded – and can be justifiably proud – of how our usefulness has been recognised: as borne out by all the attention paid to our expert appraisal topics and our ever-increasing workload. This is also reflected by our work in 2019, with topics relating to major recurring societal issues such as food safety, prevention of health crises associated with animal diseases, preservation of environmental quality in the face of chemical contaminants, noise or electromagnetic waves; as well as other more recent issues such as the human impact on ecosystems and effects of global changes on our daily lives, food, modes of transport and working conditions.



INTERVIEW WITH



ANSES's growing activity also reflects the volume of our exchanges with the different spheres of public decision-making, starting with our supervisory authorities and French and European parliamentarians. I would like to commend the exceptional efforts of our staff, expert groups and governance bodies to achieve a health ambition that is constantly being challenged.

Being an integral part of the health landscape does not however mean that we can become complacent: our missions are expanding every year, new health risks are constantly emerging, and expectations are ever higher, in a context marked by the erosion of our fellow citizens' trust in scientific institutions and a science faced with the complexity of assessing uncertainty, as shown so clearly by the COVID-19 health crisis we have been experiencing.

"ANSES's value is and will be increasingly correlated with our ability to anticipate crises."

Publication of this annual report coincides with the COVID-19 crisis. How have you responded to it? What future impact do you foresee?

→ Lubrizol a few months ago, African swine fever at our borders, and now COVID-19. Crisis is inherent to our operations, even if the pandemic currently affecting us has been particularly trying, leading us to put in place an unprecedented and exceptional system to enable us to issue our opinions and recommendations as a matter of urgency during the lockdown.

Fortunately, however, many crises give rise to early warning signals that make them completely avoidable. In fact, the Agency's true value and legitimacy fully depend on working to anticipate these, a task that we will be focusing on more than ever in the period ahead. The missions of our research and reference laboratories – essential extensions of our expertise capabilities – are crucial to the acquisition of knowledge, development of innovative techniques and orchestration of our alert and crisis management abilities in three areas: food safety, animal health and plant health. The third part of this report sheds considerable light on these competences.

Anticipating crises also means working tirelessly to break down barriers and work without borders, in every sense of the word. This is part of the "One Health" mindset we have embraced, a holistic approach to the health of humans, animals and the environment that the broad scope of our competence inclines us to develop, and whose significance is now fully appreciated. We are also actively increasing our links with the various sources of knowledge, expertise and surveillance, in particular with our counterpart agencies in France, Europe and further afield.



INTERVIEW WITH

While some risks are quickly identified, this is less true of others. What progress is ANSES making in tackling health uncertainties and the fears they fuel?

→ We are faced with a paradox in that the more scientific knowledge advances, the more we become aware of the extent of the uncertainties, in terms of hazards, exposure and cumulative effects at a given time or in the longer term. The challenge in investigating them is compounded by the fact that the health effects may be chronic, delayed or even transgenerational. And since there is often uncertainty in health risks associated with our lifestyles and technological innovations, questioning certain types of exposure upsets production or consumption choices, and therefore becomes the subject of debate.

ANSES's 10th anniversary is marked by the

Agency's ambition to become more proactive regarding the role of scientific expert appraisals in public decision-making. Expectations and the ways in which they are expressed are changing, and these changes are echoed in our very operating principles and recent proposals. Indeed, the entire last part of this report makes extensive reference to them. But we have to go further. The mobilisation around pesticides, which has been omnipresent in recent months, typically calls for the establishment of new forums for discussion, new consultation methods. While science is but one element of the decision, we are also committing to make it ever more robust and inclusive.

ANSES fully committed to the fight against COVID-19

From the beginning of the pandemic, ANSES made its expertise available to the public authorities to help prevent SARS-CoV-2-related health risks. Its teams, largely working from home, quickly helped to refine the scenarios for human exposure to the new coronavirus. This required analysing the possibilities of contamination via food, livestock and pets, the aquatic environment and the agricultural spreading of urban sewage sludge. They also proposed a general framework for the prevention of occupational exposure.

To limit the health impact of the lockdown, the Agency updated its recommendations on physical exercise and vitamin D intake. It used its website and social networks to issue information on good hygiene practices to adopt in the kitchen and when shopping for food. Lastly,

it warned about the use of food supplements that could lower the body's immune response to COVID-19, as well as the domestic misuse of disinfectants, as reported by poison control centres.

ANSES's laboratories harnessed their research capabilities and knowledge of animal coronaviruses to develop animal models (ferret and hamster) for assessing therapeutic protocols, and also to observe the effect on facemasks of several treatment processes, in support of the government's deliberations on their recycling.

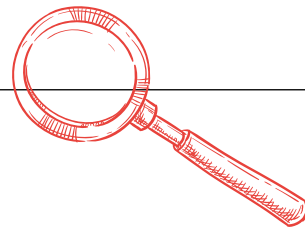
ANSES's staff worked to support hospitals and medical research (contribution to Inserm's REACTing programme, support for hospital diagnostic laboratories), ministerial initiatives («testing» unit, Ministry of Health job descriptions) and the High Council for Public Health (working

group on hygiene measures specific to the epidemic).

Lastly, the COVID-19 crisis should not make us forget about the other threats to health. Throughout the crisis, ANSES has maintained its ability to assess other alerts relating to animal health, plant health and food. In late May, it looked into the maintenance of vector control practices in the overseas territories affected by dengue, since the measures taken against COVID-19 have tended to restrict the actions of professionals and the population.

As this report goes to press, the epidemic is unfortunately still topical and ANSES is continuing its work. The updated list of ANSES opinions and recommendations on COVID-19 can be found on our website: <https://www.anses.fr/en/content/covid-19-all-anses-news>

ANSES: a brief description



Since 2010, ANSES has been providing public decision-makers with the scientific benchmarks needed to protect humans and the environment from the biological, physical or chemical risks to which they are exposed. A public agency working for the general interest, ANSES comes under the responsibility of the French Ministries of Health, the Environment, Agriculture, Labour and Consumer Affairs.

EVERY DAY, ANSES WORKS TO:

→ **advance scientific knowledge and methods**, especially on emerging threats and topics characterised by high uncertainty;

→ **assess the health risks** to which we are exposed daily through our food, environment or occupational activities, or which affect the health of animals and plants, and make recommendations to the public authorities by mobilising independent expert groups and the latest scientific knowledge. ANSES also deals with marketing authorisation applications for plant protection products, biocides and veterinary medicinal products;

→ **safeguard the health of humans, animals and plants** through surveillance and vigilance schemes that pick up warning signals, and an overall operation designed to act promptly to support the authorities.

A BROAD SPECTRUM OF ACTION

→ Biological, chemical and physical risks associated with water, air, soil, food and other consumer products, particularly technological innovations

→ Food quality

→ Risks associated with specific occupations and occupational behaviours, assessment of occupational diseases

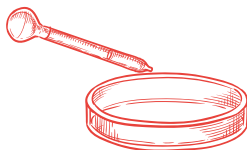
→ Plant diseases and pests

→ Animal diseases and welfare on farms

→ Epidemiological surveillance in animal and plant health, food-chain safety

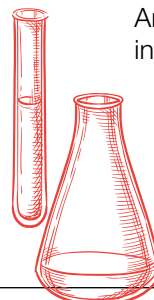
→ Resistance to antibiotics in animals and to plant protection products in plants

→ Toxicovigilance, nutriviigilance and phyto-pharmacovigilance, vigilance regarding other products



1,402
employees

A network of **9**
laboratories
throughout France



Around **800**
independent experts

To find out more, visit www.anses.fr/en

The four principles guiding our work

A COMPREHENSIVE APPROACH TO RISKS

→ Because safeguarding the health of some means safeguarding it for all, ANSES has developed an integrated approach to human, animal and plant health in order to assess the risks of today and anticipate those of tomorrow. The vast scope of its work has enabled the Agency to adopt a comprehensive view and develop a “One Health” approach to health risks and their consequences for humans and ecosystems.

INDEPENDENCE & TRANSPARENCY

→ To assess health risks, ANSES sets up multidisciplinary expert groups and transparent, collegial working methods that guarantee the independence and scientific integrity of the work carried out, on which its opinions are based. The Agency is also assisted by its Ethics Officer, Committee for Ethical Standards and Code of Ethical Standards, which oversee and ensure compliance with its ethical principles. Lastly, the Agency publishes the declarations of interests of its staff and external experts.

SCIENTIFIC EXCELLENCE

→ Every day, ANSES relies on recognised scientific methods, networks of experts with proven skills in their respective disciplines, and the best available scientific knowledge. This constant requirement ensures that its expertise is renowned for its scientific robustness. In all its activities, the Agency also maintains numerous co-operations with counterpart agencies, risk assessors and research players at national, European and international level.

DIALOGUE & OPENNESS

→ Health risks are a source of both interest and concern. To foster informed debate that can benefit public action, ANSES makes its findings available, publishing them as widely as possible. Voluntary associations, trade unions, businesses, elected officials and government ministries are represented and involved in its governance. ANSES is committed to listening to and engaging with its stakeholders and civil society. As such, it organises discussions on the implementation and results of its expert appraisal work and leads dialogue committees on nanotechnologies, radiofrequencies and plant protection products.

ANSES in 2019: key dates



/01

14-15/01

→ ANSES took part in the **National Environmental Health Meetings** held in Bordeaux.

06/02

→ ANSES and the **French National Research and Safety Institute (INRS)** renewed their partnership to bolster their joint work in **occupational risk assessment and prevention**.

23/05

→ Inauguration of the **new building of the French Agency for Veterinary Medicinal Products** in Javené, near Fougères.

09/05

→ ANSES hosted and co-chaired with its Dutch counterpart, RIVM, the meeting of the Directors General of institutions participating in the “One Health” European joint programme (EJP) coordinated by ANSES.

january

may

february

march

26/02

→ At the 56th Paris International Agricultural Show, ANSES renewed its partnership agreement with the **French Agricultural Research Centre for International Development (CIRAD)** to strengthen their joint research and expert appraisal work in **animal health, plant health and food**.

18/02

→ **ANSES and the University of Rennes 1** signed a framework agreement for scientific co-operation focused on environmental health, particularly on the study of the **exposome**.

/02

26-28/03

→ ANSES, the German Federal Institute for Risk Assessment (BfR), the National Food Institute of the Technical University of Denmark (DTU) and the Republic of Korea's National Institute of Food and Drug Safety Evaluation (NIFDS) held an **international conference on foodborne pathogens and whole genome sequencing**.

/03





/05

01-03/07

→ ANSES's work was presented to the **Chlordecone Plan** regional committees in Martinique and Guadeloupe.

/08

27/08

→ ANSES's Plant Health Laboratory announced that it had obtained three of the five new **EU reference mandates for plant pests**: for fungi and oomycetes, insects and mites (with the Austrian agency AGES), and nematodes (with the Belgian institute ILVO).

august

june

03/06

→ **Roger Genet** was reappointed for a **second three-year term** as Director General of ANSES.

10-14/06

→ **US Food and Drug Administration (FDA)** inspection, led by an inspector from ANSES-ANMV, as part of preparation for mutual recognition agreements between the European Union and the United States.

/06

july

08/07

→ **ANSES and the National Research Agency (ANR)** organised a meeting to present the results of research projects funded by the two institutions on **endocrine disruptors**.

18/07

→ **Annual bilateral meeting between ANSES and the European Food Safety Authority (EFSA)** in Parma, to strengthen co-operation and discuss the new European regulation on the transparency and sustainability of risk assessment in the food chain.

/07

24/07

→ Bilateral meeting between ANSES and the **International Agency for Research on Cancer (IARC)** in Lyon, to exchange views on topics of common interest concerning the study of cancer hazards and risks.





03/09

→ ANSES hosted the Minister of Ecological and Inclusive Transition, the Minister of Solidarity and Health and the Secretary of State to the Minister of Solidarity and Health for the **signing of the second National Endocrine Disruptor Strategy**.

18/09

→ Meeting in Strasbourg with **MEPs** in the framework of the new mandate of the European Parliament.

27/09

→ Unconditional renewal of ANSES's **ISO 9001 certification** for all activities and processes audited.

september

october [start]

03/10

→ ANSES and the **University of Paris-Est Créteil** signed a framework agreement to develop joint work on **emerging risks**, according to a "One Health" approach.

7-8/10

→ Bilateral meeting between ANSES and the **Friedrich Loeffler Institute**, a German federal research organisation specialising in **animal health and welfare**.

11/10

→ ANSES took part in setting up the transparency and dialogue committee on the fire at the **Lubrizol** plant in Rouen.

15/10

→ The ANMV, part of ANSES, held its second **one-day meeting** in Fougères with all the stakeholders in the **veterinary medicinal product** supply chain and representatives of the World Organisation for Animal Health (OIE).

/10



15/10

→ Together with Pascal Lamy, Roger Genet co-chaired the G7 workshop on **microplastics research**, as part of the French Presidency of the G7.

17/10

→ **ANSES and the French Environment and Energy Management Agency (ADEME)** organised a meeting to present the results of research projects funded by the two agencies on the theme of **indoor and outdoor air**.

24/10

→ ANSES announced that it had been appointed to lead the new **European Reference Centre for the welfare of poultry and other small farmed animals**, in co-operation with its partner organisations in Spain, Italy and Denmark.

24-26/10

→ ANSES took part in the international conference on **Sargassum seaweed** organised by the Guadeloupe regional authority.

29-31/10

→ Along with EFSA and INRA, ANSES co-organised the second European conference on ***Xylella fastidiosa*** in Ajaccio.

october
(end)

december

09/12

→ **ANSES and EFSA** held an international one-day scientific meeting on **bee health** and the contribution of research to risk assessment, in Paris.

11/12

→ ANSES, INRA and the Ministries of Health, Consumer Affairs and Food signed a new framework agreement for the **French Food Observatory (OQALI)**, for the period 2020-2023.



/12

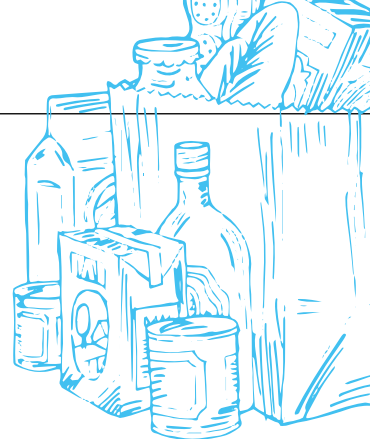
DAILY LIFE





Understanding
the risks
to ensure
better
protection

Improving our food's nutritional quality and safety



Food is a major determinant of our health. It has to meet our daily energy and nutrient needs, in constant pursuit of balanced, safe intakes. ANSES continuously studies changes in the French population's eating habits and the products on offer, in order to propose dietary guidelines tailored to each individual and to assess risks by taking consumers' actual exposure into account. We take a look back at the work carried out in 2019.

DIETARY GUIDELINES SPECIFIC TO EACH AGE AND SITUATION

ANSES develops the dietary guidelines on which the public health recommendations of the French National Nutrition and Health Programme are based. In 2017, it published new guidelines on the main food groups to enable the nutritional requirements of each population to be met while preventing risks of chronic diseases. To do this, it conducted collective expert appraisals over five years that considered the consumption habits of the French population, their nutritional needs, contaminants found in food, and new scientific data including epidemiological studies on the links between food and health. This work was adapted to establish guidelines tailored to specific

populations: children from birth to three years and from four to 17 years of age, the elderly, and pregnant or breastfeeding women. In 2019, the Agency then published four opinions, in which experts took account of the nutritional needs of each of these populations. Each one faces specific risks that can be limited as long as the diet is healthy, varied and appropriate.

Among other things, the Agency stressed the importance of a balanced diet for all women of childbearing age, in order to ensure a good nutritional status right from the start of pregnancy. This work also questioned the nutritional intake of processed products in children's diets, laying the scientific basis for a

future risk assessment on the potential role of these products in inducing certain eating habits.

In 2020, ANSES will continue its work on the nutrition of specific populations, focusing in particular on diets that exclude foods of animal origin.

ANSES's recommendations

GENERAL POPULATION

- Eat more pulses, wholegrain starches, vegetables, fruits and certain vegetable oils.
- Limit meats other than poultry, and delicatessen meats and sugar-sweetened beverages even more so.

CHILDREN FROM BIRTH TO THREE YEARS

- Start complementary feeding no later than between the ages of four and six months.
- Introduce the widest possible variety of foods between the ages of five and 18 months, which is a favourable window for the acceptance of new foods.
- Persist in offering foods that are initially rejected.
- Give priority to mealtimes.

CHILDREN AGED 4 TO 17 YEARS

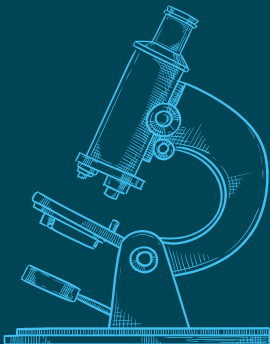
- Replace sugar-sweetened beverages and pastries/biscuits/cakes by sugar-free dairy products (or other calcium-rich foods), fresh fruits and nuts.
- Reduce the “added sugars” found in many processed products and encourage “homemade” dishes to better control sugar intakes.

PREGNANT AND BREASTFEEDING WOMEN

- Eat dairy products, fruits, vegetables and fish to meet iron, iodine and vitamin B9 (folic acid) requirements, and ensure vitamin A and C intake when breastfeeding.

POSTMENOPAUSAL WOMEN AND THE ELDERLY

- Increase physical activity slightly and decrease sedentary time to maintain the quantities usually consumed, or decrease portion sizes slightly for certain foods except fruits, vegetables, fish, molluscs, crustaceans and wholegrain starches.



UNCERTAINTIES ABOUT THE SAFETY OF THE ADDITIVE E171

The food additive E171 is used in many different food products for its colouring and opacifying properties. It consists of titanium dioxide particles (TiO₂), mainly in nanoparticle form. ANSES examined the risks associated with ingesting this additive and concluded that it is currently difficult to assess them and set an acceptable daily intake because of the lack of data provided by manufacturers. On completion of its most recent expert appraisal on the topic, in April 2019, the Agency therefore concluded that it had not obtained any new information that would resolve the uncertainties regarding the safety of this substance. Following this opinion, the Government announced a ban on the placing on the market of foodstuffs containing the additive E171 as of 1 January 2020.



Focus

OQALI TAKES STOCK OF FOOD ADDITIVES

In its work for the French Observatory of Food Quality (OQALI), in 2019 ANSES published a ground-breaking study on trends in additive use in food products marketed in France. The study assessed the presence of additives in processed foods, based on more than 30,000 products collected between 2008 and 2016.

While the majority of products contained at least one additive, they were used to a greater degree only in certain food categories: frozen pastries and desserts, fresh delicatessen products, ice creams and sorbets. It was also noted that the use of food additives over the period in question had tended to decrease overall, except for four of them: carotenoids, sodium carbonates, pectins and anthocyanins. Lastly, the study concluded that it was important to monitor the alternatives used by industry to replace conventional additives, such as the use of new technological



78% of food products contained **at least** one additive

53% of food products contained fewer than **three** additives

4% of food products used at least **ten** additives



VIGILANCE CONCERNING FOOD SUPPLEMENTS

→ The French population is consuming a growing number of food supplements and there are ever more products on offer, particularly on the Internet. Although they are often considered harmless, they can, under certain conditions, expose consumers to health risks.

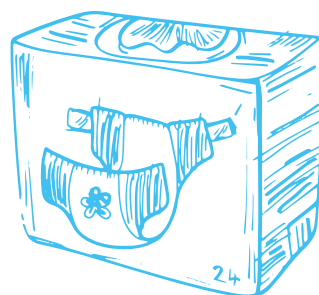
→ For the past ten years, using reports from health professionals in particular, the nutrivigilance scheme coordinated by ANSES has been documenting adverse effects associated with the consumption of food supplements and other specific products such as energy drinks, fortified foods and infant foods.

→ On the basis of these data, ANSES has published some ten opinions on a wide range of supplements containing spirulina, melatonin, red rice yeast or hive products, or those intended for athletes, pregnant women, or the elderly. ANSES's recommendations are designed to control the risks associated with consumption of these products and provide users with precautions for use.

→ In general, the Agency points out that in the absence of a specific indication, consumption of food supplements is generally unnecessary: nutritional requirements can be met by a varied and balanced diet, combined with suitable physical activity.



Making consumer products safer ↘



We use products containing chemicals in our homes every day. Some of these substances can be harmful to health under certain conditions, especially for children or pregnant women. ANSES has conducted ground-breaking studies and expert appraisals to gain a better understanding of the actual exposure of populations, in order to be able to control the chemical risks associated with the use of certain consumer products. In 2019, the Agency made recommendations to industry on how to protect the health of the most vulnerable people. It also took action to strengthen the regulations and make the manufacture of these products safer.



“European regulations need to be changed to make certain consumer products safer.”



TEN YEARS OF EXPERT appraisals on everyday chemical risks

2010

→ First assessment of the health risks associated with the presence of micropollutants in **drinking water**.

2011

→ **Total Diet Study (TDS)** to provide information on exposure of populations to 445 chemicals found in food.

2011

→ Work on the health effects of **bisphenol A** and its uses, including its use in food contact materials.

2014

→ Assessment of the risks associated with exposure to **flame retardants** used in upholstered furniture.

2010

Three questions for...

CHRISTOPHE ROUSSELLE, HEAD OF UNIT AND HEAD OF THE "SUBSTANCE HAZARDS" DIVISION

Why has ANSES recently been looking into the chemicals in certain consumer and hygiene products?

→ Certain everyday products – such as baby nappies, feminine hygiene products and textiles – are not covered by specific regulations. However, they come into direct contact with the skin or mucous membranes, very frequently, over a period of many years. Following formal requests received from the Ministries of Health, Ecology or the Economy, we looked into the hazardous substances not added intentionally by manufacturers but potentially found in these products, such as polycyclic aromatic hydrocarbons, dioxins, pesticides and metals.

What recommendations were made as a result of these expert appraisals?

→ It should be noted that these products are manufactured and sold at a European or even global level. Besides consumer recommendations on practices and conditions of use, we wanted to take steps to improve the safety of these products, which entails changing the European regulations. For example, following the risk assessment we carried out on disposable baby nappies, we are now developing a restriction dossier for the chemicals found in these products under the European REACH Regulation on chemicals. The objective is to limit the presence of these contaminants and to make nappy manufacturing safer, in order to better protect babies' health.

What other products have you tested?

→ We conducted an expert appraisal on textile clothing and footwear that revealed the presence of undesirable substances at unacceptable concentration levels. Here, too, we recommended prohibiting or limiting the presence of more than a thousand substances that can cause skin allergies. On the other hand, for feminine hygiene products such as sanitary towels, tampons and menstrual cups, no risks to consumers were identified, although some undesirable contaminants were detected. This is why we made recommendations for greater vigilance by manufacturers to reduce the presence of these substances, as well as for better information for consumers on the conditions of use.

2015

→ Study of the risks of chemicals migrating from **food packaging** to food when using a microwave oven.

2015

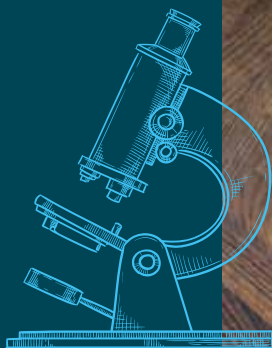
→ Identification of substances released from **furniture products** with a view to specific labelling.

2016

→ Infant TDS study on **children's dietary exposure** to 670 substances.

2016

→ Assessment of the risks associated with hazardous substances in **plastic toys and equipment** that can be put in the mouth by children under 3 years of age.



ANSES's recommendations

BABY NAPPIES

- Eliminate the use of fragrances, especially skin sensitisers.
- Improve control over the origin of natural raw materials, which can become contaminated by undesirable substances.
- Improve nappy manufacturing processes to minimise the presence of dioxins, furans, DL-PCBs, formaldehyde and polycyclic aromatic hydrocarbons.

FEMININE HYGIENE PRODUCTS

- Improve the quality of raw materials.
- Revise certain manufacturing processes in order to eliminate or reduce the presence of chemical contaminants, particularly for substances with carcinogenic, mutagenic or reprotoxic (CMR) effects, endocrine disruptors and skin sensitisers.

TEXTILES AND FOOTWEAR

- Ascertain with suppliers the absence of CMR or sensitising substances at levels above regulatory thresholds.
- Work on an appropriate information system (labelling, packaging) to indicate the potential presence of such substances.



TEN YEARS OF EXPERT appraisals on everyday chemical risks

2017

→ Work on the safety and effectiveness of water filter jugs and **indoor air purification** devices.

2017

→ Initial recommendations on the proper use of external **antiparasitics** for pets.

2017

→ Kannari study updating knowledge on dietary exposure to **chlordecone** in the French Caribbean population.

2018

→ Assessment of the safety of **feminine hygiene** products.

Focus

PESTI'HOME: DOMESTIC USE OF PESTICIDES

Pesticides are also used in the home! From products to protect indoor and outdoor plants, biocidal products against insects, rodents, wood parasites or mould, through to antiparasitic drugs to treat lice, fleas and ticks, the list goes on and on.

To better understand French practices and uses of pesticides, in homes or gardens or to treat pets, ANSES conducted "*Pesti'home*", a vast survey whose results were published in October 2019.

This is the first national study ever conducted in this field, with more than 1,500 households interviewed throughout metropolitan France. The study provided information on the actual everyday uses of pesticides and identified different user profiles. These data are essential for better understanding exposure and the potential health risks and, in particular, for identifying situations of cumulative exposure. In view of the results, ANSES recommended better informing the public on how these products should be used (ventilation, wearing gloves, etc.) and disposed of (they should never be thrown in the bin or poured down the sink).

60%

of households throw unused products in the bin, whereas they should be taken to a waste disposal centre or similar facility provided by their local council



5,408

different products are stored in homes

75%

of households reported using at least one pesticide in the previous year, of which:

84% were insecticides
(3 times a year on average)

22% were herbicides
(twice a year on average)

12% were mosquito repellents
(6 times a year on average)



2018

→ Expert appraisal on the potential risks associated with the use or installation of synthetic pitches made from tyre aggregates for sports fields and playgrounds.

2019

→ Assisted *Santé publique France* with the "**Agir pour bébé**" website for current and future parents, in particular on exposure to harmful chemicals and endocrine disruptors.

2019

→ Work by ANSES on the presence of chemicals in disposable **baby nappies**.

2019

→ **Pesti'home** study to find out more about how the French use pesticides.



Risks associated with new technologies

Mobile telephones, screens, LEDs, virtual reality... Much of ANSES's work drives forward knowledge of the risks associated with technological progress and the new lifestyles and ways of working that come with it. These scientific benchmarks are essential for devising regulations and public policies to better protect populations – especially the most vulnerable – from their harmful effects.



ANSES pays particular attention to risks induced by changes in technologies, sources of exposure (physical agents) and behaviour, in terms of both public health and workers' health. The term "physical agents" refers in particular to the acoustic and electromagnetic environments in which humans live, including audible and inaudible noise, low-frequency and radiofrequency electromagnetic fields, visible light and ultraviolet radiation, for example. For the past 10 years, the Agency has addressed all these areas using the most recent scientific data.

In 2019, ANSES updated several of the opinions it had published in 2010. On exposure to low-frequency electromagnetic fields, the Agency reiterated its conclusions that exposure

should be better documented, exposure of vulnerable populations limited, and occupational exposure controlled. Concerning the health effects associated with the use of LEDs, which have become widespread in domestic and public lighting, the Agency confirmed the toxicity of blue light to the retina and demonstrated disruptive effects on biological rhythms and sleep. The Agency recommended limiting the use of LED devices with the highest blue-light content, especially for children, and reducing light pollution as much as possible to protect the environment. Lastly, in its work on mobile phones carried close to the body, it looked at the specific absorption rate (SAR) and recommended that measures be taken to limit user exposure.



More than a decade of work on radiofrequencies

The rapid development of wireless technologies has raised health, environmental and societal concerns. For more than 10 years, ANSES has been at the forefront of advancing scientific knowledge on the health effects of radiofrequencies. In 2011, it set up a specific “radiofrequencies and health” scheme in order to be able to respond to the many questions raised by this topic, with the creation of an expert group tasked with updating the available knowledge and setting up a forum for dialogue with all the stakeholders.

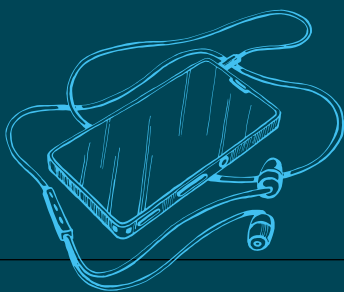
This dialogue committee, whose members include representatives from industry and non-governmental organisations, enables the Agency to explain its methodologies and expert appraisal results, listen to questions from civil society, and debate with researchers and scientific experts.

Since 2011, the Agency has funded around 60 research projects on this theme under the National Research Programme for Environmental and Occupational Health (PNR-EST) that it leads. The results then go on to provide input for the Agency’s health risk assessments.

After publishing two expert appraisal reports in 2009 and 2013 on all the systems using radiofrequencies and the associated health risks, the Agency then produced various targeted expert appraisal reports, such as the one on electromagnetic hypersensitivity published in 2018.

Other work focusing specifically on children’s exposure to radiofrequencies has demonstrated possible effects on cognitive functions and the need to limit exposure to mobile phones. Among the most recent work to date is the expert appraisal on “Linky” smart electricity meters.

The Agency concluded that there was a low probability that exposure to electromagnetic fields emitted by the smart meters, as they are currently deployed, generated health effects in the short or long term. The Agency has also undertaken an assessment of the risks associated with the deployment of 5G technology.



SUPPORTING RESEARCH ON RADIOFREQUENCIES

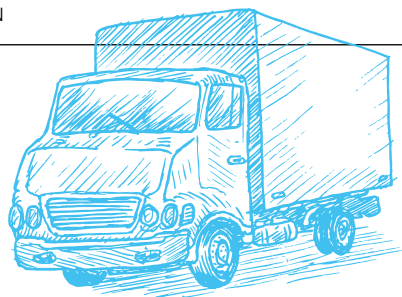
→ Through the National Research Programme for Environmental and Occupational Health and its specific “radiofrequencies and health” call for projects, ANSES funds research to produce the data needed to assess health risks.

→ “Exploratory investigation projects” proposed and funded by ANSES enable specific targeted research to be carried out. This has included an epidemiological study on the symptoms reported by people living near mobile telephone base stations; a project to improve the collection of clinical data for the study of electromagnetic hypersensitivity; and a study to identify and characterise changes in exposure to radiofrequencies linked to new uses and technological developments in wireless telecommunications.

→ The Agency is co-funding the French part of the COSMOS study, a major international epidemiological study on the potential health risks associated with the intensity of use of new wireless technologies (mobile phones, tablets, etc.).

→ TEN YEARS OF ANSES
see our selected highlights on www.anses.fr

Occupational health



Work is very much a part of daily life, and has its own specific and multiple health risks: exposure to pathogens, chemicals, waves, noise, the impact of night work and new technologies, and so on. Preventing these risks is a public health priority in which ANSES plays a major part, working with stakeholders in the field to provide scientific benchmarks for preventive measures according to industry sector.



“The main challenge is to precisely characterise workers’ actual exposure. Before we can act, we need detailed knowledge of the health risks specific to each activity.”

Three questions for...

GÉRARD LASFARGUES, MANAGING DIRECTOR GENERAL OF THE SCIENCE FOR EXPERTISE DIVISION

What are the risks associated with work?

→ There are numerous risks, with health effects ranging from one-off accidents to chronic conditions. In many sectors, there are multiple exposure situations that further complicate risk assessment and the implementation of suitable preventive measures. This is why it is important to fully understand what a job actually involves and the conditions in which it is performed, in order to be able to characterise exposure in as much detail as possible.

What is ANSES's role in the area of occupational health?

→ Our work enables companies, authorities and other prevention stakeholders to better protect workers, in particular by anticipating emerging risks. We act as a watchdog while encouraging the acquisition of data on hazards and exposure, with the help of ongoing monitoring by the National Network for Monitoring and Prevention of Occupational

Diseases (RNV3P). We also fund research. Over time, the National Research Programme for Environmental and Occupational Health has made it possible to organise scientific teams on the theme of occupational health. In addition, ANSES carries out very specific expert appraisal missions for the Ministry of Labour, including providing recommendations for setting occupational exposure limits. Since 2019, ANSES has also been responsible for scientific expert appraisals prior to the creation or updating of occupational disease tables, and formulates recommendations to the regional committees for the recognition of occupational diseases (CRRMP). The Agency is currently examining the expert appraisal on the link between prostate cancer and exposure to pesticides, particularly chlordane, in support of the possible creation of such a table.

What issues do you look at?

→ The Agency responds to requests from ministries, trade unions and employer organisations that are members of its

Board of Administrators. It can also investigate issues on its own initiative. In particular, we look at debates or questions related to new techniques or new occupations. We are interested in all occupational hazards and all workers, from shopkeepers to sewer workers, and from self-employed delivery drivers to underground railway workers. We have thus assessed occupational exposure not only to chemical agents such as ethanol and its compounds, or formaldehyde — which is used in multiple sectors — but also to physical agents such as electromagnetic fields and noise. We have also assessed the risks associated with particular ways of organising our activities, such as night work. We favour an approach based on occupations or industry sectors to take better account of the diversity of exposures, especially when the health risk assessment proves to be scientifically and methodologically complex. In 2019, we assessed the health risks incurred by firefighters and also published an initial study on workers in the recycling and waste management sector.

Focus

THREE EXPERT APPRAISALS IN 2019

Exposure to crystalline silica poses high risks for worker health

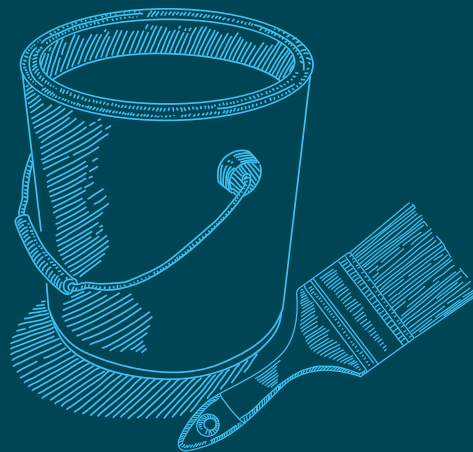
→ Diseases associated with crystalline silica can be seen as a resurgence of the silicosis of the inter-war years, a disease that was linked to coal mining. Nearly a century later, new types of materials containing 80-90 % crystalline silica – such as synthetic resin containing quartz used for kitchen countertops – are available on the market. In many countries where they are manufactured, workers have developed severe and early forms of silicosis. ANSES decided to review the new uses of crystalline silica and the new forms of exposure, as well as the state of available knowledge, in order to inform prevention managers. In its opinion of April 2019, it identified exposure that could exceed health limits, the result being a high risk of developing serious diseases (silicosis, but also lung cancer, autoimmune diseases and respiratory disorders). It also recommended several measures to strengthen worker protection and screening for these diseases, as well as their recognition as occupational diseases.

Food processing and construction: better prevention of the risks associated with titanium dioxide

→ Titanium dioxide is a pigment widely used in food and cosmetics to give products a white colour. It is also found in construction, where it is used in the production of paint and other materials. In 2019, ANSES worked on establishing toxicity reference values to enable public authorities and stakeholders in the field to implement preventive measures. It formulated a proposal on France's behalf for titanium dioxide to be classified and labelled as a carcinogen under the European CLP Regulation, which since 2009 allows for the harmonised classification of chemicals for all Member States of the European Union.

Hairdressers particularly concerned by occupational asthma linked to persulphates

→ A number of workers, especially in the hairdressing sector, are exposed to alkaline persulphates via the inhalation and dermal routes. Persulphates are used in hair bleaching products. They are respiratory sensitisers that promote the development of allergies, sometimes even requiring the sufferer to change occupation. ANSES warned of the large number of hairdressers and apprentices sensitised to this substance, and recommended restricting its use in hair products as much and as quickly as possible.



THE NATIONAL NETWORK FOR MONITORING AND PREVENTION OF OCCUPATIONAL DISEASES

→ Coordinated by ANSES, this network of occupational health professionals includes the 30 hospital-based occupational disease clinics (CCPPs) in France. Based on nearly 30,000 consultations carried out each year, it provides input to a national database (data on patient demographics, disease, exposure, industry sector, occupation). This enables it to identify emerging or re-emerging situations involving an occupational risk at an early stage. In particular, a report on cancer and at-risk occupational situations has been published on the ANSES website. The network also works on prevention and the harmonisation of diagnostic practices for diseases related to work and the environment. It is the first network of clinicians to have promoted the issue of early identification of new occupational diseases at the international level.

HOW ARE OCCUPATIONAL EXPOSURE LIMITS SET?

→ Some occupations expose workers to potentially harmful chemicals by inhalation. In order to prevent risks, the Ministry of Labour sets occupational exposure limits for substances considered to be hazardous.

→ With the help of a specific expert committee, ANSES conducts a scientific expert appraisal prior to setting these values, which enables it to recommend atmospheric or biological concentration levels that protect workers' health. Each year, ANSES assesses between three and five substances defined with the social partners, and proposes suitable measurement methods.

→ Before finalising its expert appraisal, the Agency organises a public consultation on the draft limit values, to enable interested parties to comment on the scientific data identified and used for the expert appraisal, as well as on how they have been interpreted, and to provide additional information if necessary. In late 2019, for instance, ANSES held a consultation on the exposure limits for nanometric titanium dioxide, the solvent 2-methoxy-1-propanol and its acetate, and 2-methoxypropyl acetate.



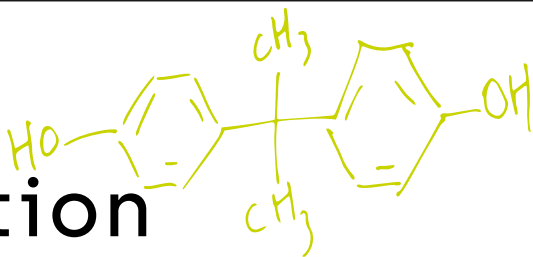
An aerial photograph of a parking lot. In the upper portion, a large building with a facade of horizontal wooden slats is visible. Below the building, several cars are parked in designated spaces. In the lower portion, a road with white lane markings has several cars driving. The overall scene is captured from a high angle, looking down.

ENVIRONMENT- EVENT



Reducing our
exposure
to environmental
pollution

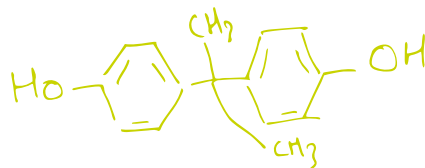
Improved knowledge and identification of endocrine disruptors



Substances identified as endocrine disruptors interfere with hormone functioning and have harmful effects on exposed humans and animals. ANSES is actively developing specific methods to identify them and better understand the hazards and risks they pose. The Agency was one of the first to warn of the health issues associated with these substances, and is heavily involved in the National Endocrine Disruptor Strategy. It is also committed to European initiatives to harmonise scientific and regulatory approaches and better characterise and prevent the health effects.



“We are heavily involved in the National Endocrine Disruptor Strategy, working on 18 of the 50 actions launched in 2019.”



Three questions for...

MATTHIEU SCHULER, RISK ASSESSMENT DIRECTOR

What is an endocrine disruptor?

→ Hormones and their regulation form part of the essential biological mechanisms of living beings. Certain substances, which may be natural or man-made, can interfere with these mechanisms. When these interferences disrupt hormone functioning and have adverse effects on human or animal health, they are known as endocrine disruptors.

What are the issues involved?

→ We are working to identify the substances that cause these effects in humans or animals and understand their mechanisms of action. This identification is complex because the mechanisms of action of endocrine disruptors, like those of hormones, may only be expressed at certain stages of development and may not be correlated with the exposure dose. ANSES studies and assesses the available scientific literature on these substances and, as part of the PNR-EST, has been funding specific research projects with an annual budget

of €2 million since 2018. This enables the Agency to help advance knowledge on the identification and characterisation of these substances, and the search for alternatives. ANSES has now been working for more than ten years on characterising and assessing the risks of endocrine disruptors. We broke new ground by proposing a revision of the methodology previously in force, including in the assessment the concept of “windows of exposure”, i.e. periods during which individuals were more susceptible to endocrine disruption. Their assessment has therefore become more complex, but also more precise.

What is ANSES working on?

→ In addition to our assessments of specific substances, the first National Endocrine Disruptor Strategy, supported by the Ministries of Ecology and Health, led us to identify a method for characterising endocrine disruptors that can be applied to specific substances. We will continue this work in the second National Strategy, launched at the Agency’s headquarters last September. We really are heavily

involved, working on 18 of the 50 actions launched in 2019. Our dedicated group of experts, the Working Group on “Endocrine disruptors”, had already been looking to identify the various lists of substances of interest drawn up. It had also been working on the complex development of a method for obtaining a more detailed post-assessment classification of the substances studied according to whether their behaviour as endocrine disruptors is proven, presumed or just suspected.

At the European level, ANSES is taking part in several regulatory schemes seeking to identify substances that are endocrine disruptors in order to limit their health impact. We therefore act within the framework of the REACH Regulation by filing what are known as use restriction dossiers, and that of specific regulations for biocides and plant protection products. The latter regulation enables the detection and withdrawal of endocrine disruptors identified during the plant protection substance approval process, involving national health agencies alongside the European reference health authority, EFSA.



BISPHENOL A AND BISPHENOL B IDENTIFIED AS ENDOCRINE DISRUPTORS BY ANSES

Very early on, ANSES took an interest in the issue of bisphenol A, now identified as a substance of very high concern in the REACH Regulation. As early as 2011, the Agency published two reports on the health effects and uses of bisphenol A. It identified the priority as preventing exposure to the most vulnerable populations: infants, young children and pregnant or breastfeeding women, and recommended, among other things, replacing bisphenol A in food contact materials. Following its conclusions, in 2012 the French Parliament adopted a law suspending the manufacture, importation, exportation and marketing of all food packaging containing bisphenol A. Thus, since 1 January 2015, it has been prohibited in infant feeding bottles and other food containers. More recently,

ANSES experts conducted an assessment of the endocrine-disrupting properties of bisphenol B, sometimes used as an alternative to bisphenol A, notably in the United States as an indirect additive for certain coatings and polymers in contact with food. The results of this work, published in October 2019 as a paper in the journal *Environmental Health Perspectives*, concluded that the endocrine properties of bisphenol B are similar to those of bisphenol A. Although it is not manufactured or used as a chemical in Europe, its identification as an endocrine disruptor under the REACH Regulation will prevent industry from developing its use or manufacture and will require importers of items to declare the presence of bisphenol B as soon as it exceeds 0.1 %.



National Research Programme for Environmental and Occupational Health

For more than ten years, ANSES has been coordinating and supporting research by funding projects as part of the National Research Programme for Environmental and Occupational Health (PNR-EST). In over a decade, around 500 projects have been funded and more than €70 million have been mobilised to generate new scientific knowledge on occupational health, links between cancer and the environment, air pollution, endocrine disruptors, nanomaterials, plant protection products, etc.

This work, which is published in scientific journals, then feeds into the Agency's risk assessments. Over time, the PNR-EST has adapted to new issues arising, such as the effects of climate change, new technologies or the emergence of contaminants such as microplastics. Each year, new scientific disciplines are integrated in the teams conducting the work. This programme also contributes to the training of doctoral and post-doctoral students, providing ANSES with a pool of future experts for risk assessment. Twice a year, the Agency organises a day of scientific meetings during which researchers present their projects to all interested parties (supervisory ministries, associations, unions, the media, etc.) and exchange views and ideas.

Nearly **500** research projects have now been funded by ANSES in over a decade,

representing more than € **70** million allocated for the production of new scientific knowledge.

IN 2019

Forty projects were selected by ANSES, for a total amount of €6.5 million, including a specific budget of €2 million dedicated to the issue of endocrine disruptors. These projects relate to one or more types of environmental exposure:

- twenty projects concern **chemical agents**, including 11 on **endocrine disruptors** financed mainly by the dedicated budget allocated to this theme. Four specifically address issues of **neurodevelopment** and **neurological disorders**;
- six projects concern **physical agents**, including four on **radiofrequencies** and two on **light pollution**;
- eight projects address questions of **indoor** or **outdoor air quality**, four of which are related to **respiratory diseases**;
- four projects focus on **pathogen vectors** and **vector control**;
- three projects focus on **mineral fibres** and **nanoparticles**, including one on **co-exposure** with **endocrine disruptors**.

They will contribute knowledge in several different fields or disciplines, including:

- **occupational health** (8 projects);
- **cancer** (7 projects);
- **ecosystems** (3 projects);
- **the human and social sciences** (1 project).

↘ **TEN YEARS OF ANSES,**
see our selected highlights on www.anses.fr

Improving air quality ↘



The quality of the air we breathe, both inside and outside our homes, is a major public health issue. ANSES's work advances knowledge of the hazards, exposures and risks associated with air pollutants. It provides a scientific basis for developing public policies and enabling action at the source to better protect our health.

Air pollution includes multiple pollutants (fine particulate matter, nitrogen oxides, volatile organic compounds, ozone, etc.), many of whose harmful respiratory, cardiovascular and neurological effects on health (to name but a few) are already known. While outdoor pollution, such as that caused by vehicle traffic, factories, heating or fires, is what springs to mind most readily, air pollution also affects the indoor environment of our homes and workplaces, because certain materials and human activities emit pollutants into enclosed spaces. For more than a decade, the Agency has been working on developing indoor air quality guidelines (IAQGs) for substances identified as particularly problematic in indoor environments.

IAQGs have now been proposed for 13 substances. In 2019, the IAQGs for trichloroethylene that had been established in 2009 were updated on the basis of the continuous scientific monitoring conducted by the Agency. In addition, ANSES's work in conjunction with research organisations and air monitoring stakeholders has helped improve scientific knowledge as well as public policies and regulatory texts on air quality, in particular by targeting pollutants of concern.

This year, ANSES also provided scientific and technical support for the revision of the ATMO index, designed in 1994 by the Ministry of the Environment and several approved air quality monitoring associations

and used to inform the general public. The revised index will better reflect air quality, for example by including PM2.5 fine particulate matter. Lastly, the Agency has also been studying the links between outdoor and indoor air. In 2019, ANSES conducted an expert appraisal on the transfer of outdoor air pollution to the interior of buildings. Although there are many factors that can influence pollutant transfer, it does not seem possible to rank them. These aspects therefore need to be considered on a case-by-case basis with a broad integrative vision, in the context of construction, building refurbishment or land planning projects.



Focus

EXPERT APPRAISAL ON AMBIENT AIR PARTICULATE MATTER AND THE IMPACT OF ROAD TRAFFIC

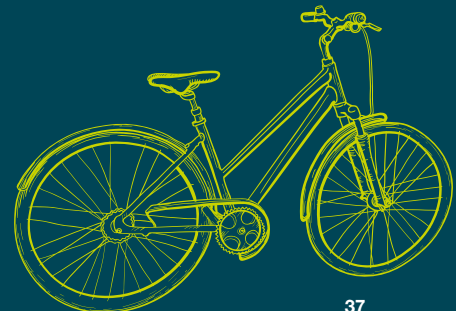
As part of its missions on air quality, ANSES conducts collective expert appraisals to analyse knowledge or assess risks associated with specific situations.

This helps advance risk assessment or monitoring, as it did in 2019 for ambient particulate matter. A systematic review of the scientific literature provided ample evidence and enabled ANSES to confirm the health effects associated with certain components of this particulate matter. The Agency recommended that ultrafine particles, black carbon and organic carbon be tracked as a priority in public policies addressing air pollution.

In the same work, ANSES also confirmed the health effects of exposure to different emission sources such as road traffic or the combustion of coal, petroleum products and biomass, and stressed the need to act on them. While the Agency highlighted technological developments in the motor vehicle fleet, it noted that these alone will not be sufficient to improve ambient air quality in large cities. According to ANSES, reducing road traffic and implementing alternative non-polluting forms of transport are therefore essential for effective action.

SCIENTIFIC MEETINGS ON AIR QUALITY

→ On 17 October 2019, ANSES co-organised a scientific symposium with ADEME to present the progress on expert appraisal of air quality achieved through the research projects it funds under the National Research Programme for Environmental and Occupational Health. The day was a testament to the complementary nature of the two agencies' work, sharing the same goal of encouraging dynamic research and productive dialogue on the issue of air quality. It provided an opportunity to discuss the work carried out on characterisation of pollutant sources and human exposure, along with studies on the health effects and societal impact.



Accidental pollution: the Lubrizol fire ↘

Following the fire at the Lubrizol plant in Rouen, ANSES was promptly asked to assess the potential risks associated with the substances found in the smoke plume. From September to December 2019, the Agency issued six opinions on this industrial accident and, more specifically, on its potential impacts on food safety in the short and medium term.

The large plume of smoke produced by the fire of 26 September deposited particles over a very large area. The authorities rapidly commissioned measurements and sampling in order to determine which hazardous substances may have been emitted. To supplement the emergency

strategy implemented, ANSES was asked to identify the main substances likely to have health effects, according to the different routes of exposure. Its contribution complemented the work of INERIS, the reference body for industrial risks, which drew up a list of substances that

may have been released into the environment, and the areas exposed following a fire of such magnitude. The Agency also gave its view on the adequacy of the specific surveillance and sampling measures taken with regard to agricultural and food production, and drinking water.

PROTECTING HUMAN HEALTH IN THE SHORT TO MEDIUM TERM

In the days following the fire, farm animals may have consumed food contaminated by particle deposition. Moreover, although soot-contaminated crop production was excluded from consumption, other crops may have been polluted by less visible particles. ANSES's work, based on the analyses received, did not find any contamination levels that could lead to increased

risks of dietary exposure in the short term. Medium-term concerns related to the possible persistence in the environment of pollutants that could migrate into food, or even accumulate via water, soil, plants consumed by farm animals or directly by humans, thereby constituting sources of chronic exposure to pollution from the fire.

With a view to optimising surveillance and sampling plans over time, ANSES therefore recommended that soil, pasture and food contamination should continue to be monitored for one year, especially for open-field crops and livestock reared outdoors. Production to be monitored more closely included milk, eggs, farmed fish, root vegetables and maize silage.





The fire at the Lubrizon plant and its consequences: ANSES's six opinions in 2019

10 OCTOBER

→ Food risks associated with the fire

14 OCTOBER

→ Specific expert appraisal on milk analyses

18 OCTOBER

→ Post-accident food risks

21 OCTOBER

→ Specific expert appraisal on monitoring of drinking water

28 NOVEMBER

→ Long-term monitoring of food

18 DECEMBER

→ Monitoring of drinking water in the Hauts-de-France region

LEAD POLLUTION: VIGILANCE REGARDING EXPOSURE VIA OUTDOOR AREAS

→ Lead is toxic to health, especially for young children. It is emitted into the air from industrial or small-scale work sites, or released due to erosion from architectural features. Lead can contaminate various media, including food, and dust from outdoor or indoor air. Contamination can also be caused by accidental pollution, as was the case with the fire at the cathedral of Notre-Dame de Paris in April 2019.

→ ANSES therefore examined lead exposure via contaminated dust deposited on the surfaces of outdoor public areas such as pavements, roads, street furniture, outdoor playgrounds, etc. In its opinion issued in early 2020, the Agency concluded that it should be considered as a source of exposure, and made recommendations on reducing it, targeting mainly children and certain professionals, who are especially likely to be exposed through contact or ingestion.



Assessing and monitoring the impact of plant protection products ↘

Plant protection products are part of the arsenal that can be used to combat plant pests. Because these products are not without danger, their authorisation and monitoring has been entrusted to a health authority. In 2019, ANSES granted authorisations but also withdrew products from the market, and suggested some changes to strengthen the European regulatory framework. It also continued its work to gain a better understanding of the health effects of using plant protection products on both humans and the environment, in order to improve their protection.

PROTECTING THE HEALTH OF RESIDENTS

→ Protecting populations when plant protection products are used is a European regulatory requirement. For each marketing authorisation application, ANSES therefore assesses the health risks to operators, workers and local populations, and prescribes minimum distances from residents and walkers when treating crops. Pending changes to existing marketing authorisations, in June 2019 ANSES recommended establishing minimum safety distances at values at least equal to the distances taken into account in the assessments. As a precautionary measure, it also recommended increasing these distances for products containing active substances with assumed or suspected carcinogenic, mutagenic or reprotoxic effects. In December 2019, ANSES published an additional opinion on the different ways of reducing exposure to product drift during spraying.



→ ANSES is involved in the European process to assess and authorise plant protection active substances and products. It also closely monitors the effect of products available on the market with the help of phytopharmacovigilance, a scheme specific to France that coordinates some 20 partner organisations. This is used to collect field data (residues in soil, water, air and food, exposure levels, health effects) and also funds specific studies. These missions concern all products, including those used in organic farming.

When ANSES identifies any effects for a product or product class, through either its own studies or a careful review of the recent scientific literature, it does not hesitate to review the marketing authorisations for these products in order to restrict or even withdraw the authorisations, or just some of the authorised uses. In 2019, on the basis of the new European guidance document on the identification of endocrine disruptors, it withdrew from the market 76 products containing epoxiconazole, a fungicidal active substance widely used on cereal and beet crops, after having assessed and confirmed its

↘ **Plant protection products, however useful they may be, are not completely harmless. They also contribute to overall exposure to chemicals from human activities. ANSES supports the principle of reasoned use of these products that is as low as possible, in order to limit the exposure of workers and the general population, as well as that of living organisms and ecosystems. Minimal use also means it is possible to protect crops from the main pests while preserving the effectiveness of plant protection products from resistance phenomena observed in pathogens, insect pests and invasive plants.** ↙

endocrine-disrupting nature. This withdrawal went ahead without waiting for action to be taken by the European Union.

ANSES is also responsive to reports from whistleblowers. In early 2019, it published the results of an emergency collective expert appraisal on succinate dehydrogenase inhibitor (SDHI) fungicides. This concluded that in light of the available scientific data, there was no health alert. However, ANSES called for vigilance at European and international level and made funding available to step up research on the potential toxicological effects of these substances for humans. The phytopharmacovigilance scheme has since been used to document exposure and detect possible health effects of SDHIs in the field. In 2020, the Agency will also publish the results of its internal request on cumulative exposure to different SDHIs via food.

While ANSES's mission is to conduct scientific assessments of plant protection products with regard to the requirements of European regulations, it also regularly makes proposals for improving the methods used for assessing these products. For example, in 2019, it recommended to the regulatory authorities improvements in the methodology for assessing long-term risks to bees and other pollinators based on the guidance document proposed by the European Food Safety Authority (EFSA).

Focus

ANSES'S WORK ON GLYPHOSATE

Glyphosate is an active substance used in herbicides and approved by the European Union until December 2022. Following the controversies of recent years, in particular regarding its carcinogenic potential, the European framework for assessing products containing glyphosate was strengthened. In 2018, France initiated a national glyphosate withdrawal plan designed to phase out its main uses by late 2020. In this context, ANSES took part in a number of actions, with several highlights in 2019:

European re-assessment of the active substance glyphosate

→ ANSES took part in this re-assessment initiated on 15 December 2019 and led by a consortium of States (Hungary, Sweden, the Netherlands and France/ANSES). The Assessment Group on Glyphosate will submit its draft report to EFSA by June 2021, the first step in the European assessment needed for the decision on whether or not to renew glyphosate's approval after 2022.

Call for tenders issued to study the carcinogenic potential of glyphosate

→ The specifications were developed with a group of experts convened by the Agency. The call for tenders issued in August 2019 will enable research teams to be selected to conduct independent toxicology studies. The aim is to improve knowledge of the hazard characteristics of glyphosate, and in particular its carcinogenicity. Work will start in 2020 with results expected in 2021.

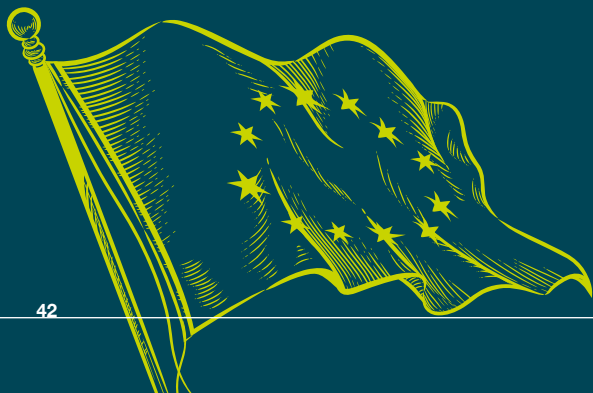
Comparative assessment with non-chemical alternatives

→ As part of the implementation of Article 50.2 of the European regulation on plant protection products, ANSES re-assessed glyphosate-based products for which marketing authorisation (MA) applications had been submitted. On the basis of this article, uses of glyphosate-based products for which there are accessible alternatives may no longer be authorised. ANSES was assisted in this task by INRAE, which publishes reports that analyse non-

chemical alternatives for the main agricultural uses. In addition, in December 2019 the Agency announced the withdrawal of marketing authorisations for 36 products and its refusal to authorise six new products. The reason given was that the studies provided by the MA holders to demonstrate the absence of any genotoxicity of the products as formulated were incomplete or inadmissible.

Publication of data from the phytopharmacovigilance scheme

→ In order to watch out for any possible adverse effects of plant protection products, the Agency collects data on the presence of substance residues in the environment, and on exposure and the impacts on human health and ecosystems. In October 2019, it published a summary of monitoring data on the presence of glyphosate and its main metabolite, aminomethyl-phosphonic acid (AMPA), in water and food, as well as on blood contamination levels.



ASSESSMENT AND AUTHORISATION OF PLANT PROTECTION PRODUCTS

Plant protection products must obtain authorisation before they can be placed on the market, on the basis of a scientific assessment whose criteria are laid down in specific European Union regulations. The active substances contained in these products must first go through a scientific assessment and approval process at European level.

Commercial products containing these substances are then assessed by geographical zone containing several countries, before marketing authorisation can finally be granted at the level of each Member State. In France, ANSES has been responsible for this task since 2015.

1. Before a plant protection product can be marketed in France, the active substance it contains must first have been approved at European level. If this is the case, the manufacturer must then submit a marketing authorisation application to ANSES, including the studies required by the regulations and any relevant scientific publications. The studies must have been carried out with the formulated product as it will be used, in order to take into account the effect of all the components: active substance(s) already approved by Europe as well as co-formulants.

2. The Market Authorisations Department at ANSES checks the administrative admissibility of the application dossiers, then forwards them to the department responsible for evaluating these products, for a scientific assessment of the data provided and their compliance with regulatory requirements.

3. ANSES assesses the products' effectiveness and the risks associated with their use for applicators, workers, residents and people in the vicinity of application sites, as well as for consumers, the environment, fauna and flora. To do this, the Agency calls on teams of scientific assessors specialising in different disciplines (chemistry, toxicology, ecotoxicology, etc.) and is supported by an independent expert committee. The assessment takes into account data from the scientific literature and from surveillance schemes.

4. On the basis of this assessment, which is shared with the other Member States in Europe's South zone, decisions to grant or refuse authorisation are issued for each use of the product and for a defined period of time. The decisions define the conditions of use and, if necessary, restrictions on use according to any risks identified.

5. ANSES authorises the sale and use of each product through this marketing authorisation. However, the authorisation, which allows products that have been tested for effectiveness and the absence of any harmful effects to be made available for a given use, does not constitute a prescription for use.

ANSES supports the principle of the lowest possible use of these products in circumstances where there is no alternative to their use to protect crops. Authorisations may be restricted or withdrawn at any time if justified by new scientific or surveillance data.



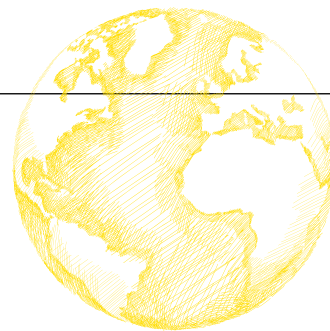
ECO-SYSTEMS



Getting
a head start
on health
threats

3

Dedicated to “One Health” ↘



ANSES’s scope of action covers health threats to humans, animals and plants. In a world where borders are blurring and unprecedented new threats are emerging, such as the COVID-19 pandemic, the Agency reaffirms its commitment to European and international “One Health” scientific co-operation. The aim is to increase the alert and action capabilities of health authorities worldwide.

With expertise in human, animal and plant health, it is only natural that ANSES adopts a cross-cutting approach to health issues. As all living organisms and ecosystems are interconnected, the Agency can plainly see how closely the health of some depends on the health of others, and how they are all suffering the health consequences of the globalisation of trade and global warming. This is why ANSES is guided by the “One Health” principle – an integrated, holistic approach to health – as set out in the various national, European and international action plans in which the Agency is involved.

As part of the European Commission’s Horizon 2020 programme, since January 2018 ANSES has been coordinating the “One Health” European Joint Programme (EJP), which seeks

to build a genuine European research area for foodborne zoonoses, antimicrobial resistance and emerging risks. Because a global perspective is needed now more than ever before to anticipate new threats, the Agency has also been taking part in the recent MOOD project to develop innovative tools for health monitoring and early detection of warning signals. In particular, it has contributed its expertise on antibiotic-resistant bacteria in the animal world, a subject on which it also actively promotes broad and reinforced surveillance of animal exposure to these bacteria. The RESAPATH network, which it coordinates, is the only monitoring scheme on this subject in the European Union. ANSES is also heavily involved in three fields of health risks where a holistic view is necessary: vector-borne

diseases transmitted in particular by mosquitoes, ticks and phloem-feeding insects; bee health; and the interface between wildlife and domestic animals, which plays a crucial role in the emergence or resurgence of many animal and human diseases. In 2019, the Agency actively contributed to improving the scientific benchmarks mobilised to combat the spread of bovine tuberculosis by badgers, or of African swine fever by contaminated wild boars at the Belgian border. It also helped advance knowledge on the modes of transmission and circulation of Lyme disease in our country. Lastly, ANSES is an international reference laboratory for several diseases transmitted by wildlife, such as rabies and bovine tuberculosis.

THE “ONE HEALTH” EUROPEAN JOINT PROGRAMME (EJP)

This programme, coordinated by ANSES, brings together more than 40 partners from 19 Member States, including the MED-VET-NET network of excellence on foodborne zoonoses. It supports scientific research on micro-organisms and contaminants that affect human health, animal health and the environment, particularly through food. Besides ANSES, the other French partners of the “One Health” EJP are INRAE, the *Institut Pasteur* and *Santé publique France*. Launched in January 2018 for five years, it has a budget of €90 million provided by the European Commission and the Member States.

Its objectives are to:

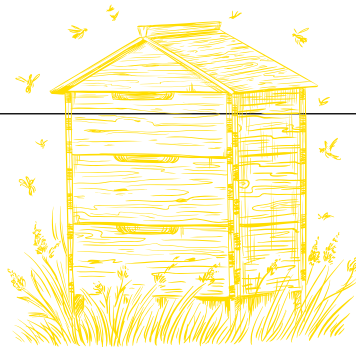
- fund research projects in the areas of foodborne zoonoses, antimicrobial resistance and emerging risks;
- generate scientific data to be used as input for the analysis and assessment of health risks by national and European agencies;
- bring public and veterinary health agencies closer together and ensure the effective dissemination of information within the scientific community.

ANSES's laboratories responded to the second call for research projects in 2019 and are participating in 12 new partnership programmes with a total budget of €3.5 million. These activities were highlighted at the first annual scientific meeting of the “One Health” EJP in Dublin in May 2019, an event that consolidated the foundations of the project's scientific community. This joint programme is also a powerful tool for responding to health crises: in early 2020, it set up a “Joint Integrative Project” to organise its members' response to the SARS CoV 2 crisis.

MOOD: RETHINKING GLOBAL HEALTH MONITORING TO ADDRESS EMERGING DISEASES

- The European MOOD project – MOnitoring Outbreak events for Disease surveillance in a data science context – aims to unify and strengthen health monitoring systems. Improving epidemic intelligence tools and services could, in particular, enable earlier identification of the risk of introduction and spread of a new pathogen, and of the areas favourable to its spread. Coordinated by CIRAD as part of the European Horizon 2020 programme, MOOD has a budget of €14 million and brings together 25 research institutions, public health agencies and veterinary services from 12 countries. When it comes to an end in late 2023, its participants will have developed new monitoring tools to complement existing ones, for sharing by all countries. The epidemiologists of ANSES's Lyon Laboratory are contributing to this project.

Protecting bee health



Diseases, predatory insects, pollen depletion, pesticides... ever since it was founded, ANSES has been studying and assessing co-exposure to stress factors that threaten bees, and proposing scientific and regulatory solutions to protect their health. Its Sophia-Antipolis Laboratory has established itself as a national and international reference in the field.

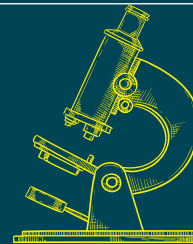
Pollinating insects are essential to the reproduction of many plants. Honeybees and wild bees, which together account for 90% of these insects, are affected by a worrying worldwide phenomenon of excess mortality that threatens plant diversity and the food supply. Since its creation, the Agency has been particularly active on this subject, with a global approach to risk factors that takes no account of national borders.

Among other things, the Agency has distinguished itself by highlighting the multifactorial nature of bee colony collapse, showing a complex situation of interactions between pathogens, parasites such as *Varroa*, and chemicals. Some of these chemicals, particularly insecticides of the neonicotinoid family, reduce the bees' immune defences and make them more susceptible to pathogens. They also inhibit their detoxification abilities, and interfere with their orientation and communication.

These stress factors are compounded by declining food resources due to the loss of biodiversity, especially in the flowers most prized by bees, and climate change. In view of these findings, ANSES has recommended several avenues of work to be explored, such as the development of improved multi-residue measurements on bee specimens and hive products to better identify the molecules found in the insect's environment, and the creation of a network of reference apiaries to better analyse the situation of colonies in the different regions. The Agency has also recommended strengthening requirements for the protection of bees and other pollinators in the preparation of marketing authorisation applications, and restricting the use of certain plant protection products in order to limit their contact with pollinating insects.



ANSES's recommendations on reducing bee exposure to plant protection products



→ Systematic assessment of acute and chronic risks to adult bees, larvae and bumble bees in the context of product marketing authorisation applications.

→ No application of any products — not just insecticides — during periods when crops are attractive to bees and other pollinating insects.

→ In the studies to be carried out for marketing authorisations, better assessment of long-term risks to bees and other pollinators, including the introduction of measurement of the time taken to return to the hive.



10 YEARS OF EXPERT APPRAISALS ON BEE HEALTH

2011

→ The Sophia-Antipolis Laboratory, which has been in operation for more than 40 years, was named European Union Reference Laboratory for bee health.

2014

→ The Sophia-Antipolis Laboratory contributed to the European SmartBees project, focused on the natural resistance of bees to the major parasite *Varroa destructor*.

2018

→ Recommendations to strengthen national provisions imposing restrictions on the use of plant protection products during periods when crops are attractive to these insects.

BETWEEN 2012 AND 2015

→ ANSES conducted an expert appraisal on the effects of co-exposure of bees to various stress factors and their respective role in colony weakening, collapse or mortality phenomena.

2015

→ Expert appraisal on the ranking of bee diseases.

2019

→ Recommendations to improve risk assessment methods in the framework of marketing authorisation applications for plant protection products.

2014

→ The Sophia-Antipolis Laboratory coordinated the EPILOBEE survey, a vast European epidemiological surveillance programme seeking to better characterise the phenomenon of excess bee mortality.

2016

→ Expert appraisal on the risks of insecticides containing substances from the neonicotinoid family.

2019

→ ANSES and the European Food Safety Authority (EFSA) organised an international scientific conference in Paris on bee health and how research can contribute.

2018

→ The Sophia-Antipolis Laboratory contributed to the European PoshBee project to quantify the pesticide hazard for bees.

2011

↳ TEN YEARS OF ANSES,
see our selected highlights
on www.anses.fr/en

2019

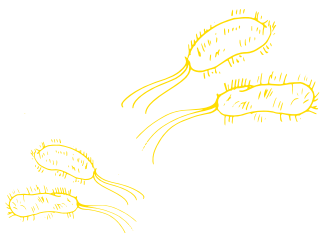
Combating bacterial resistance to antibiotics ↘



Animal health is one of ANSES's areas of excellence, supported by its research laboratories and, within its Regulated Products Assessment Department, by the French Agency for Veterinary Medicinal Products (ANMV).

At the crossroads of their activities, the use of antibiotics on farms, the selection of resistant bacteria and their consequences for human health are a subject where vigilance is still required, despite the progress observed.

ANSES is the National Reference Laboratory for antimicrobial resistance, and as such it monitors bacterial resistance in the food chain as part of surveillance plans that have been harmonised at European level. For its part, the ANMV grants marketing authorisations for veterinary antibiotics in France and monitors their use and effectiveness under actual conditions of use, taking into account the particular risk of selection of resistant bacteria.



In November 2019, to mark World Antibiotic Awareness Week and European Antibiotic Awareness Day, ANSES published three reports reviewing the situation regarding antimicrobial resistance in animal health in 2018:

→ The first report was its sales survey of veterinary medicines containing antimicrobials in France, based on sales data from the ANMV and one-off surveys on livestock farms carried out by ANSES laboratories, which provided descriptive data on the prescription and use of antibiotics.

→ The second report consolidated the findings of RESAPATH, the French Surveillance Network for Antimicrobial Resistance in Pathogenic Bacteria of Animal Origin. Coordinated by ANSES, RESAPATH is the only surveillance network of its kind in Europe.

→ The third report focused on post-marketing authorisation surveillance of veterinary medicinal products, including the monitoring of adverse effects reported by the pharmacovigilance scheme for veterinary medicinal products run by ANSES.

These reports' main findings are encouraging: since 2011, exposure to antibiotics for all animal species combined has decreased overall by 38.4% and the volume of sales of veterinary antimicrobials has fallen by 48%. Efforts for the prudent and responsible use of antimicrobials in veterinary medicine must however continue. ANSES's data on antimicrobial resistance are used to assess the effectiveness of public policies on antibiotic use, in line with the 2016 interministerial roadmap to control antimicrobial resistance by taking human, animal and environmental health into account according to the "One Health" approach.

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VETERINARY MEDICINAL PRODUCTS: ACTIVE PARTICIPATION IN IMPLEMENTING THE NEW EUROPEAN REGULATIONS

→ New EU regulations for veterinary medicinal products and medicated feeds came into force in January 2019. Their implementation will require numerous delegated and implementing acts. In order to prepare these, the European Commission mandated the European Medicines Agency (EMA) to provide scientific and technical opinions. The ANMV experts within ANSES

have been heavily involved in the working groups set up by the European agency, holding several chairs and co-chairs. In particular, they have been working to define criteria for drawing up the list of antibiotic substances to be reserved for human medicine, and the arrangements for collecting data on the sale and use of antimicrobial drugs used in veterinary medicine at Euro-

pean level. Concerning the establishment of a common database of veterinary medicinal products in the European Union, an expert group chaired by the Deputy Director of the ANMV made recommendations in late August 2019 to set up a reference database that is interconnected with other European databases and tools.

Preserving the health of plants and ecosystems ↘



The plants populating our natural and cultivated areas face threats that are continually evolving. Climate change and human activities are altering ecosystems and promoting the emergence or re-emergence of diseases and pests. International trade is increasing and can also accelerate the introduction of pests from neighbouring or distant countries. The Plant Health Laboratory helps prevent health crises and protect our plant heritage and crops. It saw a number of major events in 2019.

AVOID CONFUSING EDIBLE PLANTS WITH TOXIC PLANTS

→ Some toxic plants (such as horse chestnut or lily of the valley) resemble edible plants, and may be confused with them not only in the wild, but also in the garden or vegetable patch. Two hundred and fifty cases of confusion are documented by the French poison control centres every year. ANSES, which coordinates the national toxicovigilance scheme and the activities of the poison control centres in this area, reviewed these poisonings and called for greater vigilance with regard to such cases of mistaken identity.

↘ Find out more on www.anses.fr/en

XYLELLA FASTIDIOSA, A THREAT TO OUR OLIVE TREES

The *Xylella fastidiosa* bacterium threatens more than 500 plant species, including grapevines, almond, citrus, oak, coffee and especially olive trees. Transmitted by insect vectors that feed on sap (xylem), it causes infected plants to dry out. After the disease arrived in France in 2015, a surveillance plan was put in place to prevent its spread. If detected, any infected plant is destroyed. The Plant Health Laboratory is the National Reference Laboratory for identification and detection of the bacterium. Since 2015, 48,000 samples taken from ornamental, wild, aromatic or cultivated plants have been analysed by the specialised unit in Angers. In Montpellier, the Pests and

Invasive Plants Unit identifies insect vectors of the disease, such as meadow spittlebugs, a members of the leafhopper family. In 2019, ANSES confirmed the presence of *Xylella fastidiosa* on two olive trees in the Provence-Alpes-Côte d'Azur region. Scientists were able to determine that one was contaminated with subspecies *pauca* and the other with subspecies *multiplex*. This discovery led to the introduction of enhanced surveillance measures, the only way to combat this disease. Along with INRAE and EFSA, ANSES co-organised a scientific symposium on the subject, which brought together more than 300 participants in Ajaccio.

PHILIPPE REIGNAULT, DIRECTOR OF THE PLANT HEALTH LABORATORY

"The Plant Health Laboratory plays a major role in hazard detection and risk assessment thanks to more than 40 years of experience, scientists with rare expertise in mycology, entomology, virology, national and European reference mandates for all pests, state-of-the-art technologies and a unique quarantine system. Together with the Lyon Laboratory, which studies phenomena of resistance to plant protection products and is involved in monitoring outbreaks, ANSES has a coherent whole, capable of advancing science to keep pace with the changes observed. This means producing ever more comprehensive scientific knowledge, developing yet more effective detection and identification methods, and acting in synergy at European and international level, in order to remain vigilant and ready to tackle threats and emerging phenomena, which are today global and diverse."



HIGH ALERT FOR PINE TREES AND TOMATOES

The pinewood nematode *Bursaphelenchus xylophilus* on the doorstep of the Landes forest

A microscopic worm responsible for significant dieback in conifers, the pinewood nematode poses an imminent threat to forests of maritime pine in France. Currently found in Portugal and Spain, it could contaminate the Landes area. Following the interception of bark and wood packaging containing the nematode, ANSES conducted several expert appraisals to assess the risk of the pest's entry and spread in France. The Agency immediately made recommendations on the use of wood and bark likely to be affected.

Alert regarding Tomato brown rugose fruit virus (ToBRFV)

ANSES also worked to tackle a new emerging virus threatening tomato, chilli pepper and sweet pepper crops in France. Simple physical contact with a diseased plant is enough to contaminate a healthy plant. The virus can also survive in the open air for several weeks or even months without losing its infectivity. There is currently no treatment, and no variety is resistant to this virus. In its expert appraisal, ANSES warned of the high risks of introduction of the virus and reiterated the importance of the measures to be adopted to prevent its spread across France. The Plant Health Laboratory conducted the analytical tests that confirmed the case of contamination in Finistère.

Our laboratories, risk watchdogs ↘

Always on the lookout for recurring and emerging health risks, the ANSES laboratories explore threats and help combat them in three areas of key importance: animal health and welfare, plant health and food safety.

Besides their contribution to the Agency's expert appraisals of health issues, they conduct scientific research, often in partnership with French and international research organisations, and design ever more powerful detection and identification technologies that improve understanding of both the spread of pathogens and their interactions with hosts. They hold numerous reference mandates, and help public authorities monitor, prevent and manage health crises in France or beyond our borders.

In 2019, ANSES obtained three of the five new reference mandates in plant health introduced by the European Commission. These cover fungi and oomycetes, insects and mites (with the Austrian

agency AGES), and nematodes (with the Belgian institute ILVO). For the latter two, ANSES is in charge of managing the consortia formed. These were the very first European mandates established for plant pests.

At the same time, ANSES took the helm of a new reference centre for animal welfare. In late 2019, it was appointed to lead the new European Reference Centre for the welfare of poultry and other small farmed animals, together with its partner organisations in Spain, Italy and Denmark. The objective is to improve husbandry conditions at all key stages in the animals' lives: from birth or hatching through to slaughter or end of life.

WHAT DO WE MEAN BY REFERENCE?

→ For certain pathogens or chemical contaminants of major importance, the health authorities set up specific surveillance schemes. At the national level, for each theme, State services approve a network of field laboratories to carry out official analyses, and appoint a "National Reference Laboratory" (NRL), whose role is to guarantee the reliability of the analyses carried out and

to manage the network of laboratories.

→ The schemes in each country are supplemented and coordinated at European and international level. For example, the European Commission appoints "European Union Reference Laboratories" (EURLs) to run the network of National Reference Laboratories on the same topic. Meanwhile, at the

international level, the World Organisation for Animal Health (OIE), the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) appoint reference laboratories, reference centres or collaborating centres to provide the necessary technical assistance to these organisations and to Member States.

Reference mandates

→ At end 2019, ANSES held 65 national reference mandates, 13 European mandates and 28 international mandates including:

MAISONS-ALFORT - NORMANDIE

Animal health

- 11 international mandates (FAO & OIE)
- 3 European mandates
- 19 national mandates

MAISONS-ALFORT - BOULOGNE-SUR-MER

Food safety

- 2 European mandates
- 9 national mandates

FOUGÈRES

Animal health, veterinary medicinal products, food safety

- 1 European mandate
- 2 national mandates

French Agency for Veterinary Medicinal Products (ANMV)

- 1 OIE international mandate

PLOUFRAGAN - PLOUZANÉ - NIORT

Animal health

- 4 OIE international mandates
- 1 European mandate
- 16 national mandates

NANCY

Hydrology

- 2 national mandates

Rabies and wildlife

- 2 international mandates (WHO and OIE)
- 2 European mandates
- 2 national mandates

LYON

Animal health, plant health, food safety

- 1 national mandate

ANGERS

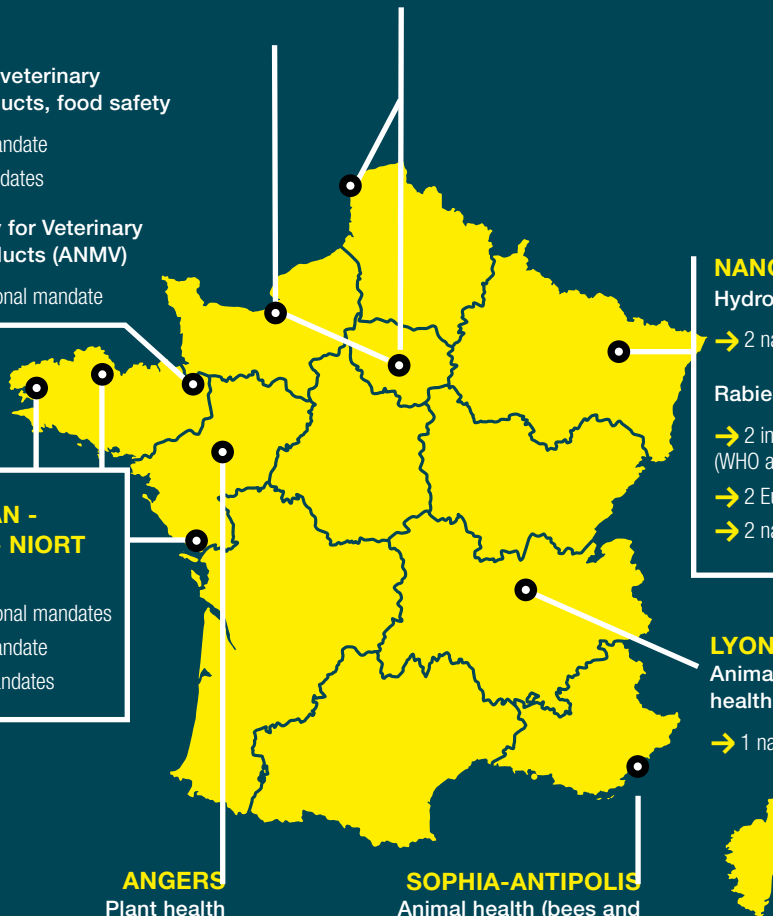
Plant health

- 3 European mandates
- 12 national mandates

SOPHIA-ANTIPOLIS

Animal health (bees and ruminants)

- 2 OIE international mandates
- 1 European mandate
- 2 national mandates



GILLES SALVAT, MANAGING DIRECTOR GENERAL OF THE RESEARCH AND REFERENCE DIVISION



CROSS-CUTTING LINKS

"Our scientific skills and the co-operation between teams give us a broad vision of the issues at stake, which is needed to answer increasingly complex questions. For example, a unit of ANSES's Laboratory for Animal Health worked with the French Agency for Veterinary Medicines on the resistance of certain cattle parasites to antiparasitic compounds, and on the release of these products into the environment with possible impacts on bee health. This has led us to consider alternative control concepts and review animal husbandry conditions, which then also responds to societal demand for more ecological solutions and improved animal welfare."

OUR SCIENTIFIC DYNAMISM IN FIGURES

394 ANSES scientific publications in international peer-reviewed journals (category A+ and A) in 2019

A success rate in competitive calls for projects of **46%**

58 foreign scientists hosted in our laboratories to carry out activities as part of scientific co-operations

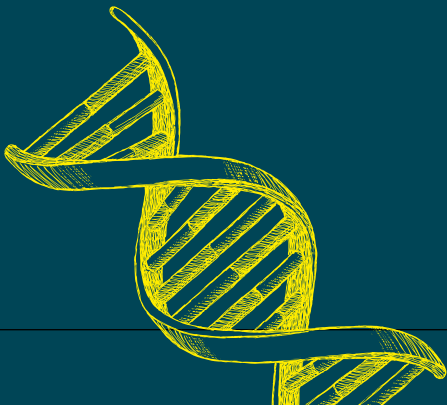
3 framework agreements signed in the past year, with:

- French Agricultural Research Centre for International Development (CIRAD);
- University of Rennes 1;
- University of Paris-Est Créteil

Focus

GENOMICS FOR IDENTIFYING FOOD PATHOGENS

ANSES is interested in cutting-edge research and diagnostic techniques, and particularly in the opportunities provided by genomics. In 2019, with its German, Danish and Korean counterparts, the Agency organised an international symposium on the impact of an approach that is becoming increasingly widespread: whole genome sequencing of foodborne pathogens, in order to explore and discuss international practices and partnerships, whether already established or to come. Last year, for example, this major technological leap helped identify genomic markers of the animal species that was the original host of *Campylobacter jejuni* (the bacterium that is the primary cause of food poisoning in France), and led to the discovery that in addition to poultry meat, consumption of undercooked beef was also a major source of food poisoning in France. This work, published in a leading international scientific journal, will in the future play an essential role in guiding prevention policies against this bacterium.



RESEARCH: FLAGSHIP PUBLICATIONS IN 2019

While support for public authorities is the priority for ANSES's laboratories through their monitoring and reference work, research is the basis of their activity. The work carried out covers the entire spectrum, from fundamental research through to methodological developments specific to applied research.

Our teams' scientific publications in 2019 perfectly illustrate this continuum. For example, they have led to improved methods for the detection of *Xylella fastidiosa* and of hepatitis E virus in foods, and the development of three-dimensional liver cell culture methods for use in toxicology models. Other teams have shown how the pandemic H1N1/2009 influenza virus passed from humans to pigs and then from pigs to humans, or the role of cleaning and disinfection practices in selection of antibiotic resistance genes in bacteria of the *Salmonella* genus.

In a more fundamental research field, several studies have furthered knowledge of the interactions between pathogens and their hosts or pathogens and their vectors, which will help improve techniques for combating the animal and human diseases transmitted by these pathogens. For example, modification of tick cell microRNAs by *Anaplasma phagocytophilum*, understanding of novel functions of the bluetongue virus NS3 protein in regulation of the MAPK/ERK intracellular signalling pathway, or the role of the α -synuclein protein in the expression of Parkinson's disease, are just some of the flagship publications in the broad field covered.

SOCIETY





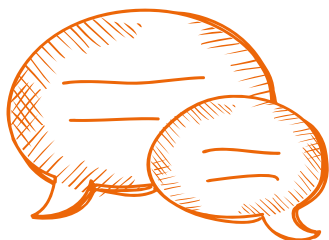
Cultivating dialogue and openness

In tune with stakeholder expectations ↘

Information and dialogue lie at the heart of ANSES's value and the trust it inspires. To take account of society's concerns and expectations, the Agency has set up dialogue committees on several topics of debate: nanotechnologies, radiofrequencies and plant protection products. In addition to fostering the sharing of information, this proximity demonstrates the Agency's desire for transparency and the requirement it has set itself to stay in tune with society.



"ANSES has been a pioneer, forging links with stakeholders right from its inception."



Three questions for...

RÉGINE FRAYSSE-BOU TRAIS, SOCIOLOGIST, TASKED WITH DEVELOPING RELATIONS WITH STAKEHOLDERS

What are the positive effects of opening ANSES up to society?

→ ANSES has been a pioneer in this field right from its inception, forging links with stakeholders on emerging societal issues such as environmental health and animal welfare. Over time, thanks to this dialogue, we have seen an increase in the skills and knowledge of stakeholders. Initially, misconceptions about ANSES's work processes and the regulatory framework in which it operates gave rise to tensions and misunderstandings. Openness to society has led to a better understanding of the Agency's opinions and an awareness of the limitations it sometimes faces due to scientific uncertainties or gaps in knowledge.

Does this openness have benefits for ANSES?

→ Dialogue improves the Agency's ability to understand societal concerns and makes its expert appraisals more robust as they then take better account of society's doubts and questions about different types of exposure and their effects. This then strengthens the credibility of ANSES's recommendations and its reputation. We are also better able to identify emerging societal expectations, particularly on subjects such as new technologies or plant protection products. Lastly, opening up to all the stakeholders helps the Agency keep its distance from influence and lobbying strategies, for which we have also set up in-house training and awareness-raising initiatives.

What are the prospects offered by openness and dialogue?

→ The Agency is just one part of a much larger process of public policy development. We are sometimes the repository for concerns that go beyond the Agency's risk assessment missions or the regulatory framework in which some of them take place. Should new dialogue interfaces be created? Can we imagine ANSES being part of a broader mechanism for consultation and debate with society? These issues are among the themes that will be addressed at the international symposium "Credibility of public expertise and public decision-making" that the Agency is organising in early 2021.

"Opening up to all the stakeholders helps the Agency keep its distance from influence and lobbying strategies."

WHAT IS A STAKEHOLDER?

→ A stakeholder is a person or organisation that can influence, be influenced by, or feel influenced by a decision or activity. In all its areas of activity, ANSES considers associations (of citizens, consumers, patients,

victims, or for environmental or animal protection), professional organisations (including industry representatives), and trade and agricultural unions. These players are all represented on its Board of Administrators.

The Agency is also naturally in contact with public institutions and elected representatives, as well as scientific experts, laboratories and technical institutes.



THE PILLARS OF ANSES'S OPENNESS TO SOCIETY

→ Its Board of Administrators and thematic steering committees.

→ Dialogue committees on controversial subjects: health risks associated with nanomaterials and risks associated with radiofrequencies (since 2011-2012), platform for dialogue on the issuing of marketing authorisations for plant protection products (since 2017).

→ Hearings, consultations and stakeholder reporting sessions organised during the scientific expert appraisal process, which enable the integration of data and information from organisations with field knowledge, experience or technical information.

→ The charter on openness to society signed in 2011 by seven public research and expert appraisal agencies, including ANSES.

→ The Agency's website, a platform for publishing its scientific reports and opinions.

During 2019, ANSES also chaired a steering and monitoring committee on transverse agenesis of the upper limbs, in conjunction with *Santé publique France* and a dedicated scientific committee.

Focus

CONTINUED SUPPORT FOR THE WORK OF PARLIAMENT

ANSES's work often lies at the heart of the concerns of our fellow citizens and elected officials. As part of its mission to support decision-making, the Agency responds to many parliamentary requests. In 2019, the General Directorate and staff took part in some 50 hearings and meetings with parliamentarians (MPs and senators).

As part of fact-finding missions or investigation committees, or before various study groups, they were given the opportunity to shed light on some of the Agency's work, such as in occupational health and endocrine disruptors, to take stock

of ongoing actions, particularly in the context of the glyphosate withdrawal strategy, or to present certain studies such as its expert appraisals on baby nappies and feminine hygiene products. ANSES was also asked to provide details of the risk assessments conducted following the fire at the Lubrizol plant. All these actions contribute to the work of parliament, in order to revise existing standards, adopt new measures, or address emerging issues. The Agency also appeared before the Economic, Social and Environmental Council to discuss its work relating to animal welfare and the European REACH Regulation on chemicals.



Four questions for...

BERNARD CHEVASSUS-AU-LOUIS, CHAIR OF THE PLATFORM FOR DIALOGUE ON MARKETING AUTHORISATIONS FOR PLANT PROTECTION PRODUCTS

What is the purpose of the platform set up two years ago?

→ ANSES wanted to accomplish its missions to the best of its ability, and decided to initiate a dialogue with all civil society organisations and professional representations interested in the issuing of MAs for plant protection products.

The aim of this platform is to enable everyone to do their job better. This is a mutually beneficial offer because in exchange, ANSES provides all these organisations with the information they want.

More than 50 organisations on average take part in this platform's meetings, with one participant per organisation, or two in the case of federations. But more than 150 of them are actually invited. They include plant protection product manufacturers or other players (UIPP), representatives from the agricultural world (unions, technical institutes), associations such as *France Nature Environnement* or *Génération Futures*, and even beekeepers.



"As long as there are topics on the agenda, we will continue at the rate of two platforms per year."

What have been the main topics discussed?

→ We realised that there was a huge need for information and understanding, for example on the definition of the term “substance of low concern”, on pharmacovigilance, or on the respective roles of the European Chemicals Agency and ANSES. Answering these questions has required in-depth work on the part of the ANSES teams. A large part of our session agendas concerns these requests for understanding. As soon as a topic is on the agenda, any of the platform members can present their position or analysis to the others.

Other topics have included regulations on bees and other pollinating insects, coordination between Europe and the Member States, the glyphosate dossier, product application distances, and use of the information platform on plant protection products, for which specific training has been introduced.

What do you think are the mutual advantages of this type of body?

→ As can be seen from the number of people attending each platform meeting, I think that participants appreciate this type of forum where they can easily speak and ask questions. Regulating all these exchanges is relatively easy and I learn something new at each session. On the other hand, there is still only limited debate between the players in terms of horizontal dialogue. I have the impression that ANSES also finds it beneficial, because it is able to see that subjects that it thought were self-evident are not always so well understood by civil society. I would like to pay tribute to the staff of ANSES, who prepare these meetings very seriously and work hard to provide input for this platform. The participants notice and appreciate it.

What are the challenges and prospects for the platform's continuity?

→ The platform is not intended to last indefinitely. As long as there are topics on the agenda, we will continue at the rate of two platforms per year. However, plant protection products will probably remain in the spotlight for several years to come. Perhaps ANSES will suggest extending this platform principle to the area of other biocides or veterinary products, if other topics emerge. Lastly, questions about assessing the effects of low doses of plant protection products over a very long period of time, cocktail effects or effects on other living organisms are often raised, and will no doubt still need addressing in the coming years.

Human and social sciences in risk assessment ↘



The Agency is regularly required to work on highly controversial subjects involving different types of uncertainty, whether scientific, social or political. In order to enhance and improve the quality of its expert appraisals in support of public decision-making, ANSES therefore relies on the human and social sciences (HSS), mobilising experts in these disciplines through working groups and academic partnerships.

The HSS are an integral part of ANSES's risk assessment processes.

They can help provide a better understanding of the behaviours and positions of players with regard to a given risk, or the history, nature and evolution of arguments on controversial situations. They also generate knowledge useful for understanding what determines individual or collective exposure to risk in real life. In addition, they can shed light on critical points of the expert appraisal, particularly in

areas characterised by uncertainty or a lack of knowledge. Lastly, the analysis of socio-economic dimensions, for example in terms of the benefit-risk or even cost-benefit ratio, can help to guide management measures.

While ANSES carries out or assesses studies of the impact of management measures required by the regulatory framework, it also conducts occasional socio-economic studies, whether or not in connection with formal requests. Depending on the topics, sociology, political science, psychology, law, economics, history, philosophy or communication sciences may be mobilised. The expert appraisals drawing on these disciplines meet the same demanding criteria as all the other work produced by ANSES: competence,

transparency, independence and collective expertise.

In 2019, some 15 expert groups set up to deal with formal requests to the Agency therefore included HSS skills, and two expert appraisal reports mobilising these skills were published: one on occupational risks in the waste management and recycling sector, and the other on the use of herbicide-tolerant varieties (HTVs).

ANSES is also working to increase the use of the human and social sciences. Implementing an expert appraisal system that can take socio-economic aspects into consideration for regulated products and formal requests is one of the priorities of ANSES's 2018-2022 goals and performance contract.



ANALYSIS OF THE CONTROVERSY AND SOCIETAL DEBATE ON THE USE OF HTVs

Herbicide-tolerant varieties (HTVs) are crop varieties that have been developed to be tolerant to a specific herbicide. Given their expansion in France, and in response to public concerns, ANSES reviewed the use of these plant varieties. ANSES's 2019 opinion was formed in the wider context of a debate on the use of biotechnology in agriculture and of the ruling by the Court of Justice of the European Union on organisms obtained by mutagenesis, which is likely to have an impact on the regulatory framework.

A twofold analysis was carried out to provide input for the expert appraisal with, on the one hand, a socio-historical comparison of the multiple dimensions (scientific, legal, economic, environmental) of the controversy surrounding the definition, use and control of HTVs, and on the other hand, an exploration of the arguments put forward by opponents and supporters of HTV use. Due to their dissenting positions, the various stakeholders interviewed disagreed on the nature, extent and implementation of monitoring of agricultural practices

associated with HTVs and the potential adverse effects.

ANSES concluded that the limitations of the data collected in terms of their quantity and quality did not enable it to reach a decision on potential adverse effects or to carry out an *a posteriori* assessment of the health, environmental and agronomic risks. Noting the existence of risk factors regarding the potential development of weed resistance and/or increased herbicide use, the Agency recommended improving the traceability of HTV seed use through to when it is ultimately used as crops.

EXPLORING THE CHALLENGES OF THE WASTE MANAGEMENT SECTOR

The waste management and recycling industry is central to circular economy policies and is growing all the time. The occupational health of workers in this industry is a real challenge and was examined by ANSES in an initial expert appraisal in 2019. The Agency looked at 28 waste management sectors that provided an overview of the industry.

Several criteria were studied to identify and distinguish the sectors in terms of their impact on the health of professionals working in them: potential risks associated with the toxicity of chemicals and the presence of bacteria or mould in waste;

the level of documentation on these health risks; the quantities of waste produced, collected and processed within each sector; the numbers of workers involved; and consideration of economic and technical developments in the sectors over the coming years. In addition to the lack of data, the expert appraisal highlighted multiple exposures: to chemicals and pathogens found in the waste, noise and mechanical vibrations, and the impact of organisational constraints. Risks to mental health associated with the working conditions, organisation and attitudes to occupations in this sector were also

pointed out. ANSES therefore made recommendations with a view to enhancing knowledge, raising awareness of risk prevention and improving medical monitoring of waste workers. It also recommended that the health impacts on these professionals be integrated into eco-design activities.

Lastly, for the sectors where potential risks have already been identified, ANSES plans to conduct health risk assessments for workers, starting with the household packaging waste sector, with its many health and socio-economic challenges.

ANSES's governance bodies ↘

ANSES's governance model is designed to reconcile two essential principles: on the one hand, the independence of the scientific expert appraisal process and on the other, transparency, openness and respect for the roles of all parties involved. The composition of the Agency's Board of Administrators therefore reflects the five colleges of the *Grenelle* environmental round table, with representatives of the State, various associations, professional bodies, trade unions and elected officials; it also includes staff representatives. It is supported by five thematic steering committees that also involve Agency stakeholders. Lastly, ANSES's Scientific Board ensures the excellence of its work, while its Committee for Ethical Standards ensures its independence.

THE BOARD OF ADMINISTRATORS

The Board of Administrators decides on ANSES's general policy, including its multi-year strategy, its annual work programme and its goals and performance contract with the State. It deliberates on the Agency's general organisation, the creation of Expert Committees and the establishment of agreements with external organisations, and is involved in setting ethical standards. Half of the voting rights are attributed to the members of the college of State representatives and half to members of the other colleges. In late 2019, the ANSES Board of Administrators was renewed for another three-year term.

Fourteen new members, including representatives of three new consumer associations, were appointed by Ministerial Order on 11 December 2019, published in the Official Journal on 18 December 2019. The ANSES staff representatives, elected by personnel in accordance with the procedures defined by the Agency's internal rules and regulations, were appointed by Ministerial Order in February 2020.

To support it in its mission, the Board of Administrators has set up five **thematic steering committees**. In addition to the colleges represented on the Board of Administrators,

these committees are open to civil society organisations involved in the Agency's spheres of competence: associations, professionals, industry, trade unions, agricultural unions, etc. They help define ANSES's strategic orientations and work programme, and are an important forum for expressing risk assessment and research needs, in five areas: environmental health, occupational health, food, animal health and welfare, and plant health and protection.

Composition of the Board of Administrators



→ Chairman
of the Board



→ State
Representatives



→ Representatives of **Associations**



→ Representatives
of **Professional Organisations**



→ Representatives
of **Trade Union** Organisations



→ **Elected Officials**
and **Qualified Individuals**



→ **Staff** Representatives

THE SCIENTIFIC BOARD

The Scientific Board guarantees the scientific quality and independence of expert appraisals by choosing experts, reviewing public declarations of interest and monitoring how expert appraisals are conducted. It also oversees the evaluation of the Agency's research activities. It is independent of the Agency's operational bodies and made up exclusively of scientists, giving a considerable number of seats to foreign scientists.

In late 2019, the Scientific Board was renewed for a period of three years. Eleven new members were appointed by Ministerial Order dated 23 December 2019 and thirteen outgoing members were reappointed. The composition of the Scientific Board responds to the need for scientific knowledge and a concern for balance between ANSES's major areas of competence, as well as between the member organisations. With 13 men and 11 women, it is approaching gender parity.

THE COMMITTEE FOR ETHICAL STANDARDS AND PREVENTION OF CONFLICTS OF INTERESTS

The Committee rules on compliance with the ethical standards applicable to ANSES, its staff and occasional employees, in terms of both general rules and specific issues, bearing in mind that in accordance with the law, effective day-to-day implementation of the requirement to prevent conflicts of interest is the responsibility of the Agency's Ethics Officer. The Committee for Ethical Standards can be petitioned by a member of the Board of Administrators, the Scientific Board or a CES, or by the Director General or an ANSES employee. It can intervene in all ANSES's areas of activity at any stage, for example from the formal request through to ANSES's opinion in matters of collective expert appraisal. Its members are appointed for five years by Interministerial Order.





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