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2020 ANNUAL REPORT

ANSES in action

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DESCRIPTION

2020

1,439
employees

32% men

68% women

**Almost
half**

work in the
laboratories

Around

800

independent
experts mobilised

15 expert
committees
supported by
working groups

ANSES laboratories
named as references

for **100**
regulated pathogens
and contaminants

65 national
reference mandates

13 European
reference mandates

28 international
reference mandates

112 formal
requests and calls
for support received,
of which **34**
were urgent

155

opinions and reports
published

492

category A+
and A scientific
publications

1,987

decisions issued in
the field of plant
protection products,

261 for biocides
and **3,396** for
veterinary medicinal
products

114

news items
published

12 scientific events
organised, of which

8 were in virtual
format

3

committees
and platforms
for dialogue with
stakeholders

34

projects
selected under the
National Research
Programme for
Environmental
and Occupational
Health, with around

6 million
euros mobilised

A budget of
€144.40 million ↘

TOTAL BUDGET EXPENDITURE (€M)

97.8
Staff



36.7
Operation

9.9
Investments

BREAKDOWN BY ACTIVITY (€M)

69
scientific
activities



26.7
support
activities

48.7
assessment
activities

INVESTMENTS MADE (€M)

2.5
Real estate



1.6
Other

2.8
Scientific
equipment

3
IT



Anses and figures facts and figures



Roger Genet

Director General ↘

Besides the impact of the health crisis, what are the main lessons you have learned from 2020?

ANSES experienced a period of intense activity in 2020. Looking back, I note unprecedented changes compared with previous years, due to the effects of the health measures on our operations, such as the marked acceleration in digital working, for example.

The Agency obviously worked hard in 2020 to analyse the many impacts of the COVID-19 pandemic on human and animal health, food and the environment (see the page devoted to this subject). But ANSES also had to tackle many other issues and crises, including the avian influenza epidemic – which had a severe impact on duck farms this past winter – and the identification of emerging plant pathogens such as ToBRFV, a particularly aggressive tomato virus identified in France in early 2020. Incidentally, at the last Paris Agricultural Show, we had focused on plant health alerts, as they seem to be increasing every year.

The Agency also broke records last year in terms of its researchers' scientific publications, which were up by 25% compared with the previous year; this figure alone illustrates the vitality of our research work. In this respect, it is worth pointing out that research, whether carried out by our teams or funded through our calls for projects, is an activity in its own right that ANSES promotes and coordinates with its expert appraisal activities through its cross-functional scientific departments, and that it is constantly strengthening. The assessment of the Agency's scientific activities for the period 2016-2021, which will be carried out in the coming months, will be an important milestone in the Agency's progress here.

This annual report also touches on the record number of emergency formal requests received by the Agency last year, yet again reflecting the high expectations placed on scientific expert appraisal. Although we strive to provide an agile response to this trend, it is nevertheless important to remember what is involved in anticipating and prioritising the questions we are asked, at every level (scientific, political, economic and societal), because the pace at which science operates is not necessarily that of public debate and decision-making.

Lastly, our work over the past few months testifies to ANSES's ongoing commitment to produce the scientific benchmarks needed to document symbolic transitions for our society, industry and agriculture: alternatives to glyphosate, potential risks of 5G, vaping products, nanomaterials, etc. You will find many examples in this report.

How has the COVID-19 pandemic changed the Agency's outlook?

ANSES's first decade, which we were unfortunately unable to celebrate as we would have liked in July 2020, has been marked by a clear shift in the health paradigm, beginning with the rising importance of the "One Health" dimension at each step, from the identification of new threats through to the management of crises. The pandemic has also, via numerous debates and controversies, highlighted the need to devise new ways of using science and expert appraisal to guide public decision-making.

Because of its position at the crossroads of health and other areas of research, the Agency has been or will soon be entrusted with work or responsibilities as part of public measures that closely reflect these new trends, whether on a national (such as the fourth National Environmental Health Action Plan), European (as part of the "Green Deal") or global scale (in the implementation of new health governance schemes).

These trends consolidate our role as a scientific expert appraisal agency with a broad spectrum of intervention, and reinforce our ambition to be a driving force for questions and proposals on topics of great importance, such as the link between expert appraisal and decision-making, the mobilisation of human and social sciences to address socio-economic assessment, and the coordination of efforts between the different players and countries. This is because it is important for us not only to be useful in our actions but also to promote consistency and efficiency for the entire health system. This annual report will provide you with several illustrations.

What does the exercise of the annual report mean to you?

Making our work known and giving it meaning is one of the Agency's integral missions. The increase in health concerns, the need to provide reliable scientific benchmarks to respond to certain disinformation strategies, the challenge of constantly revising these benchmarks in light of the rapid development of scientific and technical knowledge and changes in regulations, all make it necessary to provide more information on our action.

In addition to the essential figures and data on our activity in 2020, this report is intended to be an effective way of sharing some reminders and illustrations of our methods, results and challenges, all of which are necessary to build trust, mark our differences in the world of "opinions", and improve the rightful recognition of our contribution to debates and decisions or to the prioritisation of issues to be addressed. One chapter is dedicated to scientific expert appraisals and how we implement and develop them in order to enhance their relevance, utility and independence.

Through numerous interviews and testimonies, this report also gives a voice to the people who make ANSES what it is, and on whom our credibility, effectiveness and attractiveness depend. I would like to finish by paying them tribute and thanking them for their commitment and the satisfaction we have had in working together this year, despite the distance and isolation imposed on us by the health situation.

I hope you enjoy reading it.



The COVID-19 pandemic has placed great demands on ANSES's expertise for over a year now; but unfortunately this has not meant an absence of other health threats during this period, with avian influenza being just the most newsworthy. ANSES was therefore required – and successfully managed – to continue its activities in spite of all the essential measures limiting travel and contact. So it is with the deepest gratitude that I salute the constant, firm commitment shown by ANSES's teams and its expert and governance groups during these difficult months, against a backdrop of multiple crises and with many of the staff working mainly from home.



↳ **Benoît Vallet**, Chairman of the Board of Administrators



Highlights

January

20 January

Meeting of the International Heads of Food Agencies Forum in Riyadh, Saudi Arabia.



5 February

ANSES and the French National Institute for Health and Medical Research (Inserm) formalised their long-standing collaboration on public health issues such as the effects of air pollution and pesticides, and antimicrobial resistance, by signing a scientific cooperation partnership.

February

22-29 February

On the occasion of the 57th Paris International Agricultural Show and the International Year of Plant Health, ANSES dedicated its stand to plant health. It also signed or renewed partnership agreements with:

- the Agricultural Mutual Insurance Scheme (MSA), on the health issues of workers in the agricultural sector;
- the Alfort National Veterinary School, to advance scientific knowledge of animal infections;
- the French Horse and Riding Institute;
- the Environment & Energy Management Agency (ADEME), to integrate human health issues into their scientific work and develop solutions to combat climate change.



March

▸ 16 March

Lockdown measures against COVID-19

ANSES deployed its activity continuity plan: its laboratories' essential reference activities continued, while it switched to remote operations for its vigilance, expert appraisal and authorisation work.

April

▸ 21 April

Annual bilateral meeting of ANSES and the European Food Safety Authority to strengthen cooperation and discuss implementation of the European regulation on transparency and sustainability of risk assessment in the food chain.

June

▸ 29 June

Together with the National Research Agency (ANR), the National Cancer Institute (INCa), the French Research Agency on HIV/AIDS and Viral Hepatitis, and the French Agency for Ecological Transition, **ANSES made a commitment to open science and to a joint approach for disseminating and sharing scientific knowledge more widely.**

▸ 16 June

The Pathophysiology and Epidemiology of Equine Diseases Unit, within ANSES's Laboratory for Animal Health, was appointed **international reference laboratory for dourine.**

September

3-15 September

The **ANSES Scientific and Doctoral Days** took place in a new online format.

10 September

Professor Benoît Vallet was appointed Chairman of ANSES's Board of Administrators.

14 September

Publication of the book *Face aux risques* tracing the history of the health and safety system.

16 September

Partial renewal of ANSES's Committee for Ethical Standards and Prevention of Conflicts of Interest.

November

18 November

ANSES held a scientific conference on antimicrobial resistance in animal health and the environment.

25 November

ANSES was appointed **FAO Reference Centre** for antimicrobial resistance.

27 November

ANSES, BRGM, Ifremer, Ineris, INRAe, IRSN, the Gustave Eiffel University and *Santé Publique France* signed the **charter on openness to society**.



December

↘ 14 December

ANSES and the Singapore Food Agency strengthened their cooperation on food safety.

↘ 16 December

Renewal of the cooperation agreements between ANSES and its Belgian counterpart Sciensano, mainly on diagnosis, research and reference activities relating to pathogens.

↘ 17 December

ANSES organised a **scientific conference** on control of vector-borne diseases. It reported on the projects the Agency is funding in this area under the National Research Programme for Environmental and Occupational Health.

Action against COVID-19



From the very start of the COVID-19 pandemic, ANSES took action in its areas of competence to provide scientific benchmarks and responses to help manage this major health crisis.

HUMAN-ANIMAL TRANSMISSION

- Assessment of the role of domestic and wild animals in transmission and spread of the virus in France. [↘ March, April, November 2020](#)
- Health surveillance to be implemented for SARS-CoV-2 on mink farms. [↘ September 2020](#)

PRESENCE OF THE VIRUS IN THE ENVIRONMENT

- Assessment of the potential risks associated with the spreading of municipal sewage sludge during the pandemic. [↘ April 2020 and February 2021](#)
- Airborne viability and infectivity of SARS-CoV-2 and associated risks. [↘ June 2021](#)

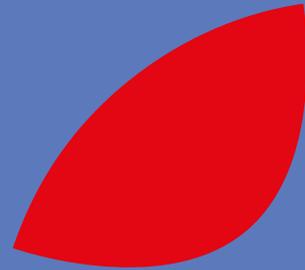
EFFECTS OF LOCKDOWN

Recommendations for:

- Mitigating the effects of reduced physical activity and increased sedentary periods. [↘ April 2020](#)
- Ensuring adequate vitamin D intake. [↘ April 2020](#)
- Avoiding disruption of the body's natural defences through the consumption of herbal food supplements. [↘ April 2020](#)
- Benefit-risk assessment of the vector control practices usually implemented to combat dengue fever, in the global lockdown context. [↘ May 2020](#)

DAILY HYGIENE

- Warning about hand sanitiser being accidentally splashed into young children's eyes. [↘ August 2020](#)
- Recommendations on hygiene practices when shopping and cooking. [↘ March 2020](#)
- Stability and effectiveness of alcohol-based disinfectants for human hygiene throughout their lifecycle. [↘ June 2021](#)
- Alert on the use of essential oils as a means of combating COVID-19. [↘ March 2020](#)



PROTECTION OF WORKERS AND THE PUBLIC

- Preventing exposure to SARS-CoV-2 in the workplace (outside the healthcare sector). [↘ March 2020](#)
- Health surveillance to be implemented for SARS-CoV-2 on mink farms and relationship with the health of mink workers. [↘ February 2021](#)
- Development of a standard for treating FFP2 and equivalent surgical masks, with a view to their reuse. [↘ December 2020](#)
- Estimating the potential risks associated with wearing masks treated with silver zeolite and silver-copper zeolite. [↘ October 2020](#)





1 & People Animals

One
Health ↗



On the lookout for emerging diseases and zoonoses



While animal and human health have always been closely linked, globalisation of trade and climate change are leading to new risks. An integrated approach to health is more important than ever. Our work, which covers both wild and domestic animals, helps improve understanding and prevention of pathogen transfer from one species to another.

The great diversity of animal species combined with the significant capacity of viruses and bacteria to mutate results in a multitude of pathogens to which humans are potentially exposed. They can cause diseases of varying severity if they cross the species barrier. A better understanding of the pathogens circulating in animals helps us prepare for future epidemics in humans.

For a disease to emerge, the transmitted pathogen must adapt to the new host and then spread among individuals of the newly infected species. This spread depends on many factors related to the pathogen, the infected hosts and environmental conditions. ANSES's animal health and food safety laboratories study animal diseases affecting both wildlife and domestic species (livestock and pets).

ANSES is also developing methods to detect pathogens and surveillance systems to try and pre-empt emerging threats. For example, genetic sequencing of pathogens detected through epidemiological surveillance enables better identification of the spread of new pathogens or variants and adaptation of control measures.

“Today, 60% of infectious diseases are common to humans and animals”

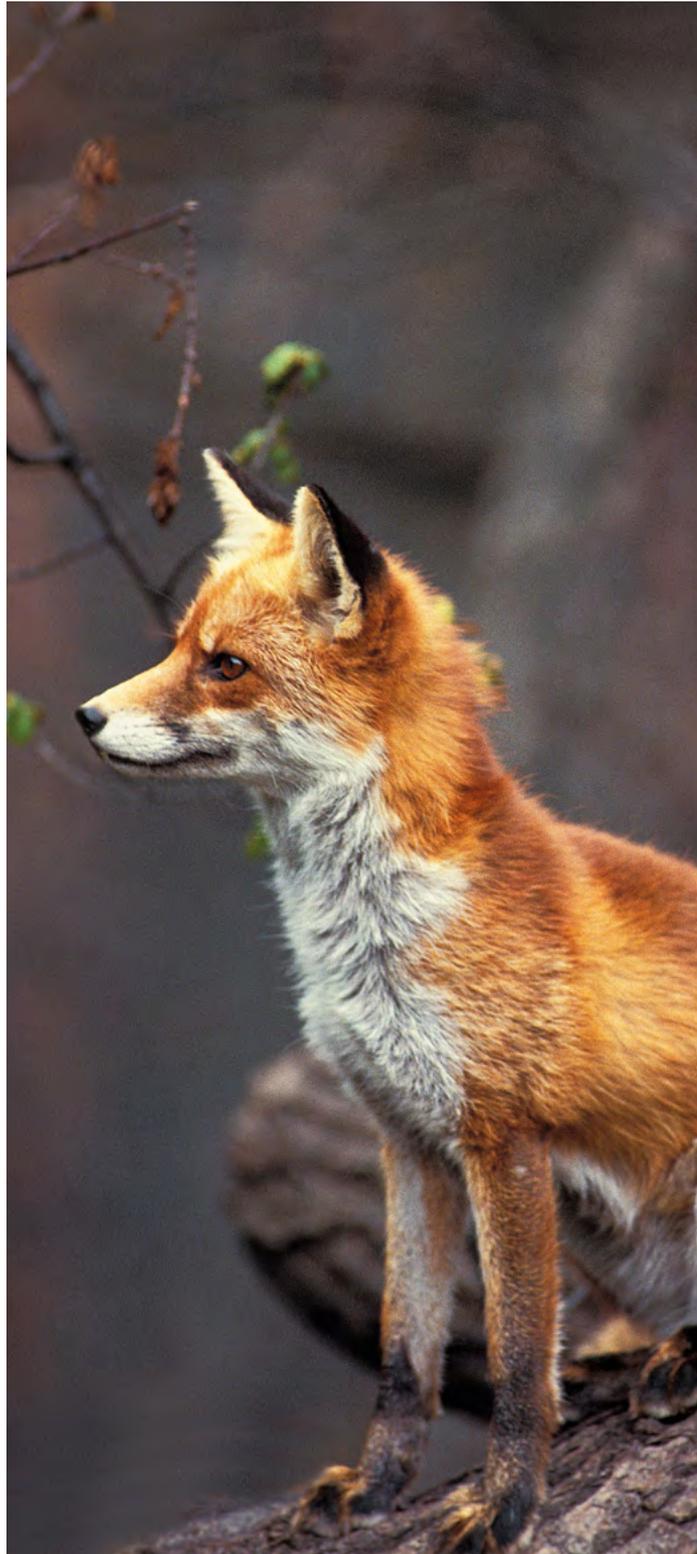
ZOO TOPIQUE

five podcasts to imagine human-animal relations in the future

With its first podcast series launched in early 2021, ANSES is taking listeners on a trip into the future, to examine the links between human and animal health. Through the voices of researchers, we offer to shed light on the scientific advances that could prevent tomorrow's risks, on key topics such as the emergence of zoonoses, the disappearance of bees, control of ticks and mosquitoes, livestock farming conditions and human-animal relations. To address these themes, the five episodes alternate between fictional reports set in 2031 and interviews from today. Based on an idea by ANSES, the *Zootopique* series has been developed and produced in collaboration with the independent media network *The Conversation* and the agency *Moustic Studio*.



[Listen to the Zootopique podcasts.](#)



Coronaviruses shared with animals

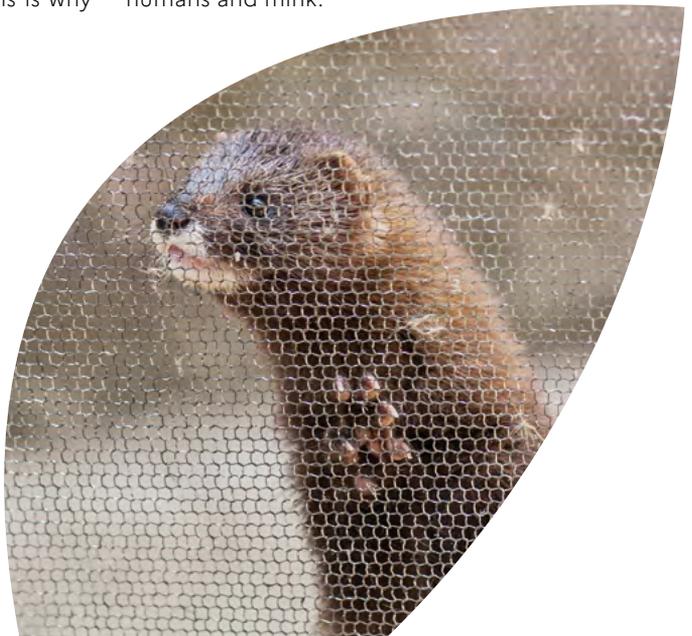


This family of viruses, which have been thrust into the spotlight with COVID-19, are already well known in animal health. For more than 40 years, our laboratories have been working on animal coronaviruses and, in particular, on interspecies transmission and diagnostic and treatment techniques. This knowledge has been invaluable in the current fight against the COVID-19 epidemic.

When asked at the start of the pandemic about potential transmission of the COVID-19 disease via contaminated domestic animals or food, ANSES urgently convened an expert group to answer this question, and published several opinions on the risks of transmission of the SARS-CoV-2 virus from animals to humans. This group determined that although some species – such as cats, ferrets, mink and hamsters – were susceptible to the virus, domestic animals and wildlife play no role in sustaining or spreading SARS-CoV-2 in France, where its spread is due to human-to-human transmission by the respiratory route. However, there is a risk of development of an animal reservoir that could generate variants that are transmissible to humans. This is why

the Agency recommends exercising particular vigilance during contact between humans and species capable of harbouring the virus, especially in conditions of high animal density and close proximity between animals and humans, and in closed or confined environments.

Following the discovery of an infected mink farm in November 2020, the Agency urgently assessed the details of a surveillance plan for both the animals and the workers in contact with them. It stressed the need to put in place a screening strategy for animals in parallel with that organised for workers or visitors on these farms, in order to prevent or rapidly stop any transmission of the SARS-CoV-2 virus between humans and mink.





➤ **Nicolas Eterradossi,**
Director of the Ploufragan-Plouzané-Niort Laboratory

➤ **Élodie Monchâtre-Leroy,**
Director of the Nancy Laboratory for Rabies and Wildlife

In 20 years, we have seen three emerging coronaviruses, SARS-CoV, MERS-CoV and SARS-CoV-2, all due to human contamination by an animal species that served as a bridge between bats and humans. There are a wide variety of coronaviruses in animal species such as mammals (dogs, cats, cattle, pigs, horses, rabbits, bats, hedgehogs, certain species of voles, etc.) and birds (turkeys, guinea fowl, ducks, etc.). We study them not only to control diseases in livestock, but also to better understand their evolutionary capacities, crossing of the species barrier and emergence.

Like a number of other RNA viruses, they are constantly evolving, either through mutation (error in copying their genome during replication) or recombination (exchange of genome portions during replication between different coronaviruses simultaneously infecting the same cell). These two mechanisms give coronaviruses a strong capacity to evolve, which can lead them to cross the interspecies barrier. Studying the evolution of the coronavirus genome in different animal species and in humans enables screening methods and vaccines to be continuously adapted.

To understand the emergence of SARS-CoV-2, the virus responsible for the COVID-19 epidemic, one of the challenges is to identify which animal species may have been infected by a common viral ancestor originating in bats, and which therefore acted as intermediate hosts for the virus's adaptation to the human species.

Drawing on the knowledge gained from our research on animal coronaviruses, in 2020 we developed animal models that have been invaluable for understanding the behaviour of SARS-CoV-2. For example, working with scientific teams from other research institutes, we developed a golden hamster model that has enabled us to decipher the mechanisms of anosmia, the loss of sense of smell (one of the characteristic symptoms of SARS-CoV-2 infection), and to explore the immune response following infection.

“Drawing on our research, we developed animal models that have been invaluable for understanding the behaviour of SARS-CoV-2”

Using the golden hamster and ferret animal models, ANSES worked with different teams to develop therapeutic and prophylactic compounds and supported the medical teams of the preclinical trials group in assessing future treatments and vaccines, in order to more quickly pre-select those that will undergo subsequent clinical trials in humans. Vaccine studies in animal models are an essential first step in understanding the different types of immunity induced by a vaccine model, which will broaden the spectrum of population protection and help achieve herd immunity.

The experience acquired by ANSES scientists on animal coronaviruses and vaccination is crucial for understanding these mechanisms of vaccine protection. Lastly, as the resistance of SARS-CoV-2 to physical and chemical agents is comparable to that of animal coronaviruses, the latter have been used to validate certain decontamination procedures for surgical masks.

Insight



Our research on coronaviruses



Since the start of the COVID-19 pandemic, ANSES has been deploying its research teams and its network of laboratories to improve knowledge of SARS-CoV-2 and respond to questions that have arisen from this crisis.

Laboratory for Animal Health – Virology Joint Research Unit

(ANSES – ENVA – INRAE UMR)

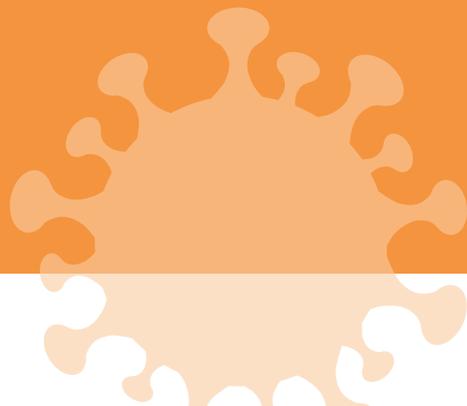
- **Scientific study on the potential infection of pets, especially cats.**
 - ↳ First infected cat detected in France.
- **SARS2BlockEntry project** (Engineering nanobinders to block SARS-CoV-2 entry). Funded by the ANR and coordinated by INRAE.
 - ↳ Development of drugs to block SARS-CoV-2 entry into cells, using hamsters as the animal model.
- **Work on potential central nervous system infection with SARS-CoV-2.**
 - ↳ Study of the virus's ability to infect central nervous system cells handled in the laboratory.
- **MUSECoV project**, call for projects from ERA-Net ICRAD (International coordination of research on infectious animal diseases). Coordinated by the Alfort National Veterinary School and managed by the Virology UMR.
 - ↳ Better understand the dynamics of coronavirus infections in various animal populations and therefore rapidly detect the emergence of particularly pathogenic variants.

Laboratory for Rabies and Wildlife

- **Timing project**, funded by the ANR and coordinated by INRAE.
 - ↳ Determine the appropriate moment to administer interferon treatment, in order to eliminate the infection and reduce the development of COVID-19 symptoms and lesions, without causing excessive inflammation.
- **EvoZOOone project** (WHO's R&D Blueprint call for projects).
 - ↳ Study of the evolution of SARS-CoV-2 and assessment of its zoonotic potential.
- **Studies in mink.**
 - ↳ Sequencing analysis of the virus found on the infected farm.

Laboratory for Hydrology

- **WHO's R&D Blueprint project.**
 - ↳ Study of the persistence and behaviour of SARS-CoV-2 particles in aqueous environmental matrices.



Ploufragan-Plouzané-Niort Laboratory

- **Identifying coronavirus inactivation treatments for surgical face masks.** In collaboration with Grenoble University Hospital, the French defence procurement agency (DGA), Tours Hospital, various private partners and using the facilities of the Dupuy de Lôme Research Institute (University of Southern Brittany), within the framework of the AgriFood Transition Carnot Institute. Patent application for a process for treating surgical masks with UV light.
- **Developing a new specific serological test for European turkey coronavirus.** In partnership with the EPISABE Unit and the CTPA ZOOPOLE Development centre of expertise, with financial support from the AgriFood Transition Carnot Institute.
- **Studying the persistence of coronaviruses in coastal waters.** As part of the ANR's RA-COVID-19 call for projects and in collaboration with the French Research Institute for Exploitation of the Sea (Ifremer).
- **Conducting SARS-CoV-2 diagnostic testing.** The virology units on the Ploufragan site were called on by the Brittany Regional Health Agency to strengthen SARS-CoV-2 diagnostic capacities in Brittany.

Risk Assessment Department

- **SACADA project.** Subsidised by the National Research Agency (ANR) and conducted in collaboration with the Institut Pasteur, INRAE, *Santé publique France* and the National Veterinary Schools of Alfort (ENVA) and Nantes (Oniris).
 - ↳ Understanding transmission of SARS-CoV-2 in food preparation facilities with the emphasis on meat processing plants.

Other collaborative projects

- **Various projects to develop animal models** using ferrets and hamsters to test new therapeutic approaches. Conducted by the Nancy, Lyon, Ploufragan and Maisons-Alfort laboratories in collaboration with hospital research teams, INRAE and veterinary schools.
- **COVRIN-SARS-CoV-2 "Research Integration & Preparedness for Future Coronavirus Outbreaks".** As part of the EJP One Health programme. In collaboration with the Nancy, Ploufragan-Plouzané-Niort and Maisons-Alfort laboratories.
 - ↳ Identifying the factors determining emergence and spread of SARS-CoV-2 and generating data and building models for assessing coronavirus risks.
- **DIM One Health.** For scientific management of the project.
 - ↳ Research on coronaviruses in domestic carnivores, new anti-coronavirus therapeutic approaches.

Laboratory for Food Safety

- **Impedance SARS-CoV-2 project** (WHO's R&D Blueprint call for projects).
 - ↳ Adding to knowledge of SARS-CoV-2 and viral persistence under different environmental conditions, including methods of food packaging and transport.



Controlling vector-borne diseases



Vector-borne diseases account for 16% of the estimated global burden of human infectious diseases. Lyme disease, Zika, chikungunya, dengue... recent years have seen a re-emergence of the pathogens responsible for diseases transmitted by arthropods such as ticks and mosquitoes. We conduct scientific expert appraisals in order to better prevent and control the pathogens responsible for vector-borne infectious diseases.



The limitations of insecticide use and the appearance of mosquitoes that are resistant to the products used mean that new control strategies have to be developed. Data on vector ecology and resistance mechanisms are therefore crucial in order to offer innovative approaches to vector control. Research funded by ANSES through the National Research Programme for Environmental and Occupational Health (PNR EST) has led to a better understanding of what attracts mosquitoes to vertebrates, as well as of the various factors – food, climate, environment, smell, reproduction – that condition their behaviour.

The future of mosquito control lies not in one technique but in a combination of measures, including public awareness and the elimination of mosquito breeding and egg-laying sites. In 2020, ANSES organised a scientific webinar to review new prospects for vector control, particularly for mosquitoes, which are the main vectors of human pathogens worldwide, and to report on projects funded under PNR EST.

The Agency reiterates the need to keep up efforts to control dengue-carrying mosquitoes in the French overseas territories. In its May 2020 opinion, it provided guidance on measures to enable those responsible for vector control to continue their work, while taking care to limit the spread of the SARS-CoV-2 virus.

Johanna Fite, In charge of the Vectors mission



What does ANSES's expert appraisal mission on vectors involve?

It is primarily about better understanding vectors; how they function, spread and transmit pathogens. To assess the risks of transmission of pathogens responsible for vector-borne diseases, the vector-pathogen pair must first be studied. Vector competence, i.e. an arthropod's intrinsic ability to transmit a pathogen, results from genetic and biological factors that allow the pathogen to multiply in the vector and then be transmitted to a host. However, the infectious agent can only be transmitted if this competence is accompanied by favourable ecological

conditions. The vector has to be abundant, have sufficient longevity, and maintain close contact with reservoir hosts and receptive vertebrates. Vectorial capacity thus expresses the degree of co-adaptation of the "vector-infectious agent" pair in a given ecosystem.

How can the spread of vectors be pre-empted?

It is important to study the ecosystems in which the vectors live and the conditions under which they develop. For example, water plays a key role in the lifecycle of mosquitoes, which have an aquatic life stage. Temperature is also an important factor in determining the geographical

range of arthropod vectors. With climate change and increased global trade and transport, the geographical distribution of vectors is changing rapidly. We therefore draw up projections and scenarios based on different factors in order to assess the probability of introduction and spread of certain vectors, as well as the risks of emergence of vector-borne diseases.

What work are you doing in vector control?

ANSES assesses vector control strategies, including their effectiveness and impacts, and can recommend prevention and control measures geared to the context. It looks into the effectiveness and risks of biocidal products as part of marketing authorisation procedures, as well as the vectors' resistance to insecticides or acaricides. We are also developing a systemic assessment guide to cover all aspects of vector control strategies: community mobilisation and health education, integrated surveillance, intra- and inter-sectoral collaboration, insecticide treatments, etc.

“We are developing a guide for assessing integrated vector control strategies”

3 questions for



Sara Moutailler,
Project manager
Laboratory for Animal Health



Our research on ticks, the pathogens they transmit and their distribution in France enables us to identify situations where there is a risk of exposure to bites.

There are a huge number of tick species, each of which can transmit several pathogens. Most of these are zoonotic, which means that they can replicate in several animal species – such as horses, dogs and cattle – and be transmitted to humans. With ticks, there is a problem of co-infection, i.e. they can be infected by several agents at the same time. All these factors make ticks a rather complex subject to study.

At the ANSES laboratory, we conduct research projects that address specific problems related to the ticks' unique characteristics. This involves taking tick samples from the forest for analysis and rearing them for several years. We are able to artificially feed the ticks in our rearing facility through different techniques, so we have hundreds of ticks at different stages (larvae, nymphs, adults) for our experiments and are able to visualise their organs or the pathogens in these organs via the latest microscopy and fluorescence systems.

With the disruption of ecosystems and climate change, the geographical range of ticks is also in transition. It is important to know which tick species are found in which areas, in order to map the risks and predict the emergence of disease. For example, recently for the first time

in France, several people contracted encephalitis after consuming raw goat's milk cheese contaminated with tick-borne encephalitis virus. This type of infection is quite rare and it was discovered that the goat farm was located on the edge of a forest where ticks infected with this virus were collected, despite there being no suspicions of the virus's presence in this area until this event occurred. We are also closely monitoring the risk of emergence in France of Crimean-Congo haemorrhagic fever virus, which can be fatal to humans.

This surveillance of emerging pathogens that could potentially appear depending on changes in the ticks' geographical range requires close cooperation with our colleagues from different French institutes but also with the general public in order to obtain data from the field. This is why citizen science projects have been set up.



Citizen participation in research

Signalement-Tique: better understanding and prevention of Lyme disease

As part of the CITIQUE project, researchers from INRAe, ANSES and the Alfort National Veterinary School developed the *Signalement-Tique* website and app with their scientific partners and the support of the Ministry of Solidarity and Health. This practical and interactive tool gives hikers access to information on prevention and advice on how to remove a tick and then report where it was found. The 2020 version of the app offers new features, such as the option of reporting a bite while offline, or consulting information on what to do after a bite.

Signalement-moustique.anses.fr: detecting the presence of the tiger mosquito

By 2020, the tiger mosquito had become established in around 60 French *départements*.

Created in 2014 at the request of the Ministry of Health and managed by ANSES, the purpose of this website is to improve early detection of the presence of the tiger mosquito. Everyone can help monitor the tiger mosquito by reporting where it is found. The list of colonised communes in metropolitan France is regularly updated thanks to photos of mosquitoes sent in by members of the public. The data collected are used by health authorities to implement suitable targeted control measures depending on the spread of the tiger mosquito across the country.

“Collaborative work is crucial for monitoring tick-related diseases”



Avian influenza: at the heart of the crisis



In December 2020, new outbreaks of highly pathogenic H5N8 avian influenza were reported, particularly in the western half of France, severely affecting fattened duck farms in the South-West. Faced with this epidemic, ANSES mobilised its laboratories and expertise to support the health authorities in diagnosis, investigative epidemiology, modelling and risk assessment.

During the previous outbreak in 2016-2017, ANSES had determined criteria for raising or lowering the level of disease transmission risk depending on the migration period of wild birds, the geographical areas frequented by these birds and the number of poultry farms in these areas. Before this new epidemic, these points were implemented by the authorities, which took into account the alerts identified in wildlife and placed the whole of France at a high level of risk on 17 November 2020.

During this health crisis, the National Reference Laboratory for avian influenza (ANSES Ploufragan site) mobilised its teams of epidemiologists to investigate outbreaks in support of the veterinary services and to analyse the circumstances of the disease's introduction or spread on farms. In addition, the laboratory reactivated its emergency organisation for confirmatory diagnoses. It also deployed new confirmation methods such as qRT-PCR specific to the circulating virus and the generalised use of high-throughput sequencing thanks to the ANSES platform, which meant it could analyse introductions and transmission chains, and verify the zoonotic potential.

Our laboratories specialised in wildlife

The ANSES laboratories specialised in wildlife and animal health study the risks of disease transmission from animals to humans. In particular, they seek to understand the origin of diseases occurring in livestock or wildlife, and the risk of transmission when a new disease is detected. They study pathogen evolution and the factors that determine whether or not they can jump from one species to another. Their work covers coronaviruses, influenza virus, various bacterial zoonotic agents (such as the one responsible for tuberculosis) and certain parasites. This knowledge contributes to the formulation of recommendations for limiting the risk of transmission and managing epidemics caused by pathogens transmitted by wild animals. Their research also involves developing control measures. The Laboratory for Rabies and Wildlife has been working on vaccine baits that have been successful in eradicating rabies in foxes in France. Other control measures are being developed, such as a vaccine for badgers against bovine TB.

Gilles Salvat, Scientific Director for Animal Health and Welfare



What lessons have you drawn from this latest avian influenza crisis, which began in 2020?

There have been two serious crises in three years. This is why it is essential to ask ourselves what is enabling these outbreaks in duck farms and what needs to change to avoid another massive outbreak. Indeed, production methods need to be adapted, not only to prevent the disease from being transmitted to poultry by infected wild birds during their annual southward migration, but also to avoid any further spread between farms.

How can ducks be prevented from coming into contact with wild birds?

We are not saying that all ducks need to be kept indoors all the time, but we must be able to protect the animals at least during the period of maximum risk – including on small isolated farms – by keeping them under shelter, to avoid the virus being introduced by animals left to roam free that then attract wild birds.

Is it possible to avoid such a large-scale spread in the future?

It is important to understand that keeping animals under shelter is not enough if the virus is provided with a high density of susceptible livestock that act as “carriers” enabling it to multiply.

In this situation, the virus was just in the wrong place at the wrong time. Contaminated wild birds landed in an area with the highest density of ducks, not only in France but also in Europe. The density of birds in this area was such that many farms were infected from the initial outbreaks. Consideration should therefore be given to reducing animal and farm densities during risk periods in these high-production areas and continuing to raise the overall level of biosecurity on farms, in order to slow down the spread of the disease in the event of a future outbreak.

European research on animal diseases



In 2020, five European research projects in which ANSES is participating were selected under the first ERA-NET ICRAD call for projects on infectious animal diseases.

ERA-NET ICRAD (International coordination of research on infectious animal diseases) projects are European collaborative ventures co-financed by national research funding agencies, including the National Research Agency (ANR) in France and the European Commission. The aim of this call for projects was to fund multidisciplinary research on major animal epidemics such as African swine fever and avian influenza. Each project involves at least three organisations from three different countries.

Four projects are being coordinated by ANSES:

- **The PIGIE project** (Understanding the dynamics and evolution of swine influenza viruses in Europe: relevance for improved intervention and sustainable pig production) will study recurrent influenza infections in pig herds. The aim is to determine the factors promoting this recurrence and suggest measures to curb it.

- **The FMDV_PersIstOmics project** (From proteogenomic host response signatures of persistent foot-and-mouth disease virus infection to diagnostic markers and therapeutic control) will examine persistent infections due to FMD virus in ruminants. Its goal is to determine the molecular mechanisms involved in establishing and sustaining the virus, in order to improve the diagnosis of asymptomatic carrier animals and develop therapeutic tools.

- **The MUSECoV project** (Multi-scale eco-evolution of coronaviruses: from surveillance toward emergence prediction) will seek to improve understanding of the diversity of coronavirus strains circulating in animal populations, including SARS-CoV-2, responsible for COVID-19. The aim is to better understand the dynamics of coronavirus infections in various animal populations and therefore to rapidly detect the emergence of particularly pathogenic variants.

- **The ASFVInt project** (Decoding a virus Achilles heel: the African swine fever virus interactome) aims to improve understanding of the molecular interactions between the virus and pigs, with the aim of developing new antiviral solutions or vaccines.

ANSES is also involved in a fifth project, coordinated by the Pirbright Institute in the United Kingdom: **NEOVACC** (Novel strategies to enhance vaccine immunity in neonatal livestock), which aims to develop vaccination strategies tailored to newborn calves and piglets.

Several ANSES laboratories involved

The Laboratory for Animal Health is coordinating the FMDV_PersIstOmics and MUSECoV projects and participating in the ASFVInt project. The Ploufragan-Plouzané-Niort Laboratory is leading the PIGIE and ASFVInt projects and is involved in the NEOVACC and MUSECoV projects. The Nancy Laboratory for Rabies and Wildlife is also taking part in this last project.



Innovating for animal welfare



Animal welfare is becoming increasingly important in our society. It is a concept at the crossroads of numerous, sometimes conflicting influences, that may be philosophical, moral, scientific, economic, regulatory, etc. Through its research and scientific expert appraisal capabilities, ANSES is helping to develop livestock farming systems that improve animal welfare.

As part of its expert appraisal work, the Agency assesses the impact of farming systems on product quality and animal and human health. It also conducts laboratory research to improve and develop innovative farming systems. The work focuses on poultry, pig and goat production using a multidisciplinary approach, i.e. integrating the study of behaviour, physiology, animal health, and product quality and safety. Among other things, ANSES teams are experimenting with housing systems that meet the animals' needs and enhance the potential for expression of positive emotions, such as giving poultry access to a "winter garden" (a sheltered outdoor run). The Agency is also studying the impact of perinatal experiences on the development and well-being of young animals, as well as farming methods that avoid mutilation such as beak trimming, tail docking, etc.

Definition of animal welfare (ANSES, 2018)

The welfare of an animal is its positive mental and physical state related to the fulfilment of its physiological and behavioural needs and its expectations. This state varies depending on the animal's perception of the situation.

In addition, ANSES is a member of the National Reference Centre for Animal Welfare and, since 1 February 2020, has been coordinator of the European Reference Centre for the welfare of poultry, rabbits and other small farmed animals. As such, it supports the French and European public authorities in the application of animal welfare regulations, mainly by providing validated indicators.

“Today, we need to adapt the animal's environment to its needs”



Virginie Michel, National Coordinator of animal welfare activities



What do we mean today when we talk about animal welfare?

The study of animal welfare is an animal-centred approach in which we put ourselves in the animal's position in order to identify its needs and expectations. In practical terms, this means thinking about the animal's feelings, perceptions and emotions such as fear or pleasure. In particular, it involves studying animal well-being in different farming systems, during transport or at the slaughterhouse, where we talk more about animal protection.

What are the criteria for animal welfare?

Animal welfare is currently assessed using animal-centred

metrics relating to their behaviour, physiology and health. Production is not necessarily strongly impacted by the welfare status of livestock and is in any case one of the last factors to be affected. So while a drop in yield may indicate a state of unease or a health problem, adequate production should in no way be taken as synonymous with optimal welfare.

How is animal welfare assessed?

Today, we need to stop trying to adapt the animal to its environment and instead adapt the animal's environment to its needs. The study of animal behaviour is essential for this, and researchers have put mechanisms into place for assessing animal welfare.

Various indicators and tools have been developed to assess the welfare of livestock, such as the Welfare Quality® protocol developed for dairy cows, pigs and some poultry.

The major challenge at the moment is to develop breeding, transport and slaughter systems that are more respectful of the animals' well-being and that meet at the very least the characteristic needs of their species: scratching, pecking, flying and perching for poultry; exploring and rooting for pigs, etc.



2 Environment

Reducing problematic exposure ↗



Detecting contaminants in water



Many chemicals, whether of natural or anthropogenic origin, are found in water. Some, such as toxins, heavy metals, pesticides and antibiotics, can have an impact on ecosystems and the health of living beings. We assess the risks associated with their presence, from natural resources through to the consumer's tap, as well as in recreational water. The Agency is also involved in optimising water quality control and managing problematic contamination, mainly from chemicals.

In 2020, ANSES examined the issue of cyanotoxins produced by cyanobacteria in aquatic environments. These micro-organisms, which together contain more than 250 toxins, proliferate on all continents under favourable environmental conditions and contaminate drinking water, recreational water and fish. Several cases have been reported in metropolitan France in recent years.

ANSES has updated the list of toxin-producing cyanobacteria in fresh water that pose a threat to humans. In order to limit the contamination of surface water and protect aquatic ecosystems, it emphasised the need to reduce nitrogen and phosphorus inputs from human sources such as sewage sludge or fertilisers applied to agricultural soil. The Agency also proposed a strategy for harmonising water surveillance, quality monitoring and analysis.

In 2020, ANSES also provided some initial insights on the contamination of French aquatic and terrestrial environments by antibiotics, and on the presence of resistant bacteria that are pathogenic to humans and of antimicrobial resistance genes. Some of these genes that are currently a problem in human medicine originate from environmental bacteria, but their dissemination in environmental media is poorly understood. The key point here is that antibiotics are found in small quantities in both water and soil. These tend to be the drugs that deteriorate the least, and not necessarily the ones that are most commonly used. The antibiotics present, the resistant bacteria and the resistance genes identified are mainly due to discharges of treated wastewater and the spreading of sewage sludge and livestock manure.

These results are likely to evolve with climate change and, in particular, the reuse of treated wastewater or artificial recharge of aquifers.

Pascale Panetier, Head of the Water Risk Assessment Unit



What are the sources of water contamination?

Depending on where it comes from, water may contain mineral elements of natural origin (fluorine, magnesium, calcium, etc.), some of which – such as arsenic – are known to be toxic to humans. The resources used to produce drinking water, whether supplied to the tap or in bottles, may also be subject to diffuse contamination resulting from urban, industrial or agricultural activities or accidental pollution.

How are chemicals in water regulated?

In order to protect consumer health, the presence of substances such as chemicals is governed by the Public Health Code, which incorporates the requirements of European Directive 98/83/EC of 3 November 1998. Maximum concentrations have therefore been set for some 40 individual chemicals or families of substances in drinking water, which are regularly

monitored by regional health agencies. “Quality limits” are also defined to protect the health of consumers and “quality references” are used to check that the water treatment plants are functioning properly and that the quality of the water produced and supplied to the tap remains high.

How do you manage situations where the regulatory limits are exceeded?

The regulations allow for the quality limits to be exceeded in exceptional cases for certain

parameters, provided that there is no hazard to health, while waiting for compliance to be restored. During this period, an exceptional maximum value (guideline value) must be applied to ensure that public health is not put at risk. ANSES’s role is to determine whether the quality limit or reference can be waived and to propose this guideline value after having characterised the hazard for human health and the population’s exposure. The Agency has thus determined guidelines values for around 20 substances, including selenium and manganese, for example.

Transfer to ANSES of decisions in the area of water

As of 1 March 2021, Act no. 2020-1525 of 7 December 2020 on accelerating and simplifying public action transferred to ANSES responsibility for issuing, amending and withdrawing laboratories’ approvals to conduct sampling and physico-chemical analysis for water quality monitoring, for drinking water, bottled water, natural bathing water and water for swimming pools and artificial bathing pools.

Groundbreaking European work on pesticides



Of all chemicals, pesticides are among the most symbolic of the impact of human activities. In order to limit the risks they potentially pose to populations and ecosystems, in 2020 we continued our unique and innovative work, whether through the phytopharmacovigilance mission or under the regulatory system for assessing and authorising plant protection products.

COMPARATIVE ASSESSMENT OF ALTERNATIVES TO GLYPHOSATE

As part of the government's glyphosate withdrawal plan, ANSES conducted an assessment of non-chemical alternatives to this herbicide. Its results were published in October 2020. The purpose was to determine the uses for which this substance could be substituted by non-chemical alternatives, and to identify deadlock situations where no suitable alternatives are currently available. This approach, the first of its kind in the European Union, is based on an article of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. It

focused on four main areas of use: viticulture, fruit trees, arable crops and forestry. ANSES therefore worked to identify the practical or economic drawbacks of alternatives to glyphosate. The conclusions of this comparative assessment are now taken into account when considering marketing authorisation (MA) applications. For products receiving MA, there are limitations on conditions of use and rates applied, which will help reduce the quantities of glyphosate used in France from 2021.

NATIONAL EXPLORATORY CAMPAIGN TO MEASURE PESTICIDES (CNEP) IN AIR

In July 2020, the results of the CNEP conducted by ANSES, Ineris and the network of approved air quality monitoring associations (AASQA) were published. Over a period of 12 months, this huge campaign led to an unprecedented review of the presence of 75 pesticide substances in ambient air, including plant protection products, biocides, veterinary medicines and antiparasitics for human use. Along with Belgium, France is one of the only countries in Europe to have undertaken this kind of campaign for measuring pesticides in outdoor air on a national scale. The Agency carried out an initial health interpretation and identified 32 substances requiring further examination, including lindane, which has long been banned but is highly persistent in the environment.

ANSES recommends not renewing the approval of certain active substances

As part of France's national action plan to reduce the use of plant protection substances, in April 2020 ANSES published its expert appraisal on the substances requiring particular attention, in view of their hazard level and phytopharmacovigilance data. On the basis of its work, it recommended not renewing the approval of thiophanate-methyl and mancozeb, and fast-tracking the European assessment of other substances. At the same time, the Agency undertook its own risk assessment for several authorised products and assessed one substance for its endocrine-disrupting potential without waiting for renewed approval of the active substances contained in these products. In December 2020, the European Commission issued an implementing regulation confirming the non-renewal of mancozeb.



Phyto-pharmacovigilance



The phytopharmacovigilance scheme that we coordinate, which is specific to France, focuses on the effects of plant protection products and their residues, observed under their actual conditions of use. Ohri Yamada, Head of the Phytopharmacovigilance Unit, gives us an overview of the scheme.



Ohri Yamada, Head of the Phytopharmacovigilance Unit

What is phytopharmacovigilance?

Created in October 2014 by the Act on the future of agriculture, food and forestry, phytopharmacovigilance relies on some 20 partners including human and veterinary poison control centres, the Agricultural Mutual Insurance Scheme (MSA), and ministries and public bodies in charge of monitoring environmental media, water, air or food.

The scheme gathers data from these networks, as well as reports submitted directly by professionals who use or sell plant protection products, or who advise the users of these products.

It therefore enables a large amount of data to be collected on the presence of pesticide residues in the environment, the exposure observed and the health impact on living beings and ecosystems.

The aim is to ensure exhaustive monitoring of the effects of using these products. The literature and media monitoring we carry out also provides information that can give rise to alerts, bearing in mind that we pay specific attention to epidemiological studies. As part of the scheme, ANSES produces summary sheets for each active substance, all of which are available on our website.

“Ensure exhaustive monitoring of the effects of using plant protection products”

What do the studies funded by phytopharmacovigilance examine?

To analyse reports of adverse effects or compensate for the lack of exposure data, ANSES funds studies and measurement campaigns with a budget specifically allocated to phytopharmacovigilance. In 2020, 25 studies were finalised and five new ones were initiated, corresponding to around 1.4 million euros. For example, following the report of a cluster of paediatric cancers in a wine-growing community, the decision was taken to launch two studies to provide information on exposure in wine-growing regions. One was on pesticide contamination of people living near agricultural crops, carried out in conjunction with *Santé Publique France* (PestiRiv), and the other on geographical and statistical associations between childhood cancers and residen-

tial proximity to agricultural activities, conducted by Inserm and *Santé Publique France* (GEO-CAP-Agri). If the contamination of an environmental medium is not sufficiently documented, the decision may be taken to fund a measurement campaign, as was the case for ambient air and soil. In total, more than 40 studies have been financed since the phytopharmacovigilance scheme was set up.

What impact has this scheme had?

All of these data are systematically examined when marketing authorisations are reviewed. If the assessments reveal frequent contamination exceeding the thresholds, this may lead to a product’s use being restricted or even prohibited. In the event of a health alert, the data are analysed without waiting for

the regulatory re-assessment of marketing authorisation. As an example, the episode of multiple poisonings with metam-sodium in Maine-et-Loire in autumn 2018 led to the accelerated withdrawal from the market of products containing this active substance.

Phytopharmacovigilance also contributes to the development of regulatory systems. For example, the data documenting bee mortality and hive contamination led ANSES to recommend extending the regulatory system protecting pollinators from insecticides and acaricides to also cover fungicides and herbicides. This provision is being considered as part of the 2021 Pollinator Plan.

The phytopharmacovigilance scheme therefore gives ANSES a global, integrated view of the impact of plant protection products, throughout their use.

Limiting the spread of pollen and mould in air



Many respiratory diseases, such as allergies and asthma, can be caused by biological contaminants in the ambient air. We are closely studying their causes and health impacts, which affect many people's quality of life. In 2020, work focused on mould and ragweed pollen.

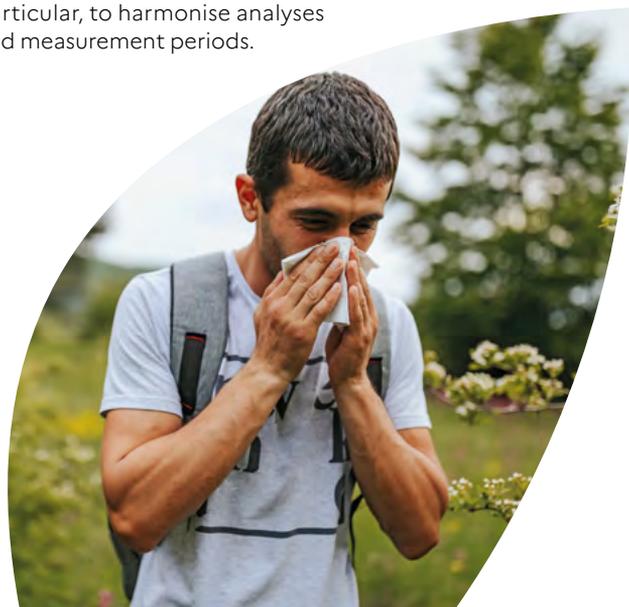
MONITORING MOULD IN AIR

Mould refers to different types of microscopic fungi that colonise soil and vegetation. It accounts for nearly 25% of biological air contaminants, alongside pollen, bacteria and viruses. In Europe, the highest concentrations of mould in outdoor air are found in summer and autumn, related to the lifecycle of plants. ANSES's expert appraisal on mould in outdoor air, published in November 2020, showed that it exacerbates asthma in children just like the mould found in the air inside buildings. Its development is mainly determined by climate and vegetation, and reducing the main sources of its growth is not a simple matter. In its opinion, the Agency stressed the need to optimise the surveillance scheme and, in particular, to harmonise analyses and measurement periods.

Mould accounts for nearly

25%

of biological air contaminants, alongside pollen, bacteria and viruses.



CONTROLLING THE SPREAD OF RAGWEED THROUGH AN INTEGRATED MANAGEMENT STRATEGY

Common ragweed is an invasive plant that is spreading across the country. Its pollen causes strong symptoms in people suffering from allergic rhinitis due to pollen. Its spread is favoured by certain human activities such as the transport of ragweed-contaminated soil or seeds, agricultural or mowing machinery, etc. In 2020, ANSES produced a completely new estimate of the costs associated with the health consequences of ragweed's presence in France. It predicted that these costs will increase, due to the expansion of ragweed-infested areas and an increase in pollen levels in ambient air, mainly as a result of climate change. In its expert appraisal, ANSES also found that ragweed management is still confronted with regulatory obstacles, such as the limited enforcement power of local mayors on private land.

Estimates of the health impact and associated costs of common ragweed in France, based on ANSES's 2020 expert appraisal

- Cost of medical care (e.g. medicines and consultations): between 59 million and 186 million euros per year;
- Cost of production losses calculated based on absences from work: between 10 million and 30 million euros per year;
- Cost of lost quality of life for allergic individuals: between 346 million and 438 million euros per year.

Recommendations to limit the spread of ragweed in France

- Introduce specific and locally coordinated regulations in areas on the margins and areas still relatively unaffected by the presence of ragweed.
- Involve the building and public works sector more closely, alongside the agricultural sector.
- Expand and intensify monitoring of the plant and its pollen on a national level.
- Modernise the monitoring system for ragweed pollen by coupling it to models that can predict its dispersion throughout metropolitan France.
- Raise awareness among healthcare professionals and allergic or potentially allergic individuals.
- Foster information exchanges between regions through the development of networks of doctors and "sentinel" patients.

Understand- ing risks

Protecting
on a daily
basis ↗



Vaping: new practices and the associated risks



While the adverse health effects of cigarettes are now widely known and documented, what about vaping products? We defined a work programme to better identify and assess the risks associated with new technologies and practices with rapidly evolving uses.

From 2007 onwards, the use of electronic cigarettes, or e-cigarettes, spread very quickly in Europe. Vaping has given rise to scientific and societal discussions on the potential benefits of this practice in reducing tobacco use and the risks associated with the inhalation of chemicals by vapers and the people around them. These include e-liquid ingredients and compounds that potentially form in the mixture or in the spray, and those that could migrate from the constituent materials of the electronic cigarette. To conduct a risk assessment, ANSES initiated work to rank the substances according to the potential risk from inhalation and estimate exposure from different consumption practices. In 2020, it published three studies which it coordinated and financed, in order to gain a better understanding of this booming market:

- mapping of market players and controversies;
- results of a survey by the BVA polling institute on the practices of French vapers;
- analysis of reports of accidental poisoning cases from poison control centres.

Cases of accidental poisoning due to vaping reported to poison control centres

ANSES established a partnership with poison control centres to monitor reports of acute poisoning cases due to vaping. After an initial study published in 2017 entitled “Are electronic cigarettes responsible for serious accidents?”, the poison control centres launched a second study in July 2019. Preliminary results were reassuring and showed no deaths or lung illness similar to the American outbreak in late 2019. They also indicated that 10 to 20% of accidental exposure corresponded to “do it yourself” practices and that most cases were due to domestic misuse.

FIRST REVIEW OF DECLARATIONS OF TOBACCO AND VAPING PRODUCTS

In 2020, as part of its new mission, ANSES conducted an unprecedented review of these products on the basis of the manufacturers' declarations. It published a list of products sold on the French market, along with data on identified substances, and ingredients and additives used in product composition. It found almost 850 additives in tobacco products, almost 1,200 substances in the ingredients, and over 600 in the emissions from vaping products. ANSES also carried out major methodological work and built a database to structure and analyse the large volume of information. It analysed the declarations concerning over 3,000 tobacco products and over 33,000 vaping products. Inconsistencies and non-conformities were identified, and manufacturers were asked to take appropriate corrective action.

In light of this first review, making France the first Member State to publish this level of information on these products, the Agency made recommendations to improve the reporting process at European level.

Tobacco and vaping products: ANSES's mission

Since the entry into force of EU Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products in 2016, manufacturers of tobacco and vaping products must declare certain information on the composition, emissions, toxicity or sales volumes of their products before marketing them. In France, ANSES has been tasked with collecting and analysing all this information. It is also responsible for informing the public about products sold in France, providing scientific and technical support to the authorities, and assessing the risks associated with vaping products and heated tobacco. Lastly, ANSES is involved in the European joint action on tobacco control.



Assessing the effects of 5G



5G expands the range of radio frequencies used by mobile telephones, thereby contributing to changes in digital practices. These innovations entail new types of exposure to waves. The topic of radiofrequency effects is one of ANSES's historical areas of expertise. In 2020 and 2021, we published two reports that shed light on the potential risks associated with the rollout of 5G.



Olivier Merckel,
Head of the Unit for assessment
of the risks related to physical
agents

What is 5G technology?

5G, for "fifth generation", actually encompasses a number of technical innovations in the area of electromagnetic waves. The most visible at the moment is mobile broadband. But the rollout of 5G infrastructure should also enable a huge number of connected objects to communicate with each other and with various networks, or to exchange data very quickly, almost in real time, via wireless links.

What are the health issues associated with exposure to waves?

The development of wireless technologies using radiofrequency electromagnetic waves has accelerated sharply over the last twenty years. This includes new features for mobile communications, the rise of Bluetooth standards, Wi-Fi, and connected objects. Consumption behaviour and uses are also changing very rapidly, with mobile internet, online viewing, networked games,

etc. The proliferation of technological offers and networks and the changes in practices are increasing the population's exposure to electromagnetic waves, with situations that vary enormously depending on the place, for example. Regarding knowledge of the health effects of exposure to waves, the most recent expert appraisals, based on more than 25 years of research, have not found any causal link between exposure to waves in our daily lives and possible short- or long-term health effects.

What did the ANSES expert appraisal on 5G involve?

This expert appraisal was a continuation of the work we have been conducting at the Agency for the past 10 years on the hazards and risks of exposure to electromagnetic fields, whether they are emitted by high-voltage lines, mobile telephones or “Linky” smart electricity meters, for example.

Regarding 5G, we published a preliminary report in January 2020 that highlighted the scarcity of data available, both in terms of predicted exposure levels and, in the area of research, possible effects at specific 5G frequencies. One of the main questions raised at the time, which the expert appraisal attempted to answer, concerned our ability to interpret the data available from current technologies in order to adapt them to new frequency bands. Our assessment therefore focused on the fact that 5G is being deployed in a variety of frequencies; those used by current mobile technologies from 2G to 4G (700 MHz to 2.1 GHz), as well as specific new frequency bands (around 3.5 GHz and 26 GHz). These three distinct frequency bands imply different interactions with the human body.

In the end, the deployment of 5G in the frequency bands used for 2G to 4G technologies is not expected to lead to any different exposure. The Agency’s

messages calling for exposure to be limited, in particular for children, therefore remain entirely relevant. Especially given the proximity of the frequencies around 3.5 GHz to those used by 2G to 4G mobile technologies, we do not believe that deployments in this band, which are now under way, should give rise to any new issues regarding health effects. Of course, this is based on the data currently available and requires careful monitoring of the rollout, especially to obtain information on the actual level of people’s exposure.

Regarding 5G applications in the 26 GHz band, we will have to wait for the first experiments in order to obtain exposure measurements. The Agency’s expert appraisal also showed that research is needed to obtain a clearer picture of effects that could more specifically concern the skin or eyes, insofar as this radiation does not penetrate any further than the first few millimetres of skin.

How was this expert appraisal carried out?

The expert appraisal coordinated by my unit was conducted by a dedicated working group bringing together 12 experts from various disciplines: physicists, biologists, epidemiologists, doctors and sociologists. The work was then submitted to the Expert Committee on Assessment of the risks

related to physical agents and new technologies. In addition, the Interdisciplinary Laboratory on Science and Innovation in Society (LISIS) was asked to conduct two supplementary studies in order to provide an overview of the controversy surrounding 5G: its timeline, the players involved and its arenas of expression. The issues around the effects of 5G were also discussed in our Dialogue Committee, which brings together stakeholders in the field of radiofrequencies: associations, trade unions, and mobile phone operators and manufacturers.

Why was the report submitted for public consultation?

For some years now, the Agency has been giving scientists and stakeholders the opportunity to contribute new data to the expert appraisal process through the public consultation of key expert appraisal reports, such as those on radiofrequencies and children, or on electromagnetic hypersensitivity. Given the controversy surrounding 5G and the deployments still under way, new data could emerge quickly, which is why the expert appraisal report and related opinion have been put out for public consultation. ANSES will publish the responses to the comments received and, with the help of the expert group, will supplement the expert appraisal report and opinion if necessary.

Diet and sedentary behaviour among young people



Adolescence is a pivotal period: the habits acquired at this time tend to be perpetuated or even accentuated in adulthood. In terms of young people's physical activity, we sounded the alarm about the increase in «screen time». Other studies drew attention to the growing popularity of fast-food restaurants among young people, where the nutritional quality of the food is inferior to that of school canteens. The misuse of nitrous oxide as a «laughing gas» by adolescents and young adults also led us to make recommendations to better protect them from these hazards.

Using data from the third study on the food consumption and eating habits of the French population (INCA3), ANSES assessed the health effects of young French people's exposure to sedentary behaviour and low levels of physical activity. The expert appraisal showed that the health thresholds were exceeded in two thirds of 11- to 17-year-olds, which means a high level of risk for young people's health. ANSES therefore alerted the public authorities: inadequate physical activity should be considered as a health risk in its own right. To combat sedentary behaviour and promote physical activity, the Agency reiterated the need to create an overall environment conducive to behavioural change, both at an individual and collective level: at home, at school, in public spaces through the development of cycle paths, etc.

FAST FOOD, A DIRECT COMPETITOR TO SCHOOL CANTEENS AMONG ADOLESCENTS

Using data from the INCA3 study, ANSES also conducted a review of food consumption and nutritional intake from meals eaten outside the home over the period 2014-2015. It found that 40% of adults and 75% of children and adolescents eat in work or school canteens at least once a week, which offer the most nutritionally adequate food outside the home. However, consumption of fast food at least once a week doubled between 2006 and 2014, including among school-age young people. Although its contribution to food consumption and nutritional intake is still limited (5% or less), this trend is cause for concern because food groups such as sandwiches, pizzas, pies and soft drinks are consumed in large quantities. For ANSES, improving the range and quality of fast food is therefore a priority. It also advocates facilitating direct access to mass catering – especially school canteens – for as many people as possible.





↘ Main findings of the expert appraisal on physical activity and sedentary behaviour among 11- to 14-year-olds

66%

spend **more than 2 h** a day behind a screen

and

engage in **less than 1 h** of physical activity a day

49%

spend **more than 4.5 h** a day behind a screen

and/or

engage in **less than 20 min** of physical activity a day

17%

spend **more than 4.5 h** a day behind a screen

and

engage in **less than 20 min** of physical activity a day

Young people from disadvantaged backgrounds are particularly badly affected by sedentary lifestyles. Girls (11-14 years old) are more impacted by inadequate physical activity than boys.

Protecting young people from the harmful uses of nitrous oxide



Nitrous oxide, a gas used in the medical field for its analgesic properties, is also marketed as a compressor in canisters for whipped cream dispensers. The practice of inhaling nitrous oxide recreationally has spread rapidly, because of its euphoric effect. The number of poisoning cases recorded by poison control centres is increasing, particularly among young people, as ANSES noted in a toxicovigilance study published in mid-2020.

66

nitrous oxide poisoning cases recorded by poison control centres between 2017 and 2019

75%

of cases had at least one neurological or neuromuscular symptom

More than half

of poisoning victims were between 20 and 25 years of age



Cécilia Solal,
Toxicology Expertise Coordinator



Our study found that since 2019, there has been a real democratisation of nitrous oxide use from these canisters, which are freely available in shops and on the internet. Young people use the small nitrous oxide capsules to inhale the gas via balloons. It gives a feeling of euphoria that lasts 20 or 30 seconds, which many people believe to have no consequences over time. However, the poison control centres have identified multiple effects: tingling, loss of balance, tachycardia, asphyxia, and neurological and neuromuscular disorders. Some of these problems may persist even after the nitrous oxide use has ceased. We

made three main recommendations to better protect young people from these hazards: provide more information to young people, raise awareness among healthcare professionals, and strengthen the regulations to at least prohibit their sale to minors and require clearer labelling on the dangers of nitrous oxide. Our work contributed to the bill on preventing the harmful uses of nitrous oxide, which was adopted in June 2021.

“There has been a real democratisation of nitrous oxide use among young people aged 20 to 25 years”



Insight

Vigilance for food supplements and essential oils



Food supplements – concentrates of nutrients often based on plants – and essential oils are increasingly used by the French. However, this use can expose them to health risks. Our latest opinions on cases of poisoning involving food supplements illustrate the importance of the nutravigilance scheme in protecting consumer health. They also show that essential oils are not always harmless.

Created in 2009 and led by ANSES, the national nutravigilance scheme is used to rapidly identify any adverse effects associated with the consumption of food supplements, energy drinks and other new foods and ingredients on the market, with the support of health professionals. These data are invaluable for alerting the public authorities and informing producers and consumers. To facilitate reporting, ANSES launched a new more user-friendly website in early 2021, which now makes it easier to submit more precise information on the products consumed or the adverse effect observed. Reports containing sufficient information are analysed by a group of doctors who assess the severity of the adverse effect and the probability of a link between consumption of the product and occurrence of this effect. In the event of strong causality and high severity, the Agency's alert can lead to measures such as product inspections, labelling changes, amendments to regulations or even the withdrawal of products from the market. More than 5,000 reports have been registered since 2009.

Food supplements: the latest major alerts

- **2019:** Food supplements containing glucosamine and/or chondroitin sulphate, which claim to contribute to joint comfort.
- **2019:** Berberine herbal supplements used to regulate blood glucose and cholesterol levels.
- **2020:** Chewable Hair Vitamins®, a product in chewable capsule form used to maintain healthy hair.
- **2020:** Food supplements containing Melaleuca essential oils for treating certain infections.

More than **5,000**
reports have been registered since
2009



MISUSE OF FOOD SUPPLEMENTS CONTAINING MELALEUCA ESSENTIAL OILS

Derived from the leaves of *Melaleuca* species, tea tree, niaouli and cajepout essential oils are used in numerous food supplements. The antimicrobial properties claimed in various aromatherapy books have led consumers to misuse these food supplements to treat sore throat, sinusitis, cystitis etc. In its 2020 assessment, ANSES confirmed that the oral absorption of certain compounds of these essential oils posed neurological (niaouli and cajepout), carcinogenic, genotoxic and potentially reprotoxic risks. To prevent them, the Agency issued recommendations on storage, dosing, avoidance and even banning of these essential oils. It particularly advised against their use by children and pregnant and breastfeeding women.

ESSENTIAL-OIL SPRAYS AND DIFFUSERS: BEWARE OF ADVERSE EFFECTS

Described as having the ability to “cleanse” or “purify” the air, essential-oil based sprays and diffusers are increasingly present in our homes. ANSES’s analysis of cases of poisoning reported to French poison control centres highlighted a range of adverse effects under normal conditions of use, including irritation of the eyes, throat and nose, and difficulty breathing. These products also emit volatile organic compounds which, even if they are of natural origin, can have irritating or sensitising properties. Lastly, some of the compounds emitted may oxidise, particularly with naturally occurring ozone, and constitute a source of indoor air pollution. ANSES therefore recommended keeping essential oils out of the reach of children, providing better information on the precautions for use, and generally limiting sources of indoor pollutants.

“It is therefore necessary to undertake new independent studies on essential oils, whether used alone or in combination, in order to better characterise the potentially harmful health effects in the short and long term.”

JULIETTE BLOCH, Director of Health Alerts and Vigilance

Nanomaterials: better understanding risks and limiting unnecessary uses



Nanomaterials have specific physical and chemical properties due to their very small size. Various materials used in industry are made entirely or partly from nanoscale particles. The large number of substances used, along with the lack of knowledge of effects and exposure, still constitute major obstacles to risk assessment. In recent months, the Agency has shed new light on these two issues.

In 2013, France launched a national scheme making the reporting of nanomaterials mandatory for manufacturers, importers and distributors of more than 100 grams per year of substances in nanoparticle form. ANSES, which manages the scheme, published its first assessment in 2020.

R-NANO: LESSONS LEARNED FROM THE ANSES ASSESSMENT AFTER EIGHT YEARS IN OPERATION

- More than **400,000 tonnes** of nanomaterials are produced and imported into France each year.
- **52,000 reports** were recorded in R-Nano between 2013 and 2017.
- **90% of the characterisation data** for nanomaterials (on size, specific surface area and surface charge) **were unusable**.
- Only **10%** of data provided correct information on use.

Two major conclusions can be drawn from this assessment: the absence or poor quality of data provided hampers the traceability of nanomaterials and the use of these data by public health agencies. And action needs to be taken to optimise the system's efficiency, including ending the exemptions on reporting.

Aurélie Niaudet,

Deputy Head of the Unit for assessment of the risks related to physical agents



What kind of difficulties do you face when assessing the effects of nanomaterials?

Depending on their shape and characteristics, nanomaterials interact with living organisms in different ways. A wide variety of parameters can influence their toxicity: their chemical nature – for example silica, titanium or silver – but also their size, shape, surface area and the characteristics of any coating they may have. In general, assessing the risks associated with nanomaterials involves three steps: agreeing on criteria for defining them, describing the main types of exposure, and understanding their behaviour and effects. In fact today, there is still no single clear definition of nanomaterials. Apart from their size, few physico-chemical parameters are taken into account in the definition currently proposed by the European Commission. In order to protect people, we need to be pragmatic and above all understand the nanomaterials to which we are most exposed.

What is the focus of ANSES's work on nanomaterials?

We have been working on this issue for a long time at ANSES. We assess the risks of nanomaterials to the general population, to workers handling these substances – for example in product manufacturing – and to the environment.

Among other things, our work covers titanium dioxide, which is used as a food additive, and nano-silver, which is used for its antibacterial properties. We have also been working on methodologies to offer alternatives to the assessment methods classically used and better integrate the different behaviours of these compounds. We recently published a review of the presence of engineered nanomaterials in food and recommended a suitable method for assessing the health risks of these materials when found in food.

Also, through the National Research Programme for Environmental and Occupational Health managed by the Agency, we fund research projects on the effects and environmental

fate of nanomaterials, as well as on monitoring population exposure, etc. In May 2021, with the National Research Agency, we organised a scientific conference to review progress in this field and recent work on microplastics and nanomaterials.

To conclude, what are your recommendations to protect people?

Now you can see that there are still many grey areas regarding population exposure to nanomaterials and the potential impact on health and the environment. As well as strengthening the regulatory framework, it is also important to limit exposure of the population and the environment as a precautionary measure, by choosing safe products that are equally effective but free of nanomaterials. Moreover, given the persistent unknowns about nanomaterials, some uses seem artificial, and the Agency reiterates its recommendation to restrict the use of products containing nanomaterials that are of little benefit to the population.

3 questions for

Progress on endocrine disruptors



We were pioneers on the issue of endocrine disruptors, and in early 2021 we published major work to identify and eliminate these substances, which negatively interfere with essential biological functions.

As part of France's Second National Endocrine Disruptor Strategy (SNPE 2), ANSES drew up a list of substances of interest and identified a selection of priority substances to be included in its assessment programme. Among the 906 substances of interest for which the data available are sufficient to consider an assessment based on the three points of the WHO definition – adverse health effects, alteration of functions of the endocrine system, a biologically plausible link between these two findings – ANSES prioritised a selection of substances to which the population is exposed in Europe and for which there are no current plans to examine the endocrine properties.

For the substances to be assessed, the Agency recommended a method to weigh up the scientific evidence and determine whether the substances are known, presumed or suspected endocrine disruptors. This method is a precursor to the one that will be applied at the European Union level. This graduated approach should better account for uncertainties and facilitate expert judgement, as is currently done for carcinogenic, mutagenic and reprotoxic substances.

PREVENTING THE UNDESIRABLE REPLACEMENT OF BISPHENOL A BY BISPHENOL B

In early 2021, ANSES proposed identifying bisphenol B as a substance of very high concern in the REACh Regulation. Bisphenol B is currently used as an alternative for some uses of bisphenol A and bisphenol S in a number of countries, particularly in the United States, where it has been registered as an indirect additive used in certain food-contact coatings and polymers. The purpose of this classification is to prevent industrial uses of this chemical on the European continent as a replacement for bisphenol A, and to require importers of consumer goods to declare its presence whenever its concentration exceeds a threshold of 0.1%.

With this expert appraisal, ANSES is helping to provide an operational response to two challenges:

1. identify, among the multiple lists of possible endocrine disruptors, the substances that can and should be assessed rapidly;
2. strengthen and accelerate the identification of endocrine disruptors while taking uncertainties into account.



Cécile Michel,
Head of the Chemicals
Assessment Unit



The substitution of hazardous chemicals is a cornerstone of current strategies to reduce health and environmental risks. This principle was recently reaffirmed by the European Commission, in particular for product categories that come into contact with vulnerable populations. Now it also has to align with the industry's approach to sustainability and the circular economy.

Determining that a chemical is harmful is a first step. Companies must then find alternatives, which is not always easy: the new substance must be technically equivalent, economically substitutable, sustainable and also safer.

Substitution of chemicals often requires companies to implement changes in systems, materials or processes. In addition to the substitution-CMR.fr website, ANSES has developed and published on its website a methodological document for comparing alternatives to a hazardous substance. Currently, to find updated information on alternatives, professionals can also consult the database of the European Chemicals Agency (ECHA), set up following the REACH Regulation (for Registration, Evaluation and Authorisation of Chemicals). It lists all the potential substitutes that are already in use or produced in excess of one tonne per year in Europe.

“Substitutes sometimes share the same hazardous properties as the substance they are replacing”



Insight

Occupational diseases: ANSES's contribution



Work forms part of our daily lives. However, some activities may expose workers to hazards such as toxic substances. In some cases, they may contract an illness that can be recognised as an occupational disease and give rise to compensation. Since 2018, our new expert appraisal mission supports the definition of occupational disease tables.

“Take better account of progress in scientific knowledge and professional practices”



Henri Bastos, Scientific Director for Occupational Health



Why carry out independent collective expert appraisals for the recognition of occupational diseases?

To improve access to this recognition, in 2018 the government decided to carry out independent, collective scientific expert appraisals. This preliminary expert appraisal stage was entrusted to ANSES. In France, occupational disease tables are the main pillars of the system for the recognition of work-related illnesses. Their creation and modification require scientific knowledge for establishing causal relationships between exposure or working conditions on the one hand and diseases on the other. However, these relationships are neither simple nor direct. So far, scientific considerations have been dealt with in the same framework as social and economic issues during consultations between social partners. This is why the government decided to separate the scientific expert appraisal stage from the negotiation stage.

Can you describe the methodology developed by ANSES? Also, what will the Agency's initial appraisals focus on?

In order to be able to respond to the formal requests it receives, in 2020 the Agency developed a working methodology and a framework for identifying and characterising the links between occupational exposures or working conditions and health problems.

This methodology resulted from a collective expert appraisal conducted by a dedicated working group made up of experts in various fields including epidemiology, medicine, toxicology, sociology, exposure assessment, ergonomics and social legislation. Its aim was to define a framework for collecting and analysing scientific data. This methodology covers the definition of diagnostic criteria for diseases, the description of potentially related occupational exposures, and above all the establishment of causal relationships between the two. It also includes a human and social sciences component, enabling various issues, especially sociological and legal issues, to be taken into account.

What does ANSES's expert appraisal contribute to the system for recognising occupational diseases?

The arguments leading to the adoption of tables are not always known and can be interpreted differently by the various stakeholders in the occupational disease recognition system: workers exposed to risk factors who develop a disease and wish to initiate a claim for recognition; doctors who are supposed to assist them in this process by drawing up the certificates attesting to their state of health; social insurance funds responsible for the medical-administrative management of claims; or employers receiving occupational disease declarations. ANSES therefore helps improve the recognition system's ability to take account of advances in scientific knowledge and professional practices.



4 Scientific expert appraisal

Principles and challenges ↗



Harnessing science for expert appraisals: yesterday, today and tomorrow



Ten years on from its founding, ANSES's commitments are just as relevant today: to produce scientific benchmarks to help public authorities better protect human, animal and plant health and the quality of our environment. To this end, we are resolved to implement independent, robust and transparent scientific expert appraisals. These are based on intangible principles and recognised benchmarks, but are also constantly adapting to keep abreast of emerging challenges and new scientific possibilities.

Face aux Risques: a book retracing the history of the health and safety system

To mark its tenth anniversary, ANSES decided to retrace and publicise the long journey that led to the creation of our health and safety system and, in particular, the founding of an agency dedicated to food, environmental and occupational health and safety. This decades-long story is told by Pascal Griset, Jean-Pierre Williot and Yves Bouvier in the book *Face aux Risques* ["Dealing with risks"], a history spanning food safety and environmental health.

Matthieu Schuler

Managing Director General of the Science for Expertise Division since February 2021



Faced with the immense diversity of our fellow citizens' concerns regarding risks for humans, the planet and its ecosystems, harnessing science for expert appraisals must address three major challenges:

- methodically take into account the latest scientific and technical knowledge in order to characterise and prioritise risks, and recommend ways of mitigating them in the short and medium term;
- through dialogue with civil society, economic players and public authorities, encourage all concerned to act to reduce these risks, within their own areas of responsibility;
- promote the emergence of new data and knowledge needed to build tomorrow's global health and safety system with our European and international counterparts, by actively mobilising scientific research and vigilance in relation to field observations.



G rard Lasfargues

ANSES scientific integrity adviser

“ What does scientific expertise mean to ANSES? It is the overall state of scientific knowledge of a health risk: the hazards of a physical, chemical or biological agent, the routes of exposure and exposed populations, and the resulting health risks.

Scientific expertise is important in order to say what we know, but also what we don't know and to point out uncertainties. It informs public decision-making at a given point in time, meaning that its credibility is crucial. Expert appraisals should provide the right answer to the questions posed, and should under no circumstances be open to challenge – on the integrity of an expert or the conduct of a study.

To earn and maintain credibility, scientific expert appraisals must ensure:

- the scientific quality of their results, thanks to a collective, multidisciplinary, collegial expert appraisal process and a debate between scientists where minority opinions can be heard;
- transparency of methods, processes, the way in which uncertainties and the level of evidence associated with its conclusions are qualified (possible, probable or certain risk); as well as transparency of expert appraisal results, by presenting them to the various interested parties in the most comprehensible way possible and by making them public;
- openness to society at every stage, through interactions with stakeholders from the outset in order to answer their questions, during the expert appraisal itself through hearings or public consultations, and on completion with reporting of the results. It is a question of following the scientific process but also knowing how to open up and reach out to society..

Roger Genet

Director General of ANSES, in the postscript to the book Face aux risques

“ ANSES has largely capitalised on the experience acquired by AFSSA and AFSSET to structure its expertise, recognised by all the stakeholders. Its first ten years in operation showed that its initial choices were the right ones and that a model based on transparency was not incompatible with scientific rigour; in fact the opposite has been true. The archetypal scholar, who remains in his ivory tower in order to better seek out and convey truth, has given way to a science constructed collectively in a way that transcends disciplinary barriers, and is open to and engages in dialogue with society.

However, the ANSES of 2020 is now no longer the Agency founded in 2010. Over the years, in response to new questions raised by developments in knowledge, techniques, risk perceptions and societal aspirations, as well as the new missions entrusted by the State, the Agency has continued to evolve. The practice of collective expert appraisal has been deepened at many levels by constantly seeking a balance between adversarial debate and formulation of relevant opinions by consensus. This way of working is enriched by ever-stronger interdisciplinary cooperation, whose aim is to integrate the human and social sciences into the process in an even more operational way. ANSES is also committed to an assessment approach that is gradually becoming less “risk by risk” in order to consider the overall risks, aggregated at a given moment and accumulated over time.

Scientific expert appraisals at ANSES: principles and challenges



To answer a question, the scientific expert appraisal process relies on proven methods implemented by groups of experts competent in this field. The way the expert appraisal is carried out is designed to ensure its independence and build trust.

The scientific expert appraisals carried out at ANSES form part of a defined framework, structured by the charter for health-related expert appraisal and by the NF X 50-110 Standard “Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals”.

In order to conduct the expert appraisals it is tasked with, either through formal requests or on its own initiative, ANSES relies on its 15 expert committees supported by thematic working groups. These groups bring together more than 800 experts from many basic science disciplines: toxicology, epidemiology, medicine, chemistry, occupational health, biostatistics, industrial hygiene, exposure biomarkers, physical chemistry, etc. Some working groups also include scientists from the human and social sciences.

Depending on its purpose, the expert appraisal is coordinated within ANSES by the Risk Assessment Department, the Regulated Products Assessment Department or the Health Alerts & Vigilance Department. In a few months’ time, the Social Sciences, Expertise and Society Unit, whose role is set to change, will also be leading expert appraisals, supported by a new expert committee dedicated to socio-economic analysis.

After being extended until 31 December 2020 due to the COVID-19 situation, six expert committees began a new three-year mandate on 1 January 2021 with new members: Water, Assessment of chemical risks of consumer items and products, Assessment of the risks related to physical agents and new technologies, Assessment of the risks related to air environments, Chemicals covered by the REACH and CLP Regulations, and Health reference values.

Among them, the Expert Committee on Assessment of the risks related to physical agents and new technologies has increased in size from 23 to 27 members, with priority given to disciplines related to health and life sciences.

Scientific expert appraisals rely on the available scientific data and may involve the development of new methodologies. Partnerships with other organisations, sometimes from other countries, may also be established because the questions raised do not necessarily have a simple answer and may go beyond our borders. All fields need to be addressed to better inform the decisions that are made.

Integrating the concept of the exposome into the Agency's work

The exposome refers to the totality of exposure faced by a human body from the moment of its conception and covers all chemical, physical and infectious agents. In 2019, ANSES's Scientific Board set up a working group on the exposome to fully integrate the concept into the deployment of all the Agency's activities: scientific expert appraisal, vigilance, and the research it conducts and finances.



Expert Committees (CESS)

- Animal feed
- Water
- Assessment of the biological risks in foods
- Assessment of chemical risks of consumer items and products
- Assessment of the risks related to physical agents and new technologies
- Assessment of the risks related to air environments
- Assessment of the physical and chemical risks in foods
- Fertilisers and growing media
- Human nutrition
- Plant protection substances and products, biocontrol
- Biological risks for plant health
- Animal health and welfare
- Chemicals covered by the REACH and CLP Regulations
- Biocidal substances and products
- Health reference values

How does ANSES assess health risks?

➤ The main stages of the collective expert appraisal

ANSES IS PRESENTED with a question on a health issue

⤵ **AT THE REQUEST OF AN AUTHORISED BODY**

Ministry Association Trade union...

or

⤵ **ON ITS OWN INITIATIVE (INTERNAL REQUEST)**

To prevent risks of conflicts of interest, ANSES analyses the interests declared by experts before they are appointed and then throughout their work. To guarantee the equanimity of the debates and protect the experts from any external requests or pressure, their names are only communicated at the time of publication of the expert appraisal.

IT MOBILISES the expert groups

Depending on the question to be investigated, ANSES mobilises one or more of its expert committees (CESs). The expert appraisal is sometimes entrusted to an *ad hoc* working group, in support of the CESs.

⤵ **15 CESs APPOINTED FOR 3 YEARS**

⤵ **WORKING GROUPS SET UP FOR SPECIFIC EXPERT APPRAISALS (WGs)**

⤵ **EMERGENCY COLLECTIVE EXPERT APPRAISAL GROUPS (GECUs)**

⤵ **+800 FRENCH AND FOREIGN EXPERTS**

HOW DOES IT SELECT ITS EXPERTS

ANSES issues public calls for applications. Selection criteria include competence, personal interests, balance between disciplines, availability, etc.

THE EXPERTS submit their report

An expert appraisal can last from a few days (in extremely urgent cases) to several years.

ANSES coordinates the work according to the NF X 50-110 Standard.

The experts draw on the available scientific data and hearings with stakeholders.

TO ENSURE ITS QUALITY AND INDEPENDENCE, ANSES'S EXPERT APPRAISALS ARE:

- _ Multidisciplinary: all the scientific skills needed to address the issue are brought together
- _ Collective: all different points of view are expressed in order to form a conclusion
- _ Adversarial: the various evidence is debated in light of the scientific knowledge and related uncertainties

ANSES FORMULATES an opinion and recommendations

FOR ITS SPONSORS AND STAKEHOLDERS

Public authorities

Professionals

Citizens

Research

The experts' opinions,
reports and debates
are made public on
www.anses.fr

Assessing exposure to chemical mixtures, a methodological challenge



It is currently estimated that there are more than 150,000 chemical substances or compounds in our daily environment. We can be exposed through a variety of different routes such as food, water and air, but also through consumer goods such as cleaning products, cosmetics and even the clothes we wear. We talk about the “cocktail” effect when people are exposed to several chemicals at the same time: the action of these substances can then combine to cause additive or even synergistic effects. Assessing the potential risks of these combinations involves rethinking the existing methodological frameworks.

ANSES: prospective coordinator of the European partnership for improving the assessment of chemical substances

ANSES is currently playing a central role in developing the European Partnership for the Assessment of Risks from Chemicals (PARC), which will be part of Horizon Europe, the new EU Research and Innovation Framework Programme (2021-2027).

Building on the studies undertaken and the experience acquired through the European HBM4EU (Human Biomonitoring for Europe) joint programme, the partnership will provide new data, knowledge, methods, networks and skills to help European and national risk assessment and management bodies address current and

future challenges in chemical safety. PARC is in line with the ambitions of the new European public policies of the “European Green Deal”.

ANSES has been lined up to coordinate the partnership. Together with more than 30 European expert appraisal and research institutions, it is currently preparing the strategy and work programme to be submitted to the European Commission in 2021.

Amélie Crépet,

Scientific Project Leader Methodology and Studies Unit



How are cocktail effects assessed?

In general, the hazardous nature of a substance is assessed in isolation. We observe its effects and the dose at which they occur, then define the dose that should not be exceeded. In order to assess cocktail effects, we need to be able to understand the combined effects of several substances on an organism: this requires a new approach.

What is this new approach to observing possible effects?

Firstly, methods and tools need to be developed to identify and prioritise the substances to which people are exposed. At ANSES, we have developed an approach that makes it possible to cross-reference data on exposure to a

multitude of substances and identify the main mixtures to which we are most exposed. Using this approach, we have been able to establish a link between diets and recurrent mixtures. We have observed, for example, that people whose diet consists mainly of pasta, pizza, bread, cheese and potatoes are more exposed to mixtures of mycotoxins, polycyclic aromatic hydrocarbons, metals and polybrominated compounds, whereas people with a diet based mainly on fruit and vegetables are more exposed to mixtures of pesticides, bisphenol A and heavy metals.

Once the mixtures have been prioritised, toxicity studies need to be set up to determine the cocktail effects. This allows us to classify substances according to their effects and predict the risks associated with these mixtures.

What are the current fields of study?

Today, we are increasingly incorporating cocktail effects into our chemical risk assessments. For example, mixtures are taken into account when developing health reference values not to be exceeded in indoor air. For children, we determine the mixtures to which they may be exposed from the prenatal period and then via breast milk, and via their diet more generally. Lastly, we work with teams of epidemiologists to introduce cocktail effects into observational studies. For example, we study the effects of pesticides on the general population, as well as on workers and bees.

Including socio-economic analysis in risk assessment, an ongoing dynamic

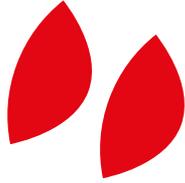


Many health risks are associated with social, economic and political considerations, to which the assessment must pay particular attention. Faced with increasing demands concerning the economic and social sciences, and particularly the need to clarify the relationship between benefits and risks, we are strengthening our expert appraisal systems in order to provide more comprehensive and useful answers to the questions we are asked.

ANSES already uses socio-economic assessment in its work, subject to the same requirements of quality, transparency, independence and collegiality as those applying to basic science disciplines. It uses it to meet regulatory requirements, especially in the context of certain procedures under the European REACh Regulation or certain risk assessments.

In view of the growing demand for socio-economic insights, the Agency's 2018-2022 Goals and Performance Contract provided for a debate within the framework of its Goal 1.5 *"know how to mobilise the human and social sciences in expert appraisal as necessary"*, with the milestone being establishment of an expert appraisal system able to take socio-economic aspects into account for regulated products and formal requests.

After an internal analysis and a report identifying the needs and resources, ANSES's objective in 2020 was to lay the organisational and methodological groundwork for a socio-economic analysis expert appraisal system, which is expected to be launched in January 2022. This implies, in particular, gearing the internal organisation to this system by consolidating the team, a move initiated in 2020 that will continue in 2021, and by setting up a new expert committee in 2021 that will be devoted to this field of expertise.



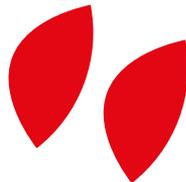
↳
Karine Fiore,
 Deputy Head of the Social
 Sciences, Expertise & Society
 Unit, in charge of
 socio-economic expertise
 since May 2020

Insight

In addition to the social sciences already mobilised, socio-economic analysis bolsters the knowledge drawn on by the expert appraisal and provides useful insights for public debate and decision-making, by:

- better characterising the exposure situations and trajectories of certain populations and their disparity, through an analysis of their socio-economic determinants and sector studies;
- documenting the socio-economic impacts of risk situations (health, environmental or organisational impacts);
- and clarifying the potential consequences of management measures considered for reducing or preventing adverse health or environmental impacts.

This diverse knowledge is important for improving understanding of the risks and the issues for different categories of stakeholders, and for more effectively targeting ANSES's recommendations.



The deployment of socio-economic analysis at ANSES through four priorities

1

A strengthened **internal team** devoted to socio-economic analysis.

2

Establishment of an **Expert Committee**.

3

Partnerships and a dynamic network.

4

Funding of research in this field.

Credibility of scientific expertise and public decision-making



The contribution of scientific expertise to public decision-making regularly generates high expectations and lively debate due to the increased complexity of health risks in a globalised world, controversies and uncertainties that are inherent to science and mistrust of the authorities. This has once again been demonstrated with the COVID-19 pandemic. ANSES examined these issues in early 2021 at an international scientific symposium focusing on two key questions: What determines whether or not scientific expertise is credible? What factors contribute to the credibility of the knowledge and information mobilised for public decision-making?

In order to be of use for risk management and stimulate thinking all round, scientific expertise must strive to answer society's questions, prove its robustness and be transparent about its methods and results. However, as COVID-19 has again shown, there are still many challenges that can undermine expertise in the public eye or weaken its lessons. In order to foster constructive dialogue between science and society, the Agency remains attentive to debates and proposals on this topic. To mark its 10th anniversary, in early 2021 it organised an international symposium on the theme **"Credibility of scientific expertise and public decision making: new challenges for health risk governance in a changing world"**, in partnership with the

Cité des Sciences et de l'Industrie in Paris and with the support of the French Parliamentary Office for Assessing Scientific and Technological Choices.

Due to the health conditions, the conference was held in digital format in early 2021 and included presentations by around 45 speakers who are authorities in their field. Through two plenary sessions and 10 thematic workshops, European and North American social science researchers were able to share their analyses of the conditions for trust in expertise and the questions these raise today, and hold discussions with experts including representatives of European and international health institutions such as EFSA and the WHO.

A COVID-19 session was devoted to initial analyses of the pandemic, including the early findings of a study of responses in 16 countries including France, resulting from the collaboration of some 60 researchers from around the world.

The thematic workshops provided an opportunity to compare different points of view, such as on the theoretical framework of risk assessment, the law and scientific expert appraisal, risk communication and fake news, the assessment of scientific integrity, the inclusion of citizen science, and challenges specific to the circular economy, endocrine disruptors and pesticides.



The videos of the symposium's many presentations can be watched over and over on ANSES's YouTube channel.



Constantly improving the ethical framework



The independence of the Agency and of the people contributing to its work is essential to the quality, legitimacy and credibility of its scientific expert appraisal system. From its inception, ANSES adopted its own ethical framework that is regularly updated. It recently revised its charter on relations with interested parties.

ANSES's ethics system is based on a code of ethical standards, several charters including the charter for health-related expert appraisal, and its Committee for Ethical Standards and the Prevention of Conflicts of Interest. Partially renewed in 2020, it began a new five-year mandate in May 2021. This ethical framework, which applies to all its activities and in particular to scientific expert appraisal activities, is regularly supplemented and updated to take account of changes in the applicable legal and regulatory framework. Among recent developments, ANSES adopted a charter of ethics for public procurement and significantly revised its charter on relations with interested parties.

When ANSES was granted the power to issue, amend or withdraw marketing authorisations for plant protection products, fertilisers, growing media and adjuvants in 2015, it adopted a charter governing its relations with interested parties in the context of examining applications for plant inputs, with a view to enhancing its ethical framework. The purpose of this charter was to define a framework of expression for the various interest groups and their representatives to the Agency, ensuring that it is both explicit and organised, while preserving the equanimity needed for examining application dossiers.

To improve the current system and take account of recent changes in regulations (the Sapin II Act on transparency, the fight against corruption and economic modernisation; guidelines from the National Authority for the transparency of public life – HATVP) along with the recommendations of its Committee for Ethical Standards, the charter on relations with interested parties and the associated register underwent a major revision, launched in 2019, at the request of the General Directorate.

The main changes include:

- The Charter's scope is no longer limited to regulated products but has been broadened to encompass all areas in which the Agency is required to take a decision, carry out an expert appraisal or issue a scientific opinion.
- The new charter includes a definition of interested parties and provides a more precise framework for their expression. Multilateral meetings are given preference and all other exchanges are recorded in the register.

According to the charter, interested parties are: *“persons or groups of persons who, on their own initiative, enter into communication with ANSES staff, when this communication is likely to influence the opinions and decisions for which ANSES is responsible. All manifestations of influence are to be taken into account, whether they are motivated by material, financial or intellectual interests.”*

2010

Creation of the Committee for Ethical Standards and the Prevention of Conflicts of Interest

2013

Adoption of the charter for health-related expert appraisal

2016

Appointment of an ethics officer

2021

New charter on relations with interested parties

**EUROPEAN AND
INTERNATIONAL
AFFAIRS
DEPARTMENT**
Salma Elreedy

**GENERAL
DIRECTORATE**
Roger Genet

CABINET
Sophie Le Quellec and
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ANSES: a brief description



Every day, whether we are eating, working or simply breathing, we can be exposed to health risks. Climate and technological changes and our societal choices have also led to the emergence of new threats to humans and the environment, both in France and abroad.



Since 2010, ANSES has been providing the scientific benchmarks needed to protect against health risks related to food, the environment and the workplace, as well as against risks affecting the health of animals and plants.



A scientific expert appraisal agency, ANSES monitors and assesses these health risks, and also devotes research activities to them.

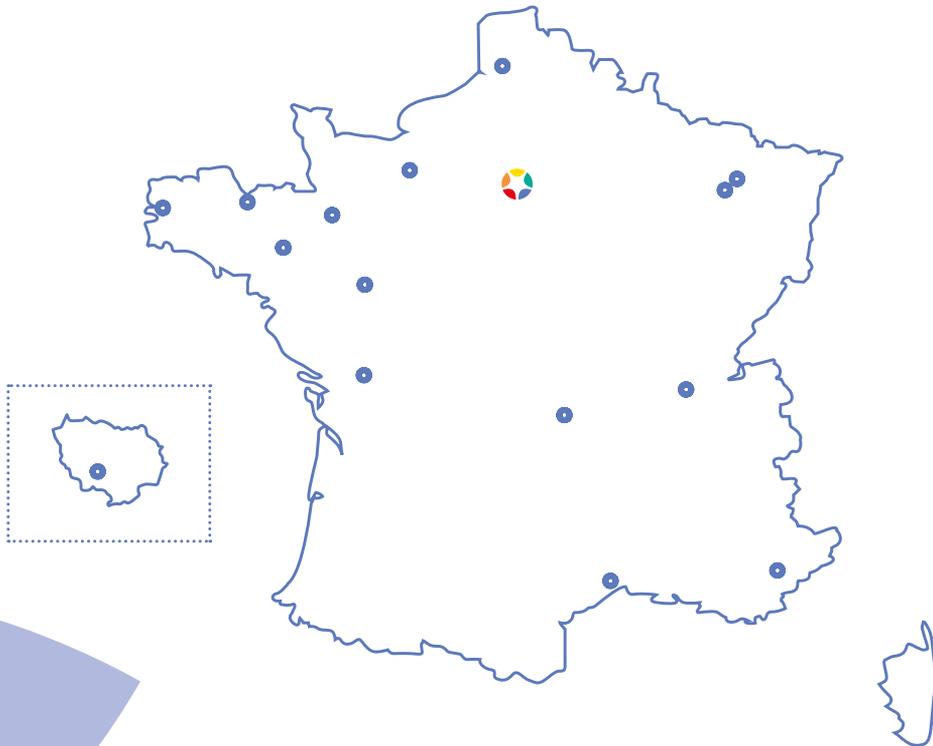


It contributes to advancing scientific knowledge to support public decision-makers, including during health crises.



ANSES is accountable to the French Ministries of Health, the Environment, Agriculture, Labour and Consumer Affairs. In the public interest, it works daily to mobilise science to make the world safer and healthier for all.

Spread out across **16** sites in France, almost **1,400** women and men are involved in fulfilling ANSES's missions on a daily basis.



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