

Liberté Égalité Fraternité





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ANSES: a brief description

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

An agency of scientific expertise, it monitors and assesses these health risks, and devotes research activities to them. It contributes to advancing scientific knowledge to support public decision-makers, including during health crises.

ANSES is a public administrative body reporting to the Ministries of Health, the Environment, Agriculture, Labour and Consumer Affairs.

Science driving a safer, healthier world for all and dedicated to One Health.









JOINT INTERVIEW

Patrick Dehaumont

Chair of the Board of Administrators

Benoit Vallet

Director General

Benoit Vallet, Director General, and Patrick Dehaumont, Chair of the Board of Administrators, analyse the challenges ANSES is facing in light of its activities over the last 18 months, along with its outlook.

European harmonisation

BENOIT VALLET. The European Union (EU) is entering a new political cycle to which we will be paying close attention. For several of its missions, ANSES is dependent on the EU's progress in terms of risk assessment and harmonisation of the rules applicable in all Member States. In particular, in the area of plant protection products, ANSES is extremely vigilant when it comes to harmonising assessments within the EU, to ensure optimum

safety and efficacy. Assessment methodologies need to be adapted to meet these objectives; it is also important that they evolve to take account of the most recent data on the exposure of certain population groups or the use of new treatment application techniques, for example. The Agency is also keeping a close eye on developments relating to endocrine disruptors (EDs): as France is taking stock of its second national strategy, let's not forget that the recent introduction of "ED" hazard classes in the European CLP (Classification, Labelling, Packaging) Regulation,

"ANSES plays a part both in the short term to respond to crises and in the long term to address systemic and global changes affecting health and the environment. Our staff and experts work tirelessly to meet this dual challenge, and I would like to pay tribute to their commitment". Benoit Vallet

enabling endocrine-disrupting properties to be taken into account consistently for all uses of a substance, was based on work carried out by ANSES. Since 2022, our role in coordinating the European Partnership for the Assessment of Risks from Chemicals (PARC) has helped to strengthen our position as a key player and driving force within the EU.

Synergies between agencies

VALLET. Inter-agency cooperation allows us to take advantage of synergies and more effectively call on the scientific community in response to common challenges. We interact daily with the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), and are working to develop exchanges with the European Environment Agency (EEA). In EFSA's Management Board and Advisory Forum, we support proposed partnership arrangements between EFSA and its national counterparts. It is at this Community level that our work on new genomic techniques, the toxicity of PFASs and animal welfare labelling takes on its full meaning.

At national level, a One Health partnership agreement will soon be signed with Santé publique France,

with which we are cooperating as part of the SAGA scheme for the active surveillance of avian influenza; this public health agency is also working with us as we prepare to launch the ambitious Albane study (see page 70). The 30th anniversary of the French Agency for Veterinary Medicinal Products (ANMV), which is part of ANSES (see page 28), echoes the long-standing ties forged with the National Agency for Medicines and Health Products Safety (ANSM). In a few months' time, teams from ANSES and the ANSM will be sharing the same building in Lyon, thereby promoting links between human and animal health and environmental quality.

Access to data

PATRICK DEHAUMONT. Whether for purposes of scientific expert appraisal, vigilance or crisis support, the Agency needs robust, interoperable databases and scientific research covering the full scope of its missions. The Board of Administrators is aware of the significant progress that needs to be made in these two areas. In this regard, I commend the Agency, on the one hand, for its involvement in the collection of new data – for example, with the new Indoor

Environment Quality Observatory, launched in early 2024 - and, on the other, for its commitment to forging closer links with agencies from programmes that will be proposing priorities for French scientific research this summer. The Board of Administrators endorses the development of a genuine data strategy at ANSES. In this context, ANSES's efforts to include the exposome in the strategy to accelerate prevention, and to help structure the cross-referencing of health and environmental data, should be supported. These data challenges should also be considered at European and international level, in the context of global health going beyond national borders.

Health and climate

PATRICK DEHAUMONT. Scientific excellence, transparency, independence, openness and dialogue: these are the principles that have underpinned the efforts of ANSES's employees and groups of experts since 2010. On behalf of the Board of Administrators, I applaud the quality of their work and their loyalty to this line of action, which are both marks of confidence in the Agency. While the 2023-2027 goals and performance contract emphases the importance of a comprehensive approach to risks, deployed by ANSES under the banner of One Health, the administrators are following with interest the integration of climate change into the range of issues, methods and priorities considered by the Agency, as well as the progress noted at internal seminars, including the recent managers' seminar held in May 2024. I will personally be paying close attention to how these orientations are reflected in the Agency's work programme for 2025, and to the involvement of the international Scientific Board in these discussions.

ANSES in 2023

106

formal requests received

16

Expert Committees and 84 Working Groups mobilised

98

opinions and reports published, including six in response to urgent requests



Signature
of the 2023-2027
goals and performance
contract



New missions covering **cosmetics**

Since 1 January 2024, ANSES has been responsible for vigilance and expert appraisal relating to cosmetics and tattoo products, activities that were previously entrusted to the National Agency for Medicines and Health Products Safety (ANSM). These missions, which were transferred through legislation, are fully in line with ANSES's expertise in chemical risk assessment.



Forty-five projects selected by the National Research Programme for Environmental and Occupational Health, with funding of €7.41 million on a wide range of topics:

- Twenty-four projects will address chemicals, including 14 on endocrine disruptors,
- Eleven projects will focus on air quality, including five on atmospheric pollution,
- Ten projects will examine the aquatic environment, including the effects of climate change and the impact of noise pollution on marine species,
- Six projects will be on radiofrequencies, including two on the assessment of their biological effects and five on the deployment of 5G,
- Six projects will address occupational health, including exposure to cleaning products and improvements to aids worn by hearing-impaired workers in the workplace,
- Three projects will focus on pathogenic micro-organisms, including their resistance to antibiotics,
- Two projects will be on vector control.

2-3 October **Scientific and Doctoral Days**

Organised every year, these in-house discussion events focus on research carried out at ANSES, whether work in progress or recently completed. The aim is to encourage exchanges and synergies between scientific teams working at different sites on a range of themes. Attendees are invited to vote for the best oral presentations and posters by doctoral students.

→ Seven thematic sessions: research in risk assessment, food safety, animal health & welfare, plant health, antimicrobial resistance, epidemiology & surveillance, exposure to & toxicology of chemical contaminants.



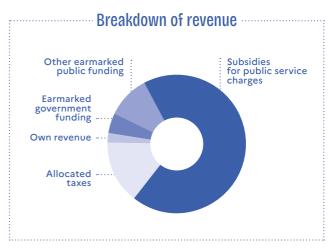
Over 4000

authorisation, refusal or withdrawal decisions for regulated products

- 1423 for plant protection products, fertilisers, growing media and adjuvants
- 286 for biocides (covering 1499 products)
- 2356 for veterinary medicinal products









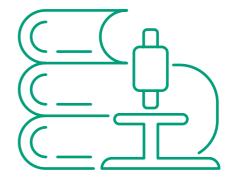
Two major scientific events:

6 June
Scientific
Conferences on
"Air and health",
organised jointly
with ADEME

7 December
Tenth science
day dedicated
to bee health

In 2023, ANSES teams published a total of **271 articles in major scientific journals***

* Impact factor in the first quartile, according to the SCImago Journal Rank (SJR)



Our environmental and climate undertakings

Society is facing many environmental changes. As a public agency committed to worldwide health, ANSES considers the impact of climate change to be a priority. Its missions place it at the forefront of efforts to assess the health consequences of this change for humans, animals and plants. ANSES therefore helps identify ways of mitigating and adapting to the changes under way, in light of the associated risks.

Sustainable development goals are integral to ANSES's missions and principles of action. Since its inception, the Agency has pursued and gradually strengthened a sustainable development approach, in line with institutional benchmarks at French (Eco-friendly Public Services, Ecological Transformation Plan, etc.) and international level (UN 2030 Sustainable Development Goals, work of the IPCC, etc.).

In July 2023, the ANSES Executive Board met to discuss how to chart a new course that would integrate climate change more fully in its expert appraisal, research, reference, monitoring and vigilance work, as well as its operations in order to reduce its carbon footprint.



Structuring new scientific projects

In autumn 2023, a "climate change" project team was set up to work with several in-house focus groups and propose a roadmap to structure the Agency's scientific action on climate. In 2024, their findings will be used to define specific measures to be taken, with the support of the Agency's Scientific Board. Tied to the "One Health" and "Exposome" systemic approaches developed by ANSES, these changes should lead to the exploration or development of new thematic fields and the definition of new expert appraisal methodologies.







Reducing its carbon footprint

ANSES has embarked on a multi-year plan to reduce its carbon footprint by improving its internal practices and operating methods in the four most carbon-intensive sectors: buildings, travel, procurement and digital technology. For example, the new Lyon Laboratory building, due for completion in 2024, will incorporate rigorous environmental criteria. Meanwhile, air travel on domestic flights has been reduced by 42% in three years. ANSES's commitment to these environmentally responsible transformations is enshrined in its Goals and Performance Contract (COP) for the period 2023-2027.



INTERVIEW

Marta Hugas

Chair of the Scientific Board

With the renewal of its Scientific Board in April 2023, ANSES wanted to give it an international dimension by bringing together scientists, researchers and experts from France and other countries. The Agency's Scientific Board functions as an independent body, to guarantee the excellence of its expert appraisals and the consistency of its scientific work. Human food and nutrition, environmental health, occupational health, animal health and welfare, animal nutrition, veterinary medicinal products, plant health and protection: the Board's work covers all of the Agency's missions, while respecting the pluralism and independence of its expert appraisals. On 7 December 2023, Marta Hugas was appointed Chair of the Scientific Board.

"The role of the Board is to guarantee the quality, relevance and consistency of scientific work in relation to health issues".

How does giving the Scientific Board an international dimension enrich ANSES's work?

The Scientific Board gives its opinion on the Agency's research orientations, methodologies and expert appraisal process, as well as on its work programme and scientific partnership policy. Its role is to guarantee the quality, relevance and consistency of scientific work in relation to health issues and trends. The Board includes members from a wide range of disciplines and from different organisations in France, Europe and abroad, enabling it to provide far-reaching insights into current health challenges. This major advantage is also an opportunity to learn from best practices and a wide variety of situations involving research and assessment, and to share information on risks in various countries. In addition, it gives ANSES great potential for going further in implementing the One Health approach and taking account of climate change and socio-economic determinants when analysing the risks that weigh on society. Last but not least, this openness provides new opportunities for strengthening scientific cooperation to achieve common strategic objectives, particularly at European level.

More specifically, how has the Scientific Board been working since it was set up?

The Scientific Board is made up of 24 scientists selected following a call for applications. It also includes three members of ANSES's scientific staff, elected by their peers, as well as two ex-officio members appointed by the chairs of the scientific boards of Santé publique France and the ANSM. These 29 members have a wide range of scientific backgrounds, and many of them come from European and international - Canadian and American, for example universities and health assessment agencies. Their expertise covers the Agency's entire scope of action, including zoonoses, infectious diseases, parasites, toxicology, and occupational and plant health. We communicate in English and meet for plenary sessions at the head office in Maisons-Alfort.

At the beginning, there was a phase of acculturation to become familiar with all the Agency's missions and how it works in France, with its partners and supervisory ministries. I would like to thank the French experts and the teams at ANSES for their hard work and for being available to shed light on all the intricacies of the Agency.

We were all surprised by its broad sphere of action, and we needed to clearly grasp the Agency's organisation and the extent of its work.

What projects are currently under way and in the pipeline?

We are in the process of refining our roadmap and priorities for this year. Following on from the challenges already addressed by the previous Scientific Board, we have identified several major projects, including undertaking further work on methodologies for the socio-economic analysis of health issues, and developing new methodological approaches to understanding microbial resistance and the hazards associated with chemicals, for example. We also need to think about how we can integrate the climate crisis into risk assessments and research. Defining data analysis strategies is another major challenge.

These are just some of the issues we want to tackle so that ANSES can continue to carry out robust scientific work and risk analyses that meet the health challenges of today and tomorrow.

ANSES's primary mission is to assess health risks associated with food, the use of certain products and technologies, occupational activities and, more broadly, pollution of environmental media such as air, water and soil. Its role is to rule on the existence, nature and extent of risks raising concerns among the authorities and society, on the basis of the available scientific knowledge. For all the assessments it carries out, the Agency applies the same scientific expert appraisal process, based on expert groups made up of independent scientists who are leaders in their field and an examination of the most recent international knowledge. A good illustration of this is the expert appraisal on new genomic techniques that was published in early 2024.

Anatomy of a collective expert appraisal

New genomic techniques (NGTs) provide for applications that are potentially broader than those observed for the transgenic plants covered by the GMO regulations: changes to plant yield or composition, tolerance to biotic or abiotic stress, or improved organoleptic characteristics, for example.

January 2022

ANSES entrusted with new missions relating to biotechnologies following the dissolution of the High Council on Biotechnology

October 2022

Creation of the "Biotechnology, environment and health" Dialogue Committee ANSES recently produced two expert appraisals on NGTs. They provide scientific benchmarks on an emerging subject marked by high expectations and uncertainties, at a time when the EU is considering changes to the legal framework.

These two expert appraisals also identify the questions that need to be asked to ensure that the debate is as open and well-informed as possible, given the concerns associated with agricultural production models and the agro-ecological transition.

This work on NGTs has been discussed with the Economic, Social and Environmental Council and the National Consultative Ethics Committee for Health and Life Sciences, both of which the Government has consulted for issues relating to NGTs in their respective fields of expertise.

February 2024

Creation of an Expert Committee (CES) on "Biotechnologies"



NGTs: the different stages of the expert appraisal



28 JANUARY 2021

ANSES received a formal request

from the Directorate General for Risk Prevention and Directorate General for Food on risk assessment methods for GMOs used in food.





8 JUNE 2022 → 31 AUGUST 2022

Public call for applications

to set up the ad hoc Working Group on "New genomic techniques" that would be entrusted with the expert appraisal.



6 MARCH 2024

Opinion and report published Key recommendations

- Case-by-case assessment depending on the technique used, the characteristics of the plant obtained, and their potential toxicological, nutritional, agronomic and environmental consequences. Proposal of a decision tree tailored to a graduated approach to risks, taking into account the knowledge available on similar plants.
 - Introduction of a comprehensive mechanism to monitor NGT plants and derived products for undesirable effects and to observe changes in cultivation practices.
- Need to take account of issues associated with intellectual property, the concentration
 of the plant breeding sector, sector (NGT and non-NGT) characteristics, consumer information,
 and the wide variety of objectives sought in the development of NGTs.





JULY 2023

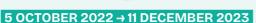
The European Commission

proposed a status of category 1 NGT plants not subject to the GMO legislation in force.









Implementation of the expert appraisal

1

Framing of the work, focusing on NGT plants obtained using CRISPR-Cas and extended to include socio-economic issues.



Review of all the available scientific data + hearings with stakeholders. The group reached a conclusion based on all the expressed opinions, including minority views. ANSES coordinated the expert appraisal.



The CESs on "Socio-economic analysis" and "Biological risks for plant health" validated the sections relating to their fields of expertise. The CES on "Assessment of the biological risks in foods", in charge of endorsing all the expert appraisal work, adopted and submitted the report based on which ANSES would issue

its recommendations.



6 NOVEMBER 2023

Internal request by ANSES

to analyse the criteria
defining category 1 NGT plants
as set out in Annex I
of the regulation proposal.
The analysis was entrusted
to the Working Group
on "Biotechnology".



21 DECEMBER 2023

Opinion published

Based on the experts' report,
ANSES called for clarification of
several definitions or classification
procedures and the scope of the
techniques covered, and highlighted
some scientific and health-related
limitations in the establishment
of the criteria.

Changes to ecosystems can create conditions that promote the appearance or resurgence of threats to human, animal and plant health. One growing concern is the establishment in northern latitudes of pests from faraway countries. In particular, greater levels of international trade are encouraging the introduction into France of ticks, insect pests and pathogen vectors. Over the last few months, our scientists and experts have been examining the extension of their geographical ranges, and exploring sustainable control methods to help the public authorities tackle new types of damage and diseases.

Diseases becoming acclimatised to France

The number of major plant health concerns doubled in 2020, with the emergence in mainland France or the overseas territories of new tomato viruses, Panama disease in bananas and the oriental fruit fly. Similar phenomena can also be observed in animal and human health, exerting greater pressure on our ecosystems and production sectors, as well as on all our living spaces and the healthcare system.

Discover our podcast series "Zootopique"

While epizootic haemorrhagic disease was completely absent from Europe in 2022, France saw more than 4000 outbreaks in cattle in 2023. This viral disease, transmitted by biting midges of the genus Culicoides, was first detected by ANSES in September 2023. It is a direct consequence of climate change. Another striking example is the growing number of indigenous cases of dengue fever among people living in mainland France, which means that the virus transmitted by the tiger mosquito is now present in our regions.

When diseases circulate between animals and humans, comprehensive monitoring is essential. The West Nile virus, which is transmitted mainly by mosquitoes of the genus *Culex* and is gradually making its way northwards in France, is a prime example of this: as many as 250 bird species can carry this virus, although it is mainly horses and humans that show symptoms in the event of infection.



Test sample taken from banana leaf homogenate for the detection of plant pathogenic viruses using the ELISA serological technique.

Research is another pillar of the Agency's work. Various projects are aiming to develop more effective methods for detecting and identifying these pests and pathogens in France. Extensive work is also being carried out in our laboratories to gain a better understanding of their characteristics, and explore the epidemiological parameters and pathways of introduction.

In the longer term, we are also working on new molecular approaches to high-throughput sequencing, involving bioinformatics. This enables non-targeted analyses while referring to databases that are as complete and generic as possible.





Tracking down ticks

First summary of French data on *Ixodes ricinus* ticks

As part of the national plan to combat Lyme disease and other tick-borne diseases, ANSES financed the first summary of all research carried out in France on Ixodes ricinus ticks since the 1960s. The study, which was conducted by the Alfort National Veterinary School, included the results of 187 scientific publications. Its findings, published in 2023 - on host animals, distribution areas, effects of the environment highlighted the need for new investigations and harmonised surveillance methods to compensate for the scarcity of data and improve control and prevention.



Crimean-Congo haemorrhagic fever:preventing transmission to humans

In June 2023, ANSES confirmed the risk of emergence of Crimean-Congo haemorrhagic fever, due to the presence in Spain and southern France of ticks of the genus Hyalomma carrying the virus. The Agency also called for nationwide surveillance of ticks. Although the main mode of virus transmission is through the bite of infected ticks, ANSES also assessed the risk of transmission through direct contact with the blood or bodily fluids of a virus-carrying animal or human. Following the discovery of the virus in ticks collected from French cattle last October. ANSES issued recommendations in early 2024 to prevent the risk of infection among people most likely to be exposed – ruminant farmers, veterinarians, abattoir staff, etc. as well as among hunters, due to the tick's life cycle in wildlife.



Counting and identifying ticks collected in the field using a binocular



Ticks are the leading vector of disease for animals, and rank second for humans. Lyme disease, the most widely known illness, is caused by a bacterium carried by certain ticks. Tests have been conducted on a vaccine candidate targeting the tick microbiota, with a view to reducing tick infection by this bacterium. This work was carried out by INRAE in collaboration with ANSES and the Alfort National Veterinary School, and the results were published in the journal *Microbiome* on 24 July 2023.

Focus

Two species gaining ground

Processionary caterpillars: mapping the risks of exposure in France

ANSES has divided French municipalities into five risk classes for the three species of stinging caterpillars found in mainland France and Corsica, at a time when their distribution is changing: the oak processionary caterpillar has extended its range in France westwards, while the pine processionary caterpillar has moved northwards and westwards. As new areas become colonised. these maps are intended to help the authorities tailor their prevention and control measures to the level of risk, at municipal, departmental or regional scales. The classification takes account of the likelihood of the caterpillars being present and the vulnerability of exposed populations, estimated on the basis of the number of inhabitants and children under the age of five, and the number of professionals likely to be exposed through their work.







Oriental fruit fly: avoid its introduction at all costs

Bactrocera dorsalis, commonly known as the oriental fruit fly, is a highly destructive pest in numerous fruit and vegetable production sectors. Although no outbreaks of *B. dorsalis* have been reported in mainland France so far, the number of flies caught by traps set up as part of official surveillance has increased in recent years. To detect the fly's introduction and eradicate any outbreaks, ANSES has recommended going further than the current regulations and stepping up surveillance of imported goods and crops in the Mediterranean area near ports and airports. According to ANSES's expert appraisal, the likelihood of *B. dorsalis* becoming established in mainland France depends on the richness of plant host species and, particularly, on fruit production in regions close to the Mediterranean and in Nouvelle-Aquitaine. In terms of climate, the low-lying Mediterranean belt, including Corsica, is the only area potentially favourable to the long-term establishment of *B. dorsalis* in France.





Whether it concerns bacteria, parasites, fungi or insects, the health of animals, humans and plants faces a common problem: resistance to antibiotics, antiparasitics, biocides and pesticides. ANSES mobilises a cross-cutting, multidisciplinary scientific community to address this threat. In 2023 and 2024, the Agency published new expert appraisals on topics such as antimicrobial resistance and resistance to insecticides used against bed bugs.

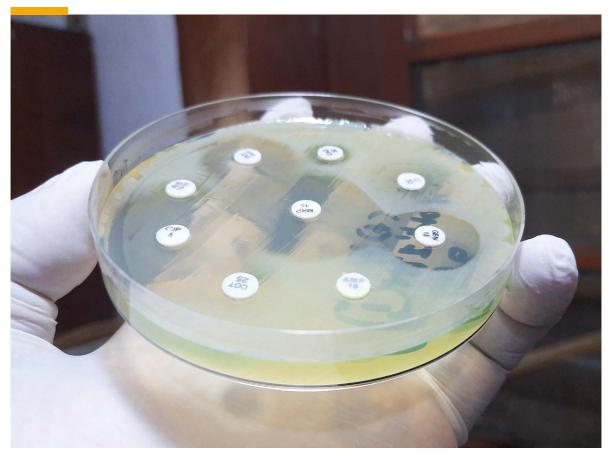
Resisting resistance

Resistance is a highly strategic issue, both scientifically and with regard to health. This theme, which cuts across the Agency's various scientific divisions and core activities, has a public action dimension in terms of monitoring and control.

Encouraged by its Scientific Board, ANSES organised a scientific seminar in November 2023 on the global subject of resistance and the associated issues. Nearly 80 scientists from the Agency and partner organisations discussed their work and what sets them apart or brings them together. They used case studies to illustrate the interconnections between human, animal and environmental health and demonstrate the vital importance of a One Health approach to better preventing and combating these resistance phenomena.

Participants also discussed monitoring, an essential aspect for informing public decision-making, providing input for the scientific community and raising public awareness. Today, there is real room for improvement in the collection of monitoring data, especially in the plant sector. Strengthening measurement systems is one way of achieving this. Lastly, the benefits of changes in practices were emphasised in the discussions on reduction strategies. To guide these changes, it is essential that we monitor resistance and usage.

Antibiogram test to assess antimicrobial susceptibility of bacteria.





Antimicrobial resistance: a battle in animal and human health

For several years now, France has ranked fifth among European countries in terms of antibiotic use in human health, 90% of which is prescribed and dispensed in the primary care sector. In this respect, continuing to reduce the use of antibiotics has to remain a priority in the strategy to prevent antimicrobial resistance – and therefore infections – in both human and animal health. This is important because the transmission of antibiotic-resistant bacteria from animals to humans is one of the causes of therapeutic "dead-ends" in the treatment of certain diseases. As part of preparations for the national EcoAntibio 3 plan, which aims to continue the progress already made in reducing the use of antibiotics in animal health, ANSES published an expert appraisal in September 2023 containing a list of 11 "bacterium/antibiotic class" combinations requiring priority monitoring in animals, given the major issues for human health. This list was based on three health criteria: the transmissibility of antimicrobial resistance, the possibility of using alternative antibiotics, and the number of infections and deaths occurring. If a bacterium resistant to an antibiotic class on this high-priority list is detected during treatment of a livestock animal or pet, the Agency recommends sequencing to determine the bacterium's entire genome.

Moreover, increased global trade can enable antibiotic-resistant pathogens to spread very quickly. The Agency therefore called for the monitoring of antibiotic-resistant bacteria in foodstuffs to be broadened to include aquaculture products and live farm animals from countries outside the European Union.

Resistance of bed bugs to chemical products: opt for alternative control methods



Between 2017 and 2022, more than one in 10 French households were infested by bed bugs. This upsurge can largely be explained by the rise in travel and the increasing resistance of bed bugs to insecticides. ANSES's expert appraisal published in July 2023 showed that there was no link between a household's level of income and its falling victim to an infestation. On the other hand, income level is a factor in the persistence of infestation, as treatment can be costly, averaging €866 per household. ANSES also calculated the cost of treatment at national level, for French households alone. This came to €1.4 billion for the 2017-2022 period, i.e. an average of €230 million per year. Added to this cost are the health consequences: the presence of bed bugs can have psychological effects and affect well-being. In 2019, the health cost of bed bugs for the French population was €83 million, including €79 million associated with lower quality of life, sleep disorders and effects on mental health, €1 million linked to work stoppages and around €3 million for physical treatment.

In its expert appraisal, the Agency recommended that certain households be provided with financial assistance to cover the costs associated with exterminating bed bugs. Whether infestations are treated by private individuals or professionals, it reiterated the importance of favouring non-chemical methods such as dry-heat treatment or freezing. This is because the use of chemical products can cause poisoning and increase resistance to insecticides, thereby reducing their effectiveness. More generally, it can also cause environmental pollution.



INTERVIEW

Franck Fourès

Director of the French Agency for Veterinary Medicinal Products (ANMV)

The ANMV celebrates its 30th anniversary this year. What is your view of the changes it has seen?

Over the years, the ANMV has become a reference agency for veterinary medicinal products in Europe. It has driven international work on topics as varied as antimicrobial resistance in veterinary medicine and harmonisation of veterinary medicinal product assessment processes, as well as the creation of international bodies such as the VICH (the international cooperation programme for the harmonisation of technical requirements for assessing veterinary medicinal products) and the JECFA section devoted to setting maximum residue limits for substances used in veterinary medicines.

In 30 years, we have expanded a system that is now fully European, even international, in which a network and share their assessment skills. However, in 2023, the ANMV handled around 30% of the scientific assessment procedures for veterinary medicinal products filed in the European Union, which was a very large percentage considering that there are 27 Member States. This leading position in the current system has led us to review our operations and develop our skills, over and above the scientific issues involved, because our teams need to be able to harness their expertise and positions to play a decisive role in European discussions on the regulation of veterinary medicinal products.

Over the years, the ANMV has become a reference agency for veterinary medicinal products in Europe.

Could you remind us of the unique features of the ANMV, this "agency within an agency" (ANSES)?

The ANMV is in fact a department of ANSES, with around a hundred staff. Although we are a small organisation, we are also one of the few national agencies in Europe devoted solely to veterinary medicinal products. Our expertise is recognised in many fields, particularly the assessment of vaccines. Another distinctive feature is the attention we pay to societal issues and our openness to stakeholders. This uniqueness takes full advantage of our place within ANSES, which also gives us a broad view of animal health issues, going far beyond veterinary medicinal products.

With regard to antimicrobial resistance, for example, we have developed a holistic approach to the risks associated with antibiotic use, along with vaccines and monitoring of resistance, in synergy with ANSES's research laboratories and expert appraisal teams.

On the emerging subject of the use of plants in veterinary therapy, consulting the scientific experts of ANSES's Working Group on "Plants" was a great help in proposing a suitable risk assessment method, which enabled us to confirm our position as a pioneering European agency on this topic.

What are the ANMV's main priorities for the coming years?

We face several challenges. How can we maintain a high level of expertise in a context where technologies are becoming increasingly complex, while staffing levels remain more or less the same? How can we support the emergence of therapies requiring regulatory frameworks that differ from those applicable to vaccines and chemical medicinal products? How can we have teams that are both specialised and sufficiently multi-skilled to deal with a wide range of medicinal products, including innovative treatments such as phage therapy, genetics and messenger RNA? If France is to remain a refeto reconcile rigorous assessments, independence from industry and a strong ability to support profes-

I would also like to mention the progress that needs to be made in the fight against antimicrobial resistance and in problems of availability of certain veterinary medicines and vaccines. Other issues are emerging on which we will need to take a stand, within the limits of the Agency's remit: these include growing veterinary drug shortages, the lack of a "medical device" status in veterinary medicine and the regulation of diagnostic tests. Innovation remains a major challenge, and the economic context is a significant factor. The ANMV will therefore continue to be attentive to market developments and their impact on the assessment and authorisation of medicinal products. The use of big data, in the veterinary pharmacovigilance scheme that we coordinate, is also a topic on which we remain vigilant. These are all areas that will continue to mobilise our teams in their day-to-day work.

Natural water resources are under great pressure from urban development, industry and agriculture, and this is increasing with climate change. Access to sufficient quantities of high-quality drinking water is a growing concern, in France and beyond. In recent months, ANSES has been asked to support the public authorities in responding to the challenges of managing water resources for their various uses, on topics such as reuse of wastewater and pesticide metabolites in tap water.

Water: a source of debate

Given tensions over drinking water supplies, the reuse of wastewater, grey water and rainwater, after suitable treatment, is being encouraged at both national and European level as a strategy for adapting to climate change.

In 2023, ANSES conducted several expert appraisals in connection with draft orders and decrees on the conditions for producing and using treated wastewater for:

- irrigating crops or green spaces,
- · urban uses such as road cleaning,
- the food industry, for example washing vegetables before processing,
- domestic uses such as toilet flushing.

The primary aim of these scientific risk assessments was to guarantee the safety of these reuses, both for human and animal health.

They take account of the hazards inherent in each type of water to be reused, the treatment methods available for the intended uses, and the control and monitoring measures required to manage the associated risks. ANSES has also examined the impact of reuse on the replenishment of natural resources, to which the water treatment cycle normally contributes.





Pesticide metabolites in drinking water





water

The resources used to produce drinking water, whether supplied to the tap or in bottles, may be affected by diffuse contamination from urban, industrial or agricultural activities or accidental pollution. In order to guarantee consumer health, ANSES provides the Directorate General for Health with invaluable scientific benchmarks for monitoring drinking water quality. Concerning pesticide residues, the Agency uses its method to identify, from among all the metabolites resulting from their degradation, those that are "relevant" to drinking water, i.e. whose presence in drinking water warrants priority attention. In recent months, it has assessed or reassessed the relevance of metabolites of several active substances: chloridazon, desphenyl-chloridazon and chlorothalonil R417888 and R471811. These assessments have taken account of new data available, in particular on the genotoxicity of these substances. In addition, the Agency is often consulted when checks carried out by the Regional Health Agencies (ARSs) reveal situations where regulatory quality limits have been exceeded. Its role then is to determine an exceptional maximum health value, as provided for by the regulations. This value applies for a limited period while corrective measures are taken to bring the water back into compliance.



Per- and polyfluoroalkyl substances (PFASs)



PFASs have been the subject of growing societal concern in recent months. The Agency has been working on this issue for a number of years. The PFAS class includes a large number of substances used for various purposes and with one thing in common: they are all highly persistent and ubiquitous in the environment. A major difficulty lies in distinguishing those with the hazard characteristics of greatest concern. The study of this class of substances has been included in the European Partnership for the Assessment of Risks from Chemicals (PARC), coordinated by ANSES. At the same time, the Agency is firmly supporting the PFAS restriction proposal presented at European level in order to reduce emissions of these substances at source. In this regard, it contributed to the public consultation organised in 2023 and is involved in the European expert committees tasked with assessing restriction work under the REACH Regulation.

ANSES is also taking action to support the French authorities in advancing knowledge and establishing scientific benchmarks (TRVs, guideline values, etc.) with a view to reducing exposure. In late 2023, it conducted an international survey of existing reference values in drinking water for the 20 PFASs listed in European Directive (EU) 2020/2184 on the quality of water intended for human consumption. In 2024, the Agency is pursuing its work to define a methodology for prioritising the PFAS substances to be monitored and establish toxicity reference values for long-term oral exposure.

Lastly, ANSES has included PFASs in its total diet study, the third edition of which is currently in progress. This is expected to clarify the dietary exposure levels of the population.

Preventing cases of Ostreopsis poisoning on the Basque coast

In June 2023, ANSES published an expert appraisal on the risks associated with the toxins produced by these microscopic algae of tropical origin, present on the Basque coast for several years now. To protect the health of workers and visitors to the beaches, who may inhale contaminated sea spray, the Agency provided local authorities, including the regional health agencies, with a decision tree. Depending on the concentration of microalgae in the water or the number of poisoning cases reported, it recommends measures ranging from informing the public through to banning water sports and closing beaches. ANSES also advised stepping up the monitoring of bathing water when microalgae are detected, as the situation can change rapidly.





Confirmed impact of chemicals on corals in the French overseas territories

In an expert appraisal carried out with support from the French Biodiversity Agency, ANSES examined the impact of chemical pollution on the health of coral reefs. The findings were published in September 2023. Of the hundred or so substances identified as potentially toxic to corals, the Agency conducted a risk assessment for around fifty of them, mainly using data available in Guadeloupe, Martinique, Reunion Island and Mayotte. These substances include UV filters, hydrocarbons, pesticides and metals. The expert appraisal showed that half of the substances assessed could pose risks to coral reefs and contribute to their degradation. Due to a lack of available data, the Agency believes that this number is very likely to be underestimated.

The seven vigilance schemes coordinated by ANSES monitor adverse effects in a wide variety of fields: food supplements, veterinary medicines, plant protection products, high-risk occupational situations, etc. Since January 2024, the Agency has also been responsible for vigilance schemes covering cosmetics and tattoo products. We take a look at these new missions and, more generally, at the fundamental principles governing the Agency's vigilance schemes and its work on examining signals.

Vigilance to guard against adverse effects



"Identify the toxic effects of certain products, foods and behaviours".

INTERVIEW

Juliette Bloch

Director of Health Alerts and Vigilance

What do the various vigilance schemes have in common?

The seven vigilance schemes we coordinate are all very different, but although each one has its own way of operating, they are all based on the same principle: identifying adverse effects associated with specific products and exposure situations.

Several of these schemes are based on reports we receive from healthcare professionals, manufacturers or individuals via dedicated reporting sites, in particular the ANSES website and the Ministry of Health's adverse health events reporting portal. We analyse each one and discuss it with our experts

where necessary, in particular those from poison control centres. Next, we look for similar cases in our databases and, in the event of an anomaly, we pass on the alert to the competent authorities, which then take appropriate action.

The act of reporting therefore benefits the whole community. It helps us identify the toxic effects of certain food supplements and everyday products such as hygiene products, as well as any new adverse effects of veterinary medicinal products, for example.

What are their main principles, which you recently described in a specific document?

Each vigilance scheme is monitored by a dedicated ANSES scientific team. A vigilance coordination committee oversees implementation of the general fundamental principles. These guarantee the same standards in the analysis of reports; they also ensure consis-

tency between the methods used in the schemes for characterising signals and health alerts, following up reports and publishing our analyses.

In accordance with these principles, we work to ensure that the method used in each vigilance scheme to determine causality is robust and has been scientifically tested and validated. These methods enable us to estimate the strength of the causal link between exposure to a product, for example, and an observed adverse effect. We also monitor the measures taken by the authorities in response to the alerts we send them. This serves as a performance indicator for our vigilance missions.

To raise awareness among the groups most concerned, especially healthcare professionals, and highlight the value of reporting, we have created the *Vigil'Anses* newsletter, which features articles that are quick to read and can be understood by non-specialists.

→ CONTINUED ON NEXT PAGE



What is the outlook for the years to come?

Since January 2024, we have been responsible for two new areas of vigilance: cosmetics and tattoo products. These were previously managed by the National Agency for Medicines and Health Products Safety (ANSM). These two schemes rely on reports of adverse effects that can be submitted by healthcare professionals, manufacturers and distributors, but also by other professionals such as hairdressers, beauticians and tattoo artists, or even by private individuals. We are currently deploying the resources needed to successfully carry out these two missions; in practical

terms, we are recruiting new staff members in order to be able to analyse a greater number of reports.

Another challenge for the vigilance schemes is to develop the detection of weak signals. Together with Santé publique France and the ANSM, we are working on automated detection models for identifying new phenomena and unusual events in large datasets, including online discussion forums.

The four-monthly
Vigil Anses
newsletter presents
the main results of
the Agency's work
as part of its
vigilance missions,
reflecting current
events.

→ VISIT

vigilanses.anses.fr/en



The seven vigilance schemes coordinated by ANSES



Nutrivigilance

aims to rapidly identify possible adverse effects related to the consumption of food supplements, fortified foods or novel foods.



Phytopharmacovigilance

seeks to document the presence of plant protection product residues in different media (including food) and identify adverse effects on human, animal or environmental health associated with the use of these products.



The National Network for Monitoring and Prevention of Occupational and Environmental Diseases

(RNV3PE) has been tasked with identifying risk situations in the workplace, based on data from consultations carried out at the 28 occupational and environmental disease consultation centres.



Toxicovigilance

monitors both acute and chronic toxic effects on humans, following exposure to natural or synthetic substances or substance mixtures available on the market or present in the environment.

This scheme is supported by the network of poison control centres.



Veterinary pharmacovigilance

monitors the side effects of veterinary medicines on the health of treated animals, veterinarians and individuals, as well as on the environment and food, after these products have been placed on the market.



Cosmetovigilance

aims to identify adverse effects in humans associated with the use of cosmetics.



Tattoovigilance

monitors the adverse effects caused by the use of tattoo products.

Three alerts issued with poison control centres

Continuing prevention of carbon monoxide poisoning

This deadly gas continues to be responsible for around 1300 poisonings a year in France; cases that are both common and serious. Between 1 and 8 November 2023, the power cuts caused by storms Ciarán and Domingos led to people misguidedly using power generators to heat indoor spaces. Serious poisoning caused life-threatening symptoms in four people and one death. In 2023, ANSES once again joined in the awareness campaigns organised with poison control centres and the Directorate General for Health to prevent unsafe practices, particularly during the winter period.





Beware of the risks to young people from **nicotine and tobacco pouches**

Poison control centres are receiving more and more calls about products such as nicotine pouches, tobacco pouches (snus) and flavour beads for cigarettes. ANSES therefore reviewed these poisoning cases. Since children and adolescents are the main victims, the Agency called for heightened vigilance with regard to the promotion of nicotine sachets among young people, who are at high risk of both nicotine poisoning and addiction. It believes it is vital to establish a regulatory framework for products that currently have no clear status and are not monitored in any way.





SNIPER insecticide: ANSES and the public authorities alert consumers

With the number of poisoning cases on the rise and bed-bug infestations receiving extensive media coverage, ANSES joined forces with the health authorities to reiterate the potential hazards of using banned insecticides. In a December 2023 study, ANSES and the poison control centres analysed poisoning cases occurring since 2018 and involving the use of SNIPER 1000 EC DDVP containing dichlorvos, an insecticide that is banned in France: 206 people were exposed between 1 January 2018 and 30 June 2023. Nearly 10% of reported poisonings were of moderate severity but 5.5% were serious, including several deaths.

Plant

on the health of living beings and ecosystems. In 2023, two actions in particular illustrated the value of this scheme for health investigations and public health protection.

Prodection

products:

cultivating

clata

Once applied to crops, plant protection

environment. The phytopharmacovigilance scheme run by ANSES, which is the only one of its kind in Europe, gathers extensive data on the presence of these products in the environment, any exposure observed and their possible impact

products and their residues can have effects on both health and the

The phytopharmacovigilance scheme receives reports of adverse effects associated with the use of plant protection products from professionals, measurement systems and research work. Each report is analysed to decide whether it constitutes an alert requiring risk management measures to be taken, or whether it needs to be further investigated, for example via specific studies or heightened surveillance.





The work carried out on the herbicide prosulfocarb illustrates the value of phytopharmacovigilance in limiting unintended exposure to these products.

Drawing on data from this scheme, ANSES examined cases of spray drift leaving residues on non-target crops (apples, watercress, rocket), as well as air concentration peaks reported in Charente-Maritime. Even though these signals did not constitute a health alert, the Agency noted that the tightening of the products' conditions of use that it had insisted on in 2018 had not put

an end to unintentional residues. As this active substance is particularly volatile, ANSES revised its assessment of the risks to local residents, which found that certain risks to children could not be ruled out.

In October 2023, the Agency therefore further strengthened the conditions of use and asked for data to verify that they were sufficient.

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In October 2023, publication of the results of GEOCAP-Agri in the journal Environmental Health Perspectives demonstrated the value of investigating the presumed links between plant protection products and cancer, but also the obstacles encountered. This study, funded by the phytopharmacovigilance scheme and conducted by the CRESS research laboratory (Inserm/Paris Cité University), in collaboration with Santé publique France, examined the potential links between paediatric cancers and the surface area of vines near children's homes, for all the vineyards in France. It followed a request from the association Alerte des Médecins sur Les Pesticides, in response to a series of cases of paediatric cancers suspected of being linked to exposure to plant protection products in the Nouvelle-Aquitaine region.

Launched in late 2023, GEOCAP-Pest will follow on from this in order to further examine the results, as statistical links have been observed between certain cases of leukaemia and the density of vines up to a kilometre away. This new study, again funded by phytopharmacovigilance, will also seek to identify product groups, chemical classes and even active substances responsible for an increased risk.

Although new knowledge was acquired, this situation highlighted the difficulties encountered in determining the causes of adverse effects attributable to plant protection products in the absence of a digitised database on the use of plant protection products, by field, crop and year.



Phytopharmacovigilance

Created by the 2014 Act on the future of agriculture, this scheme was set up by ANSES in 2015. It brings together around 20 partners, networks and monitoring or vigilance bodies appointed by the Ministerial Order of 16 February 2017 on the organisations involved in phytopharmacovigilance, amended by the Order of 14 December 2018.



1. Collect and continuously examine

information on environmental contamination by plant protection product residues, as well as exposure, human contamination levels and impacts on living organisms and ecosystems as a whole. This information is published in the form of fact sheets for each active substance.



2. Collect and analyse reports

from professionals and from international research and studies, to enable appropriate measures to be put in place.



3. Fund studies and generate new

knowledge: epidemiological studies, studies on contamination levels in the population, measurements in environmental media and surveys of practices. Each year, around €1.4 million is allocated for this purpose.



"With this phytopharmacovigilance scheme, we have taken a real step forward in capturing data on plant protection products".



INTERVIEW

Matthieu Schuler

Managing Director General of the Science for Expertise Division

How does phytopharmacovigilance address concerns about pesticides in the environment?

In our role as a health agency, we need to be able to answer the questions asked by our fellow citizens: are certain diseases linked to specific types of pollution? When our attention is drawn to an observation, is it just "background noise" or is it a report that needs further investigation to determine whether or not it constitutes a health alert? The phytopharmacovigilance scheme collects information on plant protection substances and products found in the environment that are a source of specific concern, with a view to detecting risks that have not yet been identified.

It can also fill gaps in the data by funding measurement campaigns, research and epidemiological studies. In 2023, for example, the second national campaign to measure air quality in homes took account of the presence of pesticides in the air inside buildings,

as well as in dust, which can be a major source of exposure. These results will be analysed in 2024 and submitted to the Scientific Board of the brand new Indoor Environment Quality Observatory (OQEI) run by ANSES and the French Scientific and Technical Centre for Building (CSTB).

What challenges do you face in identifying high-risk exposure?

With this phytopharmacovigilance scheme, we have taken a real step forward in capturing data on plant protection products as used and their residues in the environment. Now we have to organise and store these environmental data and cross-reference them with other data, particularly on health, in order to identify any links with chronic diseases, because this automatically means past exposure! In the absence of a register to keep track of the products applied, investigations to retrace past exposure are tedious and have to fall back

on considerable approximations based, for example, on data on sales to farmers.

Expert appraisals of health alerts are always more effective when carried out using geolocated information from the field, as this enables them to be linked to the substances or products raising concerns. Digital technology opens up many possibilities in this regard. The Agency therefore stresses the importance of practicality and sustainability when collecting data on the use of plant protection products. This of course requires a strict framework to be put in place, with access limited to usage data only, protection of the rights of professionals sharing their data,

For example, if such data had been available, rationally and regionally based, it may have been possible to go further in the GEOCAP-Agri conclusions on the exploration of potential links between childhood cancers and residential proximity to vineyards.

What can we do to further exploit the data generated?

Regardless of the source of exposure, ANSES calls for greater opportunities to collect data, and recommends taking the time to consider in advance the best format and use for these data. This is essential to ensure they are easy to analyse and effective in public health terms. This means considering an open data collection system, and anticipating future uses and interconnections with other types of data – on the state of health of

people or soil, and on exposure to other risk factors, to give just a few examples.

To meet these ambitions, a number of policy and regulatory options are available. The new national biomonitoring strategy will enable the links between environmental health and human health to be explored in greater depth. The Green Data for Health (GD4H) project under the Fourth National Environmental Health Plan (PNSE4) is also a very promising option for institutionalising a multidisciplinary approach, by combining all environments and product types, obviously including plant protection products.



Ecological and technological transitions, along with changing professions and work patterns, create new challenges for occupational health. ANSES monitors these developments closely and has recently published several expert appraisals on emerging risks. In the last few months, the Agency has also produced new scientific benchmarks to support the recognition of occupational diseases.

Occupational health: analyses and recommendations

Workers who have fallen sick as a result of exposure while carrying out their occupational activities are entitled to claim compensation. Recognition of their condition is facilitated when there is an occupational disease table.

1800

cases of work-related cancer in France recognised annually by the occupational accidents and diseases branch of the French health insurance scheme

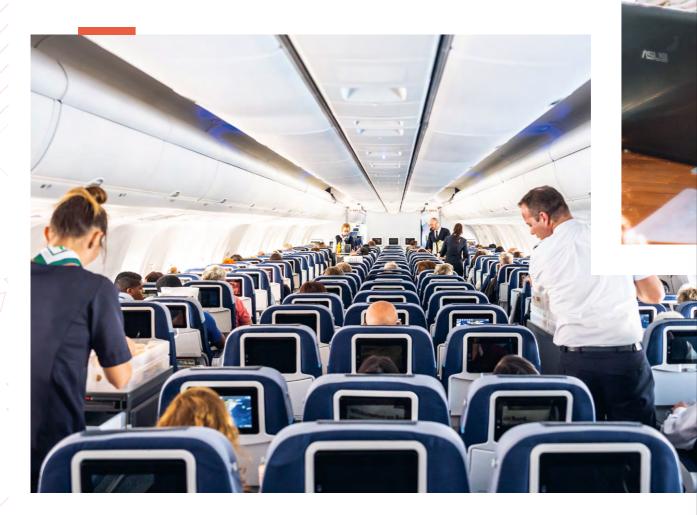
While a 2018 French study estimated that there were around 12,000 cases a year of work-related cancers in France, only 1800 cases are recognised annually by the occupational accidents and diseases branch of the French health insurance scheme. What explains this lack of recognition? Under the French system, applications for recognition are made by the victims or their families. However, many things can get in the way of declaring an occupational disease, including lack of knowledge or failure to identify the link between disease and work, by the victims or even by the doctors assisting them in getting treatment.

The opinion published in November 2023 provides a perfect example. Not only did ANSES conclude that there was a proven link between occupational exposure to formaldehyde and myeloid leukaemia, which is a strong argument in favour of creating an occupational disease table, but it also issued a recommendation to haematologistoncologists and their teams: in conjunction with general practitioners and occupational physicians, they have an important role to play in improving detection of occupational exposure to formaldehyde and helping their patients obtain recognition.



Focus on the health of **flight crews**

In October 2023, ANSES conducted a review of knowledge on the specific hazards and working conditions of flight crew members. When flying, these workers are particularly prone to working irregular hours and night shifts, which is known to have health effects. This is combined with exposure to ionising radiation from cosmic rays and sunlight, which increases with altitude. ANSES stressed that epidemiological studies still need to be undertaken to clarify the health effects of these employees' working conditions and multiple exposures. Concerning the "aerotoxic" symptoms reported by flight crews, which are thought to be associated with potential contamination of the air in the aircraft cabin or cockpit by various pollutants, the available studies do not enable these symptoms to be confirmed or their causes to be identified. Moreover, the Agency noted that multiple sources of pollution have been identified and that these may be linked to the materials used, the functioning of the aircraft (including the ventilation system), operations carried out on the ground and in flight, etc. The Agency therefore called for further research to be carried out, considering the situations of multiple exposure involving these workers.





Several potential health effects of **teleworking**

The widespread adoption of teleworking and related technologies has had major consequences for the organisation of work. After receiving a request from the French Confederation of Christian Workers (CFTC), ANSES asked the **Environmental and Occupational** Health Research Institute (IRSET) to review the current state of knowledge based on the available scientific studies. The results of this work, published in February 2024, show that there are still not enough available data to be able to precisely characterise the effects of teleworking on health, and that these data are not necessarily representative of the post-COVID situation. The study did, however, identify potential health effects of teleworking, in particular a series of adverse effects and aggravating factors relating to health (including mental health), social life and work activity. In addition, ANSES emphasised that teleworking is a form of work organisation in its own right: it is not simply the practice of working in a different location. Identifying the risks associated with teleworking for prevention purposes requires the mobilisation of all stakeholders to develop knowledge and solutions that take account of the reality of teleworkers' occupational situations and activities.

To have a better knowledge base with regard to the effects of teleworking, ANSES therefore recommended establishing a reference definition and continuing research efforts, in particular by conducting quantitative and qualitative studies. The consequences of teleworking should also be investigated as a remediation solution or an aggravating factor in the context of climate change.



National Network for Monitoring and Prevention of Occupational and Environmental Diseases (RNV3PE)

The RNV3PE, coordinated by ANSES, is a network of occupational and environmental health professionals that includes the 28 occupational disease consultation centres (CCPPs) in France.

Every year, the network records almost 30,000 consultations carried out in these centres, which are fed into a national database with data on patient demographics, diseases, exposure, industry sectors and occupations.

The data are used in scientific work carried out in partnership with five organisations: the National Health Insurance Fund (CNAM), including the scheme for self-employed workers, the Central Fund for the Agricultural Mutual Insurance Scheme (CC-MSA), Santé publique France, the National Research and Safety Institute (INRS) and the French Society for Occupational Medicine (SFMT).

MAIN OBJECTIVES OF THE RNV3PE



Describe

occupational situations involving health risks and disorders with a link to the environment in France.



Identifu

emerging or re-emerging occupational or environmental health risks in France.



Improve and harmonise

diagnostic practices for diseases related to work and the environment.



"Data used for the purpose of occupational disease prevention".

INTERVIEW

Eva Ougier

Coordinator of the RNV3PE team, Health Alerts & Vigilance Department

How are the RNV3PE's data used?

The RNV3PE has an information system shared by all the network's partners, which collects data from the 28 occupational disease consultation centres (CCPPs) in France. More than 500,000 consultations have been recorded in it since 2001. These precious data are used for scientific studies carried out by ANSES's expert groups, for the purposes of prevention.

They include the Working Group on "Emergence", made up mainly of occupational health physicians, which monitors the literature, discusses clinical cases reported by the CCPPs and assesses the level of action to be taken if a signal is identified. In 2023, the group examined the health risk associated with exposure to psyllium seeds. Why?

In 2023, we reported on the risks associated with psyllium seed powder. While its sensitising effects are well known in the pharmaceutical and healthcare sectors, it is also increasingly being used in the food industry to replace gluten and eggs, respectively in gluten-free and vegan products. A case of occupational rhinitis due to psyllium was identified in the RNV3PE database. concerning a production worker in a food processing company. This is now expected to lead to increased vigilance for these newly exposed workers, including bakers.

We therefore identified a new "triad", i.e. a disease-exposure combination that we already knew about but that constitutes an emerging risk in a new industry sector. This emerging occupational risk was described in an article in our Vigil'ANSES newsletter and in communications in scientific journals and conferences. The aim is to reach and raise awareness among as many occupational physicians as possible, as they are on the front line when it comes to detecting high-risk situations in the workplace.

The network has broadened its scope to include environmental exposure and has become the RNV3PE: what challenges does this change bring?

A 2019 decree added an environmental component to the scope of the CCPPEs' expertise and the nomination of a regional occupational and environmental disease centre (CRPPE) for each region (possibly comprising several units within the region).

To take this change into account, in January 2024 the network became the National Network for Monitoring and Prevention of Occupational and Environmental Diseases, with a new set of challenges. First of all, we need to determine which types of environmental disorders should be recorded by the CRPPEs and define the rules for coding environmental exposures, to ensure that these data can be exploited in a robust manner. It is also essential to develop the information system so that it can absorb all these new data. It is the working tool for the entire network, whose remit now extends beyond the field of occupational health to fully encompass environmental health.

Setting indispensable for risk assessment, also help the public authorities set regulatory concentrations that must not be exceeded. benchmark Values

The chemicals we are exposed to on a daily basis, including in the course of our occupational activities, can potentially be harmful to our health. To provide us with better protection, ANSES develops various health reference values. These values, which are

Developed by ANSES with the support of the relevant scientific expert group, each health reference value is specific to a substance, a duration of application, a route of exposure (oral, respiratory, dermal) and a target population (general public, workers).

The Agency assesses the human health effects on the basis of the available experimental and epidemiological studies, using methodological guides it has developed. In 2024, it plans to publish an updated guide that will compile the practices used to derive the different types of values, i.e. all the methods rigorously applied to establish them.

Moreover, back in 2022, ANSES carried out expert appraisal work to develop reference values for chemical mixtures. After reviewing the methods already available, it proposed indoor air quality guidelines (IAQGs) for mixtures of irritant chemicals, and toxicity reference values (TRVs) for the BTEX mixture (benzene, toluene, ethylbenzene and xylenes). It will be continuing its work on mixtures in the coming years, in particular a phthalate mixture.



The different types of health values developed by ANSES



Toxicity reference values, or TRVs, establish a relationship between a quantity of a chemical and a harmful effect or the probability of an effect occurring. These toxicological indicators are intended to protect the population as a whole, including susceptible groups such as children, pregnant women and sick people. There are external TRVs specific to an exposure route (oral, respiratory, dermal) as well as internal TRVs (measured in a biological matrix such as blood).



Indoor air quality guidelines, or IAQGS, correspond to the concentration of a chemical in indoor air below which no health effect or nuisance should be observed for the general population.



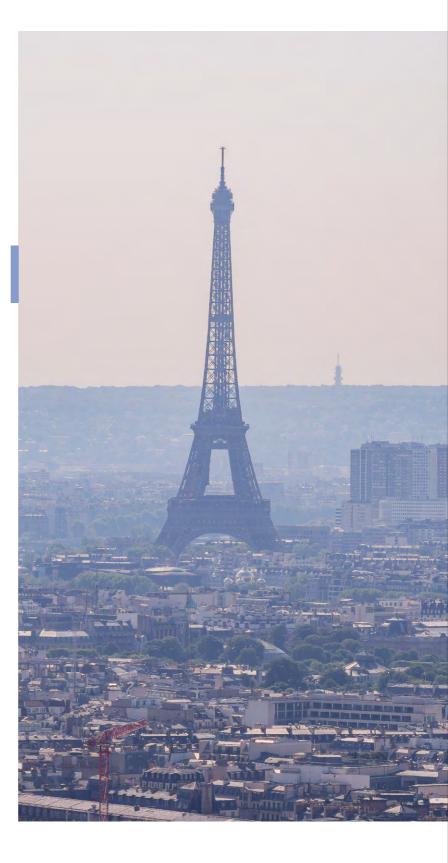
Occupational exposure limits, or OELs, relate to concentrations of a chemical that workers can breathe during a specified period without experiencing adverse health effects. The levels are determined for a homogeneous exposed population that excludes children and the elderly.

Some substances cause non-threshold effects, i.e. even at very low doses.

In this case, as it is not possible to identify a concentration below which no effects are expected, ANSES recommends several concentrations corresponding to the probability of an effect occurring, for example, the risk of an additional case of cancer in a population of one million people exposed.

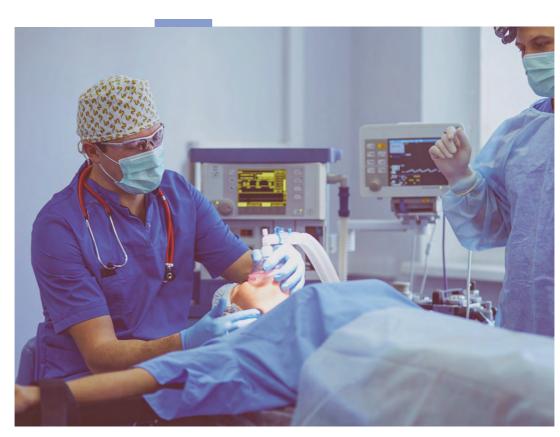
TRVs for particulate matter in outdoor air

In an expert appraisal following an internal request, whose results were published in January 2023, ANSES recommended a TRV by the respiratory route for long-term exposure to particulate matter in outdoor ambient air. It relates to the aerosol fraction known as PM2.5, which is the benchmark for environmental monitoring. In the case of specific particulate pollution, such as aerosols consisting of particles enriched with metals or minerals from industrial sources, the Agency recommended also considering other substances and values. Previously, in the absence of TRVs, concentrations in ambient air were compared with World Health Organization or regulatory values, but with these benchmarks, it was not possible to quantify the health risks associated with a given exposure and therefore to take appropriate decisions to protect the population.



Nitrous oxide: an OEL to limit occupational exposure

Commonly used as an anaesthetic or analgesic during medical procedures, nitrous oxide has many other industrial uses, from food processing through to rocket fuel. ANSES recommends limiting exposure to 25 ppm (parts per million) over an 8-hour period. This OEL is designed to prevent impaired cognitive performance (the effect that appears at the lowest concentrations) and should also protect against effects on the immune and haematological systems and on development. However, possible effects on fertility, for which there is a lack of reliable human and animal data, cannot be ruled out. Because concentrations well in excess of 25 ppm have been found, the Agency recommended that the OEL be transformed into a regulatory value in the French Labour Code, and urged employers to limit nitrous oxide exposure to the lowest level possible when its use cannot be avoided. ANSES's work on this topic was published in March 2024.



A central figure in several surveillance systems, ANSES supports the public authorities in preventing and managing health crises, both in France and beyond our borders. Always on the lookout for recurrent and emerging health risks, ANSES can rapidly mobilise its expertise and equipment when needed. Here we take a look back at the Agency's reference mission and two animal health crises in 2023.

Responsive to crises

ANSES carries out surveillance activities to monitor the development of problematic diseases and pathogens, and detect the emergence of new risks in animals, plants and food. It contributes to the epidemiological surveillance platforms for these three areas.

Reference mandates held by ANSES:

66
national

13 European

29
international

ANSES's laboratories are constantly improving methods for identifying, analysing and diagnosing viruses, bacteria, fungi, parasites, insect pests and vectors, invasive plants and chemical contaminants. They also carry out tasks as reference laboratories.

The authorities call on their scientific and technical support to draw up surveillance plans and manage crises affecting food, domestic and wild animals, crops and other plants. As soon as a crisis occurs, ANSES can also mobilise its state-of-the-art scientific equipment, its emergency expert groups and its networks. When receiving a formal request, the Agency takes prompt action to assess risks and recommend appropriate measures.



What do we mean by reference?

For certain viruses and bacteria, or for other pests and chemical contaminants of major importance, the health authorities set up specific surveillance schemes. At the national level, for each theme, State services approve a network of field laboratories to carry out official analyses, and appoint a "national reference laboratory" whose role is to guarantee the reliability of the analyses carried out and coordinate the network. This organisation is supplemented by European and international schemes.







Whole-genome sequencing to safeguard health

In 2023, ANSES continued to roll out whole-genome sequencing in its diagnostic and reference activities, with a view to constantly improving the precision of its risk assessments. This technique has a number of advantages in surveillance. In particular, it helps achieve more accurate identification of pathogen reservoirs and transmission vectors, provide robust genomic databases that are representative of the spatial and temporal distribution of pathogens, and improve the investigation of health alerts and the forwarding of sequences to EFSA during European alerts.

Epizootic haemorrhagic disease:setting up surveillance

Epizootic haemorrhagic disease (EHD) was first detected in Europe in late 2022. As the World Organisation for Animal Health's reference laboratory for EHD, ANSES helped identify the serotype circulating in Tunisia, sequenced the viral genome, validated PCR tests and set up a network of approved laboratories capable of identifying cases. As no vaccine is currently available, the only way to curb the spread of the virus is to test animals and ban the transport of ruminants from infected areas.







Avian influenza: a major vaccination campaign targeting ducks

ANSES has been supporting the public authorities in developing a vaccination strategy against the current epidemic of highly pathogenic avian influenza (HPAI). In 2023, it assessed preventive vaccination scenarios designed to protect poultry sectors and limit the spread of the virus by determining the priority species to be vaccinated and the types of farms, depending on the available vaccination resources. The Agency and the Toulouse National Veterinary School also demonstrated the efficacy of two candidate vaccines, on a strictly experimental basis in protected conditions similar to those in the field, both in preventing symptomatic forms of the disease and in limiting shedding and transmission between birds. The study was commissioned by the Ministry of Agriculture and involved the regions of Nouvelle-Aquitaine, Occitanie, Pays-de-la-Loire and Brittany, and professionals in the sector.

In 2023, the French Agency for Veterinary Medicinal Products (part of ANSES) issued temporary authorisations for use for veterinary vaccines effective against the strain of HPAI in circulation. These vaccines were used for the national vaccination campaign in autumn 2023.

FOOD: Providing better consumer information. Below is a recap of its recent recommendations, on the use of sweetening ingredients and animal welfare labelling. Changing The laises

Our fellow citizens are paying ever closer attention to the nutritional quality of their food and the way it is produced, with greater demands regarding livestock farming conditions.

ANSES is a reference in this area and has indisputable expertise in ways of improving the food supply and

Animal welfare considerations are currently covered by European regulations, which are increasingly being supplemented by private "animal welfare labelling" standards that have no common scientific foundation.

To address this situation, ANSES issued an internal request to propose a scientifically founded system of five levels of welfare, the lowest of which (E) corresponds solely to compliance with the requirements of European legislation. While most current labels only consider the rearing methods used and the means employed to improve them, the expert appraisal published in May 2024 put the focus back on welfare status, which means taking measurements on the animals themselves.

A number of welfare factors were broken down into indicators: genetic characteristics, rearing methods, breeder's practices and training, housing, feed, measures taken to ensure the animals' good health, limiting the use of painful practices, breeding, transport and slaughter.

Assessment also needs to consider the welfare of breeding animals. This proposed standard is aimed primarily at French and European scientists and stakeholders planning to set up a voluntary or compulsory animal welfare labelling standard.





Changes in the use of sweetening ingredients in processed foods

In March 2024, ANSES published two studies reviewing changes in the use of sweetening ingredients or ingredients conveying sweetness – sucrose, sugar, glucose-fructose syrup, aspartame, dextrose, molasses syrup fruit juice concentrate, etc. – in beverages and processed foods. Based on the ingredient lists on more than 54,000 products on the market between 2008 and 2020 and identified by OQALI, the first study showed that the majority of products, even savoury ones, contained at least one sweetening ingredient or ingredient conveying sweetness. However, their use has fallen over the last ten years, especially that of sugar syrups and artificial sweeteners.

Because the removal of one sweetening ingredient may be accompanied by an increase in the proportions of others, ANSES and INRAE carry out sector studies for OQALI on sugar content in particular foods. The study on soft drinks published in March 2024 showed a drop in sugar content, with the effect of the 2012 sugar tax (revised in 2018) and the collective agreement between the main manufacturers in the sector to reduce the average sugar content by 5%, between 2010 and 2015. ANSES believes it is possible to further reduce the use of sweetening ingredients in food and drink; efforts should therefore continue.

More than **48.000**

products in 30 food sectors (biscuits, cereals, ready-to-eat meals, compotes, dairy products, etc.)

OQALI, the observatory of the composition of processed products placed on the market in France

Created in 2008 under the French National Health and Nutrition Programme (PNNS), OQALI is led by the Ministries of Agriculture, Health and Consumer Affairs, and by ANSES and INRAE, which are also jointly responsible for its implementation. It conducts comprehensive monitoring of the food supply and objectively measures changes in nutritional quality.



An analysis of product characteristics and market conditions:

- · labelling on product packaging,
- · nutritional composition of foods,
 - prices and sales volumes.



Specific studies on:

- relationships between quality, price and consumption,
- the impact of nutrition policies,
- the presence of additives, etc.



Monitoring of the roll-out of Nutri-Score



Encouraging manufacturers and distributors

to improve the nutritional composition of the products on offer.



visits to the oqali.fr website each year



Health issues are not confined to our country, and nor is science. To safeguard the health of all living beings – humans, animals and plants – we need to continue forging ahead with scientific knowledge and methods.

The ANSES teams coordinate or contribute to many partnership research projects.

In 2023, a number of major programmes supported by the European Union came to an end, after having achieved major scientific advances. At the same time others were launched. Now is the time to take stock and look to the future.

Partnerships without borders



The curtain comes down on the **European "One Health EJP" programme**

After more than five years, the "One Health" European Joint Programme (EJP) came to an end in September 2023. Bringing together researchers from the human public health, food safety and animal health sectors, it put the One Health concept into practice. This major programme led to significant scientific advances in the fields of zoonoses that can be transmitted from animals to humans through food, antimicrobial resistance, and emerging threats. It helped to harmonise approaches, methodologies, databases and procedures for assessing and managing foodborne epidemics in Europe, and between the human and veterinary public health sectors. In addition to its scientific contribution, the programme created a unique European team of 44 partners from 22 European countries, who will continue to collaborate. The work undertaken for the programme will be used by the European One Health Association to raise the profile of the One Health approach to food safety and make it operational in Europe.

ANSES was responsible for overall coordination of the programme, with a total budget of €90 million, half of which was funded by the European Union's Horizon 2020 framework programme for research and innovation, and half by the partners. Through several of its laboratories, the Agency participated in 24 collaborative projects and four theses funded by the EJP.



Bee health: new data uncovered by PoshBee

Bringing together more than 40 European partners since 2018, the PoshBee research project sought to gain a better understanding of the causes of the decline in pollinating insects, particularly the impact of plant protection products, by focusing on three species in particular: the honey bee, the buff-tailed bumblebee and the red mason bee. Funded by the EU's Horizon 2020 framework programme, PoshBee came to an end in 2023. ANSES coordinated the component on measuring exposure to chemicals, pathogens and nutritional issues.

To analyse the vast amount of data collected on the subject, the scientists developed indices to summarise the insects' exposure to pathogens. Another PoshBee study produced an overview of the risks to these species, along with opportunities for addressing them in Europe in the next five to ten years. The results could serve as a basis for new research programmes or for developing protection measures at the national, European and even global level. One area of particular concern is the expansion of the global range of predators such as the Asian giant hornet *Vespa mandarinia* and the small hive beetle *Aethina tumida*. Extreme weather events – heatwaves, heavy rainfall or severe frosts – can also have a negative effect on pollinators.

PoshBee gave rise to several hundred scientific publications. A study to which ANSES contributed, which was published in the journal *Nature* on 29 November 2023, revealed for example the adverse effects of the use of plant protection products on bumblebee populations.

Our renewed partnerships

In recent months, ANSES has initiated or renewed a number of scientific partnerships with French, European and international organisations.

05/01/2023 O National Institute for Occupational Safety & Health (NIOSH), United States 18/01/2023 French National Research and Safety Institute (INRS) 28/02/2023 O Polish National Veterinary Research Institute (PIWet) 01/03/2023 National Reference Centre for Animal Welfare National Institute of Higher Education and Research in Food, Animal Health and Agricultural Sciences and the Environment (VetAgro Sup) National Research Institute for Agriculture, Food and the Environment (INRAE) 04/04/2023 🔷 French National Institute for Ocean Science and Technology (Ifremer) French network of technical institutes in the food industry (ACTIA) 26/06/2023 🗘 10/10/2023 Commission (CEA) 25/10/2023 O International Cooperation for Health consortium (IC4Health) 27/02/2024 Network of animal health protection groups (GDS France) 01/03/2024 Croatian Agency for Agriculture and Food (HAPIH)

A new European partnership on animal health and welfare

The European Partnership for Animal Health and Welfare (EUPAH&W) was launched on 1 January 2024. It plans to invest €360 million over seven years to boost research and help strengthen collaboration between all the players involved, through a "One Health and One Welfare" approach. Coordinated by Ghent University in Belgium and supported by a number of organisations including ANSES, it brings together 90 partners. Fifty per cent of its funding comes from Horizon Europe, the EU's current framework programme for research and innovation, and 50% from the partner institutions.



JOINT INTERVIEW



Sébastien Denys

Director of the Environmental and Occupational Health Division at Santé publique France

Éric Vial

Risk Assessment Director at ANSES

Over the last few months, ANSES and Santé publique France have been actively finalising the launch of Albane.

This major national survey will collect data on health, chemical exposure, food consumption and physical activity over two-year cycles, based on representative samples drawn from the population, from birth to 79 years of age. Funded by the Ministries of Health, the Environment, Agriculture and Labour, Albane will support both agencies' missions and generate useful indicators for monitoring the effectiveness of public policies in the fields investigated.

Other nationwide population studies were carried out by ANSES and Santé publique France before Albane. What were they?

ÉRIC VIAL. ANSES has a number of major studies to its credit, which have analysed and estimated the health risks associated with the various contaminants found in food, and assessed the nutritional risks and benefits of different consumption practices. Exploring the population's dietary habits and nutritional status is necessary to better explain and prevent certain non-communicable diseases such as cancer, obesity and cardiovascular disease.

ANSES carried out its individual and national studies on food consumption (INCA) at eight-year intervals, the last of which was finalised in 2015. Our Agency has also conducted total diet studies (TDSs) to monitor population exposure to chemicals found in food. These major studies provide invaluable data for carrying out our risk assessments and enabling the health authorities to adapt the public health measures taken with regard to food.

SÉBASTIEN DENYS. Santé publique France is responsible for monitoring the health of the French population. To do this, it deploys a range of tools, including surveys with health examinations. An example is the Esteban survey, which was conducted between 2014 and 2016 on a representative sample of the general population aged between six and 70 years. It collected various health indicators (asthma, allergies, cardiovascular disease, etc.) and data on chemical exposure of the French population. The results on exposure to chemicals via food were cross-referenced with ANSES's INCA and TDS findings, enabling a more detailed interpretation of the exposure levels measured, given that food is a major source of exposure to a number of chemical contaminants. Generally speaking, these major surveys make it possible to monitor the population's exposure over time and measure the effectiveness of the public policies deployed.

Albane follows on from the Esteban and INCA studies and goes further than a simple merger of the two. What else will it bring?

ÉRIC VIAL. The project was launched in 2018. It has a number of objectives, one of which is to strengthen the sharing and cross-referencing of data between agencies, thereby increasing efficiency in the study of the links between individual, dietary and environmental determinants and population health. It is also designed to spread the monitoring and workload more evenly over time. With shorter consecutive cycles - two years compared with eight for the Esteban and INCA studies - Albane provides greater flexibility for studying trends and emerging phenomena, in terms of exposure or diseases.

SÉBASTIEN DENYS. Combining our studies made sense and had a number of advantages. Besides the obvious benefit of optimising resources, it will help ensure the long-term viability of a survey system requiring substantial sums and mobilisation of teams in both of our agencies. Moreover, we are bringing Albane in line with internationally recognised standards and systems used in other countries (Germany, Canada, United States), enabling us to make comparisons with measures taken internationally. In 2025, the study will cover metropolitan France, and there are plans to include the overseas territories from 2028. Lastly, by sampling the same regions several times over the course of different cycles, we will eventually be able to estimate certain survey indicators on a regional scale and then support public health policies at a more local level, which is not possible with Esteban, for example.

How will it take place in practice?

ÉRIC VIAL. ANSES will be responsible for the food component of the study, and Santé publique France for the biomonitoring and health component, both in terms of drawing up the survey protocols and analysing the data. Questions of nutrition will be shared between the two agencies. Santé publique France will also be responsible for logistical implementation of the survey and for liaising with the research institute tasked with recruiting participants. Before launching the first cycle, we will begin with a pilot phase. This is scheduled to take place between September and December 2024, and will involve around 200 people selected at random. It will enable us to measure the participation rate, and test the questionnaires and the organisation in general. We will then have a few months to adjust the system before the launch of the study scheduled for spring 2025.

SÉBASTIEN DENYS. Albane has no equivalent in France. We are looking for the best response possible from participants, as this is essential if we are to have high-quality monitoring data that cover all the survey parameters. We have therefore done all we can to make participation easier, for example by using appropriate tools such as self-administered questionnaires. Albane poses a number of legal, administrative and IT challenges, such as ensuring compliance with GDPR rules, data security, the robustness of statistics, compliance of data flows with service providers, etc. We have had to be inventive and find answers to questions that had not previously arisen. This collaboration between agencies will enable us to go even further and better reflect the reality of population health.

Accounting Agency

Board of administrators

Scientific board

Committee for ethical standards and prevention of conflicts of interests

General Directorate

General Affairs Division

- · Health, Safety & Security Unit
 - Quality & Internal Audit
 Department
- Human Resources Department
 - Legal Affairs Department
- Administration & Financial Affairs
 Department
- Technical Affairs & Information Systems Department

Regulated Products Division

- Regulated Products Assessment Department
- Market Authorisations Department
 - French Agency for Veterinary Medicinal Products

7 cross-functional scientific themes

ANSES organisation chart

European and International Affairs
Department

Department of Communication and Institutional Relations

Science for Expertise Division

- Social Sciences, Economics
 & Society Department
- Health Alerts & Vigilance Department
- Research Funding & Scientific
 Watch Department
- Risk Assessment Department

Research and Reference Division

- Strategy & programmes Department
 - Fougères Laboratory
- Nancy Laboratory for Hydrology
 - Lyon Laboratory
 - Ploufragan-Plouzané-Niort Laboratory
- · Laboratory for Rabies and Wildlife
 - · Laboratory for Animal Health
 - Plant Health Laboratory
 - Laboratory for Food Safety
 - Sophia Antipolis Laboratory

FOOD SAFETY

ANIMAL HEALTH & WELFARE

PLANT HEALTH

EPIDEMIOLOGY & EPIDEMIOLOGICAL SURVEILLANCE CHEMICAL CONTAMINANT EXPOSURE & TOXICOLOGY

ANTIMICROBIAL RESISTANCE

OCCUPATIONAL HEALTH

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Authors
ANSES – Department of Communication and Institutional Relations

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AndJOY

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ANSES, Marc Chesneau/Good Pix,
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Oceanography Laboratory, DGCCRF,
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Headquarters: 14 rue Pierre et Marie Curie 94701 Maisons-Alfort Cedex – France

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