

Liberté Égalité Fraternité





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Glossary

Our areas of activity

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

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.

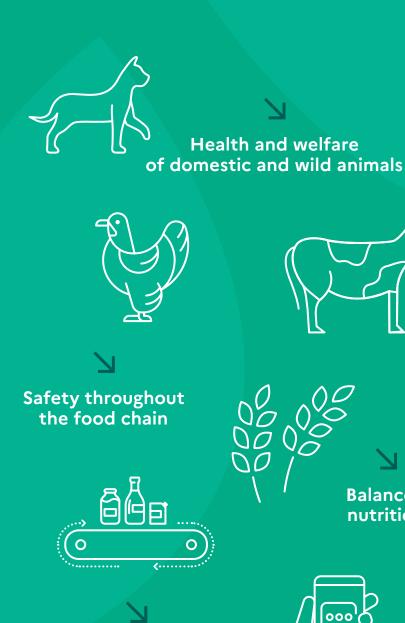
> Science driving a safer, healthier world for all and dedicated to One Health.



1,400 employees

16 sites in France, including in the overseas territories

An annual budget of around €145M









Balanced nutrition









Health risks related to the environment







Physical activity





Occupational health risks





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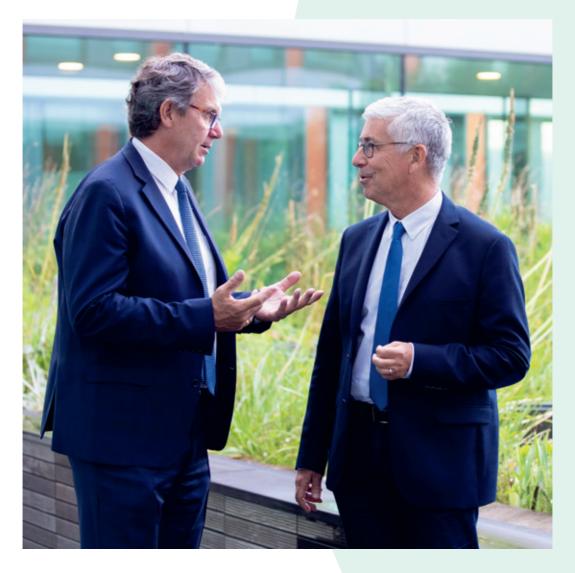
Roger Genet

Director General of ANSES

Benoît Vallet

Chair of the Board of Administrators

Conversation



What lessons can we learn from ANSES's work and challenges for 2021 and early 2022? **Roger Genet**, Director General, and **Benoît Vallet**, Chair of the Board of Administrators, give you their analysis through five key themes.

Commitment

BENOÎT VALLET

Although the epidemic waves of COVID-19 have had a profound effect on our lives in recent months, the ANSES teams have shown great resilience and commitment throughout this period. The Agency has been a constant source of scientific, organisational and ethical proposals, in order to better fulfil its missions for the benefit of society. Its laboratories were particularly active in supporting health crisis management and, in some cases, contributing to vaccine approaches. On behalf of the Board of Administrators, I would like to pay tribute to the commitment of ANSES's teams and expert groups. This commitment is reflected in the annual work programme, its activity indicators and the confidence of the public authorities, which entrust the Agency with new tasks each year. The Board welcomes this with interest but also with caution regarding the resources allocated.

New expert appraisal missions

ROGER GENET

Indeed, ANSES's missions are expanding and strengthening every year. In 2021, we were given new responsibilities in the areas of quality monitoring of drinking water, swimming pool treatment processes, and embalming, in application of the ASAP Act of 7 December 2020. On 1 January 2022, new missions concerning assessment of the environmental impact of organisms and products derived from biotechnology, as well as a new field of expertise in socio-economic analysis, were taken on by ANSES. These developments have required us to strengthen our expert groups and our own skills, especially in the human and social sciences, but also to reflect on the changes needed to further improve dialogue with stakeholders on societal and environmental issues of particular concern in public opinion.

Dialogue

BENOÎT VALLET

While science is and must continue to be the basis for public decision-making by producing reliable benchmarks for assessing the various options available to the decision-maker, we are well aware - and the COVID-19 crisis has illustrated this perfectly - that the trust of our fellow citizens requires total transparency and constant dialogue with all stakeholders. ANSES has been striving to ensure this ever since its creation, and knows from experience that the implementation of these two values needs to be constantly adjusted to changes in society and its concerns. With this in mind, I welcome the initiatives taken by the Agency in 2021 to enter into two partnerships designed to strengthen dialogue and openness to public participation, respectively with the National Commission for Public Debate (CNDP) and the Economic, Social and Environmental Council (CESE), in order to better align its expert appraisals with the debates and consultations organised by these national reference bodies.

Research and partnerships

ROGER GENET

A "One Health" agency par excellence, at the crossroads of interactions between humans and their environment, ANSES is a scientific expert appraisal agency, but also undertakes its own research and is a research funding body. This threefold mission is all the more unique in that it covers a wide range of health issues, both locally and globally. Our position as a catalyst for scientific output serving public decision-making means that we are constantly strengthening and improving our partner networks and our practices, both on a national scale with our sister agencies (Santé Publique France and the ANSM in particular), research organisations and technical institutes, and on a European scale. The quality of these partnerships goes a long way to explaining the success of the Horizon Europe framework programme, which in 2021 achieved a 28% success rate for projects involving ANSES, a score well above the European average.

Europe

ROGER GENET

Our work and scientific synergies are increasingly taking place at a European scale, whether in the area of risk assessment, where we work closely and share competencies with the European agencies, or in our mobilisation of the scientific communities on research programmes addressing the challenges of health and environmental policies. In this respect, 2021 saw intense activity in preparing the Partnership for the Assessment of Risks from Chemicals (PARC), and its official launch on 1 May during the French Presidency of the European Union. This €400 million programme, co-funded by the European Commission and coordinated by ANSES, brings together nearly 200 partners in 28 countries. This is the epitome of the role that ANSES needs to play in stimulating international research in its fields of expertise.



355
category A+
and A scientific
publications

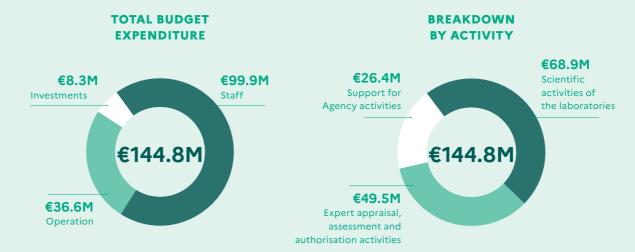
17
Scientific events organised

130
formal requests dealt
with, 10 of which
were urgent

195
opinions
and reports
published



108
reference mandates
entrusted to ANSES's
laboratories, including
two new ones in 2021





33

projects funded

by the National Research Programme for Environmental and Occupational Health

More than 5,500

authorisation, refusal or withdrawal decisions for products:



234 for biocidal products



2,411for plant protection products, fertilisers, growing media and adjuvants



2,911 for veterinary medicinal products

Tigures

INVESTMENTS MADE



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Main institutional events of 2021

PART

At the heart of of our missions

Assessing risks by mobilising collective expert appraisal

→ ANSES's primary
mission is to assess health
risks, whether in food,
the environment, the
workplace, or concerning
animals or plants. To do
this, it mobilises groups
of experts according to
principles that ensure high
standards of quality and
independence. Its reports
and opinions are used for
public decision-making and
help safeguard health.

A STRICT, TRANSPARENT FRAMEWORK

The Agency's role is to rule on the existence, nature and extent of risks raising concerns among the authorities and society in situations of high uncertainty or crisis, on the basis of the available scientific knowledge. The collective expert appraisals it performs meet strict scientific, methodological and ethical requirements. In addition to provisions laid down by regulations or ISO standards, **ANSES has developed a specific framework** establishing the fundamental principles of its expert appraisals, which can be viewed on its website.

The expert appraisals conducted by ANSES are collective, adversarial and multidisciplinary: the experts meet to answer a question put to ANSES through a formal request, and formulate their conclusions based on the different evidence available and the hypotheses expressed. On the basis of their work, ANSES draws up opinions and recommendations that it makes public.

A MULTIDISCIPLINARY POOL OF EXPERTS

Each year, ANSES calls on **nearly 800 French and foreign experts** from universities or research organisations with recognised skills in various disciplines - toxicology, epidemiology, medicine, occupational health, biostatistics, physical chemistry, human and social sciences, etc. These experts are selected through public calls for applications and are subject to public declarations of interests, which are published on the Ministry of Health's DPI-Santé website.

Collective expert appraisals at ANSES:

- > the most recent scientific knowledge at national and international level taken into account;
- y collective work performed within a strict framework ensuring conclusions that can serve as a reference;
- ☑ innovative methodologies for assessing emerging or complex risks (exposome, cumulative effects, no-threshold effects, etc.);
- y the scientific basis of ANSES's
 recommendations used by decision-makers,
 professionals, research communities
 and citizens.

Renewal of 10 expert committees and working groups in the fields of human food and nutrition, animal health and welfare, and plant health



Who can make formal requests to ANSES?

The State, the French
Parliamentary Office for
Assessing Scientific and
Technological Choices, other
public establishments, the
organisations represented on
its Board of Administrators,
and the associations identified
by the French Public Health
Code (Article L.1313-3). The
Agency may also issue internal
requests on its own initiative.





Creation of a 16th expert committee, devoted to socioeconomic analysis

Research: essential for risk assessment

→ To advance scientific knowledge and methods, ANSES conducts research, alone or in conjunction with the French and international scientific communities. It also funds research projects in its sphere of competence. The knowledge generated informs its risk assessment, surveillance and crisis management support activities.

ANSES CONDUCTS RESEARCH OF ITS OWN

Its nine laboratories, employing more than 700 people, carry out research in three main areas: animal health and welfare, plant health and food safety (including drinking water).

Their output also contributes to the analytical reference work of the Agency, which holds more than 100 national, European or international mandates. Research is also conducted by the Agency's other entities. This helps with the development of new **risk assessment methodologies**, for example. Seven cross-functional scientific directors coordinate and guide the work of the different teams.

Widely recognised within the research community, ANSES hosts around a hundred doctoral students each year and forges numerous partnerships with other organisations. It is also active and participates in many research projects funded at European level. In 2021, 11 projects involving ANSES teams were submitted to **Horizon Europe**, the EU's current research and innovation framework programme. So far, five of these projects, including the PARC programme coordinated by ANSES and a collaborative research project jointly coordinated by the Agency, have already been selected for funding. Other projects involving ANSES are currently being developed.



research projects selected under the PNR EST, with €6M mobilised

What is ANSES's research used for?

- y Gaining a better understanding of pathogens, their relationship with hosts and their ability to cross the species barrier.
- → Improving knowledge of plants and insects of concern, and chemical contaminants.
- → Better detecting, diagnosing and characterising their presence using cutting-edge analytical methods.
- → Monitoring them more closely through effective epidemiological approaches.
- Sontributing to the work of the epidemiological surveillance platforms for animal health, plant health and food-chain safety.

 ■ Contributing to the work of the epidemiological surveillance platforms for animal health, plant

 ■ Contributing to the work of the epidemiological

 ■ Contributing to the
- y Gaining a better understanding of the determinants of animal welfare and health, and in particular the impact of farming systems.
- Contributing to the development of control tools, including vaccines against animal and plant diseases, through a specific policy to promote the transfer of results.
- → Advancing risk assessment methods in all ANSES's areas of competence.

355 publications in scientific journals in category A and A+

FUNDING RESEARCH: THE NATIONAL RESEARCH PROGRAMME FOR ENVIRONMENTAL AND OCCUPATIONAL HEALTH

The PNR EST is the research component of the National Environmental Health Action Plan (PNSE) and the Occupational Health Plan (PST). Its objectives are to:

- produce scientific knowledge on environmental and occupational health risks;
- y develop new methods and tools for health risk analysis;
- y organise and stimulate research and scientific teams to tackle the targeted issues.

Every year, ANSES issues two calls for research projects, whose results can then be used in its risk assessment work or to support management measures.

Committed to preventing and managing health crises

→ ANSES is always on the lookout for recurrent and emerging health risks. In the event of a health crisis, it can rapidly mobilise its expertise in emergency risk assessment and scientific support for the public authorities.



new reference mandates

- ☑ Contagious equine metritis (international)
- $\ensuremath{\mathsf{u}}$ Monitoring of SARS-CoV-2 in wastewater and sewage sludge (national)

MONITORING HEALTH WARNING SIGNALS

ANSES coordinates or takes part in national schemes that detect warning signals and enable action to be taken against diseases and harmful exposure:

- → platforms for epidemiological surveillance in animal health, plant health and food-chain safety;
- y surveillance networks such as RESAPATH for antimicrobial resistance in animals;
- y vigilance schemes: toxicovigilance, nutrivigilance, phytopharmacovigilance, veterinary pharmacovigilance and the National network for monitoring and prevention of occupational diseases (RNV3P).

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 have a role 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.



10
urgent formal requests dealt with, including four on avian influenza. one on brucellosis in the Bargy ibex population, and two on COVID-19

ANSES held

66

national, 13 European and 29 international reference mandates in animal and plant health, food and environmental safety. They guarantee the performance of official analysis systems.

SUPPORTING HEALTH CRISIS MANAGEMENT

As soon as a crisis occurs, ANSES can mobilise its state-of-the-art scientific equipment, its emergency expert groups and its networks, according to the situation. Its reference laboratories coordinate official analyses to identify pathogens or contaminants and trace their source. When receiving a formal request, the Agency assesses the risks without delay and recommends appropriate measures.

ANSES'S COMMITMENT THROUGHOUT THE CURRENT AVIAN INFLUENZA EPIDEMIC

Since 2020, the western half of France has been severely afflicted with avian influenza. ANSES has been supporting crisis management in several ways:

- ע coordination of analyses to confirm the presence of the virus and sequence the strains;
- צ support for field investigations to determine the source of the contamination;
- ≥ scientific support to the public authorities to control the disease;
- ש participation in a duck vaccination experiment.

Seven opinions have been published since 2021.

→ Within the framework of European and national regulations and policies on the safety of chemical substances and products, ANSES helps determine safe and effective conditions of use, and reduce exposure to risks.

ANSES assessed:

■ 32 plant protection active substance applications, as rapporteur or co-rapporteur Member State:

2 biocidal active substance applications and contributed to 9 assessments by other MSs;

▶ 1 substance under REACH, and supported the harmonised classification for 4 chemicals proposed by France and validated by ECHA.

In early 2022, it also provided scientific and technical support to the French authorities for preparing a restriction dossier for creosote (REACH).

CONTRIBUTING TO EUROPEAN-LEVEL REGULATION OF CHEMICALS

The Agency supports national and European authorities in:

- carrying out scientific assessments of substances, including active substances
 REACH and the regulations on plant protection products, biocides and veterinary medicines;
- → analysing the best risk management options (classification, authorisation, restriction of a substance) - REACH and CLP:
- ☑ drafting dossiers for identifying substances of very high concern and proposals for restrictions on use in highrisk situations, including the analysis of socio-economic impacts - REACH;
- □ drafting classification dossiers CLP;
- → responding to public consultations on revisions of definitions, methodological guides, regulations, etc.

In 2021

COMMITTED TO EVER MORE PROTECTIVE REGULATIONS

ANSES's work echoes the EU's Chemicals Strategy for Sustainability and its ambition for a toxic-free environment.

In particular, it supports the "one substance, one assessment" approach.

The Agency is also proposing changes to existing regulations: in 2021, it published two opinions aimed at better defining and taking into account the hazards associated with endocrine disruptors and nanomaterials.

ESTABLISHING HEALTH REFERENCE VALUES

Every year, ANSES produces or updates health-based guidance values (HBGVs), indoor air quality guidelines (IAQGs), occupational exposure limits (OELs), etc. These values are essential for assessing health risks and enable the public authorities to define **regulatory thresholds that must not be exceeded** in air, water, food, etc. in order to protect the population, including workers.

In 2021

Production of reference values for six substances including 1,3-butadiene, chlordecone and sodium valproate

ASSESSING AND EXAMINING APPLICATIONS TO MARKET PRODUCTS

ANSES issues and withdraws marketing authorisations (MAs) in France for veterinary medicinal products, plant protection products, fertilisers and growing media, and biocides. It thus assesses their effectiveness and the health and environmental risks they pose, according to assessment methodologies that are harmonised and constantly evolving at European level. The way ANSES is organised enables it to conduct its scientific assessments independently of the examination of MA applications. As with all its risk assessments, ANSES relies on committees of experts, appointed after a public call for applications.



Authorisations and approvals: new missions entrusted to ANSES

2021

- Biocidal products contained in embalming fluids.
- Treatment products and processes for swimming pool and artificial bathing pool water.
- Laboratories conducting sampling and analysis for water quality monitoring (94 dossiers processed).
- → Testing of feed additives.

January 2022

Environmental risk assessment for organisms meeting the regulatory definition of GMOs and for which applications have been submitted for use in an open environment, for all biotechnology's fields of application agricultural, medical, agri-food.

An agency open to society

→ ANSES's governance model embodies the principles guiding its work: independence, transparency, scientific excellence and openness to society.



A variety of stakeholders contribute to the definition of ANSES's strategic orientations

through the Board of Administrators, which includes representatives of the State, various associations, professional bodies, inter-branch employers' organisations, trade union organisations and elected officials, but also through its five thematic steering committees, whose participants include other representatives of civil society.

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THE BOARD OF ADMINISTRATORS

discusses ANSES's general orientations, budget and annual work programme, and also has an internal audit committee.

"The Board of Administrators is unique in its plural composition, which reflects the Agency's openness.

Elected officials, professional and trade union organisations and associations typifying its areas of activity have a seat and a right to vote alongside its supervisory ministries. I can't help but notice, at each of the meetings I chair, the value of such participation.

We discuss fundamental, strategic issues, dialogue is constructive, and our common goal is a robust agency working for the benefit of all."



Benoît ValletChair of the Board of Administrators

\angle

at the Agency.

THE SCIENTIFIC BOARD, multidisciplinary and international, it guarantees the high standards and independence of the scientific expert appraisal process

"The Scientific Board functions as an independent body, to guarantee the excellence and consistency of ANSES's scientific work. It cares deeply about the quality and independence of its expert appraisals, and carries out methodological work designed to optimise the health risk assessment process. This work focuses in particular on integrating the weight of evidence, the analysis of uncertainties, the understanding of the exposome, and the credibility of expertise."



Isabelle Momas
Chair of the Scientific
Board

7

THE COMMITTEE FOR ETHICAL STANDARDS AND PREVENTION OF CONFLICTS OF INTERESTS

produces opinions and recommendations for the General Directorate in all areas of the Agency's activity

"There are significant uncertainties and risks in health and environmental safety. The challenge with ethical standards is to guarantee the rules of independence, transparency and plurality of experts so that, even in the absence of certainty, they can produce credible opinions that help in decision-making and provide insights on the need for further knowledge in order to progress."



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

The principles guiding our work

A COMPREHENSIVE APPROACH TO RISKS

Acting at the interface between human, animal and plant health

TRANSPARENCY & INDEPENDENCE

Expert appraisal work made **public**

All our activities comply with **principles of ethics** and **scientific integrity**

SCIENTIFIC EXCELLENCE

Experts recognised in their field

Reference scientific methods

All scientific knowledge taken into account

OPENNESS & DIALOGUE

Stakeholders represented in the Agency's **governance**

Dialogue committees on topics that are key issues for society

→ In addition to involving stakeholders in its governance, ANSES has developed its dialogue committees and entered into innovative collaborations enabling it to take part in broader mechanisms for consultation and debate with society.

Ever since it was founded, the Agency has followed an approach based on transparency and information sharing. It has set up dialogue committees and platforms on subjects generating high expectations or controversy within society: radiofrequencies, nanotechnologies, biotechnology and plant protection products. Twice a year, ANSES scientists and experts discuss their work with associations, trade unions and industry.

In 2022

Creation of the "Biotechnology, environment and health" Dialogue Committee

After having been entrusted with new missions in the field of biotechnology, ANSES will in 2022 set up a fourth dialogue committee devoted to ANSES's work on this subject. Like the other dialogue bodies, it provides a forum for discussing ANSES's scientific methods and working with stakeholders. It is not the committee's role to deal with ethical or societal issues, which will be the responsibility of the National Consultative Ethics Committee (CCNE) for the former and the Economic, Social and Environmental Council (CESE) for the latter. It brings together stakeholders with an interest in biotechnology's various fields of application, including agriculture and medicine.

ANSES AND THE CNDP: COMMITTED TO INFORMING AND INVOLVING THE PUBLIC

The health crisis of the last two years has highlighted the public's growing desire to better understand and voice its expectations on health and environmental issues.

It has also brought to light two conflicting trends: on the one hand, high demand for scientific insights, and on the other, a proliferation of information sources and distrust of public institutions. This context led ANSES and the National Commission for Public Debate (CNDP) to enter into a renewable three-year partnership with three objectives:

- u Improve the information provided to the public under participatory procedures organised or supported by the CNDP, in light of established scientific knowledge and associated uncertainties;
- u Strengthen dialogue and opportunities for public involvement within the scope of ANSES's missions, especially when it receives requests regarding topics that raise questions or are controversial with the public;
- ע Jointly reflect on the role of scientific knowledge and expert opinions in public debate.

Main institutional events of 2021



∠ 20 JANUARY-9 FEBRUARY

ANSES organised an international symposium on "Credibility of scientific expertise and public decision-making" in partnership with the Cité des Sciences et de l'Industrie and with the support of the French Parliamentary Office for Assessing Scientific and Technological Choices. More than 45 speakers and 1,600 people took part in the different sessions.

✓ 30 APRIL

ANSES, ENVA and INRAE renewed their two joint research units on animal diseases and the risk of their transmission to humans.

11 JUNE

New international reference mandate for ANSES's Laboratory for Animal Health on contagious equine metritis.



ANSES and the National Research Agency organised the scientific conference "Microplastics and nanomaterials: research on environment and health".



16 JUNE

Gabrielle Bouleau was re-elected as Chair of the Committee for Ethical Standards and Prevention of Conflicts of Interest.





14 DECEMBER

ANSES held its one-day scientific meeting on bee health, to take stock of research, expert appraisal and surveillance work.

30 NOVEMBER

ANSES and Inserm organised a one-day scientific meeting on the theme "Exposome and public health: from research to expertise".

16 DECEMBER

ANSES's Laboratory for Hydrology was appointed National **Reference Laboratory** for the monitoring of SARS-CoV-2 in wastewater and sewage sludge.



ANSES STRENGTHENED ITS INTERNATIONAL **COOPERATIONS BY** SIGNING SEVERAL **AGREEMENTS**

- **12 JULY:** on food safety with NIFDS, its South Korean counterpart.
- **12 OCTOBER:** on animal health and welfare and zoonoses with the Friedrich Loeffler Federal Institute in Germany.
- 18 NOVEMBER: on veterinary public health, food safety, nutrition and environmental health with the Istituto Superiore di Sanità, Italy's leading public health research organisation.



ANSES'S INVOLVEMENT IN THE FRENCH PRESIDENCY OF THE COUNCIL OF THE **EUROPEAN UNION IN 2022**

Throughout 2021, the Agency was closely involved in the organisation of European meetings and ministerial events on the themes in its sphere of competence - veterinary medicines, chemicals, occupational health, animal health - along with its counterpart agencies, and scientific and institutional partners.



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Taking account of all types of environmental exposure



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Supporting occupational risk prevention



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Sounding the alert in the event of adverse effects of everyday products



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Ensuring food safety

PART 2



Improving animal health and welfare

Taking account of all types of environmental

On a day-to-day basis and throughout our lives, the environment is a major determinant of our health.

It is essential to better identify exposure to the various pollutants, whether through air, water, technologies or consumer products. ANSES is fully committed to working with the scientific community to support research and develop risk assessment methods.

In 2021, it was particularly involved in the study of the exposome. a major issue for science, expert appraisal and public

ow can we better identify risks and anticipate new threats associated with different lifestyles and consumption patterns, professional practices, and environmental and climate change? In order to support public policies seeking to better protect health from a very early age, in 2021 ANSES conducted or funded new scientific studies on environmental pollution, electromagnetic waves, chemicals and particles found in everyday products or in the workplace. To refine risk assessment, it is essential to take account of the exposome, a topic in which the Agency is actively involved. Here are several examples from 2021.



The exposome

- Definition: in addition to the study of each risk factor taken in isolation, it involves integrating all exposures at a given moment, as well as throughout an entire lifetime
- a Objective: to better identify the health impact of multiple exposures and the interactions between the different types of chemical, physical and biological nuisance factors, as well as stress, organisational pressures at work and socio-economic living conditions.
- the exposome has been the subject of numerous studies since its emergence in 2005. The interest shown by researchers has convinced public decision-makers, and it was included in the Act of 26 January 2016 on the modernisation of the health system.

OCTOBER 2021: ANSES-INSERM SCIENTIFIC CONFERENCE ON THE EXPOSOME IN PUBLIC HEALTH

Attended by several hundred scientists, representatives of associations, professionals and public decision-makers, this one-day event was a chance to take stock of research in this field and the operational application of this concept to scientific expert appraisals. Discussions mainly focused on characterisation of the various facets of the exposome and its effect on the occurrence of chronic diseases such as cancer, neurodegenerative and endocrine diseases. Mention was also made of advances in epigenetics, which observes how gene expression is influenced by the environment or other factors, particularly in children, with medium- to long-term consequences on health.

This meeting also provided an opportunity to review the challenges involved in ensuring that the exposome takes its rightful place in the various fields of public health expertise and ultimately in risk management: tools to be promoted and methodological approaches to be implemented, particularly in surveillance systems and risk assessments. Videos of the presentations are available on ANSES's YouTube channel. The Agency also published an edition of *Cahiers de la Recherche* on the determinants of child health.

≥ Online at anses.fr

EXPOSOME AND RISK ASSESSMENT: ESTABLISHMENT OF A DEDICATED WORKING GROUP

Taking account of the exposome in risk assessment needs to be more structured by mobilising different scientific disciplines and highly diverse approaches. To address this issue, a working group reporting to ANSES's Scientific Board was set up and began its work in early 2021.

Its report, due in 2022, will give an account of the methods, approaches, data, tools and techniques needed to introduce the various components of the exposome into the Agency's expert appraisal work.

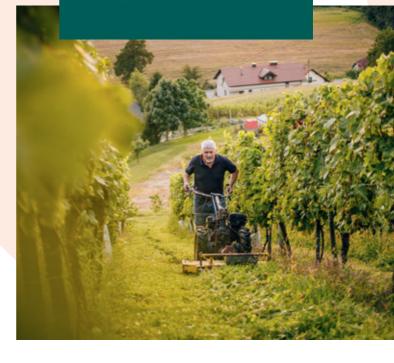
Without waiting for the report's publication, the group is already formulating specific proposals to include the exposome in ongoing expert appraisals on the effects of digital tools on the health of children and adolescents, and on the use of data collected by air sensors. An assessment of workers in the waste industry is currently incorporating a debate on the psychological, biological and socio-economic factors that determine their mental health

ANSES's Exposome Working Group is a multidisciplinary body bringing together several members of the Scientific Board: risk assessors, toxicologists, microbiologists, epidemiologists, chemists/analysts, statisticians, sociologists, economists and other professionals.

LAUNCH OF PESTIRIV ON PESTICIDE EXPOSURE IN WINE-PRODUCING AREAS

A large part of the rural population in France lives in wine-growing regions. How does this proximity to vineyards affect their exposure to pesticides through air, water and food? To find out, ANSES and Santé Publique France launched a large study in October 2021 involving 3350 participants in six regions, including control groups living far from vineyards.

The population's actual exposure level will be assessed by taking biological samples and measurements in air, dust, and garden fruit and vegetables. The results will be used to identify the sources that most contribute to pesticide exposure, clarify the impact of plant protection products used to treat vines, and strengthen preventive measures.







Initiated in 2014 to boost research on the marine environment and aquatic products of France's "Opal Coast", the MARCO project was completed in late 2021. It was funded by the Hauts-de-France region and brought together five organisations: the University of the Littoral-Côte d'Opale (ULCO), ANSES's Laboratory for Food Safety, CNRS, the University of Lille and Ifremer.

Using state-of-the-art equipment capable of visualising microplastics, ANSES and ULCO found that the occurrence of these microplastics in mussels and cockles on the Channel coast was no greater than the European average. However, they also observed that the ingestion of microplastics by mussels modified the composition of their microbiota. As for fish, it was shown that only a very small amount of microplastics ends up in their flesh, as the particles tend to remain in their digestive system.

Supporting occupational risk prevention

Ecological, digital and technological transitions, evolving jobs and work patterns have an impact on occupational health issues. In recent months, thanks to ANSES's expertise, emerging risks have been documented and progress made on the issue of multiple exposures in the workplace. In 2021, the Agency also produced its first work to support the recognition of occupational diseases.



NSES is interested in all types of occupational risks: exposure to biological agents and chemicals, noise, waves, night work, tensions in work relations, etc. In particular, it's activities contribute to reducing exposure to the most harmful chemicals, in support of French and European public policies. In 2021, for example, the Agency addressed the issue of the classification of carcinogenic substances, preparations and processes, as defined in the French Labour Code. Following its scientific opinion, an occupational disease table for prostate cancer related to pesticide exposure was also created, which will make it possible to supplement and facilitate the support offered to agricultural workers. This table takes into account workers exposed to chlordecone in the French Caribbean. As part of the expert mission to support the recognition of occupational diseases, which it was entrusted with in 2018, the Agency also produced an opinion on ovarian and laryngeal cancers related to asbestos exposure.

CUMULATIVE EXPOSURE AFFECTS ALMOST ALL EMPLOYEES

To better describe the situations of multiple exposure experienced by employees in France and identify the main occupational sectors concerned, a joint study was conducted by ANSES, Santé Publique France and DARES, based on the results of the 2016-2017 Sumer survey.

Carried out as part of the Third Occupational Health Plan 2016-2020, it shows that 97% of employees in the public and private sectors are exposed to several risks, and describes 12 typical cumulative exposure profiles. While exposure to chemical, physical or biological stress is specific to a particular job, all the multiple exposure profiles indicate exposure to organisational and relational constraints.

Specific combinations are observed among healthcare professionals, or those working in agriculture, the navy and fishing. The conclusions justify an approach that considers the different types of stress experienced by employees not in isolation but as a whole, and which possibly accentuate the associated occupational risks.

SUBSTITUTING FORMALDEHYDE WITH LESS TOXIC ALTERNATIVES

Formaldehyde (or formalin) has been recognised as a carcinogen at European level and must be substituted with other substances or processes to protect the health of exposed workers.

In a series of expert appraisals, ANSES identified less hazardous alternatives in five industry sectors.

It also pointed out the drivers and obstacles to substitution in different sectors. This work aims to support the authorities and occupational risk prevention stakeholders in enforcing substitution requirements among employers.



CYTOSTATIC MEDICINES, WELDING FUMES: RECOGNISING THEIR CARCINOGENIC NATURE

In two specific expert appraisals, the Agency recommended that the list of carcinogenic substances, mixtures or processes as defined in the French Labour Code should include:

- work exposing healthcare professionals such as nurses, caregivers, doctors, veterinarians and cleaning staff to 18 active ingredients of cancer drugs;
- all work involving exposure to welding fumes or metal fumes from related processes, concerning not only welders but also professionals in construction, installation and repair of machinery and equipment, vehicle repair and metalworking.





Joint interview

with Sofie Nørager,
Deputy Head
of the Industrial
Transformation Unit
in the European
Commission's
Directorate-General
for Research and
Innovation, and Pascal
Sanders, coordinator
of PARC at ANSES.

PARC, the Partnership for the Assessment of Risks from Chemicals, was launched on 1 May 2022. How did it come about?

SOFIE NØRAGER. It all started in 2018, with the preparation for "Horizon Europe", the European Commission's new research and innovation programme. Based on experience with projects under way at the time, in particular the HBM4EU human biomonitoring partnership, there was a need to imagine the next steps to be taken on chemical risks, as well as a desire to increase cooperation and connections between the worlds of research and risk assessment.

This led to the idea of creating a stable reference structure to establish a vision, a course, a working agenda, in particular in order to share data and knowledge generated by surveillance and research. ANSES, working with other risk assessment agencies, had suggested the concept of a European platform on toxicology, to collaborate and move forward together on chemicals. Discussions continued with Member States, health agencies and stakeholders, including industry, while Europe's Chemicals Strategy for Sustainability was being prepared.

What role did ANSES play in the construction of PARC?

PASCAL SANDERS. ANSES, together with its German, Belgian, Danish, Irish, Dutch and Swedish counterparts, had indeed suggested to the European Commission creating a toxicology programme, which laid the groundwork for PARC. The aim was to have an independent data generation tool to address health issues associated with chemicals. The Agency was already involved in HBM4EU and other related European projects. With the One Health EIP. we also had experience coordinating large European projects. When the principle of a major project financed under Horizon Europe began to take shape, our Director General, Roger Genet, wanted ANSES to be a player in this new partnership because of our cross-cutting position on health risk issues. At the Agency, we are convinced of the need for a "one health" approach. We are interested in the different uses of chemicals in our daily lives and at work, and their transfer to the environment, food, etc. PARC aims to look at chemicals and their effects on health and the environment in a holistic way rather than by sectors or products. The building of this partnership is a strong commitment by the Agency, which has invested significant human and financial resources for its launch and

coordination, with the consent of our supervisory ministries.

How does PARC support the European Union's Chemicals Strategy for Sustainability?

SOFIE NØRAGER. PARC is a research and innovation tool that will provide the scientific know-how needed for this strategy, mainly for implementing the "one substance, one assessment" approach. The principle is to conduct a risk assessment of a substance that can be reused in other areas. Indeed. if a substance is determined to be toxic in a food, why would it not be toxic in another everyday product? In PARC, the aim is to pool resources and facilitate access to data and knowledge for national and European agencies. PARC will also lead to improved measurement of population contamination by different chemicals, which is necessary for public policies. There is also a part designed to support the development of safe and sustainable chemicals from the design stage, another ambition of the EU's Chemicals Strategy for Sustainability. To create alternatives to hazardous substances, data on toxicity, exposure and uses in products are needed. All the actions undertaken in PARC are interconnected, in order to invent a new way of producing and using chemicals in the European Union.

What is your ambition in coordinating PARC?

PASCAL SANDERS. In order to more effectively deal with chemical risk, there is a need to break down regulatory silos and answer all the scientific questions: where are the chemicals, what are the routes of consumer exposure and what happens to these substances in the environment? To do this, PARC will need to bring together scientists from different countries specialising in different disciplines to work in networks. This partnership will act as an interface between European research institutions and agencies, which will be able to specify the data they need and their expectations in terms of experimental methods or software, and also take better account of endocrine disruptors and the exposome concept in risk assessment. PARC will capitalise both on the new methods and knowledge developed, and on the networks of partners who have been working together for several years. Ultimately, the aim is not only to eliminate hazardous substances but also to integrate risk assessment into the chemical industry to support the development of innovative substances, materials and products that are not harmful to humans and the environment.

PARC (PARTNERSHIP FOR THE ASSESSMENT OF RISKS FROM CHEMICALS) IN FIGURES

A partnership for

Nearly

funded 50% by the European

A budget of around

Union and 50%

by partner States

under Horizon Europe, the EU's

2021-2027 framework programme for funding research and innovation

partners in 28 countries

and at EU level, national agencies and research organisations working in the areas of the environment or public health, the European Chemical Agency (ECHA), **European Food Safety** Authority (EFSA) and **European Environment** Agency (EEA)

PARTICIPATING COUNTRIES

- **∠** GERMANY
- → AUSTRIA
- **■** BELGIUM
- □ CROATIA
- **■** DENMARK
- SPAIN
- **≥** ESTONIA
- **∠** FINLAND
- **∠** FRANCE
- **∠** GREECE
- **∠** HUNGARY
- **∠** ICELAND
- **≥** ISRAEL
- **⊿** ITALY

- LATVIA
- **∠** LITHUANIA
- **∠** LUXEMBOURG
- NORWAY
- NETHERLANDS
- POLAND
- **▶** PORTUGAL
- CZECH **REPUBLIC**
- UNITED
- KINGDOM SLOVAKIA
- **SLOVENIA**
- → SWEDEN
- **SWITZERLAND**



Health of plants and ecosystems

→ Spotlight on ANSES's activities

Through its various missions, ANSES helps prevent the emergence of plant diseases and pests, combat invasive plants and reduce the impact of using plant protection products in order to preserve the diversity of plant species and crops.

SUPPORT FOR SURVEILLANCE AND PREVENTION OF EMERGING THREATS

- Detect and identify emerging pathogens and pests
- Prevent their introduction and combat their spread in France
- Assess health risks to wild and cultivated plants

□ COMBAT INVASIVE SPECIES

- Actively monitor invasive plants such as ragweed and giant hogweed
- Identify insect pests and pathogen vectors through our insect library, which contains thousands of catalogued specimens

STUDY PHENOMENA OF RESISTANCE TO PLANT PROTECTION PRODUCTS

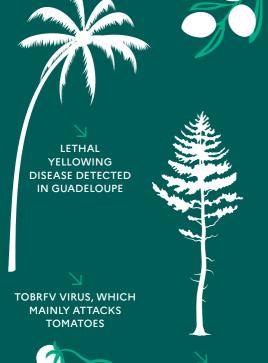
- Conduct research on the resistance of pests: fungi, oomycetes, bacteria, insects and weeds
- Study the underlying mechanisms and impact of the emergence of resistance in target populations
- Monitor the emergence of new types of resistance

→ REGULATE THE USE OF GENETICALLY MODIFIED PLANTS

- Develop official analytical methods for detecting genetic modifications in plants, whether or not they have been authorised in France
- From January 2022: assess health and environmental risks that may be associated with the release of genetically modified plants

In 2021, ANSES worked on several emerging threats and crises

THE XYLELLA FASTIDIOSA
BACTERIUM, WHICH AFFECTS MANY
ORNAMENTAL AND AROMATIC
SPECIES, AS WELL AS OLIVE TREES



BACTROCERA DORSALIS FRUIT FLY

PINE WOOD

NEMATODE



SPECIALISED SKILLS IN PLANT HEALTH

A research laboratory

- → With six sites: Angers, Clermont-Ferrand, Montpellier, Nancy, Rennes, Saint-Pierre (Reunion Island).
- → National Reference Laboratory for all plant pests and EU Reference Laboratory for fungi and oomycetes, insects and mites, and plant pathogenic nematodes.

A quarantine scheme for assessing the health status of plants before authorising their admission into France under an exemption: 147 pests kept at the quarantine unit in Clermont-Ferrand.

Risk assessments drawing on a group of independent experts bringing together all the scientific expertise on biological risks to plant health.

A cross-functional scientific director

who coordinates ANSES various plant health activities.

Right at the heart of research projects and networks, in France and internationally

The Valitest project, which came to an end in 2021, assessed 83 tests and harmonised diagnostic practices for 11 plant pests. Funded by the European Commission's Horizon 2020 research and innovation programme, it brought together 16 public and private partners,

together with the European and Mediterranean Plant Protection Organisation (EPPO).

ਪ Identify new risks with the European "Horizon scanning" programme

- ightarrow This EFSA-funded project is conducting cross-checks of more than 10,000 sources of information from the scientific literature and the media in order to identify emerging risks.
- → ANSES is thus contributing to the identification of new risks and the development of a method for prioritising pests.

ANSES is involved in the National epidemiological surveillance platform for plant health, EPPO and the International Plant Protection Convention.





330cases of wild mushroom poisoning reported between 1 July and 29 August 2021: 3 were very serious and 3 deaths were recorded

SEASONAL VIGILANCE OF POISONING DUE TO WILD MUSHROOMS

Every year, around a thousand cases of poisoning caused by consumption of wild mushrooms occur in France. These have different causes: confusion of edible species with toxic species, or consumption of edible mushrooms that are in poor condition, undercooked or not stored properly.

ANSES conducts seasonal monitoring of poisonings due to wild mushrooms using data from the poison control centres. Between 1 July and 29 August 2021, 330 cases of poisoning were reported, three of which were very serious, with three deaths being recorded.

A review of the previous season showed that 56% of all poisoning cases reported between 1 July and 31 December 2020 occurred in October, when the weather conditions combining rainfall, humidity and cool temperatures favoured mushroom growth and picking. In response to this situation, which is repeated every autumn, ANSES, the poison control centres and the Directorate General for Health issued a reminder of the steps to be taken to avoid these accidents.



PUBLICATION OF PRACTICAL DATA SHEETS ON POISONOUS PLANTS SOLD IN SHOPS

Since 1 July 2021, professionals in the horticulture, floristry and landscape sectors have been required to inform consumers about the toxicity of the indoor or outdoor plants they sell and the precautions to be taken to avoid poisoning.

ANSES and the National Aerobiological Surveillance Network (RNSA) drew up a list of 58 plants that are a health risk because they can cause respiratory allergy or are toxic if ingested or in contact with the skin. For each plant, fact sheets detail the risks involved in the event of exposure, the toxic parts of the plant, the possible clinical signs in case of exposure, the measures to prevent the risk of poisoning and steps to take in the event of poisoning. All this information is available on the website plantes-risque.info.

PETS: BEWARE OF EXPOSURE TO HUMAN HORMONAL TREATMENTS

Adverse effects occurring in small dogs, cats, puppies and kittens were reported in several European countries following repeated contact with hormone replacement therapy applied to their owner's skin. Most of these cases, affecting both females and males, involved oestrogen. The French Agency for Veterinary Medicinal Products (ANMV) – part of ANSES – reiterated the precautions for use that apply to all medicines applied to the skin. Any adverse events occurring after an animal has been exposed to a medicinal product for humans should be reported to the national veterinary pharmacovigilance scheme, managed by the ANMV.

WHICH VIGILANCE SCHEME FOR WHICH PRODUCTS AND SITUATIONS?

- ▶ Nutrivigilance: food supplements, fortified foods and novel foods.
- \mathbf{v} Toxicovigilance: natural or synthetic substances or mixtures of substances found in products on the market or present in the environment.
- \mathbf{v} **Phytopharmacovigilance:** plant protection products and their residues in media including food.
- \mathbf{v} Veterinary pharmacovigilance: veterinary medicinal products and their residues in media including food.

The National Network for Monitoring and Prevention of Occupational Diseases (RNV3P) also identifies situations involving occupational risks.

VITAMIN D: WARNING ABOUT OVERDOSE IN INFANTS

In 2021, as part of the nutrivigilance scheme, cases of vitamin D overdose were reported in young children following the use of vitamin D-enriched food supplements. ANSES, the French Health Products Safety Agency (ANSM), paediatric scientific organisations, the national college of midwives and the poison control centres alerted health professionals and parents. They emphasised the importance of taking vitamin D in medicine form rather than as a supplement. Medicines provide clear information on doses, precautions for use, risk of adverse effects and overdose.







Joint interview

with Juliette Bloch, Director of Health Alerts and Vigilance at ANSES, and Jérôme Langrand, head of the Paris poison control centre.

What are your respective roles in the toxicovigilance scheme, and how do they fit together?

department specialising in medical toxicology.
The rather unique feature of poison control centres is that their mission covers both treatment and vigilance.

Each centre provides round-the-clock telephone support for poisoning cases. Poison control centres also communicate signals to health agencies, such as ANSES or the ANSM depending on the situation, and exchange information among themselves within the framework of the coordination provided by ANSES.

JULIETTE BLOCH. Since 2016, ANSES has been coordinating the toxicovigilance scheme, along with the vigilance activities of the eight French poison control centres and the specific scheme for the Indian Ocean. To do this, we rely on the expertise of toxicologists from poison centres and other experts, within the framework of the Agency's thematic working groups on chemicals, regulated products (pesticides, biocides, veterinary medicines) and natural toxins.

How does this work in practice?

JÉRÔME LANGRAND. With each call, we take on the case and collect the related information. We add information to our database in real time: it now contains almost 4 million cases! The data can be extracted by different operators. We directly report any serious or new phenomena, or anything that catches our attention... Starting with one unusual case, we check whether others may have

gone unnoticed. Sometimes our investigations end without any health alert being issued. At the Paris poison control centre, we had two very serious poisoning cases following the consumption of morels. When we queried the database, we found others. Our experience has shown us that signal detection cannot be either 100% human or 100% computerised.

JULIETTE BLOCH. ANSES is the recipient of the reports and can also access the poison control centres' database. It can initiate studies, for example on certain types of poisoning, and performs automated signal detection. We can also set up daily surveillance on certain topics, check trends and test hypotheses. Our work may result in products being withdrawn from the market. This was the case, for example, in 2021 with adulterated food supplements, i.e. containing substances that should not have been present (in this case sibutramine and sildenafil). We work with the DGCCRF, customs and the Central Office for Combating Damage to the Environment and Public Health, which have intervention powers. These specific actions are very gratifying, they crystallise our duty to protect consumers from dangerous products. Three times a year, we publish Vigil'anses, the bulletin for all our vigilance schemes, which looks back at representative alerts issued by the network of poison control centres. Available in French and English on the ANSES website, it helps raise awareness among the public and professionals.

What are the prospects for improving consumer safety?

JÉRÔME LANGRAND. ANSES'S coordination of the poison control centres' activities enables them to share information within a structured framework and carry out joint work combining their various skills. This is a virtuous collaboration!

INCLESS FOR THE BLOCH. If you don't know what you are looking for, the database remains a black box. Without direct reports to ANSES from the experts in the poison control centres, we would have difficulty in focusing our research.

Our collaboration is working very well and is set to be strengthened, since 2022 will see the setting up of two new toxicovigilance schemes in Martinique and Guadeloupe, which will not provide an emergency telephone hotline service, but will analyse data on poisoning cases based on hospital admissions and use of emergency care.

Ensuring food safety

When it is safe and nutritious, food is a powerful ally for our health. However, an imbalanced diet or contaminated food can expose us to immediate risks or the development of chronic diseases. ANSES acts to prevent and control health risks for all aspects of food: safety from farm to fork, nutritional balance and food quality, physical activity and sedentary behaviour. These are just some of the topics it worked on in 2021, while meeting the challenges of animal welfare and environmental preservation.





aced with the globalisation of trade, the diversification of available foods and the emergence of zoonoses, great vigilance in food safety is required. This is further accompanied by new public expectations, for example in terms of animal welfare. Events in early 2022 have also shown the extent to which well-known risks, such as Salmonella or Escherichia coli, remain difficult to control and can affect large or particularly susceptible populations. For all these reasons, ANSES chose to dedicate its stand and presentations at the most recent Paris International Agricultural Show to the health challenges of today's food.

BACTERIAL RISKS OF RAW MILK AND CHEESE PRODUCTS

Over the last decade in France, the consumption of raw milk cheeses has been implicated in 34% of salmonellosis outbreaks, 37% of listeriosis outbreaks and 60% of enterohaemorrhagic E. coli (EHEC) infections. In order to further improve control of these risks, a recent expert appraisal by ANSES ranked the main bacterial hazards associated with the different types of raw milk cheeses and other dairy products made from raw milk. It stressed that levels of hygiene and risk control are now very high on farms. The self-checks implemented at the processing stage are also able to identify a large number of problematic batches. To reinforce prevention, the Agency recommends improving epidemiological investigations, ensuring early identification of poor hygiene practices and increasing consumer awareness of cheese storage temperatures in the refrigerator, use-by dates and the ages at which consumption of these products is not recommended (particularly among young children).



NEW ALERT ON THE LACK OF PHYSICAL ACTIVITY

Physical activity has long been considered beneficial to health without being essential to it. ANSES's work has confirmed its short-, medium- and long-term benefits on all the components of health. In 2016, in the framework of the PNNS, the Agency had established guidelines on physical activity and sedentary behaviour. Using this basis and data from the INCA 3 study on population habits, it assessed the health risks associated with physical inactivity and sedentary behaviour among children and adolescents in 2020, and then among adults in 2021.

This work scientifically confirmed the health emergency in this area: today, only 5% of adults are sufficiently physically active and 70% of women are below all the levels of activity identified for good health, compared with 42% of men.

Concerning sedentary behaviours, sitting for more than eight hours a day poses a health risk. Adults with a low level of education and those under the age of 45 are the most affected. Another alarming finding is that more than a third of adults have both a high level of sedentary behaviour and insufficient physical activity, resulting in higher mortality and morbidity rates.

ANSES stresses that there are currently serious obstacles to creating an overall environment conducive to changing behaviour. They mainly concern town and country planning, modes of transport, and organisation of time and space with regard to work and school.

CHLORDECONE IN FOOD: LAUNCH OF CHLOREXPO IN THE FRENCH CARIBBEAN

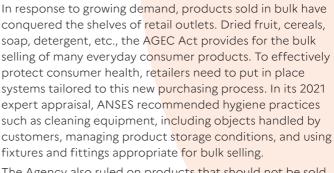
Initiated in the summer of 2021 in Guadeloupe and Martinique for a period of three years, the ChlorExpo study aims to take better account of the effects of local food procurement and preparation practices, especially the effect of cooking methods, on the chlordecone content of food. The findings will be used to identify new ways to help limit the population's exposure, without requiring them to abandon local products, or production and distribution methods. This study, which is part of the national Chlordecone IV plan, follows on from the Kannari study, which identified the most problematic supply channels and production areas, as well as the populations concerned.



THE DIFFERENT FOOD QUALITY AND SAFETY SCHEMES MANAGED BY ANSES

- ▶ CIQUAL is a public database that details the average nutritional composition of foods consumed in France. This table, one of the most comprehensive in Europe, is a reference for dieticians, nutritionists and food manufacturers. It is freely available on the Internet and generates more than 1 million visits per year.
- \mathbf{v} INCA studies, national surveys of individual food consumption, provide a snapshot of the food consumption habits of the population of metropolitan France every seven years.
- **Total Diet Studies (TDS)** identify the most problematic chemicals and quantify them according to geographical area and age, taking actual dietary behaviour into account.
- **The OQALI observatory** focuses on the composition of processed products placed on the market in France. It is run jointly with INRAE.





The Agency also ruled on products that should not be sold in bulk for public health reasons. This is particularly the case with highly perishable foodstuffs such as those sold in the chilled section (meat, fish, certain dairy products or delicatessen meat products, etc.) or certain animal feed.

Lastly, it specified the good practices consumers need to adopt to avoid contaminating products, especially foodstuffs, during purchase and storage, or to keep information on use, the presence of allergens and shelf life.







REARING CONDITIONS: THREE KEY OPINIONS

While the European Commission was considering the reintroduction of animal proteins in pig and poultry feed, the Agency gave its view on the risks this could pose to animal and human health. The experts identified situations in which transmissible spongiform encephalopathies could be transmitted, then become amplified and difficult to control a decade later, as had happened during the "mad cow" crisis. ANSES reiterated the importance of strictly separating production chain sites by species to avoid, for example, pigs consuming pig protein.

In 2021, the Agency also looked at the ingestion by cattle of metal foreign bodies accidentally mixed into their feed. This debris can cause damage to internal organs, leading to death in the worst cases. Since the expert appraisal showed that 7 to 20% of cattle were concerned, ANSES recommended practical preventive measures and stressed that magnets can be administered as an effective way of avoiding injury.

Last year, ANSES also concluded that any link between the presence of a wind farm and various disorders reported in two cattle farms in Loire-Atlantique was "highly unlikely", but recommended establishing a suitable comprehensive diagnostic protocol, in order to be able to act promptly in the event of disorders occurring in other farms close to wind turbines.

BRUCELLOSIS: SCENARIOS FOR MANAGING THE INFECTION OF IBEX IN THE BARGY MASSIF

Since 2013, ANSES has produced several expert appraisals on ibex populations in the Bargy massif (Haute-Savoie *département*) following a number of cases of brucellosis. This has a dual objective: to limit the risk of contamination in domestic animals and work towards the natural extinction of the disease in the wild population. In its opinion published in late 2021 following the detection of a local strain of brucellosis on a cattle farm, ANSES noted, without playing down the extent of the damage to farmers, that it was a one-off event that had not previously occurred since 2012. After studying six scenarios for managing the situation, it recommended management through a combination of targeted captures and shooting, in order to maintain downward pressure on the local outbreak over time until its extinction.



MEETING ON BEES: CLOSE-UP ON THE EUROPEAN POSHBEE PROJECT

Every two years, the Agency organises a one-day meeting devoted to research, expert appraisal and surveillance work on bees. Open to a wide audience of beekeepers, researchers, public decision-makers, companies, professional representatives and the media, it provides an opportunity to review recent scientific advances in the field. In 2021, the focus was on the research carried out as part of the European PoshBee project, for which ANSES is coordinating the part on bee exposure to chemical products and various pathogens. In its Sophia Antipolis Laboratory, which has several European and international mandates on bee health, among other things the Agency is developing a technology that can identify and quantify 11 different viruses, bacteria and parasites more specifically and more quickly, and even simultaneously. Other work aims to simulate the actual exposure of bees to pesticides.

VETERINARY MEDICINE: ANSES INVOLVED IN IMPLEMENTING THE NEW REGULATIONS

The French Agency for Veterinary Medicinal Products (ANMV), part of ANSES, is the competent authority for the assessment and management of risks associated with veterinary medicinal products in France. In particular, it is tasked with issuing marketing authorisations for veterinary medicinal products, and monitoring their adverse effects and quality. It is also responsible for authorising imports and temporary uses of veterinary medicinal products, as well as for inspecting veterinary pharmaceutical establishments. The ANMV is closely involved in work at European level, and especially in legislation reform.

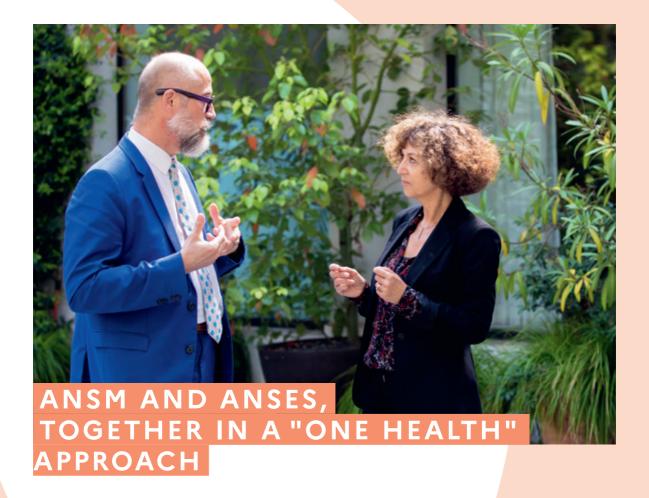
On 28 January 2022, the new European regulation on veterinary medicines came into force. Its main objectives are to improve the safety and availability of veterinary medicinal products, strengthen action to address antimicrobial resistance, enhance the EU internal market for veterinary medicinal products and reduce the administrative burden. During the preparation phase, the ANMV initiated the setting up of a task force, which it co-chairs with EMA. To harmonise implementation of the regulation and common procedures, this network of agency heads supported coordination among the competent authorities of the Member States.



PHYTOTHERAPY AND AROMATHERAPY: ADAPTING RISK ASSESSMENTS IN VETERINARY MEDICINE

Herbal veterinary medicinal products are becoming increasingly popular among farmers and veterinarians. However, the plants, plant preparations and essential oils most commonly used in veterinary medicine have generally not been assessed under veterinary medicinal product regulations and cannot therefore be used therapeutically on food-producing animals. This is due in particular to the absence of maximum residue limits (MRLs), which correspond to the maximum quantity of an active substance contained in a medicinal product that can be found in food of animal origin without posing a risk to consumer health. In order to be a driving force for ideas, the ANMV recently proposed an adapted assessment method.

This could be used to produce a list of plants for which an MRL does not need to be defined since their use is considered safe for consumers, to exclude the use of plants whose toxicity has already been proven, and to identify any missing data. The proposed method was tested on 21 plants, essential oils and substances found at significant levels in essential oils commonly used in veterinary medicine.





Joint interview

with Jean-Pierre Orand, Director of the French Agency for Veterinary Medicinal Products (ANMV) within ANSES, and Caroline Semaille, Deputy Director General in charge of Operations at the French Health Products Safety Agency (ANSM). In France, two health agencies are responsible for medicines. How do the ANSM, which oversees human medicines, and the ANMV, responsible for veterinary medicines, coordinate their actions?

caroline semaille. The ANSM and the ANMV have been working together for a very long time, mainly in the inspection of pharmaceutical establishments with combined human and veterinary activities. We pool

our resources in this area, and coordinate our efforts: in 2021, we conducted five joint inspections for non-clinical studies. Our agencies also work together during major problem situations. This was the case with the shortages of human medicines and the possibilities of supplementing them with veterinary medicines if needed during the COVID-19 crisis. We will be extending this cooperation to the assessment of marketing authorisation applications in order to capitalise on our respective expertise.

JEAN-PIERRE ORAND. We also work together at European level. The ANSM and ANMV represent France's position at the European Medicines Agency and take part in the network of European Heads of Medicines Agencies, which addresses health policy and management issues. We co-chaired the two meetings of this network during the French Presidency of the European Union, by video conference and in Saint-Malo.

On which subjects, historical or new, do you work together? And what do you get out of these collaborations?

JEAN-PIERRE ORAND. Of course, we are still heavily involved in the issue of antimicrobial resistance, one of our longest-standing areas of collaboration. We also see other issues emerging. For example, the use of herbal veterinary medicinal products

is becoming increasingly popular among farmers and veterinarians. In 2021, the ANMV produced a consumer risk assessment in which ANSM staff participated, as this is also a well-known topic in human medicine. While each agency has its own tasks and assessors, there is a clear benefit in working together, particularly on the assessment of environmental risks associated with the use of medicines

<u>CAROLINE SEMAILLE.</u> In some areas, such as herbal and homeopathic medicines, skills are scarce.

It is therefore in both our interests to exchange our respective expertise. The ANSM's toxicology experts participate in the ANMV's work and, in parallel, their experts are associated with the French Pharmacopoeia Commission. In addition, the ANMV, and ANSES more generally, has developed environmental health expertise from which we can also benefit. With the new European policies related to the Green Deal, we are moving towards a greater consideration of environmental impacts, including for human medicines.

What future collaborations have you planned?

JEAN-PIERRE ORAND. In animal health, we are seeing the emergence of new therapies, such as gene therapy or the use of stem cells, which

already exist in human medicine. This encourages us to strengthen our exchanges with the ANSM on these innovations by taking the overall "one health" approach even further. The subjects are increasingly cross-cutting and call for closer links. For example, the two agencies are partners, along with the Ministries of Health and Agriculture, in the WHO-led, EU-funded PARS project. This is designed to support structural reforms in the Member States regarding antibiotic availability. We are also jointly supporting a project to assess a European

dossier on a human vaccine

for avian influenza.

CAROLINE SEMAILLE. To put into action our desire to break down barriers in public health activities, we are launching the construction of the future joint ANSM-ANSES facility, whose first stone will be laid in Lyon in July. The teams of our two Lyon agencies will be grouped together in a single building: they will share a single laboratory offering a high level of biosafety and advanced technologies. This facility will thus enable us to pool our skills, which will focus primarily on one of the pioneering topics of our collaboration: antimicrobial resistance, for which the "one health" approach is of great importance. This is a great achievement in our cooperation.

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Composition of ANSES's Board of Administrators

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Organisation chart

PAGE

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9 laboratories on 16 sites

PART 3

Composition of ANSES's Board of Administrators

on 21 June 2022

CHAIR

Pr. Benoît Vallet

(appointed by decree of 10 September 2020)

VICE-CHAIR

Pierre-Yves Montéléon

(elected on 12 March 2020)

FIRST COLLEGE

GOVERNMENT REPRESENTATIVES

Director General for Health

Director General for Risk Prevention

Director General for Labour

Director General for Food

Director General for Competition, Consumer Affairs and Fraud Control

Director for the Budget

Director General for Research and Innovation

Director General for Enterprise

SECOND COLLEGE

REPRESENTATIVES OF ASSOCIATIONS

≥ Representatives of environmental protection associations

Member: Seat vacant – Nomination procedure under way, France Nature Environnement

Proxy: Alain Chabrolle, France Nature Environnement

Member: Jacky Bonnemains, Robin des Bois, NGO for the Protection of Man and the Environment

Proxy: Charlotte Nithart, Robin des Bois, NGO for the Protection of Man and the Environment

☑ Representatives of State-certified consumer advocacy groups

Member: Jean-Yves Mano, French Confederation for Consumer Affairs, Housing and Quality of Life (CLCV)

Proxy: Micheline Bernard-Harlaut, Léo Lagrange Association for consumer protection

Member: Jean-Louis Blanc, French Consumer
Protection, Education and Information Association
(ADEIC)

Proxy: Nicole Damon, National Council of Secular Family Associations (CNAFAL)

Nepresentatives of State-certified associations active in the field of quality of health and care of the sick

Member: François Rullier, Le Lien Association
Proxy: Marie-Agnès Besnard, National Union of Family
Associations

→ Representatives of support associations for victims of occupational accidents or diseases represented on the French compensation fund for asbestos victims (FIVA)

Member: Alain Prunier, National Federation of Injured and Disabled Workers (FNATH)

Proxy: Nadine Herrero, National Federation of Injured and Disabled Workers (FNATH)

Member: François Desriaux, National Association for the Defence of Victims of Asbestos (ANDEVA)

Proxy: Béatrice Collin, National Association for the Defence of Victims of Asbestos (ANDEVA)

THIRD COLLEGE

REPRESENTATIVES OF PROFESSIONAL ORGANISATIONS

Member: Thierry Coué, National Federation of Farmers' Unions (FNSEA)

Proxy: Nelly Le Corre-Gabens, National Federation of Farmers' Unions (FNSEA)

Member: Gérard Boivin, National Food Industry Federation (ANIA)

Proxy: Hervé Lafforgue, National Food Industry Federation (ANIA)

Member: Lionel Desencé, Federation of Trade and Retail Companies

Proxy: Isabelle Fillaud, General Confederation of Food Retailers

Member: Jean-Louis Hunault, French Union for the Veterinary Medicinal Product and Reagent Industry (SIMVR)

Proxy: Marie-Anne Barthélémy, French Union for the Veterinary Medicinal Product and Reagent Industry (SIMVR)

Member: Philippe Prudhon, French Chemical Industry Association

Proxy: Seat vacant – Nomination procedure under way, Phytéis

Member: Jean-François Loret, Professional Federation of Water Companies (FPEE)

Proxy: Flora Bourigault, Professional Federation of Water Companies (FPEE)

FOURTH COLLEGE

REPRESENTATIVES OF EMPLOYEE TRADE UNION ORGANISATIONS AND INTER-BRANCH EMPLOYERS' ORGANISATIONS

≥ Representatives of employee trade union organisations

Member: Edwina Lamoureux, French Democratic Labour Confederation (CFDT)

Proxy: Soraya Duboc, French Democratic Labour Confederation (CFDT)

Member: Bernard Salengro, French Confederation of Management – General Confederation of Executives (CFE-CGC)

Proxy: Christian Expert, French Confederation of Management – General Confederation of Executives (CFE-CGC)

Member: Pierre-Yves Montéléon, French Confederation of Christian Workers (CFTC)

Proxy: Claude Vanyek, French Confederation of Christian Workers (CFTC)

Member: Alain Delaunay, General Confederation of Labour (CGT)

Proxy: Hélène Courtin, General Confederation of Labour (CGT)

Member: Maxime Raulet, General Confederation of Labour – Workers' Force (CGT-FO)

Proxy: Francis Berrocal, General Confederation of Labour – Workers' Force (CGT-FO

y Representatives of inter-branch employers¹ organisations

Titulaire: Pierre Thillaud, French Small and Mediumsized Employers' Organisation (CPME)

Proxy: Philippe Chognard, French Small and Mediumsized Employers' Organisation (CPME)

Member: Virginie Delcroix, French Employers' Confederation (MEDEF)

Proxy: Franck Gambelli, French Employers'
Confederation (MEDEF)

Member: Sandrine Bize, Union of Neighbourhood Businesses

Proxy: Jean-Baptiste Moustié, Union of Neighbourhood Businesses

FIFTH COLLEGE

ELECTED OFFICIALS AND QUALIFIED INDIVIDUALS

≥ Elected Officials

Member: Seat vacant – Nomination procedure under way, representing the Association of Mayors of France

Proxy: Pierre Aschieri, representing the Association of Mayors of France, Mayor of Mouans-Sartoux

Member: Seat vacant – Nomination procedure under way, representing the Assembly of French Départements

Proxy: Christophe Serre, representing the Assembly of French Départements, Vice-President of the Departmental Council of Gard

☑ Qualified individuals

Member: Christophe Brard, Veterinary Doctor, President of the French National Society of Veterinary Technical Groups (SNGTV)

Proxy: Janine Guaguère, Veterinary Doctor, Elected Member of the Veterinary Association National Council

☑ Representatives of Agency Personnel

Member: Nathalie Thieriet Proxy: Corinne Sévin Member: Katell Rivoal Proxy: Jérôme Lozach

Member: Michel Laurentie Proxy: Bertrand Lombard Board of Administrators

Scientific Board

Committee for Ethical Standards & Prevention of Conflicts of Interest

GENERAL DIRECTORATE

GENERAL AFFAIRS DIVISION

- → Health, Safety & Security Unit
- Human Resources Department
 - Legal Affairs Department
 - △ Administration & Financial Affairs Department

REGULATED PRODUCTS DIVISION

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

7 CROSS-FUNCTIONAL SCIENTIFIC THEMES

Organisation chart

European and International Affairs Department

Department of Communication and Institutional Relations

SCIENCE FOR EXPERTISE DIVISION

- Social Sciences, Expertise

 & Society Unit
- → Health Alerts & Vigilance

 Department

 Departme
- Research Funding & Scientific Watch Department
- → Risk Assessment Department

Food safety

Animal health & welfare

Plant health

Epidemiology & surveillance

Exposure to and toxicology of chemical contaminants

Antimicrobial resistance

Occupational health

RESEARCH & REFERENCE DIVISION

- Strategy & Programmes
 Department
 - y Fougères Laboratory

 y
 - 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

9 laboratories on 16 sites



Glossary

- AGEC: Act against waste and for the circular economy
- ANMV: French Agency for Veterinary Medicinal Products
- ANSM: French Health Products Safety Agency
- ▲ ASAP: Act for the acceleration and simplification of public action
- ➤ CESE: French Economic, Social and Environmental Council
- CLP: European Regulation on classification, labelling and packaging of chemicals and their mixtures
- **△ CNDP:** National Commission for Public Debate
- **□ CNRS:** French National Centre for Scientific Research
- ▶ DARES: Directorate for research, studies and statistics
- **DGAL:** French Directorate General for Food
- DGCCRF: Directorate General for Competition, Consumer Affairs and Fraud Control
- **DGS:** Directorate General for Health
- **ECHA:** European Chemicals Agency
- EFSA: European Food Safety Authority
- ≥ EJP: European Joint Programme
- ≥ EMA: European Medicines Agency
- ENVA: Alfort National Veterinary School

- ¥ EPPO: European and Mediterranean Plant Protection Organisation
- ➤ FAO: Food and Agriculture
 Organisation of the United Nations
- **GECU:** Emergency Collective Expert Appraisal Group
- **GMO:** Genetically modified organism
- **∠ HBGV:** Health-based guidance value
- **HBM4EU:** European Human Biomonitoring Initiative
- ≥ IAQG: Indoor air quality guideline
- INCA: French Individual Survey on Food Consumption
- INRAE: French National Research Institute for Agriculture, Food and the Environment
- INSERM: National Institute
 of Health and Medical Research
- ISO: International Organization for Standardization
- **MA:** Marketing authorisation
- ▶ MRL: Maximum residue limit
- NIFDS: National Institute of Food and Drug Safety Evaluation, South Korea
- NRL: National Reference Laboratory
- **∨ OEL:** Occupational exposure limit
- OIE: World Organisation for Animal Health (WOAH since May 2022)

- OPECST: French Parliamentary Office for Assessing Scientific and Technological Choices
- **OQALI:** Food quality observatory
- PARC: European Partnership for the Assessment of Risks from Chemicals
- ▶ **PDI:** Public declaration of interests
- ▶ PNNS: French National Health and Nutrition Programme
- PNR EST: National Research
 Programme for Environmental
 and Occupational Health
- ▶ PNSE: National Environmental Health Action Plan
- ▶ PST: Occupational Health Plan
- **REACH:** European Regulation on the registration, evaluation and authorisation of chemicals
- ➤ RESAPATH: French Surveillance Network for Antimicrobial Resistance in Pathogenic Bacteria of Animal Origin
- **x RNV3P:** National Network for the Monitoring and Prevention of Occupational Diseases
- **SVHC:** Substance of Very High Concern
- **▼ TDS:** Total diet study
- **ULCO:** University of the Littoral-Côte d'Opale
- **WHO:** World Health Organization

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