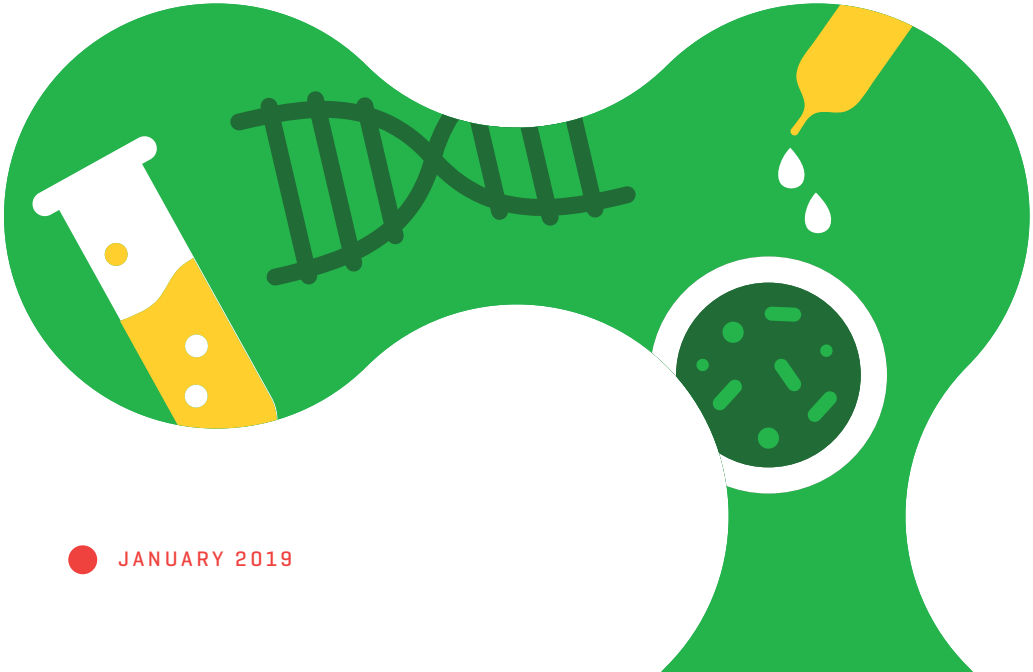
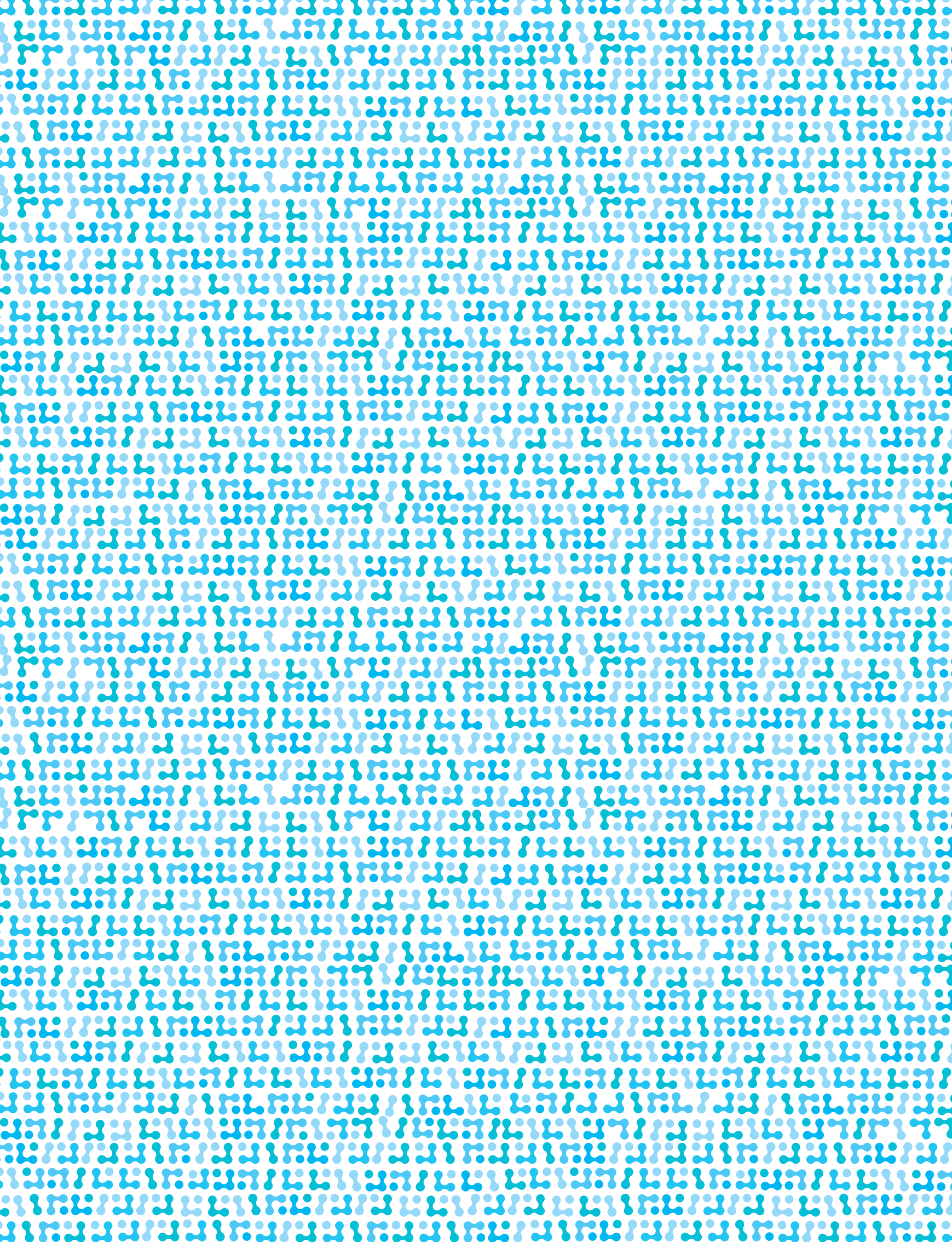


# Ambition 2025





## Ambition 2025

### ANSES will have to address a number of major challenges in the coming years.

The first of these will be to continue fulfilling its role in providing protection and information on issues of environmental health, food safety, air and water pollution, etc. in a context of wider exposure among the public. Citizens are ever more aware of these issues and increasingly well informed, with better circulation of information. ANSES will need to keep pace with this trend by providing a clear picture of the risks in a complex scientific and media-bathed universe. It will also have to ensure that scientific expertise has not been influenced, and keep its distance from lobbies and media hype.

The second challenge will be the consequences of climate change on public and environmental health. Rising temperatures will lead to changes that will have a particularly significant impact on the agricultural sector, entailing different production methods, crop types or pests to be dealt with. The Agency will have to plan ahead, prepare for future developments, and help the different industry sectors anticipate and respond.

Occupational health is another major issue, and a very important topic for us. The generalisation of the service society and the digital workplace means that we are coming across new problems, or ones we thought had disappeared (professional burnout, irregular working hours, psychosocial risks, multiple exposure, etc.). A broader view will therefore be needed in order to issue recommendations, instructions and even obligations for workers or companies that take all these occupational health risks into account. ●



**Luc Derepas**

Luc Derepas  
Chairman of ANSES's Board  
of Administrators

### The aim of the ANSES 2025 initiative, launched with ANSES employees eighteen months ago, was to develop our strategic ambition together.

We have held workshops, determined key lines of action, identified strategic levers, clarified our position on our major priority projects, proposed action plans and worked together to imagine what ANSES will look like by 2025. The goal here is to respond to the health and safety challenges we will face in the future! Our mission remains the same: we are here to investigate, evaluate, protect, and provide reliable support for public policymaking thanks to the quality of our scientific expertise. However, questions and expectations are changing and our ambition is growing. We want to make ANSES an international reference brand in scientific expertise for safeguarding health. The document you have in your hands outlines the main health and safety issues we face, and the role we see for an agency such as ANSES. Our ambition is to make ANSES – through its scientific expertise, the partnerships it initiates and the sharing of knowledge – an agency that effectively serves our fellow citizens, with influence on the international scene for the benefit of all. This is the ambition you will find described in this document. ●



**Roger Genet**

Director General of ANSES

## Our contributors either led or participated in the workshops...

Nine workshops that led to the formulation of several strategic themes and the preparation of an action plan. The aim of these workshops was to combine our efforts and together develop the Agency's strategic ambition for 2025.



**Nicolas Canivet**

Strategy and Programmes Director  
Workshop on "Methods of promoting and transferring ANSES's activities"



**Armelle Degeorges**

Research Funding & Scientific Watch Director  
Workshop on "Partnership strategies"



**Salma Elreedy**

European and International Affairs Director  
Workshop on "European & international strategy"



**Gérard Lasfargues**

Managing Director General, Science for Expertise Division  
Workshop on "Expertise and new challenges"



**Alima Marie**

Communication and Institutional Relations Director  
Workshop on "Communication and dialogue with society"



**Jean-Pierre Orand**

Director of the French Agency for Veterinary Medicinal Products  
Workshop on "Reducing irritants and improving the reporting system"



**Olivier Pierson**

Quality and Internal Audit Director  
Workshop on "Common culture: a single Agency"



**Gilles Salvat**

Managing Director General, Research and Reference Division  
Workshop on "Better management and promotion of the expert sector"



**Françoise Weber**

Managing Director General, Regulated Products Division  
Workshop on "Monitoring, vigilance, surveillance, alerts"

**... and not forgetting:**

Hélène Amar, Sarah Aubertie, Gauthier Auverlot, Labib Bakkali-Kassimi, Henri Bastos, Thomas Bayeux, Soraya Boudia, Pascal Boireau, Régine Boutrais, Marthe-Louise Boye-Elexhauser, Juliette Bloch, Coralie Bultel, Mariana Caballero, Arnaud Callegari, Didier Calavas, Patrice Carpentier, Paulina Cervantes, Céline Château, Marianne Chemaly, Bernard Chevassus-au-Louis, Christophe Cordevant, Fabrice Coutureau-Vicaire, Fanny Debil, Marie-Christine De Guenin, Anne-Cécile Desgeorges, Aymeric Dopter, Charlotte Dunoyer, Sylviane Dragacci, Nicolas Etteradossi, Karine Fiore, Catherine Gourlay-Francé, Bruno Garin-Bastuji, Dominique Gombert, Sophie Guitton, Charlotte Grastilleur, Marisa Haenni, Aymeric Hans, Pascal Hendrikx, Julien Jean, André Jestin, Pierre-Benoît Joly, Alain Kaufmann, Fanny Kouguere, Catherine Lambert, Claire Laugier, Louis Laurent, Sylviane Laurentie, Agnès Lefranc, Marie-Frédérique Le Potier, Pierre-Yves Letournel, Bertrand Lombard, Jean-Yves Madec, Charles Manceau, Irène Margaritis, Thierry Mercier, Olivier Merckel, Mathilde Merlo, Cécile Michel, Virginie Michel, Sébastien Mescolini, Céline Ménard, Élodie Monchâtre-Leroy, Gérard Moulin, Jean-Nicolas Ormsby, Pascale Parisot, Arnaud Paralleu, Adrienne Pittman, Nicole Pavo, Suzanne Pierlot, Véronique Poulsen, Marie-Odile Rambourg, Catherine Rigoulot, Christophe Roussel, Cécilia Solal, Pascal Sanders, Matthieu Schuler, Elena Seïte, Richard Thiery, Isabelle Tilly-Becker, Carole Thomann, Frédérique Touffet, Claude Vergnet, Benoit Vergriette, Manuelle Vertot, Jaqueline Vialard, Nathalie Viguerie, Sonia Vigouroux, Jean-Luc Volatier, Gwenn Vo Van-Regnault, Eric Verdon, Ohri Yamada and Stéphane Zientara.

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#### Identify the themes of each article

These are the Agency's five key areas of expertise. Identify them easily as you read through the document.



- ENVIRONMENTAL HEALTH
- OCCUPATIONAL HEALTH
- PLANT HEALTH AND PROTECTION
- ANIMAL HEALTH AND NUTRITION
- HUMAN FOOD AND NUTRITION

# Safeguarding health, a universal right

Globalisation of trade, acceleration of technological change, upheavals in production and consumption patterns, global health and demographic challenges, climate change, shifting societal expectations, new forms of work organisation, instant dissemination of information... We are experiencing a major evolution, upheavals that have profoundly changed our relationship to the world, to our planet, but above all our perception of risks.



The health and safety system has had to adapt, seek and find solutions to deal with health crises, behavioural changes, and societal and technological revolutions. But also to plan ahead for the risks we didn't know about yesterday, those that had disappeared but are making a comeback, and those from elsewhere or due to the unanticipated impact of human activities...

This is because we are aiming for "zero risks" for ourselves, our children and our fellow citizens. Thanks to prevention, which although effective is far from infallible, we are sometimes under the illusion of being fully protected and immune. And thanks to advances in science and medicine, we dream of the day when each disease will have its own pill to cure us, when each health or environmental "accident" can be predicted and repaired, and when every risk will be completely manageable.

But regardless of how we choose to live, every lifestyle entails risks! Logic leads us to realise that sometimes it is our own choices, whether individual or collective, that leave us vulnerable to exposure. Other risks may be incurred as a result of the organisation of society, technological progress or the choice of other components of society. There are also risks which, despite them being precisely identified, are difficult for us to control and against which we are passive and powerless.

The perception of these risks is both increasingly acute and very differently shared, depending on whether they are chosen or imposed, feared or denied, real or presumed. So here we are alternately and sometimes simultaneously confronted with illusion and reality, positioned between fear and a sense of security.

Even though surveys show that a majority of French people trust scientists, a divide is emerging between science and opinion. In this digital age, global access to instant information significantly weakens the scientific voice in society. Each Internet user is a potential information provider, and the abundance of available data – which nevertheless leads to the democratisation of science – generates a need for expertise that many profit from and abuse by claiming to have knowledge that has not always been subjected to the necessary scientific scrutiny.

Any major innovation, discovery or breakthrough is now also often questioned in itself, and no longer according to a more general perspective. Scientists are expected to give definitive information or answers and to be able to provide the means to avoid at all costs not only disasters – most of which cannot be predicted – but also the hint of any possible disaster in the short, medium or long term.

In addition, the various health crises that have occurred over the past four decades (Chernobyl, contaminated blood, asbestos, mad cow disease, Mediator, etc., a context that led to the establishment of the current health and safety system in France), as well as the recurring alerts in the media, have fuelled a need among the public for scientific expertise and integrity as much as they have fostered an irrevocable distrust of this expertise and the institutions that underpin it, and triggered calls for other models of assessment and decision-making.

The question is therefore what is the best social use of the knowledge and powers given to us by science? This issue is crucial for scientists and decision-makers alike, because the nature, origin and very essence of knowledge have become important issues and are themselves the subject of controversy. In a world characterised by tension and conflict, some affecting precisely the consequences of knowledge development and application, scientific advances – like the models of [...]

●  
**Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.**

**Preamble to the Constitution**  
of the World Health Organization [WHO]



[...] society they have generated – are increasingly being called into question.

And yet because they are now better informed, our fellow citizens are calling for expertise and conceptual foundations, while also intending to contribute and play their part. Some of the ways that could enable us to restore the trust that is sometimes lacking include scientific integrity, participatory science, dialogue, consultation, the joint drafting of questions and procedures for responding with all actors in society, in order to achieve a common understanding of scientific assessment models and their impact on decisions.

In this context, the role of scientific risk assessment, implemented by a health and safety agency such as ANSES, is to provide useful insight for public policymaking and more broadly for all stakeholders, through independent scientific expert appraisals based on the best available scientific knowledge.

It is then up to risk managers to deal with uncertainty and graduate their responses on the basis of objective evidence to support their decisions.

This exercise demands the greatest integrity and rigour in assessing the weight of evidence for each of the elements on which our risk analyses are ultimately based, and therefore in implementing the principle of precaution as defined in France in the Charter for the Environment.

#### What is the role of a health and safety agency in this ever-changing world?

The task of an agency such as ANSES is to provide the community with a state of the art on health and safety issues by drawing on all available knowledge, within the framework of collective, independent expert appraisals that are open to adversarial debate. Agencies are there so that everyone, individually or collectively, can understand what to expect, assess the risks they take and... make choices in full knowledge of the facts.

ANSES's role is to stimulate public debate on the basis of its expert appraisals and the research it conducts, thereby guaranteeing everyone's freedom of choice. Having access to enlightened and reasoned information contributes to the exercise of free will. The role of health and safety agencies is no longer to issue injunctions, but rather to provide the means to understand, to graduate uncertainty and to ensure access to as much reliable scientific knowledge as possible to enable individuals or groups to choose and act.

For each individual first and foremost. Because while access to scientific knowledge is not a right enshrined in the French Constitution, scientific institutions such as health agencies have a responsibility to ensure that they share their knowledge and make it accessible. Far from lecturing, dictating or scaremongering, ANSES's primary mission must be to share knowledge and be open about what we know – and above all what we do not know – about the ways and means that have led to our results.

#### For the community and public policymakers, things are a little different.

According to Professor Didier Houssin, "a health and safety agency must be a fulcrum for dialogue between scientific knowledge and political power". This is a broader, shared issue. Our role in this case is to give decision-makers the necessary knowledge and perspective, at a given moment in time, to choose and act while being fully aware of what is at stake. The strength of scientific data is that they enable public action to be developed. It is therefore up to agencies to promote trust in public policymaking through expert appraisal. This is a major challenge.

[...]

**The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.**

#### Preamble to the Constitution

of the World Health Organization (WHO)



## Ethics and scientific integrity, the cornerstone of expert appraisal work

**The need for scientific integrity is not a subject for discussion but an imperative.** The preamble to the Singapore Statement on Research Integrity (2010) pointed out that "the value and benefits of research are vitally dependent on the integrity of research". Scientific integrity cannot be separated from the scientifically rigorous nature of research if it is to guarantee the impartiality of its results, and is an essential condition for maintaining society's trust in science. As the driving force behind all research activities, it contributes to the quality and reliability of scientific output and, in turn, of knowledge and understanding. A single breach of scientific integrity is enough to call into question the credibility of science and scientific work.

Expert appraisals for health risk assessment are fuelled by scientific knowledge derived from research results. To ensure its robustness, the expert appraisal relies on methodologies and processes designed to ensure its independence from any bias or particular interest and guarantee the principles of independent judgement, adversarial debate and multidisciplinary, as enshrined in the National Charter for Expertise. The growing number of signs and hard evidence of failures to respect scientific integrity points to a new vigilance task for the Agency, which intends to maintain the conditions for reliable, indisputable expert appraisal to ensure that it can be used for public policymaking.

**ANSES's role is to maintain the conditions for trust in all its scientific output.** It must be constantly vigilant in its assessment, research, reference and observation missions, in order to produce high-quality data that meet the ethical and scientific integrity criteria it upholds, particularly by avoiding any potential conflict of interest, but also by endeavouring to use data that meet these same criteria. As the Agency is both a producer and consumer of scientific knowledge, it is therefore necessary to demand the same high standards, whether in its assessment work, the results produced in its laboratories by its own teams, or those derived from the research it funds in support of its missions.

A single study, however rigorous, is not enough to form the basis for a risk assessment. Integrating all the available knowledge implies being able to rely on methodological tools to assess the level of evidence and robustness in a traceable way. The collegial approach to expert appraisal, combined with the multiple sources of knowledge, contributes to its adversarial nature and ensures that each thesis or hypothesis is taken into account, discussed and

evaluated. Multiple sources of knowledge need to be drawn upon in order to mobilise all available information for the expert appraisal and identify scientific biases or incompleteness. Expert appraisal entails a diversity of schools of thought.

**Based on a collegial approach and involving the best experts,** recruited on the basis of their excellence and independence from any particular interest, it is therefore a strong solution that ensures the credibility and robustness of the work produced. It is now having to address the new challenge of eliminating from the knowledge base the results of work published without due regard for scientific integrity. Some can probably be excluded by methodological evaluation tools and the weight of evidence in publications, but ANSES must also work on prevention and collective action, alongside the French Office for Scientific Integrity. The Agency must also be mindful of the effects of the fundamental change in publication mechanisms. By appointing a scientific integrity adviser and an ethics officer from among its staff, the Agency deals with these vital issues in-house with a cross-functional approach covering its various activities. The challenge is twofold: firstly, to ensure that its organisation and the resources at its disposal, particularly in terms of ethics, enable it to meet the challenges of reliability and plurality; and secondly, to ensure that its research work is conducted according to the highest standards. ANSES's Committee for Ethical Standards and Prevention of Conflicts of Interest will naturally have to deal with issues such as the impact on the development of public-private partnerships within the scientific community with regard to ethical principles, or reconciling engagement in dialogue with stakeholders – which is one of ANSES's founding principles – with independence, particularly on issues concerning regulated products.

Lastly, rejecting any form of complacency must be an integral part of the internal culture. The procedures followed and stance taken by both the Agency and its scientists should foster an enquiring attitude. This includes its outlook on its own practices, with a view to changing them if necessary.

A virtuous circle is thus formed on the basis of a strict and rigorous ethical framework imposed on both the individual members of the expert groups and the institution that deploys them, to produce an open and robust expert appraisal in response to the health-related questions and challenges raised by society.

[...] This approach of sharing scientific data and making it accessible is a key strength of ANSES, whose motto is "Investigate, evaluate, protect". Indeed, the agency must conduct exemplary investigations to evaluate risks effectively in order to offer protection from them.

This mission is shared by ANSES and other agencies, to allow people to live in safety today and also head towards a safe future.

There are high expectations about the impacts of production and consumption patterns on our ecosystems and environment and, more generally, about the importance of sustainable practices, from the point of view of health, biodiversity and ethics.

The essential role of agriculture and food in a global shift towards a greener economy is also a widely shared observation. Questions are now being asked about technological upheavals, our lifestyles and consumption patterns, particularly with regard to their chronic impacts on our health and environment.

Questions are also being raised about risk governance and approach, correlated with socio-economic and ethical issues: repositioning independent reliable science at the heart of the debate for an objective approach, factoring in both the risks and benefits of technological innovations and new practices, and examining the issue of public policymaking in a situation of scientific uncertainty.

Among the expectations, a broad consensus is emerging on essential needs in knowledge acquisition through research, challenging current methodologies: in toxicology in general and particularly on endocrine disruptors, on exposure to mixtures of substances, on effects at low doses, and on emerging hazards. In another vein, science should help better identify populations at risk (specific sensitivity, new consumption patterns, social vulnerability, etc.).

Lastly, in order to meet individual and collective needs, a key aspect of public action is the dissemination of knowledge, particularly from research and risk assessment, through education and school, as well as through suitable public health messages. It seems vital more than ever before to build a common and shared culture, and protect the most vulnerable: on the one hand, social inequalities determine our health and on the other hand, our production and consumption patterns are instrumental in our exposure to risks.

These are all points that ANSES needs to take into account in order to understand and control every dimension of the risks to our health and environment. ●



## Between doubt and knowledge: the challenge of taking scientific uncertainty into account

"When the occurrence of any damage, albeit unpredictable in the current state of scientific knowledge, may seriously and irreversibly harm the environment, public authorities shall, with due respect for the principle of precaution and the areas within their jurisdiction, ensure the implementation of procedures for risk assessment and the adoption of temporary measures commensurate with the risk involved in order to preclude the occurrence of such damage."

**Article 5 of the French Charter for the Environment**

### **The paradox of scientific knowledge is that it opens up options while generating uncertainty.**

This uncertainty arises not only from the limitations of science itself, but also from the fact that science is constantly evolving. The advancement of knowledge helps reduce uncertainties, but at the same time creates new ones. In this context, the role of scientific risk assessment, implemented by a health and safety agency such as ANSES, is to reduce and specify uncertainties from a health perspective on the basis of the best available scientific knowledge. The questions put to ANSES by public authorities, associations and other stakeholders are very diverse. They may cover physical [e.g. radiofrequencies], chemical [e.g. endocrine disruptors] or biological [e.g. new vectors] hazards, health effects or risks associated with exposure to these hazards for human populations [general population, worker populations and sensitive populations], for the environment, or for animal or plant populations. They may also include the assessment of processes [e.g. water treatment or food processing, etc.] or products [e.g. veterinary drugs, plant protection products, etc.] with regard to regulatory requirements, with a view to enabling regulatory ministries to issue authorisations for use or take decisions on marketing authorisations. To answer these questions, risk assessment is based on a set of qualitative or quantitative scientific data [e.g. concentration, exposure doses, modes of action].

**It is rare for all these data to be available,** for all the available data to be of irreproachable quality, or for all the available knowledge to be sufficient for fully understanding the question[s] asked. So how can a risk to humans or the environment be assessed using data that are of heterogeneous quality, from multiple sources [scientific literature, databases, professional expertise, etc.], often of different types [toxicological, epidemiological studies, etc.], and sometimes partial or contradictory? This is the major challenge in risk assessment and knowledge production faced routinely by health and safety agencies when striving to fulfil their role in supporting public policymaking. It is in cases of uncertainty that the question of the principle of precaution becomes pertinent: it introduces the issue of a trade-off between the level of protection and the level of risk acceptable to society, and is sometimes perceived as a partial and insufficient solution to scientific uncertainty.

### **While this issue is partly a matter for public policymakers to decide,**

experts can nevertheless enhance their contribution by their ability to assess the level of uncertainty in their own work, characterise this lack of information and assess its impact on the final result. Analysing uncertainties related to expert appraisal work then makes it possible to offer a broader framework of options to address scientific uncertainty. It will then be up to risk managers to deal with the uncertainty and graduate their responses on the basis of objective evidence to support their decisions. Far from opposing scientific progress, the principle of precaution is actually one of the options if the uncertainty when faced with a risk is too great. Decision-makers need expert appraisals that allow them to characterise levels of uncertainty as precisely as possible. This is why the Agency has begun an ongoing forward-thinking exercise to formulate methodologies for systematically analysing the level of uncertainty and taking it into account in its assessment results. Through a dedicated working group, it is developing methodologies for assessing the weight of evidence and the level of uncertainty. These methodologies should help advance understanding of the origins and causes of these uncertainties, assign levels to them and, if possible, work on reducing them. This methodological work also ensures greater transparency in risk assessment. It defines five essential steps: identify and describe all the uncertainties; assess the selected sources of uncertainty; assess the combined impact of the sources of uncertainty on the result of the expert appraisal; prioritise the sources of uncertainty according to their contribution to overall uncertainty; and communicate the results of the uncertainty analysis. This is the future challenge for risk assessment: by providing an analysis of the level of uncertainty of its work, by qualifying the associated levels of evidence as precisely as possible, and by graduating their impact on the answer to the question posed, the expert appraisal enlightens risk managers and grants their work greater robustness and transparency.

# Uncertainties

Roger Genet, Director General of ANSES, gives us his vision of the Agency and its ambitions for 2025.



**"One Health:  
together  
we are building  
a global health  
and safety  
system."**

•  
**Roger Genet**

Director General of ANSES

**How can we respond to an ever-broader field of scientific expertise and a constantly increasing degree of uncertainty?**

• Roger Genet

As a scientific agency dedicated to safeguarding health, we are in a unique situation: producing knowledge on health risks means better characterising and assessing them, but also taking into account the uncertainties and questions that remain, or even arise, from our research. This is the paradox of science: exploring new fields is as much about increasing our knowledge as it is about being confronted with its limits.

This is the daily reality faced by our teams, in our laboratories and expert committees. Our role is to use the available scientific knowledge to assess the existence, nature and extent of the health risks our society is likely to face, while being aware of the remaining uncertainties.

For the Agency, risk assessment is about informing political decision-making and supporting public policymaking, reflecting risk management in the public arena.

Our responsibility is to rigorously examine the weight of evidence for each of the elements that form the basis of our analysis.

The other aspect of our action lies in our ability to challenge existing scientific paradigms. To move forward and advance science, it is necessary to know how to update practices in order to better reflect the reality of health issues on the basis of continuous improvement of knowledge. Concerning the impact of endocrine disruptors, for example, ANSES broke new ground by proposing a revision of the methodology then in force: we included in the assessment the concept of "windows of exposure" during which individuals were more sensitive to endocrine disruption. The assessment has therefore become more complex, but also more precise.

Faced with uncertainty, we must be able to challenge our practices and question ourselves in order to offer assessments that are as precise as possible.

**Isn't the detection of weak signals also a crucial issue for a health and safety agency?**

• R.G. Of course: we cannot simply act in response to an identified risk. The value of our work and expertise lies in our ability to watch out for weak signals and anticipate emerging risks, whether in France or elsewhere. In our increasingly interconnected world, where people and goods are moving around on a large scale, the risks travel with us.

Our objective is to remain one step ahead, to be able to identify potential risks and monitor the appearance of emerging risks, to enable decision-makers to prepare. This ability to anticipate must of course coexist with unrelenting vigilance regarding today's risks or re-emerging threats.

To achieve this, we need to focus on maintaining effective national, European and international vigilance schemes and networks. The Agency is now in charge of five monitoring and vigilance schemes – toxicovigilance and the network of poison control centres; phytopharmacovigilance; nutrivi-  
gillance; pharmacovigilance for veterinary medicinal products;

and the National Network for Monitoring and Prevention of Occupational Diseases (rnv3p) – which enable us to constantly monitor feedback from the field and obtain continuous input for our risk assessments.

These schemes are essential, but we must also be able to take all signals into account, including those from networks that we do not manage ourselves or that we manage collectively, such as the epidemiological surveillance platforms for animal health, plant health and food chain safety. Promoting the circulation and inter-connection of information and the exchange of data on health monitoring, vigilance, surveillance or alerts, both at home and abroad, will make us most effective and best prepared, as a key "One Health" player in monitoring, alert and safety in all our areas of competence.

**You mention the crucial role of the circulation of information. What about scientific data?**

• R.G. The availability of scientific knowledge and data is obviously central to the Agency's work. In this respect, ANSES occupies a rather unusual place in the ecosystem of health agencies. Thanks to our laboratories, we are producers of science, knowledge and know-how. Similarly, through the National Research Programme for Environmental and Occupational Health that we operate, we fund research teams on these topics and liaise on these themes with other research-funding agencies to optimise our efforts. But we are also consumers of research results: our experts base their opinions on the examination of all the existing scientific output in order to conduct their risk assessments. [...]

"Exploring new fields is as much about increasing our knowledge as it is about being confronted with its limits."



[...] This is one of ANSES's great strengths. To issue our opinions and recommendations, we rely on the data we produce or collect, while also factoring in all the other scientific data available on each subject. As a resources agency, our ability to finance research projects means that we can supplement this data. We therefore favour a plurality of sources of information: international scientific publications, research activities and work carried out by European and international counterpart organisations, monitoring data produced by public authorities and signals reported as part of monitoring, vigilance and surveillance schemes. Independence and impartiality require us to avoid depending on a single data source, and we will also be signing up to the open science movement that pursues these same objectives. In a context of uncertainty, the quality and multiplicity of the data on which our analyses are based are absolutely crucial. The reliability and relevance of our assessments depends on them, as does our ability to develop the methodologies we use.

This is also why we value pluralism in expert appraisal to the highest degree. Our expert appraisals are always collective and adversarial. We want to hear all opinions and hypotheses, and

discuss them in order to be able to propose a detailed and nuanced approach to health risks. This is what makes us both a scientific expertise agency and an agency of scientific expertise.

**The quality of ANSES's expert appraisals depends on the talents it hosts. What is the Agency's ambition in this regard?**

• **R.G.** We at ANSES are

fortunate to be able to rely on the knowledge and know-how of top-level scientists, whether in our laboratories and expertise departments, or in our committees of external experts. These specialised skills underpin the value of our work and add to the Agency's reputation and renown.

Our ambition here is twofold. For scientists and researchers employed by ANSES, it is imperative to focus on developing skills throughout a dedicated career path so as to promote their recognition within the Agency and their influence in the wider scientific community, and to give them the means to transmit their knowledge to young researchers in order to ensure its continuity.

For experts, it is both a question of making researchers more aware of the professional benefits of participating in expert committees, and of attracting the best among them to work with us. Participating in a panel of experts is both a recognition of the quality of their scientific work and a great opportunity to debate with their peers on topics characterised by great uncertainties,



and therefore to advance their own research and reflection. In a researcher's career, this is an important step. The quality of the opinions issued by the Agency depends on the quality of its expert panels. It is therefore essential for us to be able to attract the best experts in our fields. This attractiveness is one of our major ambitions for 2030.

**In terms of international influence, how does ANSES position itself compared to its counterparts?**

• **R.G.** An agency like ours must take into account both the European and international context. Our topics do not stop at national borders and our problems are not specific to France. It is crucial to join the European and international ranks through close ties with our counterparts so that together we can develop the health and safety system of tomorrow. Indeed, this is an integral part of our mission, and explains why we seek to play a decisive role in the European Union.

This is a major challenge, and we need to further consolidate ANSES's role in the construction of the European and global health and safety system. We are now engaging in issues that will have a major impact on risk assessment and health and safety strategies, whether for humans, animals, plants or the environment. This is the case with the adaptation of methodologies to take into account the concept of the exposome and the development of genomics, which is revolutionising our ability to detect and identify pathogenic strains, as well as helping us better target the most sensitive subpopulations through faster and more powerful genome sequencing methods.

To meet all its challenges, ANSES must also be a leading research player and contribute more effectively to defining research priorities, coordinating the scientific community and developing knowledge in support of risk assessment. This is the purpose of the strategic partnerships we are forging with our national and international partners in order to fully play this role in identifying strategic scientific research themes. But our ambition is to go even further and to be a driving force for joint initiatives to advance health and safety. This is the thrust of ANSES's proposal

1 2  
"Our role is to promote trust in public policymaking through our expertise."

to the Member States and the European authorities with a view to creating a common fund for toxicology research, in order to provide Europe with a facility comparable to the American National Toxicological Program and thus provide us with the means to tackle the European health challenges of tomorrow.

**Do you think that ANSES has a role to play as a prescriber, particularly in terms of public policymaking?**

• **R.G.** Our ambition is clear: to guarantee the health and safety of populations in the face of all exposure risks by providing the decision-makers who manage risks with all the components of an independent scientific expert appraisal based on the best available scientific knowledge. This means that we must also be able to help the decision-makers properly identify, prioritise and graduate the levels of risk.

We therefore need to know how to be both pioneering and agile. To raise the alert on emerging topics and be a source of ideas for adapting our methodologies in real time to advances in scientific knowledge, or to provide answers that are consistent with society's changing expectations. This is the case when we propose to lead or co-facilitate European research programmes on the cumulative effects of chemicals, or when we support the French authorities in their proposals to advance the European regulatory framework on the assessment of plant protection products or veterinary medicinal products.

To ensure the dynamism, efficiency and relevance of its scientific output, ANSES also needs to mobilise the strengths and skills of stakeholders in the field where this seems most relevant, particularly through public-private partnerships. We must of course do so while exercising great vigilance regarding all the ethical aspects and while preventing any conflict of interest, but this role as a key driver in the development of knowledge and tools for the benefit of health, at national and European levels, is fundamental. It is particularly important when the Agency alone is in a position to promote this development, for example in the field of vaccinology in animal health or in the development of innovative methods for detecting and characterising animal, plant and food pathogens to ensure better traceability.

The more robust and recognised our expertise, the more we are able to fully play this role of scientific adviser and driving force. Whether in France, Europe or around the world, our work must be seen as a benchmark, and our knowledge as being useful to the community and ultimately to political decision-making in order to better protect populations and the environment.

**What do you think is the Agency's major challenge for 2030?**

• **R.G.** Without hesitation, I would say: to build trust! It is the keystone of the science edifice and has been abused in recent years. We are living in a period of great mistrust of scientific progress and of science itself, and it is our duty to demonstrate its quality, reliability and usefulness every day. This requires a multitude of fundamentals to be taken into account: transparency on the methodology, data sources and level of uncertainty; accessibility of results; scientific and ethical integrity; inclusion and participation of citizens.

This is the trust we must strive to consolidate. First of all, with

the French, who do not always identify ANSES with our various actions. With our stakeholders, counterparts and contractors, who must be able to rely on our opinions and research to contribute to their thinking, fuel their debates and provide a basis for their decisions. With our public and private partners, we must ensure that our scientific objectives converge and feed into each other's research in a transparent manner and according to a clear and common course of action.

Trust is also a key value within the Agency itself. We must continue to work in a spirit of trust, with the equanimity and professional commitment that comes from the strong and shared sense of contributing to the public interest. It requires a shared vision and ambitions, and collective values. It is also sustained by transparent, clear and universally understood processes, synergies within our network and dialogue between our entities.

The challenge for us is to help strengthen trust in public policymaking through the quality of our expert appraisals. This requires opening them up to stakeholders as part of a dialogue based on better knowledge sharing, and also taking lay knowledge into account. The development of new communication technologies offers considerable opportunities in this respect, and the Agency must seize them. In the landscape of health agencies, ANSES broke new ground on its creation in its approach to dialogue with society and its stakeholders, and in the way this was implemented and sustained in its mode of governance. We must now commit to the emergence of a true knowledge democracy.

Scientific integrity, participatory science, dialogue and consultation with all actors in society are just some of the ways in which we can be heard and regain the trust that is sometimes lacking. ●

"We therefore need to know how to be both pioneering and agile."





# Dedicated to safeguarding health

Since its creation, ANSES's ambition has been founded on ensuring cohesion between several areas of expertise – reference, research, monitoring, vigilance and risk assessment – which sustain each other to produce recommendations and management measures in support of public policymaking.

**B**enoît Vergriette is in charge of the Social Sciences, Expertise and Society Unit within the Science for Expertise Division: "There are topics and situations that require different perspectives."

Indeed, conducting expert appraisals on a case-by-case basis, in response to questions that are sometimes limited by a technical or regulatory framework or a sectoral dimension, offers few opportunities to take systemic or integrative effects into account. It also struggles to meet more all-encompassing societal expectations, which may for example raise questions about the utility and purpose of existing technologies and innovations in relation to risks that are suspected or impossible to assess.

All the skills at our disposal now need to be combined to provide a 360° view of health issues such as the impact of climate change on living organisms, the objectives for ensuring healthy and sustainable food, expected developments in agroecology, and the consideration of multiple exposure on environmental quality or occupational health. It is therefore necessary to rely fully on integrative (food, environment, work) and innovative capabilities when conducting expert appraisals involving social issues.

One of the levers builds on the six cross-cutting strategic themes (animal health and welfare, plant health, food safety, antibiotic resistance, epidemiology and surveillance, exposure and toxicity of chemical contaminants) promoted by six scientific departments that are part of ANSES's internal governance. This scientific management leads to greater coordination and a search for synergies between the laboratories' scientific units and with the risk assessment units, by using incentives and strategies identified for each theme. This provides a better understanding of public policies, offers a strategic vision, and strengthens the Agency's capacity to plan ahead and offer cross-cutting analyses. This organisation also gives greater scope to the work carried out and the recommendations likely to result from it. The development of the circular economy, biotechnologies, nanotechnologies, the impact of new information technologies and the Internet of Things, etc. are among the emerging themes. In addition to these major topics, there are the ways in which biodiversity and environmental impacts are taken into account in the scope of the Agency's work and activities.

Lastly, in view of increasing concerns about the environment and protection of biodiversity, and the limitations of product-by-product approaches that remain the regulatory standard, knowledge of environmental and health risk assessment needs to be strengthened. Many public operators are indeed involved [...]

[...] in the field of environmental expertise, but the procedures deployed are varied. The well-organised monitoring of emerging risks, especially when associated with new technologies or sustainable development, would also benefit from being consolidated. This topic should be addressed through alliances and through the network of public bodies involved in the field of health-related expert appraisal coordinated by the Agency.

#### Aiming for benefit/risk and even cost/benefit approaches

Expectations regarding socio-economic insights provided by the Agency are a reality confirmed by the orientations set out in the ANSES's 2018-2022 goals and performance contract.

Regardless of the conditions of their feasibility, the socio-economic analyses considered may be of various kinds and cover a vast range of fields (chemicals, agriculture, food, environment, occupational health, etc.).

Those required in a regulatory context, such as with plant protection products, biocides, or the REACH Regulation, are covered by well-defined procedures and aim to compare the effectiveness and feasibility of certain alternatives, in order to justify, where appropriate, the impossibility of substituting certain substances or to conduct or appraise impact studies on restriction or prohibition measures.

Outside the regulatory framework, they concern different dimensions and can be positioned at different stages of the expert appraisal process. Three levels can be distinguished: the socio-economic determinants of exposure, the breakdown of benefits (and risks) associated with an activity, product or innovation sector, or the cost/effectiveness analysis of different management options or the cost/benefit analysis of their overall impact.

The availability of proven methodologies, access to data and the conditions for their use, as well as the deployment of a limited number of scientific skills in the field of economic evaluation are all topics on which ANSES needs to mobilise its academic and institutional partners with a view to conducting work that most often requires extensive skills and sometimes extends beyond its own scope.

This is because the Agency, which is increasingly being questioned about the relevance or effectiveness of the management measures to be considered, has to take a stance on benefit/risk and

"Today, within the Agency, openness and a cross-cutting approach are part of our daily work."



**Matthieu Schuler**  
Risk Assessment Director



Ask the right questions to give an appropriate answer.

even cost/benefit approaches. "Assessors must identify cases in which the prevention of certain risks could reveal contradictions or the need for trade-offs, for example between those relating to a food's nutritional components and those that expose consumers to a contamination hazard" explains Matthieu Schuler. The challenge therefore lies in taking better account of these developments in order to provide socio-economic insights when needed, either because of the regulatory framework or to ensure that the question raised is properly understood, with particular attention paid to marketing authorisations (MAs) for regulated products.

#### Understanding behaviour and practices, and how they affect humans and the environment

It is often essential to understand the behaviour and practices of the actors and populations (producers, consumers, workers, companies) concerned by a type of risk in order to assess the health consequences resulting from the actual conditions of marketing or using various products and substances, or from exposure to them. It is also vital to advance scientific knowledge on the cumulative effects of environmental exposure over the lifetime of individuals.

These data are mainly produced by large population studies such as Total Diet Studies (TDS), which measure the level of exposure to chemical contaminants; INCA studies on the food consumption habits of the French; or sectoral studies such as Pesti'home on the domestic use of pesticides and biocides. The availability and use of a growing variety of data is an essential tool that should be consolidated when making recommendations on consumption or use in line with the daily reality of our fellow citizens. This approach makes it possible, for example, to formulate specific recommendations geared to people on special diets, such as vegetarians; or to more sensitive populations, such as pregnant women, young children or the elderly; or to target certain populations because of their geographical location.



The health of bees and the impact of pesticides are essential topics for ANSES.



Assessing risks to ensure a healthy and sustainable diet.

Mobilising the human and social sciences for expert appraisal "Exposure of a consumer or employee to the risks generated by a particular product depends on this product's intrinsic properties, but also on the way it is used, the products with which it is used concurrently, the rules on marketing this product, the income of individuals, etc. Knowing all these data, which is the domain of the social sciences, is absolutely vital for understanding exposure situations and therefore identifying possible ways of protecting ourselves against them, for example by encouraging consumers and manufacturers to make certain choices," stresses Benoît Vergriette. An understanding and a detailed analysis of the behaviour of stakeholders – whether consumers, workers or companies – in response to applicable regulations, and the ability of public or private institutions to implement and monitor these regulations, are all necessary dimensions for understanding exposure situations and therefore identifying risk situations and possible means of preventing or reducing them. The main challenge is to get scientists from a wide range of disciplines to work together, which involves a phase of adaptation and mutual recognition. In the area of agriculture and food, and because of the broad scope of its missions (nutrition, animal health, food safety, environmental health, etc.), the Agency can no longer compartmentalise different risk components when carrying out its work. Can the issue of antibiotic resistance, the use of certain veterinary medicinal products, animal welfare, plant protection products, or the control of certain epizootic diseases be considered without also questioning production methods? This complexity cannot of course be addressed by the Agency alone, but its ability to mobilise stakeholders, whether internal or external (through academic partnerships), will enable it to clarify and objectively determine certain public health and sustainability issues.

#### Having access to all signals

The credibility of scientific expertise depends largely on the [...]



An approach to expert appraisal that takes all types of exposure to risks into account.

#### Point of view

**"Let's cultivate our strengths and cooperate more with our European partners."**



**Didier Houssin**

Former Chairman of the ANSES Board of Administrators, Chairman of the international subsidiary of the Paris Public Hospital System (AP-HP)

#### Do you see ANSES's status and positioning as assets to be maintained?

The Agency is unique in being located at the fulcrum and confrontational borderline between a number of forces. These forces are political and scientific, but also administrative, economic, associative, etc. The Agency does not have any power of its own, but provides invaluable channels for dialogue. Similarly, because of its numerous supervisory ministries\*, it reflects the different tensions to which these activities are subject. This interministerial dimension is not always easy to manage, as it requires things to be seen in a global way.

#### Does this mode of governance strengthen the Agency's objectivity?

Objectivity is based on science, scientific excellence and independent assessment. But the context can become complicated for the Agency when it issues opinions that conflict with the positions of political leaders, associations or the economic sphere. This is when the Agency may come under pressure. It is therefore essential that it preserves its independence and the robustness of its scientific expert appraisals.

#### How do you see this as a European issue?

I consider the question of European integration to be the most crucial one today. How can the Agency, as an important actor within the EU, optimise its action on the European scene, and particularly, how can it coordinate as effectively as possible with the European Food Safety Authority (EFSA)? The European Union system – agencies in each country coordinated via a European agency – is a very important asset. But we need to maximise its effectiveness. This seems to me essential to preserve the independence and scientific excellence of our risk assessment structures. I am therefore one of those who is calling for stronger European integration of health and safety.

\* the Ministries of Agriculture, Consumer Affairs, the Environment, Health and Labour.

[...] ability to anticipate and detect weak and emerging signals, particularly in order to prepare to assess the risks that are arising – and will increasingly arise in light of changing lifestyles and consumption patterns – in our daily lives. "The notion of vigilance lies at the heart of any risk governance system", points out Juliette Bloch, Health Alerts & Vigilance Director.

It is the Agency's role to ensure that all its fields are fully covered and to delegate to other partners any fields not covered by its own schemes.

The challenge is also to reach out to the right targets, particularly professionals, who will be able to draw lessons and take actions based on the Agency's alerts.

Lastly, vigilance implies being on the lookout for any unusual signal or event, even if it does not occur in France, once there is the potential for it to occur here. Establishing a network of national partners that conduct international monitoring as part of their professional practice is an effective way of detecting early signals.

The Agency's strategy is therefore based on three main themes: firstly, connecting networks to each other to ensure that the many actors managing the vigilance schemes coordinate their efforts both nationally and internationally; secondly, having access to all signals so as not to leave out any important signal that may have been detected by a third-party actor; and thirdly, greater interaction with health professionals, as well as with industry and NGOs, in order to systematise and improve the quality of health reports and disseminate the recommendations resulting from the alerts.

### Towards the tailoring of regulatory sciences

What can be called "regulatory science" helps assess the safety, effectiveness, quality and performance of all activities, products or facilities that require prior government authorisation before they can be deployed, sold or commissioned. These so-called "regulated" products – whether plant protection and biocidal products or veterinary medicinal products – are assessed by ANSES, which is also in charge of issuing, amending or withdrawing marketing authorisations.

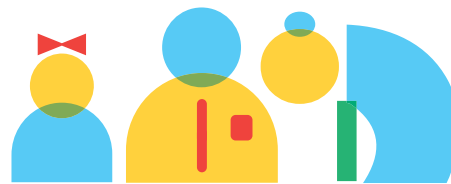
This assessment is strictly governed by European and national regulations, which formulate objectives, determine processes and set requirements in terms of the content of the dossiers submitted by manufacturers. They are supplemented as needed by regulatory or normative documents specifying the assessment criteria and applicable methodologies implemented by the assessment agencies.

While these regulations have indeed enabled the establishment of one of the world's most demanding health systems, they are also increasingly being questioned by society. These controversies are part of an often broader public debate calling for changes in production methods and consumption of fewer synthetic

"It is essential for the regulations to incorporate the most recent scientific advances as they occur."



**Françoise Weber**  
Managing Director General,  
Regulated Products Division



Taking account of risks due to cumulative exposure over a lifetime.

chemicals.

Many French and European initiatives have this same aim and will have – or are already having – an impact on both the current regulatory framework and assessment methods. This is particularly the case in France – which plans to reduce the use of pesticides and antibiotics – but is also true at European level with the revision of the Food Law, the founding text of the European food safety system. ANSES is playing an active role here, whether by contributing to the development of assessment methodologies in support of the French position, for example in the revision of the regulation on veterinary medicinal products, or in approving criteria for defining endocrine disruptors applicable to the regulations on plant protection products or biocides, or by contributing at national and European levels to the revision of the organisation of the European health agency system. ●



## Health and the proper use of chemicals

In addition to its risk assessment tasks, ANSES is the competent national authority for the granting of marketing authorisations (MAs) for veterinary medicinal products, as well as plant protection products since 2015 and biocides since 2016. This responsibility involves mobilising the best scientific expertise to carry out a rigorous and effective assessment of MA applications in accordance with the requirements of the regulations in force.

### **Developing the regulatory framework for marketing authorisations**

The impact on health and the environment of the hundreds of chemical products whose use is governed by specific European regulations is a persistent concern for ANSES and must be monitored constantly. This also requires the use of suitable monitoring and vigilance schemes (toxicovigilance, pharmacovigilance, nutriviigilance, phytopharmacovigilance) to prevent and control any possible harmful effects associated with the use of these products.

Regulations must be continuously adapted to take the most recent scientific advances into account. Although when adopted, the regulations governing the harmonised marketing of plant protection and biocidal products within the European Union were seen as a significant step forward in protection of the population and the environment, and enabled the most hazardous active substances to be phased out,

they now need to evolve by allowing the integration of multi-exposure approaches, better consideration of scientific uncertainty, and greater access to the data produced by manufacturers in support of their authorisation applications. ANSES already makes proposals to Europe within its sphere of competence on improving methodologies and processes for the assessment and authorisation of plant protection and biocidal products.

### **Besides marketing authorisations, striving for the appropriate use of regulated products**

Granting a marketing authorisation for a regulated product is a guarantee that the product is effective and does not pose an unacceptable risk to health and the environment when used under the prescribed conditions. Nevertheless, the massive use of chemical control methods over the past 50 years or so has led to widespread exposure of the population, through food, water or air, to mixtures of compounds whose medium- and long-term impact on ecosystems – including humans – cannot be predicted.

The Agency strongly reiterates that the use of chemical treatments should not be systematic and should be part of a pragmatic and effective strategy to reduce resistance phenomena, professional dependence and, in general, exposure of the population and the environment to these substances. This objective, which is part of the Ecophyto plan

set up by the French government, corresponds to a strong societal demand expressed by our fellow citizens.

In the absence of agro-ecological alternatives likely to address all needs and threats, it is therefore important to have a sufficient and varied range of plant protection products, from which the substances of most concern have been excluded, by promoting the emergence of biocontrol and low-risk products, and by limiting the use of active products to situations in which they are essential, as is the case with antibiotics in human and veterinary medicine.

As the national authority in the field of veterinary medicines, ANSES has made a strong commitment to the national Ecoantibio plan to combat antimicrobial resistance, which has become a serious threat to populations. In the space of ten years, the use of antibiotics in livestock farming and the level of exposure of animals to antibiotics has decreased by nearly 35%, and by up to 90% for some critical antibiotics. This result has been achieved through the determined and combined action of breeders and prescribers, doctors and veterinarians.

Such a collective approach is now necessary for the other classes of regulated chemicals, plant protection products and biocides, with the general aim of complying with the ALARA (as low as reasonably achievable) principle, in order to drastically reduce human and environmental exposure while preserving a therapeutic arsenal that is sometimes necessary, whether for health or economic reasons.

ANSES also intends to support the development of alternatives, whether biocontrol or non-chemical solutions, and the creation of support schemes for VSEs/SMEs modelled on innovation support schemes, in order to facilitate the preparation of MA applications for low-risk or biocontrol products, thereby enabling these innovations to be brought to market more quickly.



# Regulated products



# Aiming for synergies in actions and resources



Since its creation, ANSES has been working to play a major role in the health and safety ecosystem, and intends to consolidate its position as an international reference in this field. With this in mind, it is stepping up its policy of national, European and international partnerships with the most relevant academic and institutional reference points.

2 1

**I**n a context of broad circulation of goods and merchandise, ANSES's European and international positioning responds first of all to health and safety concerns. The scientific challenge is twofold, with the ambition of placing the Agency at the heart of the global scientific community not only to keep abreast as far as possible of all available data and knowledge, but also to be an influential force with respect to international scientific trends and approaches in support of expert appraisal or the development of risk assessment methodologies.

As a national health agency, ANSES coordinates its work at European and international levels with the French global health strategy, the strategies of its supervisory ministries, France's international commitments in the fields covered by ANSES (for example, in environmental and occupational health, by signing the declaration of the WHO/Europe Sixth Ministerial Conference on Environment and Health in June 2017), and the general framework of sustainable development objectives. The orientations adopted by ANSES are also in line with its priority cross-cutting scientific themes: animal health and welfare, food safety, plant health, antibiotic resistance, epidemiology and surveillance, and exposure and toxicology of chemical contaminants.

#### **Take and defend strong positions internationally**

"Even if the international issue involves multiple partners that are sometimes difficult to interpret and engage, ANSES needs to [...]"



Assess risks in work environments.

2 2

[...] assert itself as a reference agency in Europe, an agency whose scientific credibility is considered irreproachable," emphasises Luc Derepas, Chairman of ANSES's Board of Administrators. "This will enable us to have a real impact on the European and international scenes." In fact, by developing its international partnerships, ANSES not only enables France to occupy a leading position in Europe, but also helps Europe make its voice heard on the international scene.

**Four strategic objectives have been clearly identified:**

- be a major European and international player in risk assessment;
- actively contribute to international implementation of research actions on the priority scientific themes identified;
- promote exchanges with European and international peer organisations of excellence;
- engage in targeted participation in cooperation and capacity- and competence-building initiatives.

**European synergies in health alerts and vigilance**

To detect emerging signals as soon as and wherever they appear, the Agency must strengthen the exchange of information at European and international levels. This is the case with very strong partnerships with a number of European trade networks, including the Rapid Alert System for Food and Feed (RASFF), the Rapid Alert System for Dangerous Non-food Products (RAPEX), the WHO's International Network of Food Safety Authorities (INFOSAN) and the Emerging Risks Exchange Network (EREN) of the European Food Safety Authority (EFSA). The OccWatch platform, in the field of occupational diseases, also contributes to this dynamic. Other networks also need to be created at European level on the basis of national initiatives launched by ANSES, particularly on nutriviigilance.

It is also essential, still at international level, to establish links with learned medical, plant health and veterinary societies, in conjunction with ANSES's counterparts abroad. "To pursue an innovative policy for detecting weak signals, we must rely on the new information and statistical technologies known as data mining," says Matthieu Schuler, Risk Assessment Director. These new approaches are based on strengthening the mobilisation of the Agency's scientific partners: development of partnerships from the R31 network, with the five national research alliances, but also with European and international learned societies.

**Actively contribute to the international support of research activities**

ANSES nurtures and develops international partnerships with organisations of excellence in order to pool skills and work in expert appraisal, reference, research, surveillance and knowledge production. These partnerships, whether created for specific scientific projects or formalised by more structured framework agreements between institutions, are based on criteria of scientific excellence and, more broadly, the existence of mutual benefits, with national agencies and institutes in the EU Member States, North America, Asia, etc.

Nevertheless, the Agency would like to further increase this presence and influence. This applies not only to the specific field of risk assessment, but also to research and reference activities. Through its national or European reference laboratory mandates, which it intends to scale up, the Agency aims to be strong and effective in its ability to identify and describe hazards, both in terms of its performance and its adaptation to the identification

"It is essential that we are present, active and visible in European and international bodies."



**Salma Elreedy**  
European and International Affairs Director



of all hazards, especially new or emerging ones.

This commitment is also reflected in support for international research activities on scientific themes identified as priorities, promotion of exchanges with European and international peer organisations of excellence, and targeted participation in cooperation and capacity-building activities and research consortia. This strategic objective is in line with the "Consolidate ANSES's role in the construction of the European and global health and safety system" theme of the Agency's goals and performance contract for 2018-2022.

### Essential public-public partnerships

ANSES is strengthening and structuring its policy of partnerships with other French public actors in research (CEA, CIRAD, CNRS, Ifremer, INERIS, INRA, Inserm, etc.) and higher education (universities, veterinary and agronomy schools), as well as with health agencies (the French Public Health Agency, ANSM) and funding agencies such as the ANR and the National Cancer Institute. "Today, ANSES must favour comprehensive and integrative approaches to risks, and this requires access to a high level of scientific and foresight skills," explains Armelle Degeorges, Research Funding & Scientific Watch Director. "While we have some of these skills in-house, the bulk of them are outside the organisation, whether in research or expert appraisal."

To achieve this objective, ANSES relies on a strategic public-public partnership approach. This aims first of all to distinguish between pivotal bilateral partnerships, set up with major national scientific institutions and multilateral local partnerships, most of which are associated with local academic and scientific networks, and local authorities hosting ANSES laboratories in the regions.

"Open science, independence and scientific integrity are essential pillars for the credibility of expertise and societal trust."



**Gérard Lasfargues**

Managing Director General,  
Science for Expertise Division



Brexit has changed the stakes and is rebalancing European cooperation.

In the field of occupational health, some partnerships are intended to be consolidated with institutional actors also working in this field in France and at European and international levels (INRS, CNAMTS, MSA, OPPBTP, ANACT, SPF, etc.).

Clearly defined targeted methods – joint research units, contracted units or framework agreements – help provide a suitable organisational structure for managing these various partnerships and will need to develop in line with organisational and operational needs. Links with higher education consist in developing the mobilisation of research teams in site policies, and participating in doctoral and post-doctoral teaching and training activities.

"We are also positioning ourselves with regard to the national research alliances," says Armelle Degeorges. "We share common interests and scope with the National Alliance for Life Sciences and Health (Aviesan) and the National Alliance for Environmental Research (AllEnvi), but also with the National Alliance for the Human and Social Sciences (Athena)."

These networks, which bring together partner scientific organisations, help to mobilise skills and knowledge around health and safety issues. "Under the law, we are the only agency able to call on a dedicated network, which enables us to collectively address a certain number of emerging issues and methodological problems," she points out.

### A clearly identified framework for public-private partnerships

Faced with growing constraints and a binding obligation to guarantee the dynamism, efficiency and relevance of its expertise and scientific output, ANSES must be able to mobilise [...]



Europe for health and safety, a step forward for universal health.

[...] the strengths and skills of actors in the field where this seems relevant. "However, in many cases," says Nicolas Canivet, Strategy and Programmes Director, "whether in terms of expert appraisal, research or reference, it is only by using private partners that the Agency can access the resources – skills, knowledge, data, equipment, biological materials or field situations – essential for carrying out its activities."

In addition, collaborative work funded under national or European calls for research projects promotes the establishment of public-private partnerships that provide an important lever to accelerate the transfer of the results of its work. To meet this challenge, the Agency has adopted a strict ethical framework for contracting with its private partners, ensuring that there is no conflict of interest in the performance of any of its missions. Internal standards and procedures are necessary to ensure that any partnership with the private sector is systematically based on a detailed, homogeneous, transparent and shared analysis of the expected benefits and risks associated with such a partnership.

2 4

#### Knowledge and know-how to be developed

Because it is responsible for accelerating the development and transfer of knowledge and tools for health within France and Europe, and especially in cases where it alone is in a position to play this role, the Agency must ensure the development and transfer of its knowledge and know-how, without seeking profit but under conditions that aim to maintain its financial balance. "This entails improving our ability to identify and support the innovation potential within our teams by relying on specialised third-party structures with the appropriate skills and resources" explains Nicolas Canivet. The development effort will thus be focused primarily on innovations meeting a major need to develop diagnostic, prevention or control tools with regard to the corresponding health challenges. However, this strategy is part of a clear framework to ensure that such partnerships do not

"Transferring our innovations to benefit health is essential but must be conducted in accordance with strict rules of independence and impartiality."



**Gilles Salvat**

Managing Director General,  
Research and Reference Division



Forty European partners for the EJP "One Health" project and a budget of 90 million euros.

undermine the integrity and independence of the Agency's activities with regard to private interests, but ensure its impartiality and non-distortion of competition.

These rules concern both the choice of partner (which must be made on the basis of an open and transparent call for expressions of interest) and the contractual arrangements (no Agency's interests in the national or European market, where the Agency's influence is exercised; granting of non-exclusive operating licences as a priority), ensuring that any intellectual protection of the Agency's discoveries and innovations continues to benefit public health action. ●



## Genomics, a collective challenge that cuts across the Agency's activities

Among the technologies that have emerged over the past decade, new sequencing techniques and the high-speed sequencing of complete genomes (Next Generation Sequencing, or NGS, and Whole Genome Sequencing, or WGS) – and their democratisation – are among the key elements that have guided responses to research and assessment questions that were previously insoluble or inaccessible. The genomic revolution is thus going ahead and profoundly transforming scientific practices in the medical, agronomic and agri-food sectors, allowing new approaches to health hazard surveillance and risk assessment.

ANSES strongly asserts its strategy to begin systematically using whole genome sequencing to identify and characterise pathogens in human, animal or plant health. The objective is to identify and describe health hazards through the continuous improvement of analytical methods, both in terms of performance and adaptation to their identification, especially regarding new or emerging ones (food viruses, resistance genes, virulence genes, mobile genetic elements, etc.), but also regarding new biological matrices.

The development of technology platforms focusing particularly on technology watch and its sharing supports this objective, with the aim of strengthening ANSES's ability to

anticipate technological developments and deploy a shared strategy on the extended use of whole genome sequencing in research, reference, monitoring and expert appraisal activities.

In terms of responding to health crises, genomics and metagenomics have already demonstrated their potential in the identification of a novel pathogen (SBV), as well as in the rapid determination of a possible emerging zoonotic risk (HPAI). These rapid responses enable diagnostic methods to be adapted and control measures adjusted, producing the elements for a safer risk assessment and selecting candidate proteins for vaccine research.

They also make it possible to consider investigations on the interaction of the intestinal or respiratory microbiota with pathogenic bacteria. In addition, they aim to allow the non-targeted determination of the pathobiome of domestic or wild species in order to anticipate emerging threats, or of the "resistome" in order to assess the risks of complex phenomena concerning the flow of antimicrobial resistance genes.

### **The particular case of animal health surveillance and modelling**

Rapid and massive access to sequencing data for many viral strains is an additional contribution to the modelling of networks of

disease spread. By providing epidemiologists with data on the links between strains, it will now be possible to assess the spatial and temporal spread of viruses between farms. These data, combined with field data, will make it possible to write the storyline of an epizootic disease and thus provide decision-makers with predictive tools for risk management.

### **Surveillance and detection of emerging food safety threats**

Access to the sequences of all pathogenic bacteria collected in the field paves the way for the rapid detection of links between strains that are emerging in human health (collected and sequenced in national reference centres) and those isolated in food, thus allowing better targeting of management measures and improving traceability in the food chain. Another application where advances in genomic sequencing are setting the stage for an upheaval is human health risk assessment, where the development of population sequencing and annotation of the human genome will lead to the identification of sub-populations at risk for a number of diseases, particularly nutritional ones, or with an exacerbated sensitivity to certain environmental contaminants. These scientific advances will determine the Agency's work in many areas, making assessments more accurate and better targeted, paving the way for public policies aimed at specific populations and at the proven causes of risks to humans.

As can be seen, over the next ten years, genomics will have major consequences on the research work and tools available in health and safety, thus enabling ANSES and its partners to answer new research questions that have not yet been investigated.





# Yet more openness and data



# W

hile openness is one of ANSES's founding principles – reflected particularly in the composition of its Board of Administrators, which welcomes all stakeholders, and its governance structure – this issue is increasingly crucial and strategic. To extend and consolidate its role in the

construction of the health and safety system, the Agency is positioning itself dynamically and adapting its forums for dialogue and discussion to changes in both societal expectations and the challenges and forms of modes of expression.

The Charter on the openness to society of expertise, which ANSES initiated and signed in 2011 with six other public bodies involved in research, expert appraisal, and assessment of health and environmental risks, affirmed the need to forge closer relations and constantly improve interactions with civil society, consumer or employee groups, NGOs, and professional or trade union organisations. To enable a shared understanding of the complex issues, levels of scientific uncertainty, risk situations and alternatives for addressing them, the challenges now are to integrate the accelerated pace of information and knowledge production – now coming from a multitude of sources – and make the most of new modes of communication, and also to adapt to growing expectations in terms of the right to information – including access to raw data – and participation, as foreseen by the Aarhus Convention.

ANSES is strengthening and enhancing its relations with all its stakeholders and with civil society in the broader sense. Moreover, in the context of a digital transformation that is having a major impact on the production and dissemination of scientific information, it is placing the question of data firmly at the heart of its concerns.

## **Communicate the results and explain how they were produced**

Given its scope and the nature of its opinions, ANSES is confronted with strong expectations from the general public regarding information and clarification, relayed particularly by the media and elected officials. The Agency therefore implements a communication strategy aimed at both fully carrying out its tasks to raise alerts and support public policymaking, but also at producing accessible scientific information in order to inform its stakeholders and the public in a transparent manner, consolidate its credibility and thus strengthen trust. Being known and recognised is the guarantee of more effective scientific expert appraisal to benefit public policymaking.

The Agency's 2018–2022 goals and performance contract formally incorporates the commitment to communicate not only the conclusions and recommendations of the scientific expert appraisals it conducts, but also the foundations of its collective and adversarial scientific expert appraisals, the methodological principles adopted, and the internal rules on integrity and ethics. "The hierarchy of risks as perceived by the general public is [...]

[...] not necessarily the same as that prevailing within the scientific community", asserts Régine Boutrais, who is responsible for developing relations with stakeholders. "This is why it is not only a question of transparency, but also of the ability to explain our methodology and working framework, and to contribute to skills development among the actors."

Beyond sharing, this also implies engaging in dialogue, and ensuring that the knowledge and data produced are made available. The goal is thus to make data from its observatories and studies systematically available as open data.

In line with this idea of greater proximity, the Agency's opinions and recommendations – which are already systematically made public – are also intended to be made more accessible, to the extent that they are used to support public policymaking.

The Agency is part of the international open science movement, promoted at national level by the Ministry of Higher Education, Research and Innovation, which consists in disseminating research materials and results without any technical, legal, geographical or commercial obstacles, and ideally without any delay.

#### Adapting the forms of dialogue with stakeholders

Since its creation in 2010, ANSES has promoted openness to stakeholders as one of its four founding values, alongside the independence of expert appraisal, transparency and scientific excellence. The decree establishing the Agency thus specified that it must promote and nurture public debate by providing scientific knowledge.

The strategy of openness to stakeholders has therefore made it possible to rebalance – or at least redefine – asymmetries of information and power between stakeholders, by enabling new societal actors to engage in a philosophy of constructive dialogue. Many forums have thus been set up: thematic steering committees (food, environment, work, animal health and plant health) in support of the Board of Administrators; dialogue committees whose purpose is to exchange views on issues relating to the conduct of expert appraisals and research questions in support of expert appraisal; and finally, a platform for dialogue on marketing authorisations (MAs) for plant protection products. At the same time, the Agency has developed the use of hearings during the expert appraisal process, stakeholder reporting sessions when the work is published and public consultation on some of its work.

Changes in ANSES's activities and in the mapping and expectations of actors have led to the forms of dialogue being continuously adapted. New questions have also emerged, often at the frontier of ethical considerations. How can the Agency promote and develop dialogue with all stakeholders while preserving its independence from influencing strategies? How can the different intermediaries be identified and integrated when they are concerned by issues of both risk assessment and issuing of MAs? How can new means of communication be integrated into exchanges?

Ensuring a balance of representations requires the different categories of stakeholders to be clarified. This has been done as part of the adoption of a charter on relations with interested parties.



Explaining how expert appraisals are carried out.

Initially undertaken to organise discussions on the topic of plant protection products, this charter is expected to be extended. This is the task of the delegate for relations with the Agency's interested parties who, on the basis of the work of the Committee for Ethical Standards and Prevention of Conflicts of Interest, will also have to ensure application of a shared framework enabling the identification of the various categories of interested parties, the balance of representations, and also equitable access to the Agency's dialogue forums.

#### Aiming for citizen scientific data

If the public are now invited into the scientific debate, it is no longer only as recipients of information and explanations. With the multiplication of crowdsourcing initiatives and participatory science, citizens are becoming producers of data useful both to themselves and scientists. "This involvement of civil society is gradually gaining momentum," says Matthieu Schuler, who heads the risk assessment activity within the Agency's Science for Expertise Division. "We must consider this crowdsourcing and interact with it when engineering our activities. In the fields of environmental surveillance and anticipation of emerging risks, in order to broaden the field of expertise, it is essential to confront science with lay knowledge and enrich it through feedback from the field."

#### Enhancing scientific production and bringing research communities together

Research is the essential foundation of the risk assessment work carried out by ANSES and the basis for the legitimacy of its reference laboratories and assessment departments to fulfil their missions, in terms of detecting emerging threats and developing new analysis or assessment methods. In addition to the scientific skills of some of its staff, the Agency ensures this proximity through its research activities:

- as a research operator, through work mainly carried out in the Agency's nine laboratories;
- as a research planner, through the funding of research or

development work, within the framework of the National Research Programme for Environmental and Occupational Health.

Exploiting the results of these research activities with a view to disseminating knowledge is an important step in ANSES's national, European and international strategies.

Certain themes are primarily associated with this objective: for instance, enhancing vigilance and risk assessment activities in occupational health, as this activity requires an investment from all stakeholders, but also research funding, to raise awareness and bring research communities together in support of scientific expert appraisal.

### New data paradigms

The issue of openness is linked to another fundamental issue for the Agency: that of "data" in the broad sense. These data must first be accessed and shared with ANSES's scientific ecosystem, i.e. with all the other agencies and monitoring and vigilance schemes in France and abroad. It appears essential to interconnect all the databases and information systems, in order to consolidate the different courses of action by ensuring a form of sharing, particularly in the field of vigilance.

In addition, the question of the openness of scientific data is now being raised at international level, in line with an increasingly pressing demand. On this subject, a number of studies are underway at the French, European and global levels, including on the legal and legislative issues involved.

With the development of digital technology, the production of scientific and technical information from researchers, universities, companies and citizens has also grown exponentially over the past two decades. The volume of information generated is such that its exploitation brings us fully into the era of artificial intelligence. Questions arise about the media, uses and tools for processing this scientific and technical information. It can cover a wide range of data (including the notion of metadata) and serve different purposes: bibliometrics, analysis of scientific output, processing of data production by consumers, users, etc., for monitoring, surveillance or vigilance purposes. ANSES examines them with regard to the expert appraisal needs to be addressed as a priority.

### Artificial intelligence for real-time analysis

With connected objects, open data, cloud storage of information and data lakes accumulating huge volumes of various kinds of data, etc., we are facing rapid and profound technological change that is affecting the Agency's expert appraisal work. While technological acceleration is an undeniable challenge, it also brings new opportunities and new levers for action, particularly in terms of anticipating and detecting weak signals. It now enables knowledge to be generated in real time and emerging issues or signals to be identified at an earlier stage. The use of computer and statistical tools grouped under the term data mining has therefore become essential when it comes to strengthening monitoring, vigilance, surveillance and alert schemes. And above all, it is essential to be able to rely on the exponential advances in artificial intelligence and big data, whether for data mining



The charter on relations with interested parties was adopted in 2015.

to query databases on specific points, or for setting up systems able to detect "anomalies" revealing possible health and safety problems, in conjunction with our national partners, particularly the French Public Health Agency (SPF) and the French Health Products Safety Agency (ANSM).

In the long term, there is even the prospect of a real revolution in risk assessment. The progress of artificial intelligence, based on simultaneous access to different data flows, makes it possible to imagine ever more responsive assessment rationales, combining the almost instantaneous nature of algorithms with the necessary broader perspective obtained through human expertise. "It is obvious that we will not be managing knowledge in 2025 or 2030 in the same way that we were managing it in 2018," says Matthieu Schuler. "This is why we must look ahead today to how it will be produced, shared, assembled and exploited tomorrow." ●

"Informed opinion and active cooperation on the part of the public are of the utmost importance in the improvement of the health of the people."

Preamble to the Constitution of the World Health Organization



## Taking cumulative effects into account in health risk assessment

**Developed in 2005 by molecular biologist Christopher Wild** (former director of the International Agency for Research on Cancer) and the subject of numerous research projects since then, the concept of the "exposome" considers all type of exposure (environmental, dietary) – due to all types of adverse effects, whether chemical, physical or biological, or even psychosocial factors, and resulting from working conditions, living conditions and individual behaviour – in the assessment and identification of biological responses and subsequent health effects in terms of chronic diseases. The French Act of 28 January 2016 on the modernisation of the health system has introduced provisions in the Public Health Code referring to the concept of the exposome.

### Five determining factors must be taken into account

- the role of the accumulation of exposure over time, and the delayed nature of the emergence of certain health effects (particularly following chronic exposure);
- consideration of the "exposure window", based on the observation that the same exposure does not produce the same effects depending on the period of life in which the human being is exposed;
- the accumulation of external exposure, both in terms of stressors (physical, chemical, microbiological) and routes of exposure (ingestion, breathing, contact, etc.) leading to internal exposure of different organs and biological systems;
- the interaction between these stressors in the activation of adverse response pathways at cellular level, then in organs, leading to the expression of disease;
- the influence of psychosocial factors as determinants of exposure causes and trajectories.

**While it is readily accepted that each of these factors plays a part in the response of living beings** to the history of their exposure, their weight in this global response so far remains undetermined. This lack of knowledge is a source of uncertainty in public debates on sensitive topics such as chronic effects at low exposure doses or cocktail effects. The relevance of experimental models in determining dose-response relationships, confounding factors in epidemiological studies, the consideration of adjustments related to extrapolations (safety factors) in conventional toxicological approaches, etc. are all questions to which this concept ultimately aims to provide a response.

**To contribute to this, ANSES proposes systematically assessing the real consequences** of including the concept of the exposome to outline points of discussion and then action, with a view to developing and integrating this concept in the deployment of its activities and the skills to be mobilised: research and reference, surveillance and vigilance, risk assessment, authorisation and placing on the market of regulated products.

### 1 000 days

This is the *in utero* and early childhood period during which a child is particularly sensitive to environmental stimuli.

**The Agency is laying the methodological foundations** that will enable it to rank the priority mixtures of chemicals to be taken into account, and also to identify the methodological foundations for exploring the concept of the exposome and implementing it in its expert appraisal work. It is primarily a challenge as regards knowledge of exposure, as well as a methodological challenge for risk assessment. Taking the exposome into account also provides an opportunity to promote and exploit the integration of ANSES's various fields of expertise.



# EXPOSOME



## WHO WE ARE

A public administrative body founded in 2010 and accountable to five French Ministries: Agriculture, Consumer Affairs, the Environment, Health and Labour.

## OUR MISSION

### **Investigate, evaluate, protect**

ANSES's expertise covers risk assessment in the fields of food, the environment and work, supported by a network of nine laboratories, with a view to informing the public authorities on health issues.

The Agency is responsible for human, animal and plant health issues, subscribing to the concept of one health for the benefit of all. It assesses all the chemical, biological and physical risks to which humans may be exposed, intentionally or otherwise, at all ages and times of their lives, whether at work, while travelling, while engaging in leisure activities, or via their food. ANSES also issues marketing authorisations for plant protection products, biocides and veterinary medicinal products.

It relies on a form of governance that is open to all the stakeholders, and on dialogue committees whose mission is to inform the Agency about society's expectations in terms of risk assessment and research.

# An international reference brand

in scientific expertise for safeguarding health

**250**   
opinions and reports issued in response to formal requests in 2018

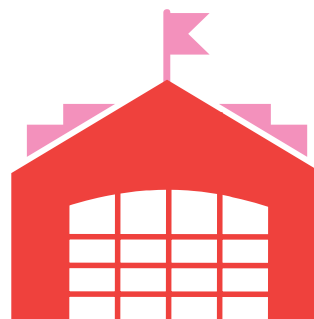
  
**5**  
vigilance schemes

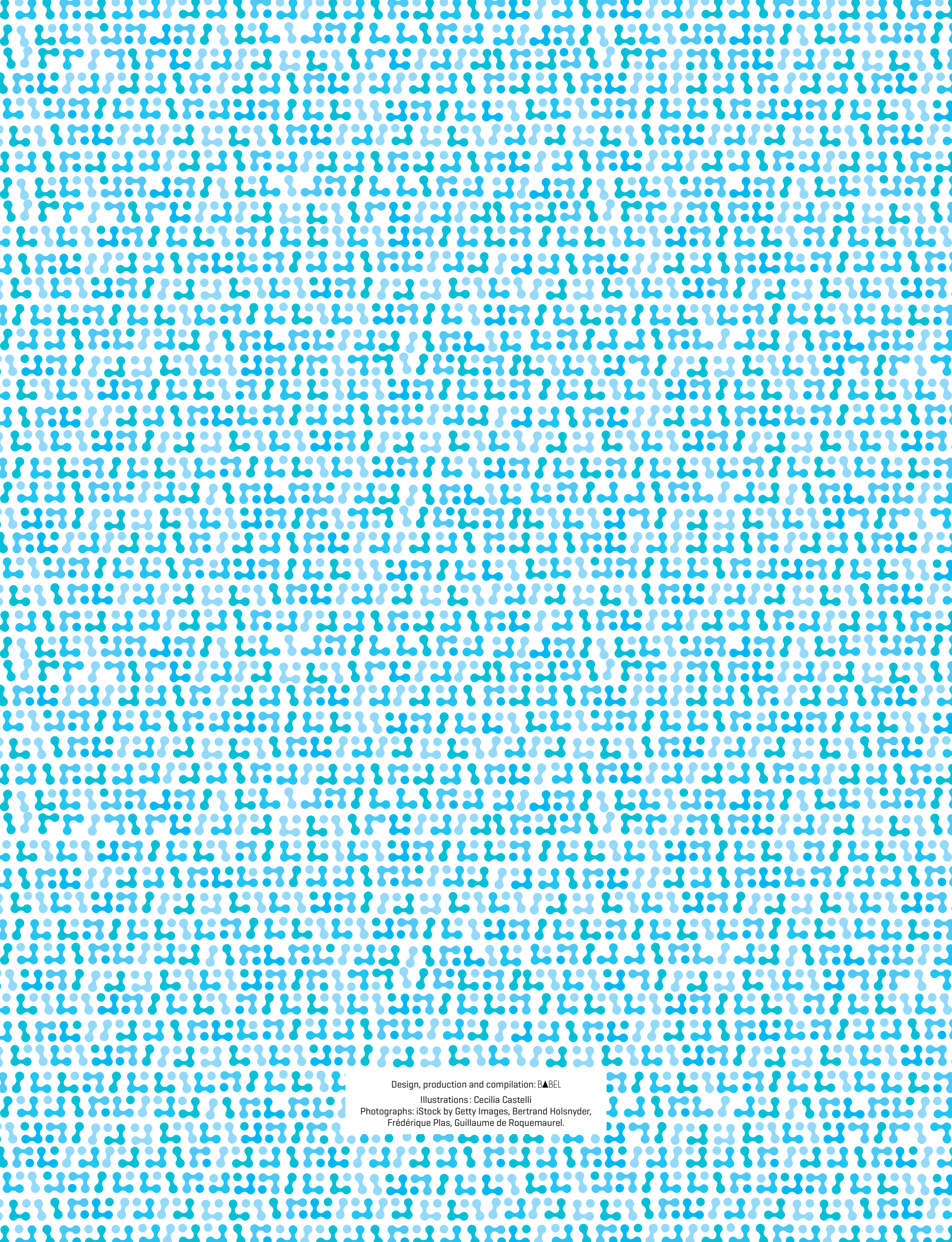
  
**4000**  
decisions issued each year in the field of regulated products

  
**1400**  
members of staff on 16 sites around France

**43**   
projects selected for funding under the 2018 calls for research projects for a total of 7.4 million euros

  
**793**  
international publications, of which 368 were category A and A+ in 2017

  
**37** scientific events organised in 2017



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French agency for food, environmental  
and occupational health & safety

*Investigate, evaluate, protect*

14 rue Pierre et Marie Curie  
94701 Maison-Alfort Cedex, France  
[www.anses.fr](http://www.anses.fr)

