



**Press file**

**ANSES work programme**

**for 2011**

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## Press release

### The French Agency for Food, Environmental and Occupational Health & Safety presents its work programme for 2011

ANSES's work programme for 2011 demonstrates its determination to address the scientific challenges raised by long-term, low-dose exposure to innumerable and varied sources of danger. It is fully in line with **the Agency's multidisciplinary and integrated approach**, which allows it to take into account, for its risk assessment work, all the potential hazards to which people are exposed, whether as workers, consumers or in their everyday lives.

In its presentation, ANSES highlights several new initiatives that contribute to the added value expected of the new Agency.

1. In the field of **phytosanitary products**, the Agency will be setting up **a study to assess the real impact of exposure to pesticides on agricultural workers**, using all the data available in the most recent scientific literature, regulatory assessments of products and substances, and data collected by the various vigilance schemes. The study will be able to exploit the skills of both the teams responsible for assessing products before they are authorised for marketing and which have now been brought together in a single Agency and the pesticide residue observatory.

This initiative will lead to **an expert group being set up in the course of 2011** to study the subject, following an open call for candidates, with the aim of producing initial results by the end of 2012.

2. Concerning **endocrine disruptors**, i.e. chemical substances capable of affecting the endocrine system at very low doses, the Agency has announced **a study on those sectors that use the main chemical products known to be potential endocrine disruptors**, with a view to estimating human exposure both in the working environment and *via* food and the general environment.

This study, which will last several years, will have at least two milestones in 2011, first next March (particularly concerning bisphenol A) and again at the end of the year. It will include international cooperation (particularly with our German and North-American counterparts), with a view to **developing new assessment methodologies** for risks recognised at an international level.

3. Concerning food, **before the summer of 2011 ANSES will publish the results of a study on the exposure of consumers to contaminants found in foods in the form of residues**. This study, known as EAT (for *Etude de l'Alimentation Totale*), covering more than 250 foods and 20,000 different marketed products that have been screened for approximately 300 potential contaminants, will enable an assessment of consumer exposure, to identify the principal changes over time from the latest available studies and to compare the results with prescribed regulatory limits.

In parallel with this study, research has been undertaken on **the effects on health of exposure to combinations of pesticide residues** and the initial results are expected in 2012.

4. Working at the interface between animal and human health, in 2011 ANSES will start **assessing the risk of the emergence of antimicrobial resistance due to the use of antibiotics for veterinary purposes**, for prophylactic, metaphylactic and therapeutic purposes for livestock, and their preventive and therapeutic use for pets.

This assessment is being done within the framework of the recently-formed **national veterinary commission for the rational use of antibiotics**, to whom the Agency will be reporting the results of its study.

5. To address the issue of the potentially harmful effects of radiofrequencies, ANSES has carried out several appraisals. Following on from this, in 2011 the Agency will set up a **permanent expert group on “Radiofrequencies & health”** whose mission will be to monitor in real time the latest scientific developments in this field.

Following the incorporation by ANSES of the *Fondation Santé et Radiofréquences* (Health and Radiofrequencies Foundation)<sup>1</sup>, a **research programme entitled “Health and Radiofrequencies”** will be set up with its own Scientific Board, in parallel with the environmental and occupational health programme, and an annual call for research projects will be launched. ANSES will also create an **outreach commission**, to act as a forum for all stakeholders concerned by this issue and ensure that the Agency is aware of the public’s concerns regarding research, expertise and information on radiofrequencies and health.

In line with its **principles of reaching out to all stakeholders**, ANSES held a series of consultations on various themes in October 2010, to discuss the directions that its work programme should take concerning each of its spheres of competence: occupational health, environmental health, food safety and animal health and welfare.

Lastly, ANSES has adopted a **deontological code** and a set of **fundamental principles for collective expert appraisal**, which can be consulted on its website, [www.anses.fr](http://www.anses.fr). To reinforce vigilance and ensure that these rules are strictly upheld, ANSES is setting up a **Commission for Ethical Standards and the Prevention of Conflicts of Interest**. This commission was created by the Board of Administrators on 8 February 2011 and will be operational by the end of April at the latest. All of ANSES’s governing bodies will thus be operational, giving it a solid basis with which to guarantee the values of **scientific rigour, independence, transparency and dialogue with stakeholders**, for the protection of civil society.

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<sup>1</sup> The *Fondation Santé et Radiofréquences* was created in 2005 at the suggestion of OPECTS (*Office parlementaire pour l'expertise des choix technologiques et scientifiques* – Parliamentary Commission for expertise on technological and scientific choice). Its missions were to define, promote and finance firstly programmes for epidemiological, experimental and sociological research into the effects of human exposure to radiofrequency electromagnetic fields, particularly as used in electronic communications, and secondly programmes for disseminating to professionals and the general public the knowledge acquired concerning these effects.

# 1- Work programme for 2011: strategic orientations

By combining food, environmental and occupational health issues in an integrated approach, ANSES aims to become more effective and to improve its services for a higher level of protection for citizens, consumers, workers and the environment, while adapting to new threats to animal and plant health.

There is now a regulatory framework for the Agency to carry out assessments of veterinary medical and phytosanitary products, fertilizers and biocides, as well as to monitor the implementation of the REACH and CLP Directives, which facilitates sharing of know-how and information.

One of the essential challenges for 2011 will be to develop cross-disciplinary cooperation between the Agency's different areas of expertise (the added value brought about by the merger) while allowing each one to maintain its specificities. ANSES intends to become a reference at national, European and international levels, based on:

- **Its ability to identify emerging risks and signs of potential threats to health**, and to provide decision-makers with information that is scientifically rigorous as well as practical and beneficial. This surveillance capability is supported by its internal and external scientific expertise, its position in European and international information exchange networks, and also its form of governance, which is open to society as a whole, to ensure that it takes into account the messages expressed by all stakeholders.

- **Implementing the best international practices concerning expert appraisal and risk governance**: to address the challenges of scientific excellence in expert appraisal, ANSES must take into account all aspects of shared progress made by authoritative international bodies and contribute to their future development. This may involve consolidating the fundamental values of expert appraisal (competence, independence, impartiality, transparency and a multi-disciplinary approach) and clarifying risk management choices as far as possible through a rigorous approach to the sociological, ethical and economic aspects of the subjects dealt with by the Agency, whenever required.

- **Its ability to deploy expertise rapidly** within its sphere of competence, and to respond to crisis situations.

- **Its resources for driving and supporting research** as far upstream as possible, when the available scientific knowledge is insufficient for a precise assessment of the risks. The ANSES model aims to combine the strengths represented on the one hand by its laboratories (responsiveness, data collection, knowledge production, national and European partnerships) and on the other by its position as the coordinator of a broad network of scientific organisations (R31) and by its calls for research proposals which are open to the entire scientific community and target emerging issues.

This is the basis on which the work programme for 2011 has been drawn up.

## 2- Work programme for 2011: focus on 5 key themes for 2011

### 2.1 Occupational exposure to pesticides

The French Agency for Food, Environmental and Occupational Health & Safety was created to be the State's authority bringing a cross-disciplinary approach to such issues as pesticide residues. The Agency is empowered to assess crop treatment (phytosanitary) products before and after they receive marketing authorisation, for setting the maximum admissible limits for residues in foodstuffs, for assessing biocide products and assessing and authorising veterinary medicinal products. It is therefore especially well equipped to investigate the health effects of pesticides and their residues, particularly as they concern occupational exposure.

Phytopharmaceuticals and biocides by their very nature contain active substances that can be detrimental to the environment and health. The methods for both using and assessing them are consequently closely regulated by law<sup>2</sup>. Over the last few years, this regulatory framework, which now applies at the European level, has been considerably tightened. Phytopharmaceutical preparations, the active substances of which they are composed and their use as pesticides are thus regularly reassessed according to increasingly strict criteria. In 20 years, the number of active substances authorised has been considerably reduced and almost 75% of molecules authorised 20 years ago have now been banned.

It is in this legislative framework that, before they can go to market, phytopharmaceutical products and biocides undergo a scientific assessment covering not only the efficacy of the substance involved but also the risks to users (farm workers, gardeners, etc.), consumers, the natural environment (soil, air, water) and living organisms (microorganisms in the soil, fauna and flora).

#### A body dedicated solely to the study of pesticide residues

The Agency has been given responsibility for running the Observatory for Pesticide Residues (ORP). The Observatory was set up in 2001 to compile, organise and optimise the use of the information and results produced by the monitoring and measurement of pesticide residues in different environments and in human foods.

The Observatory's first task was to build a network of partner organisations and to identify all available data on the use of pesticides and the presence of residues in the environment and in human foods. European requirements and those issuing from the *Grenelle* Environment Round Table have given the ORP a more important role, while also underlining its key mission. The ORP is mandated to coordinate efforts to define and set initial risk indicators as a basis for a quantitative assessment of the reduction of the impact of phytopharmaceutical products on the various compartments of the environment and on health. To achieve this, the ORP will be developing a 'pesticides' information system from which it will be possible to calculate the chosen indicators.

#### Risk assessment studies to be launched soon

In the framework of the French Ecophyto 2018 plan, the Observatory for Pesticide Residues has been given responsibility for compiling, proposing, and ultimately documenting the risk indicators and the impacts of phytosanitary products on the health of those working in the sector. In addition, the Agency has been consulted for the second French National Environment and Health Action Plan (*Plan National Santé-Environnement*) concerning work to improve the prevention and

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<sup>2</sup> Directive 91/414/EEC which is to be replaced by EC regulation no. 1107/2009 for phytosanitary products and Directive 98/8/EC for biocides.

mitigation of risks regarding the occupational exposure of seasonal agricultural workers to phytosanitary products.

The Agency aims to use these data and indicators, together with all the available field data and published studies (compiled by the body responsible for social security for French farmers – the *Mutualité Sociale Agricole* –, poison control centres, cohort data, etc.), scientific knowledge, ongoing collective expert appraisals by INSERM on pesticides and health, to **assess the real impact of exposure to phytosanitary products on agricultural workers**. These studies will lead to both improved risk assessment concerning the most closely affected agricultural workers, on the basis of the available data and publications, and to proposals for **improved documentation on exposure affecting these workers**.

ANSES also wishes to make a close examination of the means of protection for users and farm workers, with a view to reducing exposure to phytopharmaceutical products. In particular, this will entail **assessing the efficacy of personal protective clothing and equipment available on the market** in order to allow users of pesticides to identify easily, among the solutions available on the market, those whose technical characteristics guarantee a sufficient level of protection. The Agency will rank the most representative equipment on the market in terms of efficacy, both under operational field conditions and in the laboratory (in compliance with both current and upcoming standard protocols).

These studies should lead to recommendations for the revision of standard procedures that serve as models for assessing phytosanitary products prior to awarding them marketing authorisation.

This initiative will lead to **an expert group being set up in the course of 2011** to concentrate on the exposure of agricultural workers to pesticides, following an open call for candidates, with the aim of producing initial results by the end of 2012.

#### **A theme related to several other Agency activities**

The Agency also contributes to the **revision or creation of tables of occupational diseases** associated with the use of pesticides, as a member of a working group affiliated to the *Commission Supérieure des Maladies Professionnelles* (High Commission on Occupational Diseases [COSMAP]).

This working group will report on current relevant scientific knowledge from observations of pathologies with delayed effects, related to exposure to pesticides, and may recommend the revision or creation of tables of occupational diseases.

In the framework of its work on the **substitution** of carcinogenic, mutagenic and reprotoxic (CMR) substances, ANSES is considering finding substitutes for certain pesticides using substances listed among the priorities.

Lastly, *via* its **national Environmental and Occupational Health research programme**, ANSES supports research into the health effects of occupational exposure to pesticides. In 2010, four new projects received financial support through the Ecophyto 2018 plan:

- ✓ Continuing the cohort study, AGRICulture and CANcer
- ✓ *In silico/in vitro* approach to screening for endocrine disruption by pesticides in human reproductive tissues
- ✓ Human multiple exposure to pesticides: *in-vitro* assessment of metabolic and xeno-hormonal interactions

- ✓ Assessment of chronic exposure to pesticides: performance and optimisation of assays on urine and hair

ANSES will launch a call for research projects on 22 February, offering new financing opportunities to enhance our understanding of the health effects of exposure to pesticides.



## 2.2 Endocrine disruptors: developing new methodologies for risk assessment

Endocrine disruptors are natural or artificial chemical substances capable of interfering with the normal working of the endocrine glands, the organs responsible for secreting hormones. Disruptions to the normal working of the hormonal system can alter a variety of processes such as the production, use and storage of energy and, more widely, the regulation of the metabolism, and development. In addition, some of these substances are reprotoxic and detrimental to fertility, or can disrupt foetal development.

Although their toxic effects at high doses have been clearly established by studies in animals or by monitoring population groups exposed in the work environment, questions remain about their effects on human health at low doses. This is because traces of these compounds are found in the environment and an individual can be exposed to minute doses from multiple sources.

This involves exploring both the very long-term effects of minute doses of substances, found in a variety of environments (water, food, consumer products or items, etc.) and a wide variety of potential effects, which might have other causes.

The problem that arises is that our knowledge of the effects of these substances at doses found in the environment is limited by the current risk assessment methodologies, thus challenging us to develop new ones that are more suitable for the specific properties of these compounds.

### Involvement of the scientific community

At an international level, the OECD<sup>3</sup> has been focusing for many years now on the need to **develop protocols for toxicological and ecotoxicological assays** in order to detect effects related to endocrine disruptors and thus enable identification of the substances responsible. The Agency also participates in ongoing discussions concerning strategies for use of the different tests in order to broaden our knowledge of the effects associated with these chemical substances.

In 2009, the French Ministry of Health instructed various organisations (AFSSAPS, AFSSA, AFSSET, InVS, INPES) to investigate endocrine disruptors, each in its own sphere of competence. INSERM received a request to carry out a collective expert assessment on the effects of substances referred to as endocrine disruptors by listing and analysing all the available scientific literature.

INSERM identified the substances it considered as of concern because of their reprotoxicity and/or because they are endocrine disruptors, on the basis of which the Agency was requested to:

- rank the substances in terms of priority for investigation,
- identify the products and items containing reprotoxic or suspected reprotoxic substances (especially endocrine disruptors),
- analyse and, if possible, quantify the routes by which the general population is exposed to these substances. A specific analysis will be carried out concerning vulnerable populations and people exposed to these substances in an occupational context, via the use of products intended for the general public,

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<sup>3</sup> Organisation for Economic Co-operation and Development

- make a risk/benefit analysis (involving the health benefits claimed for certain products).

One of the ultimate objectives of this study is to identify possible substitutes for any products or substances that may have been shown to carry a health risk, while ensuring that any candidate substitutes identified have undergone **risk assessment** prior to authorisation.

The Agency has already carried out a first phase of screening uses in order to identify the chemical substances to be studied as a priority. After this initial analysis, a list of 12 priority substances was drawn up. The Agency has started **identifying the uses** of the substances concerned, by drawing on existing databases and sectoral surveys, in order to acquire feedback from users in the field.

**Toxicity assays for the substances, quantification of exposure and risk assessment** have been started, beginning with those substances that have been identified as high-priority.

This joint study will result in a series of risk assessment reports, each one specific to a given substance. It is likely to take several years and will have at least two milestones in 2011, first next March (particularly concerning bisphenol A) and again at the end of the year. It will include international cooperation (particularly with our German and North-American counterparts), with a view to **developing new risk assessment methodologies** for possible adoption at an international level.

### **Bisphenol A: a case study**

In parallel with this joint study of endocrine disruptors, the Agency is also carrying out a specific study of bisphenol A, to **assess the risks to consumers and users of end products or articles on sale to the public** and which contain this substance.

This involves listing the related hazards, identifying uses of the substance, characterising exposures, identifying potential substitutes and collecting available data on their toxicity and finally, in view of these various elements, determining whether it is possible and relevant to assess the health risks.

Concerning food-related risks, the Agency has published several Opinions and has noted in particular that the risk assessment methodology based on the notion of Tolerated Daily Intake is not the most suitable for compounds such as endocrine disruptors.

Several Opinions and results of international research studies on bisphenol A are currently expected (from the FDA, in particular). Scientific and regulatory monitoring has been set up by the Agency in order to keep abreast of developments.

## 2.3 Keeping food contaminants under surveillance

The issue of contaminants in foods often goes hand in hand with that of contaminants in the environment, as many substances found in the environment can also enter the food chain. Any attempt to study these issues therefore requires a cross-disciplinary approach. The comprehensive sweep of ANSES therefore offers an undeniable advantage.

Nowadays, food mostly arrives on our tables after a complex itinerary involving plant and animal production techniques and different transformation, conservation and distribution processes.

Several types of substance used in these processes (residues of phytopharmaceutical products and veterinary drugs, additives, contamination with substances from food-contact materials, etc.), or found in the environment (heavy metals, persistent organic pollutants such as dioxins, etc.) have undergone risk assessment, are regulated on the basis of these assessments and are monitored to identify any harmful effects to health.

The food sector is therefore one of the most strictly regulated and monitored, whether by producers and distributors (self-inspections) or by official monitoring authorities (monitoring and surveillance programmes set up by the Ministries of Health and Agriculture).

In this context, ANSES has adopted an all-round approach, known as "from the farm to fork", enabling it to intervene at every stage. It develops assaying methods, undertakes research work and scientifically assesses risks for products, processes and/or practices.

Its opinions provide guidance to the authorities for decisions on draft legislation, assessments of the safety of certain substances, products or processes prior to their receiving official marketing authorisation, the setting of standards regulating the presence of certain substances in foodstuffs, and support for developing monitoring and surveillance programmes by government bodies

In 2001, the Agency's cross-disciplinary approach will be particularly beneficial for the following tasks:

### **Monitoring the population's exposure to substances of interest in terms of public health**

To be able to undertake these risk assessments, it is essential that the Agency be able to base its assessment and recommendations on the analysis of a set of data that is as complete as possible, particularly including field data (data from vigilance schemes for monitoring possible pathologies and for contamination in food). For this purpose, the Agency has developed tools for calculating the actual exposure of consumers to contaminants, i.e. the amounts of contaminants consumed on a daily basis.

One of these, the second 'total food' or EAT study (for *Etude de l'Alimentation Totale*) is an analysis campaign led by ANSES that monitors the presence of a series of substances of interest for public health (heavy metals, pesticide residues, mycotoxins, etc.) in processed foods and in foods as they are normally consumed (washed, peeled, cooked). Several countries run such nation-wide surveys (USA, UK, Canada, Australia, New Zealand, Czech Republic, China, etc.), all using the same methodology, which facilitates international comparisons of consumer exposure.

The first 'total diet study' in France was carried out in 2000 jointly by INRA and AFSSA, with funding from the French Directorate General for Food. This study enabled an initial portrait of the

level of exposure of the French population to mycotoxins, trace elements and minerals found in foods "as they are eaten".

In 2006, the Agency launched a second 'EAT' study focusing on pesticide residues, trace elements and minerals, environmental contaminants, phytoestrogens, additives, acrylic amide and mycotoxins, all of which need to be characterised more thoroughly in terms of their potential impact on public health.

In this second campaign, ten times as many substances have been analysed and a wider panel of samples was taken in mainland France. Food was sampled for the study over 18 months, in 36 towns spread across 8 large regions and on 18 separate occasions, to take account both of regional disparities in contamination and of seasonal and annual variations. Eighty to ninety percent of the diet of adults and children was covered. More than 250 foods were chosen, 20,280 products purchased and analysed in 13 laboratories, which resulted in approximately 250,000 analytical results.

The data from EAT 2 are currently being interpreted and the results will be published by the summer of 2011 in a report that is expected to provide a wealth of information on the changes noted since the first EAT study. ANSES is now working on a European-level EAT and an EAT specifically concerning children's diets.

### The issue of multiple exposure and cocktail effects

Although it is important to monitor foods for a certain number of substances, it should be remembered that traces of contaminants does not necessarily mean that there is any danger to the health of consumers. After all, a very strict regulatory framework sets thresholds designed to mitigate the risk to consumers.

The question remains, however, of **combined (or 'cocktail') effects from simultaneous exposure to multiple contaminants** found as traces – and therefore at very low doses. It is therefore necessary to assess any effects caused by combinations of these substances.

The Agency has taken up this important challenge with a research project entitled PERICLES (financed by the National Research Agency – ANR) to determine the principle mixtures of pesticides to which the French population is exposed, together with their possible health effects.

PERICLES is intended to **develop statistical and toxicological methodological tools to improve our understanding of the combined effects of simultaneous exposure** when evaluating risks related to the presence of several chemical substances in food. Starting with the 79 pesticides most commonly found in foodstuffs, the Agency has identified the most frequent combinations. It has chosen seven cocktails, now being subjected by the INRA and ANSES research teams involved in the project to toxicology studies to identify any cocktail effects.

Initial results from the PERICLES project on the combined effects of exposure to multiple pollutants are expected for 2012.

## 2.4 ANSES at the forefront of the fight against the development of antimicrobial resistance

The development of resistance to antibiotics is considered, both at European level and beyond, as a major concern for human and animal health, as it raises questions about the efficacy of these drugs. In the veterinary field, this issue has given rise to a European-level strategic plan that was drawn up by the Heads of Drugs Agencies and launched during the French presidency of the European Union.

AFSSA, which became ANSES in July 2010, has been working on this issue for almost ten years. One landmark was the publication, in 2006, of the report of a collective expert appraisal entitled *Usage vétérinaire des antibiotiques, résistance bactérienne et conséquences pour la santé humaine* ("The veterinary use of antibiotics, bacterial resistance and implications for human health"), whose recommendations are today more pertinent than ever.

In order to coordinate and to draw the greatest benefit from the efforts of all the players involved, the Ministries of Agriculture and Health, working in close cooperation with ANSES, have decided to set up a national veterinary committee to promote the rational use of antibiotics: it will meet early in 2011 to draw up a plan of action.

In this context, ANSES is mobilising all its research and risk assessment resources, to identify the most appropriate measures for a determined effort to combat the selection, emergence and spread of antimicrobial resistance. This policy is in line with the initiatives taken at European level and is based on international recommendations for monitoring and research, as the issue is a global one.

It is pursuing three priority themes:

### 1. Collecting data for better identification of uses in the various sectors

- Since 1999, the French Agency for Veterinary Medicinal Products (ANMV) and the French Union for the Veterinary Medicinal Product and Reagent Industry (SIMV) have run a **national scheme for monitoring the sales of veterinary drugs** containing antibiotics. The most recent analysis shows that sales of veterinary medicinal products shrank between 2008 and 2009. It also shows that sales of fluoroquinolones levelled off while sales of cephalosporins fell. This study will continue in 2011 and the results will be published at the end of the year.
- ANSES laboratories study usage practices for each sector, and measure the prevalence of antimicrobial resistance in animals, in foods of animal origin and in the environment.

### 2. Research for a better understanding of the mechanisms at work

- In the poultry sector, research financed by the ANR is under way to assess the risk related to the development of strains of ***Campylobacter* resistant to fluoroquinolones** compared to the therapeutic benefits expected by countering avian colibacillosis. In order to assess whether it would be appropriate to ban the use of these antibiotics in poultry farming, as some countries, including the United States, have done, the aim of this research is to scientifically evaluate the consequences of the use of fluoroquinolones in

this agricultural sector, taking into account their advantages as compared to other types of treatment. This project will conclude at the end of 2011.

- Early in 2011, ANSES will launch a research project to assess the impact, in terms of antimicrobial resistance, of practices involving the use of **cephalosporins in hatcheries**, which have occasionally been observed. Third generation cephalosporins are antibiotics widely used in human medicine.
- The ANSES 2011 call for research projects could include work on the **mechanisms by which resistance is transmitted within non-cultivable intestinal flora**, to improve understanding of the way antimicrobial resistance develops in humans through the food chain, especially *via* products imported from certain regions of the world.

### **3. An assessment of the risks related to the use of antibiotics in veterinary medicine with a view to making recommendations for public authorities and prescribers**

Europe banned the use of growth-promoting antibiotics in stock breeding in 2003. In order to go one step further in preserving the efficacy of antibiotics by using them rationally in veterinary medicine, it is necessary to scientifically assess the risks of the emergence of antimicrobial resistance, related to the ways antibiotics are used in veterinary medicine, for prophylactic, metaphylactic<sup>4</sup> or therapeutic purposes with livestock and for preventive and therapeutic uses with pets.

The assessment will particularly focus on the most sensitive categories of antibiotics: cephalosporins and fluoroquinolones. The use of these molecules has increased considerably in recent years with the availability of generic versions.

The study will cover human exposure to antimicrobial-resistant commensal bacteria, whether indirectly, via foodstuffs (especially imported foods), or directly, as for breeders and pet-owners.

ANSES will be mobilising its expert collective groups to prepare scientifically-based recommendations for the authorities and prescribers of antibiotics by the end of 2011.

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<sup>4</sup> Metaphylaxis: timely treatment of groups of animals

## 2.5 Radiofrequencies

To address the questions raised by the use of radiofrequencies, ANSES has carried out several expert appraisals concerning their effects on health, publishing three opinions and reports on the subject in 2003, 2005 and 2009. In 2009 the Agency also published an opinion and a report dealing specifically with Radio Frequency Identification (RFID) systems. Since then, several new studies on the subject have appeared, new research work on the mechanisms for interaction between the body and radiofrequencies and on their biological effects has been undertaken or pursued, and the subject has continued to stimulate public debate.

Furthermore, following on from the “Radiofrequencies, Health and the Environment” roundtable organised by the government in 2009, it was decided to transfer the responsibilities of the Health and Radiofrequencies Foundation to ANSES.

As a result, in order to pursue its analytical work in the field of radiofrequencies and carry on the activities of the Health and Radiofrequencies Foundation<sup>5</sup>, ANSES plans to:

### **Set up a permanent Radiofrequencies & Health working group**

A call for candidates from which to select a dozen experts (specialists in risk assessment, metrology and dosimetry, human biology and physiology, epidemiology, and in the sociology of science and expertise, etc.) was published on 1 December 2010.

This working group will be attached to the “Physical agents, new technologies, and development areas” CES and it will:

- publish annual bulletins to update collective expertise on the health effects of radiofrequencies;
- address specific requests for scientific and technical support on this theme;
- make annual recommendations for research themes to be included in the Agency’s calls for research projects, specific to radiofrequencies;
- help inform stakeholders of the results of new research, thus contributing to the public debate on the theme of radiofrequencies.

### **Create a “Health and Radiofrequencies” research programme**

An amendment to the government’s finance bill for 2011 introduces an additional element to the tax on radio stations of as much as 5% (to be set by ministerial order). Two million Euros of the

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<sup>5</sup> The *Fondation Santé et Radiofréquences* was created in 2005 at the suggestion of OPECTS (*Office parlementaire pour l’expertise des choix technologiques et scientifiques* – Parliamentary Commission for expertise on technological and scientific choices). Its missions were to define, promote and finance firstly programmes for epidemiological, experimental and sociological research into the effects of human exposure to radiofrequency electromagnetic fields, particularly as used in electronic communications, and secondly programmes for disseminating to professionals and the general public the knowledge acquired concerning these effects.

sum yielded by this tax will be granted to ANSES each year, to help it finance and organise research activities in this field.

A research programme entitled “Health and Radiofrequencies” will be set up with its own Scientific Board alongside the Environmental and Occupational Health programme (EST). As part of this programme, there will be an annual call for research projects in this field, following the same timetable as those for the EST programme.

### **Setting up an outreach commission**

The purpose of this outreach commission will be to keep the Agency informed (and thus both the Radiofrequencies & Health working group and the Scientific Board for the “Health and Radiofrequencies” research programme) of what society expects in terms of research, expertise and information about radiofrequencies and health.

All stakeholders will be represented (associations, operators and manufacturers, local authorities and trades unions).

It will meet two or three times a year. The agenda for these meetings will include: progress reports on the work of the Radiofrequencies & Health working group and an update on the projects financed by the “Health and Radiofrequencies” research programme. Members of the commission will be able to question ANSES about both the research and expertise activities.



### 3- The governance of ANSES

The founding principles of ANSES are excellence, independence, and transparency. In order to ensure that these values are upheld at every level of its activities, the Agency has installed a series of mechanisms, some of them inherited from the Agencies from which it was formed, others developed during the process that led to the creation of ANSES.

#### A new model of governance, designed to guarantee independence

The new agency will be taking great care to keep lines of communication permanently open for dialogue with French civil society. With a view to designing a new model of governance allowing a greater say to society as a whole, the process for creating the Agency involved discussions with all the stakeholders and also the personnel of the agencies that were to merge. The result is an original form of governance, with stronger guarantees about the impartiality of the assessments made, as well as the dialogue with civil society and the players concerned. The merger process drew on the acquired knowledge, culture and strengths of each of the founding bodies, to invent a new way of operating. The new agency thus benefited from all the best aspects of the two original entities.

The Agency's Board of Administrators now has **five colleges** bringing together representatives of the State, various associations, professional bodies, trade unions and elected officials. Half of the voting rights are attributed to the members of the college of State representatives and half to the other members. Another original feature is that the Board of Administrators has established **thematic steering committees** that include non-ANSES experts who are highly involved in and/or strongly identified with specific trends in society as a whole. These committees help to define ANSES policies for these major themes and oversee the use of resources allocated to each one. There are four themes: environmental health, occupational health, food safety, and animal health and welfare.

Another innovation is that ANSES can also receive requests from several types of interested parties: the State, stakeholders and trade unions. The Agency can also undertake studies on its own initiative.

#### Expert appraisal with 'transparency' as its watchword

The Agency respects the fundamental principle of keeping risk evaluation separate from risk management, which is the domain of the State. ANSES assesses risks, issues its opinions and recommendations to the authorities, systematically publishes its reports and opinions, but takes no decisions. Risk management remains firmly in the hands of the public authorities.

To ensure that it formulates effective public health recommendations, ANSES takes an independent and multi-disciplinary approach to assessing risks and benefits to health by including contributions from the human and social sciences. It applies **collective scientific, technical and multi-disciplinary expertise** through more than 20 expert committees, mobilising close to 800 outside experts. These experts are selected after **public calls for candidates**, for their scientific competence and after examination of any potential conflicts of interest.

All experts working for the Agency must provide a **public declaration of interest**, which is published on the Agency's website, and must also not fail to update their declarations should their situation change in any way. ANSES expert appraisals are carried out in compliance with French standard **NFX 50-110, "Quality in expert activities – general requirements of competence for expert appraisals"**, guaranteeing traceability for the entire process including discussions, and all the Agency's work is made public.

At the end of 2010, the Agency published its **Code of ethical standards governing expert appraisals and the fundamental principles and key aspects of the way expert appraisals are carried out** at ANSES, with which all those involved in the expert appraisal process are required to comply. Moreover, as a further step towards its desired aim of total transparency, **the Agency recently published the declarations of interest of all of its own personnel involved in the expert appraisal process**. These can be viewed on the website along with those of the external experts.

### **A Commission for Ethical Standards and the Prevention of Conflicts of Interest set up in 2011**

In order to guarantee the quality of its expert appraisals, ANSES now has an audit mechanism and a dedicated body, the Commission for Ethical Standards and the Prevention of Conflicts of Interest, which is responsible for dealing with particularly complex situations and evaluating decisions which have been brought into question or raised doubts.

The Commission for Ethical Standards and the Prevention of Conflicts of Interest is a major innovation in the ANSES system of governance, defined in the Agency's founding charter. It can intervene in any situation and at each of the stages of expert appraisal, from the initial Formal Request through to the Opinion issued by ANSES.

The Commission for Ethical Standards and the Prevention of Conflicts of Interest can be petitioned by a member of the Board of Administrators, of the Scientific Board, of the Expert Committees or by the Director General or any other ANSES employee.

It is empowered to collect all the necessary evidence for its investigation and to interview third parties who might inform its decision. It sends its opinions and recommendations to the petitioning individual or organisation as well as to the Agency's Board of Administrators and Director General. The latter then informs the supervising Ministries.

The **Commission for Ethical Standards and the Prevention of Conflicts of Interest** was formally created by the Board of Administrators on 8 February 2011, and will be set up by the end of April 2011. It will include five to eight well-known figures recognised for their knowledge and expertise in ethical matters. The committee members, appointed for a period of five years by Ministerial Order, will not be allowed to intervene in any of the Agency's other bodies or activities.

## 4- Key dates for 2011

- 19-27 February 2011: Paris International Agricultural Show
- 8 April 2011: Inauguration of the ANSES Plant Health Laboratory, Angers
- 10 May 2011: ANSES scientific meetings: “From MSDs to nanoparticles, new hazards in environmental and occupational health”.
- 17-21 May 2011: International Conference on Surveillance in Animal Health, Lyon
- 23 June 2011: Symposium on “Regulation policies for chemical substances. Incidence and ripple effects of the REACH Directive”, organised in partnership with the Sustainable Development Chair at *Sciences Po*
- 13-16 September 2011: International Livestock Trade Fair (SPACE)
- October: Meetings on occupational health
- 12-13 December: INCa-ANSES symposium on “Cancers and environmental exposure. New data”

### **A look back in figures to the first 6 months of ANSES**

- 1044 opinions and reports published
- 162 requests received
- 1,200,000 visits to the website [www.anses.fr](http://www.anses.fr)

In addition, the Agency publishes 250 scientific papers a year.

Get the latest news from ANSES by subscribing to its newsletter on the website.

## **5- ANSES, a new public health authority**

The French Agency for Food, Environmental and Occupational Health & Safety was created on 1 July 2010 following the merger of two French health agencies, AFSSA, the French Food Safety Agency and AFSSET, the French Agency for Environmental and Occupational Health Safety. In taking over their respective missions, ANSES offers a broad, cross-functional, global perspective on health issues and is thus able to gain a more comprehensive understanding of the risks to which people may be exposed through their lifestyles and consumption patterns, or the characteristics of their environment, including the workplace.

### **Preserving human, animal and plant health**

In terms of human health, ANSES covers three fields: food, the environment and work. Its mission is also to evaluate risks to animal and plant health. On the basis of its scientific reports, it formulates opinions and recommendations for the public authorities.

### **Guaranteeing food safety and quality**

The Agency evaluates health and nutritional risks throughout the agrifood sector. It evaluates the nutritional properties of substances used in human food and animal feed, as well as the related advantages. It monitors food consumption patterns and their evolutions and identifies the most exposed populations. Finally it evaluates the safety and quality of water intended for human consumption.

### **Assessing health risks related to the environment**

Health and the environment are closely related. ANSES evaluates the impact of the environment on human health in order to better identify the health risks related to pollution of the life-supporting environments (air, water, soil). It intervenes in several specific fields: cancer and the environment, exposure to biological, chemical and physical agents and regulations governing the use of hazardous chemical substances.

### **Assessing occupational health risks**

Nowadays people are increasingly preoccupied with exposure to occupational diseases and the delayed risks related to working with chemical substances such as those found in nanomaterials or asbestos. ANSES studies exposure mechanisms in the workplace and the specific health risks affecting different professions, using innovative methods and tools for assessment. As a member of the National Network for Monitoring and Prevention of Occupational Diseases (RNV3P), ANSES plays an active role in extending our knowledge of hazards and exposure in the workplace, and also in defining vigilance strategies.