French agency for food, environmental and occupational health & safety

Press Kit

New missions for ANSES in the area of plant protection products, fertilisers and growing media

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Maisons-Alfort, 1 July 2015

Press release

New missions for ANSES relating to plant protection products, fertilisers and growing media

Since 2010, ANSES has been carrying out its risk assessment, reference and research missions in the areas of human, animal and plant health guided by two essential principles: rigour and independence of its scientific expertise; transparency and openness, respecting the role of each party.

The Agency has now been entrusted with new missions: the management of marketing authorisations for plant protection products, fertilisers, growing media and adjuvants, as well as the establishment of a "phytopharmacovigilance" scheme to monitor the effects of these products on human health, animal and plant life, and the environment.

Today it is presenting the organisational structures it has set up to ensure that the broadening of its missions will provide new ways to contribute to better protection of health and the environment, while preserving its current values (an integrative approach to risks, independence, transparency and openness to society), which are the basis of its credibility and usefulness to citizens.

Bisphenol A, Schmallenberg virus, radiofrequencies, nanomaterials, risks associated with the consumption of food supplements or energy drinks, antimicrobial resistance, bee health: in an ever-changing health context, ANSES is constantly required to adapt and to address an endless variety of topics, some of which are controversial.

Today, after five years in operation, its field of expertise is being broadened. The French Act on the future of agriculture, food and forestry, adopted on 13 October 2014, entrusts ANSES with the management of marketing authorisations for plant protection products, fertilisers, growing media and adjuvants. These authorisations have until now been issued by the Ministry of Agriculture.

A new organisational structure to preserve the independence of scientific assessment and improve transparency in the decision-making process

As soon as the Act on the future of agriculture was adopted, in October 2014, the Agency began a process of consultation with all the stakeholders, in order to develop the best configuration for adjusting its structure and operation, in a fully transparent manner, while ensuring that its current values remain intact.

To **guarantee the functional separation between the scientific assessment of dossiers and the issuing of authorisations,** the decision was taken to create two separate departments that would be independent of each other, and to **establish guidelines** that set out the criteria to be taken into account in the decision-making process for marketing authorisations (MA), based on the result of the scientific assessment, and in compliance with the requirements of the European regulations.

In addition, in accordance with the Act, a **committee to monitor marketing authorisations** will also be set up. This advisory structure will provide the Agency's management with an additional perspective on scientific appraisal, in particular to ensure that the risk management measures imposed in the framework of the MAs are feasible and effective in a real situation, with regard to the constraints of practices on the ground.

The Agency has also been asked to establish a **phytopharmacovigilance** scheme, starting in 2015. Its aim is to take better account of data, reports and feedback from the field in risk assessment, management of marketing authorisations and post-MA monitoring of products. Moreover, the Agency's own resources for funding studies and research are being reinforced.

The MA decisions taken will be made public *via* **the register of decisions,** which can be accessed from the ANSES website. The Agency is also working to redesign the **E-Phy website**, which presents all the authorised products, as well as the information included in the decisions on authorisation conditions (uses, restrictions, associated management measures, etc.).

Finally, the Agency is drawing up a **charter on relations with interest groups**, to prevent any risk of interference in the Agency's assessment and decision-making processes, while remaining faithful to its willingness to engage in dialogue.

Major ongoing risk assessment work

In the framework of the phytopharmacovigilance (PPV) scheme, the Agency has already initiated many projects: it has compiled a list of all the organisations collecting data that could fall within the scope of PPV, with a view to entering into agreements to clarify arrangements for transmitting these data; it is launching a study seeking to better assess pesticide exposure in people living close to agricultural areas; and it has also begun work to exploit all the toxicovigilance data on the impact of plant protection products on human health. This latter initiative will help target the products and substances to be prioritised in terms of post-approval monitoring.

In addition, several risk assessments are in progress, the results of which are expected in the short or medium term. In particular, two major reports are expected this year on (i) the issue of co-exposure of bees to pesticides and pathogens as a factor in bee mortality; and on (ii) the analysis of all the available data on farm workers' exposure to pesticides under real conditions, in order to improve, where appropriate, the models used in the regulatory framework.

The Agency is also continuing Pesti'home, the first national study on domestic uses of products designed to eliminate pests in and around the home, in mainland France, Guadeloupe, Martinique and La Réunion, as well as the infant total diet study, which will further our understanding of the contaminants to which children under three are exposed via food.

Finally, an expert appraisal is in progress in order to define the terms for the nationwide surveillance of pesticides in ambient air; its objective is to establish a priority list of 10 to 20 substances to be monitored in the ambient air in mainland France and the overseas territories.

In addition, the ministries recently requested that ANSES undertake two expert appraisals, on neonicotinoids and glyphosate.

New missions as from 1 July 2015

Issuing of marketing authorisations for products

Since 2006, ANSES has been responsible for assessing plant protection products, fertilisers, growing media and adjuvants, in accordance with the criteria defined by the European regulations. Marketing authorisations (MAs) are then issued on the basis of this scientific assessment of the risks and effectiveness of the products. As from 1 July, in application of the French Act on the future of agriculture, food and forestry of 13 October 2014, ANSES becomes responsible for issuing MAs and permits for plant protection products, fertilisers, growing media and adjuvants, a mission that was previously carried out by the Ministry of Agriculture.

- **What are these new missions?**

Article 51 of Act No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry provides for the transfer of new responsibilities to ANSES.
A decree on the conditions under which the Agency is to exercise its new missions relating to plant protection products and their adjuvants specifies the technical arrangements for this transfer. It revises Chapter III of Title V of Book II of the French Rural and Maritime Fishing Code in order to stipulate the adjustments made necessary by the transfer.

The text lays out how responsibility will be shared between the Minister of Agriculture and the Director General of ANSES. Accordingly, the Director General of ANSES now has the authority to issue MAs as well as permits for experimentation and parallel trade.

On the other hand, the Minister of Agriculture retains responsibility for issuing decisions on authorisation of 120-day derogations, as referred to in Article 53 of Regulation (EC) No 1107/2009.

A declarative system is also being introduced to replace the prior authorisation for certain MA amendments of an administrative nature, with the aim of simplifying procedures for which an assessment by the Agency is unnecessary.

In addition, the draft decree removes the time limits stipulated for the assessment by ANSES on the one hand, and the management by the Ministry of Agriculture on the other. An overall time limit will now apply. How the time is broken down between assessment and management will now be a matter of internal organisation at the Agency.

Finally, the text implements shorter procedural deadlines for the assessment and authorisation of biocontrol products.

Similarly, a decree on the placing on the market and use of fertilisers, adjuvants for fertilisers and growing media (collectively known in French as MFSCs) amends the procedures for obtaining MA and permits for MFSCs following the transfer of responsibility for issuing, amending and withdrawing these authorisations and permits to the Director General of ANSES.
This decree implements Order No. 2015-615 of 4 June 2015 on the placing on the market and use of fertilisers, adjuvants for fertilisers and growing media, which itself implements Article 55 Paragraph 2 of Act No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry.

It amends Chapter V of Title V of Book II of the French Rural and Maritime Fishing Code.

The procedures are broadly similar to those laid down for plant protection products. Like the draft decree on plant protection products, the MFSC decree replaces ANSES's opinions with the conclusions of the assessment and determines the overall deadline until the final decision, without distinguishing between assessment and management. The same declarative system is being introduced for amendments of an administrative nature.
In addition, the draft decree removes the option of issuing provisional authorisations for sale.

Some key figures on the work

Each year, around 2000 decisions are taken in total, but they relate to a variety of different dossiers: decisions of an administrative nature, decisions on parallel imports, new MAs, extensions of existing MAs, re-examinations of MAs (every ten years).

- **A new organisation to guarantee transparency**

These new responsibilities are an important development for the Agency, whose missions until now related primarily to the area of scientific expertise, under the principle of separation between risk assessment and risk management. The Agency has put in place a new organisational structure which aims to respond to two major issues:

- ***Preserve the independence of ANSES's scientific expertise***

The transfer of authorisation decisions must not call into question ANSES's scientific expertise work, its independence with regard to any particular interest, and the transparency of its processes. It is therefore important to ensure, through the Agency's internal processes, a functional separation between scientific assessment and management decisions.

- ***Improve the overall performance of the scheme***

This is one of the declared objectives of combining the entire MA dossier processing chain in a single body. In particular, this development should enable better management of the overall deadline for dealing with dossiers, and more rapid and systematic updating of information on the status of the authorisations via a completely redesigned website, in the framework of strict and transparent application of European and French regulations.

Strengthening study and research capabilities

ANSES now has new resources for funding studies in addition to those conducted by the applicants in their marketing authorisation application dossiers. These studies may focus on the contamination of different media, human health, animal and plant health and the environment. They may also examine the conditions of use of the plant protection products, such as the use of protective equipment.

A new organisation: two separate departments

To ensure a functional separation between the assessment of products and the management of their marketing, the Agency has two quite separate departments: a Regulated Products Assessment department (DEPR) and an MA department (DAMM).

- **Assessment of products prior to placing them on the market**

Before they are placed on the market, plant protection products, fertilisers and growing media, biocides and adjuvants are assessed within the Regulated Products Assessment department, in the framework of European Regulation (EC) No 1107/2009 whose provisions apply to Member States.

This assessment takes place in two stages:

1. Assessment of the hazards and risks associated with active substances used in the composition of plant protection products, and of their effectiveness, is conducted at European level. This phase is coordinated at this level by the European Food Safety Authority (EFSA), based on a collective assessment conducted by the Member States (ANSES for France).
2. The second step involves assessing the risks and effectiveness of commercial preparations, according to the uniform principles of European regulations.

Since June 2011, plant protection preparations have been assessed not by each Member State, but by geographical zone. The European Union has been divided into three zones. France belongs to the South Zone, along with Bulgaria, Greece, Spain, Italy, Cyprus, Malta and Portugal. Within the same zone, manufacturers wishing to apply for authorisation of a plant protection preparation can submit their dossier to any Member State in the zone. The assessment conducted by the chosen Member State then applies to all other countries in the zone.

The conditions under which the dossiers must be submitted by the manufacturer, as well as the elements subject to assessment, are determined very precisely. The studies to be provided, as well as the conditions under which they are conducted (numbers of animals, conditions of exposure, duration, etc.), are themselves defined in European guidelines. Similarly, the health agencies' assessment methods, the steps to be followed and the decision criteria to be examined are defined in guides common to the various Member States, in order to ensure that assessment is harmonised between them. The Agency's assessment is therefore based on the studies provided by the manufacturers in support of their authorisation applications, but also on any other data available from the literature, from studies carried out directly by the Agency, and data obtained from the field in the context of vigilance and surveillance schemes.

Following the work to assess a plant protection preparation, the Regulated Products Assessment department (DEPR) endorses, under its own responsibility, a document entitled "Conclusion of the assessment", which specifies, for each criterion of the uniform principles, whether or not the result complies with the requirements of European regulations. This document, which is systematically published in support of the MA decision, is itself a summary of a much more detailed document in English (the Registration Report), required by the European regulations. In the interests of transparency, part of the Registration Report will be published on the Agency's website, as well as the conclusions (in French) of the assessment.

- **Issuing of marketing authorisations (MA) for products**

This new mission for the Agency begins on 1 July 2015 and will be carried out by the recently established MA department (DAMM). This department is now responsible for implementing the regulatory provisions relating to the issuing, amendment and withdrawal of marketing authorisations for products.

It is made up of two units:

- The administrative appraisal unit, the applicants' single point of contact for their contractual and administrative relationship with the Agency, responsible for verifying the admissibility of the dossiers and dealing with applications of a purely administrative nature;
- The MA decisions unit, in charge of preparing the MA decisions, according to the guidelines drawn up by the Agency, with the support of the MA monitoring committee provided for under the Act, if necessary. It also monitors MAs and their renewal.

The MA department is supported by:

- **guidelines** concerning the process of deciding on marketing authorisation for products. The aim is to improve transparency, by clarifying which cases may require further examination in addition to an assessment of the dossiers, mainly with regard to the risk management measures integrated in the MA decisions.

Guidelines to improve transparency, readability and efficiency in the decision-making process

With the aim of clarifying the criteria that determine whether or not authorisation is granted for plant protection products, fertilisers, growing media and adjuvants, the Agency has established guidelines for the appraisal of decisions relating to marketing authorisations. These guidelines, concerning plant protection products on the one hand, and fertilisers and growing media on the other, were submitted for public consultation until 5 June 2015, in order to obtain comments from the public. These guidelines are intended to clarify the criteria that enable the Agency to exercise its discretionary powers, on the basis of the scientific assessment of the MA application dossiers, carried out in accordance with the regulations.

- **an MA monitoring committee**, as provided for under the Act, and which will be formally established in the autumn. This committee may be consulted on the following issues:
    - The conditions under which risk management measures regarding marketing authorisations would apply;
    - The safety of use of products in relation to human health and the environment;
    - The agronomic and socio-economic benefits of the different plant protection solutions available in line with the principles of agroecology, including biocontrol solutions;
    - The use of data from the phytopharmacovigilance scheme;
    - The identification of priority subjects for study regarding the use of plant protection products and adjuvants, fertilisers and growing media;

- The identification of priority subjects in terms of control of production, formulation, packaging and labelling of plant protection products and adjuvants, fertilisers and growing media;

This monitoring committee will bring together key individuals with knowledge and experience of field practice and of the difficulties encountered when implementing MAs under real conditions.

- **a memorandum of understanding** with the ministry departments in charge of controls on the ground, to coordinate the actions of the ministries and ANSES in terms of product inspection and control.

The DAMM is also contributing to the establishment of a **comparative assessment of the products** available on the market, in the context of new provisions of the European regulation due to come into force in the summer of 2015.

Drafting of a charter on relations with interest groups, in order to preserve the Agency's independence

Discussions have begun with the Agency's Committee for ethical standards and prevention of conflicts of interest to establish a charter for relations between ANSES and the different interest groups, aimed at ensuring the traceability of any exchanges with interested parties in contact with the Agency, and to prevent any risk of its independence being called into question. The ethics committee recommends highlighting the principles of transparency, traceability, pluralism and equity of access, while remaining faithful to the Agency's willingness to engage in dialogue.

Phytopharmacovigilance, a scheme to improve post-authorisation monitoring

Several recent reports (in particular the Senate mission on plant protection products) have pointed out shortcomings in the scheme in place until now, in particular the weakness of post-MA monitoring. In this regard, the Act on the future of agriculture provides for the strengthening of post-MA monitoring schemes, mainly through the establishment in 2015 of a phytopharmacovigilance scheme, which should ensure that better account is taken of lessons learned from the field in risk assessment and the management of marketing authorisations.

ANSES has been entrusted with setting up the phytopharmacovigilance scheme. Its main objective is to monitor the adverse effects of plant protection products on human health (general population and workers), the health of ecosystems, livestock and flora, and contamination of environmental media. This scheme includes monitoring for the emergence of resistance phenomena.

For the Agency, the phytopharmacovigilance scheme constitutes its main source of information on the impacts, on the ground, on a daily basis, of decisions taken with regard to marketing authorisation of products.

It relies in part on the existing surveillance and vigilance systems. An inventory of these various systems was conducted by the Agency in 2014 and proposals were made to optimise them for the benefit of phytopharmacovigilance.

ANSES is also relying on the achievements of the Observatory for Pesticide Residues (ORP), and on the **launch of independent new studies**.

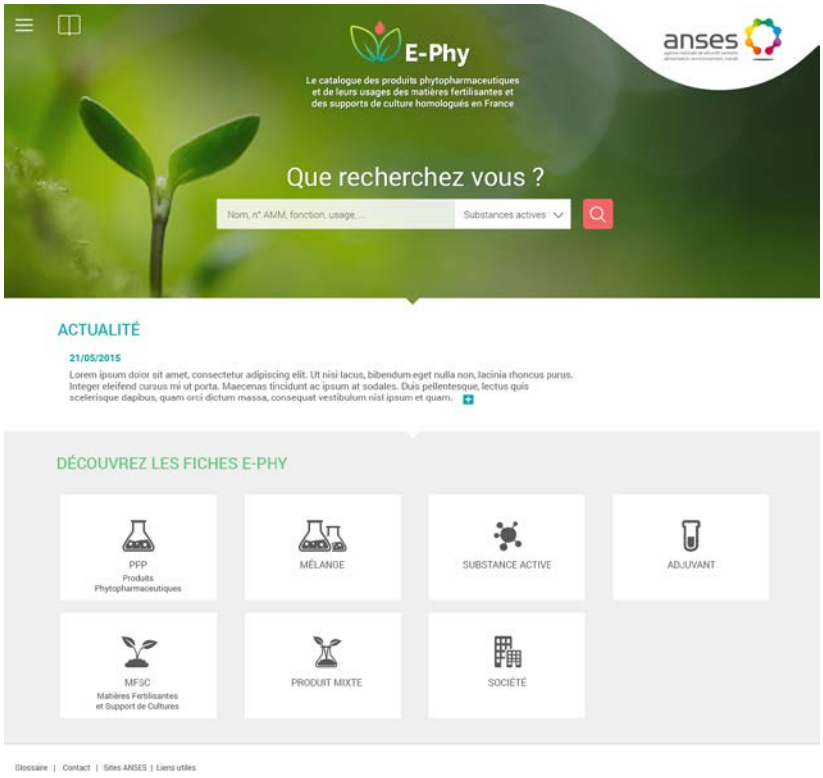
Better understanding of the exposure of residents in agricultural areas

In the framework of its phytopharmacovigilance scheme, ANSES is working to set up a study with the aim of better assessing pesticide exposure in people living close to agricultural areas.

A dedicated tool: the new E-Phy

E-Phy is a catalogue of all the plant protection products, adjuvants, fertilisers and growing media, and their associated uses, authorised in France. This database lists all the products authorised in France and their associated authorised uses. E-Phy is recognised as the gold standard by farmers, horticulturists, gardeners, and their suppliers and prescribers, but also by anyone interested in ecosystems, as well as manufacturers, scientists and the media. ANSES has been tasked with redesigning the E-Phy website, whose interface and technology had become outdated, in order to make it more user-friendly and offer features that correspond to the current standards. The new site will be available by the end of 2015.

The new E-Phy website will contain information on authorised products and substances: its aim will be to provide information both for professionals and the general public. Each product's characteristics and conditions of use, as defined in ANSES's opinions and decisions, will be referenced here. The site will also provide additional information that is more general in scope, for example on good practices and post-authorisation monitoring of products. The database will nevertheless remain the focal point of the site.



Another new feature on the ANSES website

A register of decisions on the Agency's website will show the public all the decisions taken concerning plant protection products, adjuvants, mixtures, fertilisers and growing media, and combination products. There will be improvements compared to the current system.

A comprehensive approach to the risks associated with plant protection products

When ANSES was created, it led to the emergence of a central player on the theme of chemicals in the broad sense and crop treatment products in particular. The Agency provides the competent authorities with the expertise and scientific and technical support needed to assess chemicals and the risks they pose to humans via all routes of exposure: food, ways of life and consumption patterns, or the characteristics of their environment, including at work. Understanding chemicals and their hazards is a major part of the Agency's work and requires close links to be maintained between the work carried out in the "occupational health", "environmental health" and "food safety" areas.

ANSES and crop treatment products

The assessment of plant protection products, fertilisers and growing media prior to placing them on the market, as well as the monitoring of their impacts on human, animal or environmental health, and of their residues in food and the environment, are major public health and environmental priorities.

To address these issues, the Agency mobilises its Regulated Products Assessment department, its Risk Assessment department and its laboratories in Lyon, Fougères and Maisons-Alfort (Laboratory for Food Safety) as well as its Plant Health Laboratory. In this context, the Agency:

- **assesses the effectiveness and the risks of plant protection products (commercial preparations), fertilisers and growing media for humans and the environment, before they can be placed on the market;**
- **assesses the risks to human health associated with exposure to plant protection products after they have been placed on the market;**
- **assesses** the risks associated with the use of **macro-organisms** likely to contribute to the biological control of pathogens and pests of trees and plants;
- **participates, on a European scale,** in the assessment of the **active substances** in plant protection products and the establishment of acceptable **maximum residue limits** in foods;
- **monitors the emergence of resistance to plant protection products;**
- conducts **monitoring** and **alert** missions and **collective expert appraisals** with the aim of **assessing the risks to plant health** of plant pathogens, pests, weeds and invasive plants affecting cultivated and forestry plants**.** It issues **opinions** responding to specific questions, as well as risk analyses, in particular **pest risk analyses** (PRAs), which enable the State to determine whether a harmful organism should be regulated or deregulated, as well as the nature of any plant health measures to be taken in its regard;
- **develops methods for identifying harmful organisms** and supports the State in coordinating a surveillance network;
- **quarantines plants** that are prohibited on European territory, and which have been introduced for the purposes of research for selecting new varieties;
- **provides support for the controls carried out by the French authorities** on the presence of pesticide residues in foodstuffs and helps develop surveillance plans;

- **consolidates and exploits data on the presence of pesticide residues in the environment and food,** including in drinking water, in the framework of the French Observatory for Pesticide Residues (ORP);
- **conducts studies and research** on dietary exposure to pesticides. It develops experimental models and analytical methods relating to the impact of pesticides on human health and the effects of multiple exposures.

Assessment of post-marketing authorisation risks: the Agency's tools

- Among the missions of the Risk Assessment department, the Observatory for Pesticide Residues centralises data on the presence of pesticides in different media

The Observatory for Pesticide Residues (ORP) collects, organises and optimises the use of information and results from testing and measurement of pesticide residues in different environments and in products consumed by humans. The first task of this organisation, created in 2003, was to build a network of partners and to identify all available data on pesticide use and the presence of residues in the environment and in 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. As part of the Ecophyto plan, the ORP has been mandated to coordinate efforts to define and determine initial risk indicators as a basis for a quantitative assessment of the reduction achieved in the impact of plant protection products on the various compartments of the environment and on health.

- Phytopharmacovigilance to characterise the possible effects of products after they have been placed on the market

The Act on the future of farming entrusts ANSES with strengthening post-MA monitoring systems, in particular through the establishment of a phytopharmacovigilance scheme. A phytopharmacovigilance unit has been created within ANSES's Risk Assessment department to bring together the various skills needed to organise expertise, exploiting the data from the various surveillance and vigilance networks of use to phytopharmacovigilance.

- Total diet studies to monitor population exposure to contaminants

In June 2011, ANSES published the results of its **second Total Diet Study** (TDS 2), an analysis campaign conducted periodically to monitor the presence of a series of substances of interest in terms of public health (heavy metals, pesticide residues, mycotoxins, etc.) in processed foods and foods as consumed (washed, peeled, cooked). Cross-referenced with data on food consumption, the contamination data are used to monitor the actual exposure of populations to these substances. On a hitherto unmatched scale, this second Total Diet Study (TDS 2) produced **the largest picture ever of the nutritional intake and dietary exposure to chemicals** of the population in France. In general, it confirmed adequate levels of control of the health risks associated with the potential presence of chemical contaminants in foods in France. However, for certain population groups, the study also highlighted areas where vigilance is required with regard to certain substances.

The findings of this work, which was funded with support from the French ministries for agriculture, health and consumer affairs, as well as a contribution from the French Observatory

for Pesticide Residues, have been used in a number of ways, such as the development of new analytical methods to improve detection of certain substances, the analysis of the study results on a regional level, and the screening for other contaminants (endocrine disruptors, drug residues) in the food samples stored as part of the study. In parallel, in 2011 ANSES initiated an infant TDS (on the diet of children from 0 to 3 years of age), the results of which will be available at the end of this year, and is also working to develop a European TDS.

- Assessing the impact of plant protection products on farm workers

When it was first created, ANSES issued an internal request to address two aspects of the problem of actual exposure of agricultural workers to pesticides: an *a posteriori* assessment of the risks to workers in order to propose targeted and proportionate actions to reduce or eliminate exposure and, at the same time, an assessment of personal protective equipment (PPE).

Concerning the first aspect, four main objectives were set:

- to characterise the categories of farm workers potentially exposed to pesticides in relation with the different agricultural production systems, how these affect specific agricultural tasks, and the resulting exposure;
- to identify and describe the jobs responsible for direct and indirect exposure (treatment residues in treated areas);
- to collect and analyse the available knowledge on exposure levels for these situations;
- to correlate exposure data with health data.

The work on this topic was initiated in 2011, starting, in particular, with the definition of the worker population to study. The corresponding working group was formed in early 2012.

In addition, in October 2014, ANSES published an opinion in response to its internal request relating to the effectiveness of work clothing and PPE worn by applicators of plant protection products. In the context of marketing authorisation for plant protection products (Regulation (EC) No 1107/2009), ANSES systematically assesses the risk associated with the use of these products. According to the general principles of the French Labour Code, the priority preventive measures consist in removing the hazard at the source or substituting hazardous products (in particular carcinogenic, mutagenic and reprotoxic [CMR] products). Then, when possible, collective preventive measures and adaptation of the work station are required. However, sometimes the risk is only acceptable when these measures are supplemented by the wearing of personal protective equipment (PPE).

Some PPE provides high levels of performance. However, this equipment is not always worn, mainly because it is uncomfortable and due to constraints inherent to the work activity. Therefore, in its Opinion, the Agency proposes a series of recommendations on good practice to prevent risks associated with exposure to plant protection products.

Supporting research

In the framework of its mission to coordinate and support research, ANSES supports, via the "Occupational and Environmental Health" call for research projects (APR) issued each year, projects that focus particularly on the effects of pesticides on worker health.

Furthermore, the question of "mixture effects" is a major challenge for ANSES. In order to provide answers to this central question, it conducted the Pericles project. This research programme, funded by the ANR, aimed to develop methods for determining the main mixtures of pesticides to which the French population is actually exposed through food, and understanding the potential combined effects of the substances contained in these cocktails.

The results of these tests are currently being interpreted and discussions on them in light of the different work conducted elsewhere at international level are ongoing. It is however a vast and complex challenge, requiring a great effort in terms of scientific investment and collaborative work by the international community, and still remains at the research stage, even if the science is advancing.

Some ongoing and future work on plant protection products

When ANSES was created, it led to the emergence of a central player on the theme of chemicals in the broad sense and crop treatment products in particular. The assessment of plant protection products, fertilisers and growing media prior to placing them on the market, as well as the monitoring of their impacts on human, animal or environmental health, and of their residues in food and the environment, are major public health and environmental priorities.

The Agency has already begun work in the framework of its phytopharmacovigilance scheme: in particular it is working to set up a study with the aim of better assessing pesticide exposure in people living close to agricultural areas. It has also launched a toxicovigilance study on plant protection products in order to target products and substances of priority in terms of post-approval monitoring (the Vigiphyto study).
In addition, several risk assessments are in progress, the results of which are expected in the short or medium term. They include an opinion and report on co-exposure of bees to stress factors.

On the "occupational health" topic, ANSES is conducting an expert appraisal on the issue of actual exposure of agricultural workers to pesticides.

At the same time, the Agency, through its Observatory for Pesticide Residues, is conducting Pesti'home, the first national study on domestic uses of products for the elimination of pests in and around the home, in mainland France, Guadeloupe, Martinique and La Réunion.

The end of the year should also see the results of the infant Total Diet Study, which will further our understanding of the contaminants to which children under three are exposed via food.

An expert appraisal is in progress to define the terms for the nationwide surveillance of pesticides in ambient air; its objective is to establish a priority list of 10 to 20 substances to be monitored in the ambient air in mainland France and the overseas territories.

In addition, the ministries recently requested that ANSES undertake two expert appraisals, on neonicotinoids and glyphosate.

Biocontrol: how is ANSES involved?

Phytopharmaceuticals (preparations designed to protect plants) and crop products are active substances that can be harmful to the environment or health. Their assessment as well as their marketing are therefore strictly regulated in order to ensure that they are safe to use and also to guarantee their agronomic utility. Alongside these "conventional" products, other types of products are being developed. These especially include "biocontrol" products: micro-organisms, chemical mediators and substances of natural origin. Biocontrol products, identified as a means of achieving the objectives of the Ecophyto plan, can be used as an alternative to plant protection products derived from synthetic chemistry. While the principles of biological control promote the use of processes and interactions that already exist in nature, these products can potentially present a risk, especially for the environment. ANSES has therefore been made responsible for assessing these products.

Biological pest control products include macro-organisms (insects, mites or nematodes), plant protection products containing micro-organisms (fungi, bacteria, viruses), chemical mediators such as sex pheromones (chemicals produced by insects that play a role in sexual attraction) and natural substances (of plant, animal or mineral origin).

These products aim to protect plants through the processes and interactions that govern inter-species relationships (controlling insect pests through the introduction of parasitoid insects, or introducing a non-pathogenic fungus into the environment which competes with a fungal plant pathogen) or which stimulate the natural defences of plants. The biological control principle is therefore not founded on eradication but rather on managing the equilibrium between populations of plant pests. These products have the advantage that they generally have little impact on the environment and human health.

While the principles of biological control promote the use of processes and interactions that already exist in nature, these products can potentially present a risk, especially for the environment, and cannot be exempted from assessment by ANSES, which is also working to make it easier to place them on the market.

Facilitating the marketing of biocontrol products: ANSES's work

ANSES plays an active role in facilitating the marketing of biological control products. On a regulatory level, it actively participated in defining the guideline adopted by the European Commission in 2013 for exempting certain products from the Maximum Residue Limits when they present a low risk for consumers, thus facilitating their marketing authorisation (for example heptamaloxyloglucan, laminarin, sulphur).

As a rapporteur Member State, it plays an important role in the European assessment of active micro-organism-based substances (8 substance dossiers in progress).

As one of its priorities, it assesses marketing authorisation applications for biocontrol projects (36 dossiers in progress).

In an opinion published in 2012, it also issued proposals for adapting the risk assessment procedures for biocontrol-based plant protection products and, in particular, for pheromone-based products.

Lastly, it participates in working groups on the methodologies to be applied in experimentation on certain types of these products.

Entry into the country and introduction into the environment of macro-organisms: ANSES's work

The introduction of non-indigenous macro-organisms (i.e. those not found naturally in the country) can present risks to the environment (through the introduction of invasive species for example) and therefore requires a regulatory framework. In 2012, a procedure for applying for and issuing authorisations for the entry into the country and introduction into the environment of non-indigenous macro-organisms that are beneficial to plants, especially within the framework of biological control, was established by the authorities. At the national level, this procedure is based on an assessment of the environmental plant health risk (with regard to biodiversity) as well as the effectiveness and benefits of the use of the macro-organism. ANSES has been tasked with this assessment mission.

The authorities have also provided for the creation of a list of macro-organisms introduced into the environment on the date the process was instigated. In fact, those macro-organisms that had been regularly introduced in the environment prior to this date, and which do not present any particular risk, may be exempted from applying for authorisation for introduction into the environment.

ANSES was tasked with drafting this list, based on declarations by companies marketing these types of macro-organisms and by research and experimentation laboratories and centres. To date, the list contains 448 macro-organisms. It can be found in the Agency's opinion on a request for simplified assessment of the environmental and plant health risk for a list of non-indigenous macro-organisms beneficial to plants.

The Pesti'home study, a national first

Pesticides are substances and preparations used to prevent, control or eliminate organisms considered undesirable. Plants, animals and fungi are destroyed by their action; they may be used for agricultural purposes or by individuals in their homes. Given their role, some biocidal products and human and veterinary antiparasitics can therefore be regarded as pesticides, in the same way as products for agricultural uses, or those intended for the maintenance of green spaces (plant protection products). While studies are regularly conducted on population exposure to pesticides for agricultural uses, there are no representative data for the French population concerning exposure to products used in the home, in the garden or to treat animals. In July 2014, ANSES therefore launched the first national study on this subject. It was followed in January 2015 by a second phase in Guadeloupe, Martinique and La Réunion.

This vast data collection operation is being funded by the ministries of ecology, health and agriculture, primarily as part of the Ecophyto plan. ANSES's Observatory for Pesticide Residues (ORP) is leading the study, which aims to collect data on the use of products designed to eliminate pests (insects, mites, rodents, lice, weeds, etc.) or to treat plants (insects, fungi, diseases). The study concerns products that can be used inside or around the home, including those applied on pets.

The results of this work are essential to estimate the exposure of the French population to pesticides. They will supplement existing studies on exposure via food and those related to occupational uses of these products. The information derived from this study is fundamental for defining public health priorities.

Its results will be published during 2016.

Who?

2100 homes, selected at random in Guadeloupe, Martinique, La Réunion and mainland France.

Where?

180 municipalities chosen at random from across these territories.