

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 results of scientific assessment, and in compliance with the requirements of the European regulations.

In addition, in accordance with the law, 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 (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.