December 2015

ANSES priorities for 2016

Background

Looking beyond 2015, a year that saw ANSES take on responsibility for issuing marketing authorisations for plant protection products, fertilisers and growing media on 1 July, along with implementation of the phytopharmacovigilance system, in 2016 the Agency will be given new missions: as of 1 January, **management of the toxicovigilance system** ensured by the Institute for Public Health Surveillance (InVS) until now, then on 1 July 2016, **issuing of marketing authorisations for biocides**.

The challenge in taking on these new missions is to make them a driving force to promote **better protection of health, plants and the environment**, while maintaining the Agency's achievements in terms of scientific excellence, an integrated approach to risks, independence, transparency, and openness to society, which all underlie its credibility and its usefulness in serving the population. The **new Deputy Director General for Regulated Products** will be in charge of these extended missions. She will be tasked with managing and coordinating cross-functional processes implemented for assessment, granting of MAs, and surveillance and vigilance (post-MA monitoring), while maintaining the responsibilities of each of the entities: Regulated Products Assessment department (DEPR), Market Authorisations department - Plant Protection Products and Fertilisers (DAMM), and the Risk Assessment department (DER) for phytopharmacovigilance, mission for "alerts and health monitoring" in toxicovigilance. She is also in charge of promoting experience sharing between these groups and the Agency for Veterinary Medicinal Products (ANMV).

In parallel, the Agency will need to adjust to the new priorities set by the major national plans, including the **National Environment and Health Action Plan** (PNSE3) and the new **Occupational Health Plan** (PST3), as well as deployment of the new health framework for animal and plant health, with a **reinforced contribution to surveillance from national reference laboratories (NRLs)**. The Risk Assessment Department and the respective laboratories will also contribute to implementation of the **Interministerial Action Plan for Food**. 2016 will also be marked by a **review of the scientific activities of laboratories**, which takes place every four years, and by the implementation of **new budget and accounting rules**, known as GBCP[1].

These are the main changes on the agenda for the new year, while ANSES continues the missions and activities of each of its entities.

1 Gestion budgétaire et comptable publique

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1. Management and coordination of toxicovigilance

The Health Bill, under discussion in Parliament, includes creation of a new Agency in 2016 – the National Agency for Public Health (ANSP) – by merging the InVS with the National Institute for Prevention and Health Education (INPES) and the National Establishment for Preparation and Response to Health Emergencies (EPRUS).

In view of the respective missions of ANSES and the future ANSP, it was decided to **transfer management of toxicovigilance from the InVS to ANSES**: this involves handling reports of adverse effects on health related to toxic products, collected by poison control centres (CAP-TV) located in major hospitals. ANSES is interested in the collected data for the information they provide on the effects of biocides, plant protection products and other chemical products.

This transfer is planned for **1 January 2016**. Management of toxicovigilance will be undertaken by the mission for “alerts and health monitoring” at the Agency, with the **creation of two positions and a dedicated budget** (about 1 million Euros per year) provided by transfer from the InVS, and therefore neutral in terms of ANSES’s other activities. This transfer will include:

- **major revamping of the information system** enabling access to data collected in the centres and facilitating data analysis;
- **a change in governance of the toxicovigilance (TV) system** to find a suitable balance in terms of resources based on the needs of the ministries and agencies;
- **appropriate in-house coordination between the "alerts and health monitoring" mission and all the entities interested in TV data** (DEPR, DAMM, Phytopharmacovigilance, and other units within the DER).

2. Transfer of MA decisions for biocides

The DDADUE Act of 2 December 2015 concerning provisions for adaptation to European Union law in the area of risk prevention marked the transfer to ANSES of the responsibility for issuing marketing authorisations for biocides.

Effective transfer is planned for 1 July 2016. The organisation implemented for transfer of MAs for plant protection products, fertilisers and growing media already included the possibility of taking responsibility for biocides, with the same principle of functional separation between risk assessment and management through the two departments in place, the DEPR and the DAMM, with the ability to adjust processes to the specificities of biocides.

A large-scale project to prepare for this transfer will be launched by the Biocides coordination unit of the DEPR, working with the DAMM and the Legal Affairs Unit, under the responsibility of the Deputy Director General for Regulated Products and in close liaison with the Directorate General for Risk Prevention (DGPR – Ministry for Ecology), which was responsible for biocide MAs until now. Additional funding has been granted by the DGPR to carry out the transfer in order to finance adaptation of the information system and to give the Agency the ability to fund targeted studies, like the process implemented for pesticides and fertilisers as part of phytopharmacovigilance.

3. Strategic European position of the ANMV

Europe has a strong presence within the activities of the Agency for Veterinary Medicinal Products (ANMV), since MA procedures are mainly European, at 90%. MA applicants can

select a so-called “Reference Member State” that manages the assessment, the other countries then being considered “Member States concerned”. Its role as a Reference Member State is one of the factors that underlies the strong position of France in Europe and recognition of its high level of health expertise. The presence of experts from France on the Committee for Medicinal Products for Veterinary Use (CVMP) and in the working groups of the European Agency is a second factor for international recognition.

In this context, the current revision of European regulations is of vital importance for the future of the ANMV and it is important for it to participate actively in negotiations, in support of the ministries. In parallel, an analysis of the factors underlying the ANMV’s position in Europe, and its strengths and weaknesses, will help to determine how to develop its strategic position in the future and to reinforce the position of France within the network of European agencies.

4. Four-yearly review of the scientific activities of laboratories

Every four years, the Agency voluntarily submits to a collective evaluation of the scientific activities of its laboratories by external reviewers, with support from its Scientific Board. This process enables ANSES to have an **independent diagnosis**, identify its strengths and areas for improvement, gain insight into the quality and originality of its activities internationally, and more generally provide food for thought concerning revision and adaptation of priorities and strategic objectives, specifically in terms of allocation of resources and new missions. Taking into account the conclusions of these assessments is therefore **a key factor in developing the scientific strategy of laboratories**.

In 2016, ANSES will thus organise an external review that will concern the activities that took place over the 2012-2015 period and prospectively the current four-year scientific programme for 2015-2018. This evaluation will be conducted according to the principles of the High Council for Evaluation of Research and Higher Education (HCERES). It will involve all the scientific activities of the laboratories (reference, research, expert appraisal, and contribution to surveillance).

5. Modernisation of facilities and scientific equipment

2016 will also see **functional implementation of the I^3 infectiology platform in Maisons-Alfort**, aimed in particular at compliance with regulatory standards concerning foot-and-mouth disease and at developing activities on other viruses that affect animals and that require a high level of containment. This will be a major step in the efforts to bring the Maisons-Alfort facility in line with scientific developments, the need for technical modernisation, and adaptation to regulations, within the limits of budget constraints.

Moreover, and depending on the required external funding, **the Boulogne-sur-Mer site of the Laboratory for Food Safety will be remodelled and extended** in 2016. The aim is to bring together the ANSES team in Boulogne-sur-Mer and the "Agrofood and aquatic products" team of the University of the Littoral Côte d'Opale at one facility to strengthen co-funding and existing synergies in the area of quality and hygiene of fish and aquaculture products.

Likewise, the Ploufragan/Plouzané Laboratory, as part of the CPER 2015-2018 State-Region plan, will **develop new facilities for "precision poultry farming"** to continue to ensure the best conditions for its studies on animal health and welfare in relation to farming conditions. The improvements will result in a decrease in the experiment workspace while modernising scientific equipment, making it possible to consider opening to local and national research organisations.

In the area of scientific equipment, efforts will be continued to acquire new tools and reinforce pooling of resources needed to successfully complete the laboratories' missions in both research and reference activities. These efforts are intended to **maintain the analytical capacity of the teams**, which requires updated equipment, and **ensure access to and understanding of new materials and technologies with significant potential**: reference laboratories need to propose new analytical methods that are more effective in terms of reliability and cost.

Lastly, the **ANMV** will continue the process of building a new facility to bring together all its staff and to be nearer the Fougères Laboratory. This will improve functioning of the two ANSES groups on the Fougères site by increasing proximity of support services for all the staff on the site. This project, co-funded by the local territorial authority, is part of the Brittany CPER 2015-2018 State-Region plan.

6. Adoption of new budget and accounting rules (GBCP)

The Decree of 7 November 2012 on budgetary management and public accounting (GBCP) renews the budgetary authority voted by the decision-making body through the introduction of the concepts of commitment authorisation (AE) and payment appropriations (CP) enabling better management of the organisation's expenses.

This helps enhance the financial situation by supplementing general accrual accounting by budgetary accounting providing an overview of the commitments made and greater cash-flow visibility.

In practice, for ANSES and all other public establishments, this change in budgetary accounting involves a new information system for budget and accounting management, as well as a change in procedures. This is a major project that has required considerable input from support services at ANSES since mid-2014 and that will continue throughout 2016.

7. Implementation of the risk management policy by all groups within ANSES

Further to implementation of the risk management system and initial feedback and evaluations carried out by the Audit and Evaluation Unit (CAE), effective adoption of the risk approach by all groups within ANSES as part of its specific missions has been identified as a key factor for success.

Adoption is planned through:

- consolidated risk management practices shared by all sites and explicitly described in joint documents, such as guides and audit guidelines, etc.;
- **cascading of risk mapping on each site**, depending on its context and missions;
- use of tools from the quality management system to enable each department to lead risk evaluation and management activities locally (objectives, planning, evaluation of results), in line with the national scheme.

A project leader will be nominated before the end of the year to carry out this mission in 2016.

8. Renewal of the governing bodies

Lastly, three bodies are to be renewed in 2016:

- **the Committee for Ethical Standards**: the mandate of the eight current members will come to an end on 9 March 2016, after five years of work and 11 opinions issued to date;
- **the Board of Administrators**: the mandate of the members of colleges 2 to 6 will come to an end on 9 October 2016;
- **the Scientific Board**: the 24 scientific experts on the Scientific Board as well as the three scientific personnel representatives on the board have a mandate that ends on 21 October 2016.

In addition, the three-year mandate of the members of the **Audit and Evaluation Unit** will terminate at the end of 2015. Proposals will be made to the Board of Administrators on the actions required following this initial trial period, with the aim of involving the Board more directly in policies of internal control and risk management at the Agency.