ANSES Policy Orientations
in the field of animal health, welfare and nutrition for 2016

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1. Background

ANSES is the only animal health agency of its kind in Europe, combining risk assessment for animal health and welfare, assessment and management of veterinary medicinal products, assessment and management of plant protection products and soon of biocides, assessment of environmental and occupational health risks for humans, and research and reference laboratories for monitoring and analysing pathogens and toxins. This alliance between laboratories and animal facilities, its practical experience in the field, and its expert appraisal and inspection activities in the field of veterinary medicine, calling on many internal and external scientists, means that when required, the Agency can rapidly mobilise its resources in its areas of expertise. It therefore provides the State with vital aid in establishing and supporting the implementation of risk management measures.

2. Decisive factors behind the achievements of 2015

Of all the actions carried out as part of the Agency’s work in animal health, the following stand out:

2.1 Emerging animal diseases

- In the area of honeybee diseases, the emergence of a previously exotic pathogen in the south of Italy in the autumn of 2014, the small hive beetle (Aethina tumida), is a concern for the European health authorities. A scientist from the Agency's European Reference Laboratory assisted the Italian authorities in the management and evaluation of the many cases. In the same field, in the spring of 2015 the EURL for bee health published the second report from the European Epilobee survey (2013-2014 campaign) which concludes that there was a relative decline in the winter mortality of bees (from 2.4% to 15.4% compared with from 3.2% to 32.4% the previous winter). Studies are continuing in 2015-2016 by multivariate analysis of the data obtained over two seasons, in order to highlight the major risk factors for bee mortality.

- At the beginning of September 2015, the Agency published the Expert Appraisal Report and its Opinion on the co-exposure of bees to stress factors. It is clear from this important work that the co-exposure of bees to insecticides, acaricides and fungicides makes them more susceptible to the pathogens to which they are exposed. In its Conclusion, the Report argues that these co-exposures should be taken into account during the revision of European procedures for the approval of plant protection substances.
- Similarly ANSES’s ability, as a result of its reputation, to call on renowned scientific experts, whether those who work in the Agency's laboratories, or those who have responded to the Agency's calls for applications, enabled the Agency in 2015 to publish several opinions on the possible or proven emergence or re-emergence of diseases (Avian Influenza H5N8, co-exposure of bees to stress factors, brucellosis in the Ibex of the Bargy Massif, enzootic bovine leukosis in Reunion Island, prioritisation of diseases of molluscs, crustaceans and fish, etc.).

- In the area of surveillance of possible re-emergence originating with wildlife, the essential role of our Nancy Laboratory must again be stressed: despite the disease-free status of France (less than 1% of infected herds), the number of cases of bovine tuberculosis is increasing in some regions. Alongside this new increase, the bacterium is also contaminating wildlife; red deer (Cervus elaphus), badger (Meles meles) and wild boar (Sus scrofa). This change in the epidemiological situation makes it more difficult to implement prevention and control measures. ANSES has invested considerable effort in understanding and modelling the circulation of the bacterium both within and between domestic and wild species, and is working on different measures for combating it, such as the oral immunisation of badgers.

- The likely emergence from an animal reservoir and the dissemination of the coronavirus responsible for MERS-CoV rightly concerns the world's health authorities, as evidenced by the recent episode in which the disease was imported into South Korea. For this purpose, three of ANSES's laboratories are engaged in an ambitious ANR programme (Epicorem) which aims to understand how these viruses cross the species barrier.

- In 2015, more partnerships were formed between our laboratories and the livestock professions to combat the diseases that compromise the competitiveness of our farms. In this context, the Niort Laboratory received a mandate to be the reference on bovine hypodermosis, and the work of the Ploufragan Laboratory on PRRS is continuing with the support of professionals in the pig industry. The role of this virus in the shedding of the hepatitis E virus in pigs has particularly been emphasised, serving as a reminder of the need to work on all pathologies likely to interfere with the expression of zoonotic agents.

### 2.2 Antimicrobial resistance

- The highlight of 2015 in the field of antimicrobial resistance was undoubtedly the very encouraging results of the EcoAntibio 2017 plan, which has achieved its mid-term objectives. ANSES has set up an antimicrobial resistance unit and fostered effective cross-cutting initiatives in its research, reference and surveillance activities, thus boosting the Agency's contribution to the success of the EcoAntibio 2017 plan while also supporting the Ministry of Agriculture in specific research programmes on the subject.

- In 2015, ANSES also celebrated 40 years of our Fougères Laboratory, which is one of the European leaders in its fields of activity, in particular in research into measuring levels of xenobiotics in animal matrices.

- ANSES also finalised a draft Order on good practice in the use of medicinal products containing one or more antibiotics in veterinary medicine, and submitted it for signature to its supervisory ministries.
2.3 Veterinary medicinal products

- **The final stage in the upgrading of our information systems came on stream** at the beginning of 2015: the ANMV finalised the complete redesign of its information systems started in 2006, by bringing on stream the management of the granting of export licences, tools for monitoring MA procedures and the recasting of how Summaries of Product Characteristics (SPC) are placed online. The new tool for consulting the SPCs of veterinary medicinal products authorised in France is thus accessible on the Agency's website and can now be searched easily according to various criteria. The ANMV is continuing this process in the field of veterinary pharmacovigilance with a programme to modernise its computerised tools for the surveillance of adverse effects, detection of emerging signals and online reporting (VIGIE project).

- **Regulatory reform:** In September 2014, the European Commission published two draft regulations relating to veterinary medicinal products and medicated animal feed. Negotiations are under way in the European Parliament and the Council of the European Union. The ANMV, very involved at both national and European levels in discussions on the improvement of EU regulations concerning animal and public health, contributed to the French position on these draft texts by following the negotiations at the level of the Council of the European Union and providing support for the supervisory ministries.

2.4 Partnership policy

- In 2015, the Virology joint research unit (UMR) of the Maisons-Alfort Laboratory for Animal Health was appointed OIE Reference Laboratory for Foot-and-Mouth Disease.

- In the second half of 2015, cooperation agreements with three major Chinese partners are to be renewed. These agreements are with the Chinese Academy of Agricultural Sciences (CAAS), the China Animal Health and Epidemiology Centre (CAHEC) and the Institute of Veterinary Drug Control (IVDC).

2.5 International

ANSES is particularly involved in European research networks, especially in the field of animal health. This is most notably reflected in:

- the development of joint coordinated research programmes between the teams of member institutes of the CoVetLab network created with the laboratories of five of our European counterparts.

- the active participation of ANSES in organising preparation for the European Commission’s call for tenders for a future European Joint Programme on zoonoses, focusing on food safety. The construction of this future EJP will benefit from the experience gained by ANSES and its European partners in the framework of the Med-Vet-Net network of excellence, which has now taken the form of an association, with an annual symposium held at the Agency in October.
- In 2015 the Laboratory Affairs Department took the initiative of setting up a benchmarking process with our counterparts in the European research and reference institutes. This approach, with which the European and International Affairs Department and the directors of laboratories were closely associated, reflects the Agency's ambition for greater knowledge sharing and efficiency in the years to come.

At international level:

- The ANMV provided training for its colleagues from the Chinese Institute of Veterinary Drug Control (IVDC) in: the assessment of veterinary chemical drugs and veterinary vaccines, the inspection of veterinary drug manufacturing plants; and quality control of veterinary drugs (including quality management). These courses were in the framework of a cooperation agreement between ANSES-ANMV and the IVDC signed in 2010.

3. Outlook for 2016

3.1 A burgeoning policy of technological platforms and cross-cutting scientific activities

In view of the rapid evolution of technologies in the field of life sciences and the need for ANSES to base its research and its reference activities on powerful tools, a "platform" policy is being progressively implemented within the Agency's laboratories.

These different platforms provide ANSES's laboratories with both leading-edge technology and the expertise of competent scientists for processing the results. They also enable the Agency's laboratories to respond more rapidly in the event of disease emergence. For instance, the Agency's high-throughput sequencing platform was able to sequence and align the entire viral genome of a strain of the porcine epidemic diarrhoea virus (Indel) in less than 48 hours during an emergence in France at the end of 2014. The strengthening of our bio-informatics teams should enable the Agency's scientists to become more proficient in these methods.

Most of the different activities on cross-cutting themes, presented by the Scientific Board's Scientific Committee for Laboratories, will give rise to joint projects between different units. Among the initiatives that will be taken further in 2015 are the methodologies for working on resistance to biocides and plant protection products on the basis of the scientific experience of the antimicrobial resistance unit; an exchange of scientific points of view on the barriers to inter-species transmission; and an integrated approach to vectors and vector-borne diseases, in application of the 2014-2018 scientific guidelines for laboratories.

3.2 Antimicrobial resistance

We are continuing to monitor the use of antibiotics in animal production, and the antimicrobial resistance of pathogenic and commensal bacteria, driven by support for ANSES from the Ministry of Agriculture in the framework of the EcoAntibio 2017 plan, which in 2016 will fund sixteen research and surveillance programmes.
The ANMV will continue to be active at European level, including by participating in the work of the ESVAC group on tools for monitoring the use of antibiotics in Europe or by delegating one of its staff to participate in the EMA working group on the assessment of antibiotics. In France, the ANMV will continue its work for the improvement of surveillance tools and developing the different software versions this implies, by extending its work to include the calf and poultry sectors, and domestic carnivores.

Furthermore, in the framework of the health-environment section of the 2015 road map drawn up by the French annual Environmental Conference, ANSES is expected (Measure 56) to carry out an expert appraisal to clarify our knowledge of the mechanisms involved in the development of antimicrobial resistance in the environment. The ultimate aim of the appraisal will be to determine new risk reduction measures regarding the interface between human and veterinary medicine and the environment. This represents a particularly cross-cutting request to ANSES, which will call on the multiple areas of competence found in its Expert Committees and its laboratories.

3.3 Partnership policy

For ANSES, 2016 will be an opportunity to set up new partnerships, particularly in the context of our participation in the emergence and growth of CoMUEs (communities of universities and establishments), and also of the brand new French Agricultural, Veterinary and Forestry Institute (IAVFF), of which ANSES will be a keen member.

The meeting between members of the CoDirLab and several leaders of European laboratories in the second half of 2015 will give rise to various bilateral or multilateral partnerships, particularly including a discussion on practices concerning the control of reagents in animal health. Themes for scientific collaboration have already been discussed with the PIWet (Poland), the FLI (Germany), ISZ Brescia (Italy), and APHA (UK).

In the course of 2016, in the context of the progressive establishment of surveillance networks in application of the Act for the Future of Agriculture of 2014, ANSES will work closely with the DGAL and the professional sectors to ensure that its scientific support for the development and establishment of surveillance schemes continues to play a central role, from the structuring, organising and assessment of networks to the methodology for the collection, storage and analysis of the data.

3.4 Outlook on veterinary medicinal products

In 2016, ANSES will continue to follow negotiations relating to future changes in European regulations concerning veterinary medicines. The outcome of these reforms is important for the future activities of the ANMV and discussions are in progress and will continue on the potential impact of this reform on the ANMV as to its missions and the organisation of its work.

Other strategic issues will continue to play an increasingly important role. One example would be the strengthening of post-MA surveillance. First of all the ANMV will continue with the modernisation of its information system, particularly with bringing into service a new and more suitable tool for pharmacovigilance in the course of 2016. The VIGIE project involves redesigning the management of pharmacovigilance declarations, in order to have a suitable tool that is long-lasting, scalable and fully controlled. This will mean the provision of appropriate analytical tools (for detecting signals and issuing alerts) and will lead to improvements in terms of interfacing with the national database of veterinary medicines; the online reporting system will also be upgraded and
made more user-friendly. As regards counterfeit drugs, after the development of analytical methods, the ANMV will be able to start putting into practice a test campaign on samples acquired from the market.

Finally, as in 2015, the ANMV will continue its international activities, especially with China and the project to work with the Cameroon veterinary drug testing laboratory, under the OIE twinning programme.

3.5 Risk assessment

In terms of risk assessment in animal health, animal welfare and animal feed, the prioritisation of the animal diseases present in the French Overseas Départements will respond to a request from the DGAL to prepare a specific categorisation for these French regions. The risk assessment work on the use of antibiotics will continue, with questions related to the evaluation of possible alternatives to antibiotics. We must also emphasise the joint request by the DGAL and the DGCCRF for ANSES to assess microbiological hazards in animal feed.

In 2016, both the Animal Health and Welfare and the Animal Nutrition Expert Committees and the Animal Welfare Working Group will start their new terms, and will face a heavy work load given the current health situation and upcoming animal welfare issues. In the area of animal health, the Agency will be especially involved in the preparation of emergency plans, the finalisation of the third national action plan against bovine tuberculosis, the rethinking of some regulatory elements related to highly pathogenic avian influenza, and the regulations concerning Salmonella in animal feed.

In 2016, risk assessment activity in the field of animal welfare will focus, among other issues, on animal protection, regarding both pets and farm livestock.

It should be noted that three of our scientists have been chosen to sit on EFSA's AHAW and BIOHAZ panels for their new terms, which started in July 2015.

3.6 Strategic investments for the Agency

In the framework of the preparation of its multi-year investment plan and by contributing to the strategic joint State-Region projects, ANSES will continue to pursue an ambitious and reasoned property investment policy in 2016, which is necessary to improve the security of its research and reference activities or to modernise its research infrastructure. In this context, the completion in 2016 of the "I cube" building offering A3-level containment at the Maisons-Alfort Laboratory for Animal Health is a critical operation for the future of the Agency's virology activities. On this same site, studies will commence for the construction of a similar containment building for the bacteriology activities of the bacterial zoonoses unit. Studies for making the non-contained experimental buildings more suitable for work on the welfare of poultry by the Ploufragan-Plouzané Laboratory will be undertaken, jointly financed under the CPER. Finally, there will be a new investment plan for the construction of premises suitable for the ANMV’s activities at Fougères, which will also benefit from support by the local authorities.

The changes to the regional landscape following on the one hand the remodelling of the country's Regions and on the other the regional elections in December will no doubt raise questions as to whether to retain or modify the locations of laboratories integrated in the production sectors they serve. This will particularly concern the Laboratory for Rabies and Wildlife (Lorraine) and those of Niort (Poitou-Charentes), Dozulé (Basse-Normandie) and Lyon (Rhône-Alpes).