ANSES Policy Orientations for 2018

presented to the Scientific Board on 19 September 2017
and to the Board of Administrators on 26 September 2017

1. Introduction

The purpose of this document and its annexes is firstly to review the actions undertaken in 2017, and secondly to present the main proposed policy orientations for 2018 to the Board of Administrators for consideration.

The year 2017 saw substantial changes in the Agency's internal organisation, adopted at the Board of Administrators' meeting of 27 June 2017, and addressing three main objectives:

- to enable clearer distinctions between specialities, missions and responsibilities by grouping ANSES's activities into four divisions;
- to simplify the current structure by reducing the number of entities reporting directly to the Director General;
- to further develop cross-cutting relationships between the Agency's research, reference and inter-laboratory monitoring activities, and also promote synergies with the Risk Assessment and Regulated Products Departments.

Following this **pooling into four divisions**, we now have:

- a Deputy Director General for General Affairs to oversee the support departments. The Quality and Internal Audit Department, whose missions have been extended, has joined this division;
- a Managing Director General coordinates the Regulated Products Division. The French Agency for Veterinary Medicinal Products (ANMV) is associated with this division;
- a Managing Director General coordinates the Science for Expertise Division. The Risk Assessment Department is now attached to this Division, as is the new Social Sciences, Expertise and Society Team;
- a Managing Director General coordinates the Research and Reference Division. The Laboratory Affairs Department, which becomes the Strategy and Programmes Department, is overseen by the Division's Managing Director General. It is responsible for ensuring that the work of the Agency's laboratories is scientifically consistent with Agency policy, and for proposing multi-year scientific orientations. Lastly, it coordinates the annual planning exercises and the periodic evaluation of the scientific activities of the research units, based on a matrix system with six cross-cutting scientific departments: animal health and welfare, plant health, food safety, antimicrobial resistance, epidemiology and surveillance, and toxicology and contaminants.

The Department of Information, Communication and Dialogue with Society, which henceforth becomes the Department of Communication and Institutional Relations, and the European and International Affairs Department remain under the authority of the Director General.

This new organisational structure will enable ANSES to further improve the way it fulfils its various objectives and tasks, as listed in its Goals and Performance Contract (COP). A new State-ANSES Goals and Performance Contract for 2018-2020 will follow on from ANSES's first COP, signed in 2012 shortly after the creation of the new Agency following the merger of AFSSA with AFSSET.

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This new COP is the result of a process in which the Agency and its supervisory ministries were engaged throughout 2017 and builds on the recommendations of the unit set up to evaluate the preceding COP, whose report was published in July 2017. It defines the broad strategic framework and the objectives that will enable ANSES to continue to fulfil its health and safety missions effectively. It has five main themes:

- **Strengthen the Agency's scientific excellence, and the quality and independence of its expert appraisals** (for its health and safety missions);
- **Anticipate emerging threats and risks;**
- **Consolidate ANSES's role in the construction of the European and global health and safety system;**
- **Promote dialogue with society and better information for the general public to improve the perception of the issues and the terms of public debate;**
- **Improve the Agency's overall efficiency and develop more effective cross-cutting actions**.

In parallel, in order to prepare for future conditions and anticipate the challenges for each of the Agency's specialist activities in the medium and long term, **in the spring of 2017 the Director General launched the "ANSES 2025"** project, which will continue until the end of the year. In connection with the preparation of the next goals and performance contract, the "ANSES 2025" project will **provide a clear strategic vision for ANSES over the next ten years**.

To formalise the discussions, three workshops divided into nine working groups have been set up around targeted themes:

- **The effectiveness of internal processes**
- **Strategic missions on health and safety**
- **A strategy for cooperation, partnerships and communication**

These collective discussions concern all of ANSES's 1400 employees. They are organised in the form of working groups where proposals are collected and discussed relating to the major issues facing the Agency in the field of expert appraisal, monitoring, alert and vigilance, working methods, relations with its partners or the position it takes regarding openness to society and dialogue with stakeholders.

The results of these discussions, which will be presented in early 2018, have a dual purpose: **to consolidate**, by identifying and implementing practical ways to continue the improvement of the daily running of the Agency, and **to anticipate**, by laying the foundations of a common strategy and renewed scientific ambitions.

These policy orientations are in line with those set by the Agency's COP, and with the various national plans that are either led by ANSES or for which the Agency is responsible for many actions (PNSE3, SNPE, PST3, PNNS, EcoAntibio plan, etc.).

In 2017, the Agency also remained very involved in providing scientific and technical support in the framework of work carried out under the aegis of its supervisory ministries or the French Parliament, and this will continue in 2018.

This is and will continue to be the case for the **National Consultation on Food** (EGA), in particular for its component "*A healthy, safe and sustainable diet that is accessible to all*" or in the definition of an ambitious policy for environmental health desired by the Government, including the new **National Endocrine Disruptor Strategy**. The Agency will also respond to requests from parliamentary committees and the French Parliamentary Office for Science and Technology to provide a scientific perspective.

2. Main events of 2017

The Alert and Vigilance Unit, which has since become the Health Monitoring & Alerts Department (DAVS), has set up a computerised alerts management system, referred to as SALSA (the acronym for the French for ANSES Health Alert System), which also records all alerts received by the Agency, for better coordination within ANSES. It has launched the publication of a four-monthly newsletter covering all of the Agency's vigilance schemes, **Vigil'Anses**, to better publicise the work done by ANSES in terms of vigilance (two issues have been published so far).

A number of alerts were issued to the DGS and led to management or communication actions: for example, thanks to the analysis of data from the Poison Control Centres (CAPs), the DAVS tracked the number of cases of adder bites in France and the consumption of antidote, on a weekly basis, during a stock shortage. Two toxicovigilance working groups (WGs) were transformed into ANSES WGs: the "Toxicovigilance of regulated products" WG (formerly the "Phytowatch" WG of the Toxicovigilance Coordination Committee) and the "Vigilance for chemical products" WG (formerly the "Chemicals" WG).

Lastly, the DAVS took part in work to overhaul the CAP information system and the Ministry of Health's reporting portal for adverse health effects, for all of ANSES's vigilance units. The portal came online in March 2017.

In the area of food, 2017 saw some large-scale projects take form. First of all, the publication of the INCA 3 study is a major milestone for the Agency: the data collected on eating habits and food consumption provide an essential scientific basis for the Agency's expert appraisal activities and also enable it to identify certain behaviour that it can then help improve in line with the National Nutrition and Health Plan, for which ANSES has also published a contribution (nutritional guidelines for adults).

Furthermore, the Agency's comprehensive debate on the overhaul of the system of official surveillance and control in food safety following the recommendations of the Interministerial Committee for the modernisation of public administration (CIMAP), with the first deliverables in 2017 on source attribution for infectious diseases, is one of the most important tasks for the Agency, which supports the public authorities in their general strategy for consolidating food safety.

ANSES's activity concerning the issuing of marketing authorisations (MAs) for plant protection and biocidal products continued at a sustained pace in 2017, in particular with a steady increase in the number of applications to be examined concerning biocidal products, for which the Agency has also had MA responsibility since 1 July 2016.

ANSES has decided on an action plan designed to improve its processes and, in particular, to reduce the time needed to examine applications. In this framework, in mid-2017 it commenced the second phase of the project to **digitise submission of MA applications for plant protection products**.

Since 2016, the Agency has been closely involved in **a benefit/risk assessment of neonicotinoid-based insecticides and their alternatives**, in the framework of Article 125 of Act No. 2016-1087 of 8 August 2016 on the restoration of biodiversity, nature and landscapes.

ANSES continues to be very occupied with **assessing plant protection and biocidal active substances at European level**. This activity, combined with strong involvement in the methodological work carried out at European level, has the result of promoting French expertise.

As regards **phytopharmacovigilance**, the network of partners for the collection of data has been designated by ministerial order and a system for reporting adverse effects, accessible on the Agency's website, has been set up.

Concerning plant inputs:
806 decisions relating to authorisations and permits were issued, 737 of which were for plant protection products (126 parallel trade permits, 76 experimentation permits, 108 MAs, re-examinations or major uses, 15 mutual recognition applications, 138 other decisions resulting from assessments, 274 administrative decisions not requiring assessment), 47 for fertilisers and 22 for adjuvants.

Concerning biocidal products:
126 decisions were issued for biocides, 46 of which were first MAs, national authorisations or major changes, 17 mutual recognition applications and 58 administrative decisions; 2 Opinions and Scientific and Technical Support Notes were issued in response to formal requests.

Concerning the assessment and marketing authorisation of veterinary medicinal products, by 1 July 2017:
- 62 MA applications had been submitted;
- 52 MAs had been issued;
- 414 procedures for amending MAs had led to 1002 decisions;
- 62 MAs had been renewed;
- 328 import applications had been received, 319 of which had been accepted;
- 18 clinical trial applications and 17 amendments had been processed;
- 4 provisional authorisations for use had been issued.

With regard to expert appraisal, the methodological work conducted by the WG on the Methodology of Risk Assessment (MRA WG) under the auspices of the Scientific Board resulted in the publication of two reports on **the level of evidence**, and **the taking into account of uncertainties in risk assessment**. In 2017, the phase to assess the applicability of the recommendations of these reports, validated by the Scientific Board, based on practical case studies, included a seminar for discussions between the experts of the MRA WG and ANSES's expert groups. The year 2017 thus provided an opportunity to test the **methodological guidelines** arising from these studies in several WGs or Expert Committees. This methodological work, designed to help harmonise risk assessment practices, is also fully in line with the deliberations with the partner organisations in the R31 network and, at European level, with counterpart agencies, in particular EFSA and ECHA.

The seven expert groups working on the theme of "environmental health" were renewed in 2017. The committee for the evaluation of chemical substances and the one for the development of occupational exposure limit values were brought together in a single CES for the development of health reference values, so as to strengthen the coherence of the work to produce these values.

The Agency launched an activity concerning its new missions relating to tobacco and tobacco-related products (vaping). A permanent WG on "*Tobacco and vaping products*" working under the aegis of the Expert Committee on consumer products will begin its work in September 2017. In connection with this activity, the Agency will be taking part in a joint European initiative on tobacco with several organisations from other Member States.

ANSES published several opinions and reports on major topics in the first half of 2017:

- Report and Opinion on exposure to smart meters;
- Report and Opinion on the health risks associated with infrasounds generated by wind turbines;
- Various opinions on endocrine disruptors (EDs), including a dossier identifying bisphenol A as an ED;
- several Opinions on the avian influenza risk;
- updates to dietary reference values for adult men and women;
- a Report and Opinion on the risks to the health of sewage workers;
- a Report and Opinion on the total diet study devoted to children under three years of age;
- an Opinion on the dangers of titanium dioxide:
- the results of the INCA 3 study on French dietary habits;
- various Opinions on the risks related to fipronil from the ingestion of contaminated eggs or egg-based products;
- various notes on the establishment of scientific criteria for defining endocrine disruptors;
- Report and Opinion on standards regarding the quality of ambient air.

Eighty-four new dossiers responding to formal requests or internal requests were started in the first half of 2017 and 114 dossiers were closed over this same period.

Other major Opinions and Reports that are sometimes the culmination of many years of expert appraisal work will also be published before the end of 2017. These include the continuation of the publication of the National INCA 3 Study (Third French Individual Survey on Food Consumption), the first results of which were published in June and will continue to be exploited into 2018. Lastly, the Agency's expert appraisal resources were heavily mobilised on complex cases involving the production of multiple studies, sometimes with very tight time constraints (brucellosis in the Massif du Bargy, toxic red sludge in the Mediterranean, nutritional labelling, etc.).

The Agency has been including **the social sciences** in its work for many years. **In 2017, assistance with social science issues was introduced in approximately fifteen WGs,** some of which have completed their work during the last year (smart meters, wind turbines and infrasound, nutritional labelling, dealing with uncertainty and expert appraisal methodology).

Regarding societal monitoring and dialogue with the stakeholders, and in addition to regular activities (dialogue committees on radiofrequencies and nanomaterials, consultation process and feedback associated with expert appraisals), **the year's events included a seminar on how best to publicise and exploit the work of the Agency and the adhesion of other public research and expertise institutions to the Charter on openness to society, which now has seven signatories.**

ANSES issued three calls for research projects as part of the National Research Programme for Environmental and Occupational Health (PNR EST) in 2017:

- **a "General" call for projects**: 252 letters of intent were received from research teams, of which 114 were shortlisted and asked to provide complete dossiers. From these, 21 projects should be selected for funding;
- **a call for projects on "Radiofrequencies and health"**: 24 letters of intent were submitted and 14 have been accepted. Another half-dozen projects are also likely to be funded:
- **a call for projects on antimicrobial resistance**: 40 letters of intent were submitted and 17 have been accepted. Another half-dozen projects are also likely to be funded.

Two scientific project feedback conferences are organised each year, during which researchers present their results. One notable event, on 17 May 2017, was the opportunity to present the results of approximately one third of the "*Radiofrequencies and health*" projects funded by

ANSES. Since 2011, 45 projects have been supported for a total of approximately €9.1 M in funding. They involved 67 separate teams.

ANSES also **participated in several trade fairs in 2017**: the occupational medicine and health conference in Paris, the international livestock show (SPACE) in Rennes, and the International Agricultural Show in Paris.

Among the symposia organised by the Agency in 2017, we should mention the annual scientific symposium on **antibiotic resistance** in animal health, the annual scientific conferences on **bee health**, and the **laboratory open days** as part of the science festival (*Féte de la Science*).

At European and international level, the first half of 2017 was marked by the bilateral meetings between the General Directorate of ANSES and many European and international partners, including:

- **the services of the European Commission**: Directorate-General for Health, Directorate-General for Research and Innovation, the Cabinet of the European Commissioner for Health and Food Safety;

- **during a mission to North America**, two memoranda of understanding were signed with long-standing partners of ANSES: the Canadian Food Inspection Agency (CFIA), to strengthen the links on food-related risk assessment and on joint actions by their respective laboratories (in food safety, animal health and plant health); and the National Institute of Environmental Health Sciences (NIEHS) in the United States for research in environmental health and on the work of the National Toxicology Program (NTP), hosted at the NIEHS, and to which the NIEHS is a major contributor;

- **in response to an invitation from EFSA and the Food Safety Commission of Japan (FSCJ)**, with which ANSES signed a partnership agreement at the end of 2015, the Director General visited Tokyo in order to participate in discussions between Europe, Japan and ASEAN during a conference organised jointly by EFSA and the FSCJ. The visit also provided an opportunity to hold discussions with our German counterpart, the BfR (Federal Institute for Risk Assessment) and representatives of the Asian institutions present, and to clarify certain issues with the FSCJ on bilateral partnerships;

- **the Director General's first visit to EFSA, accompanied by four senior managers,** took place in May. There were a number of subjects to discuss, which were dealt with over several meetings on the strategic issues and priorities for the work programmes of each of the two agencies, the procedures for risk assessment, scientific partnerships and cooperation on specific subjects, and international cooperation.

These activities will continue through the last quarter 2017, with:

- in September, **meetings with the European Commission**: the European Commissioner for Health and Food Safety and the DG Environment;

- **a mission in November 2017 to China** focused on food safety in the framework of the "China International Food Safety & Quality Conference 2017", where the Agency will be participating in the one-day event on the Global Harmonization of Principles and Methods for Risk Assessment of Chemicals in Food, co-organised by ANSES, the BfR (Germany), the CFSA (China) and EFSA;

- at the end of November, a **conference in Berlin organised jointly by the BfR, ANSES, the DTU-Food in Denmark and the Republic of Korea's NIFDS** (National Institute of Food and Drug Safety Evaluation), which will focus on the past, present and future challenges of risk assessment, to strengthen the protection of consumer health, with many contributions planned by ANSES scientists;

- **at the end of November there will also be the final conference in Paris of the European Joint Action on Nutrition and Physical Activity (JANPA)**, which aims to halt the rise of overweight and obesity in children and adolescents, within the overall framework of the EU Action Plan on Childhood Obesity 2014-2020. Thirty-nine partners from 26 European countries have worked together for two years on the economic aspects of the subject, on the selection of the best practices for early interventions (pregnant women, children under 3 years of age) and interventions at school, on the use of nutrition information and the monitoring of the nutritional composition of foods. JANPA is coordinated by France (Directorate General for Health and ANSES). The final conference aims to present the findings and key recommendations of JANPA.

Concerning ANSES's laboratories, during the first half of 2017 the laboratory teams continued to work closely with the assessment departments and to support the public authorities in the management of health crises such as emergences or re-emergences (emergence of three highly pathogenic avian influenza H5N1 viruses at the end of 2016, and the emergence of the *Xylella fastidiosa* bacterium, which is harmful to many plant species, the emergence of Q fever in the Deux-Sèvres and the Indre-et-Loire *départements* in the summer of 2017 in particular).

Following the collective assessment of its laboratories' scientific activities carried out in 2016, for which the process was presented to the High Council for Evaluation of Research and Higher Education (HCERES), the work of strengthening the cross-cutting links between the Agency's laboratories in connection with the risk assessment departments has continued. **Six scientific departments corresponding** to **six strategic cross-cutting activities (animal health and welfare, plant health, food safety, antimicrobial resistance, exposure and toxicology of chemical contaminants, epidemiology and surveillance) were created or strengthened** as part of the new organisation adopted at the Board of Administrators meeting in June. The objective is to ensure coordination between the various entities, the efficient running of the Agency and the search for synergy between the laboratories' scientific units and the risk assessment units, within their fields of competence. In addition, a start has been made, with the support of the six Scientific Directors, on drafting the Agency's scientific orientations for 2018-2022, whose section on the laboratories will serve as a reference document for the next collective assessment.

Regarding reference activities, work continued to develop processes and tools for harmonising practices and improving efficiency for all of ANSES's 65 mandates as national reference laboratories and the nine European Union reference laboratory mandates also held by the Agency. In particular, a common guide for the transfer of analytical methods for use by the networks of laboratories concerned should be finalised during the second half of 2017. Furthermore, a common software application for the management of the inter-laboratory tests organised by the Agency's laboratories is under development and will be deployed among the various teams before the end of 2017. In addition, an in-house seminar has been organised to bring together all the coordinators of the Agency's inter-laboratory tests for the first time, in order to foster the exchange of best practices and experience; it is planned to repeat the seminar on an annual basis.

Regarding surveillance, the self-assessment matrix concerning the Agency's involvement in surveillance completed at the end of 2016 has been deployed and used on different surveillance schemes. The objective is to assess our involvement (both as regards our teams responsible for reference activities and/or epidemiology and other entities within the Agency) with a view to continual improvement in the way the Agency carries out its missions, and the extent to which it meets the expectations of the laboratories and the managers of surveillance schemes.

Lastly, 2017 was a very busy year at the international level for ANSES's laboratories holding reference mandates who worked to **strengthen the Agency's position by preparing applications to become reference laboratories**: applications to the EU and the FAO for foot-and-mouth disease, and as a Reference Centre on antimicrobial resistance.

3. Principal policy orientations for 2018

ANSES's proposed policy orientations for 2018 are detailed in the annexes for each of its five major spheres of competence:

- **Food safety and nutrition**
- **Environmental health**
- **Occupational health**
- **Animal health and welfare**
- **Plant health and protection**

These 2018 policy orientations are in line with those set by the goals and performance contract and its 2016-2017 amendment, taking into account the discussions currently under way in preparation of the next COP, and with the various national plans that are either led by ANSES or for which the Agency is responsible for many actions (PNSE3, SNPE, PST3, PNNS, EcoAntibio plan, etc.).

They also reflect the 2018 work programmes, which provide a more detailed description of the actions being considered. These will be discussed with the stakeholders, along with the draft work programme, during the Thematic Steering Committee meetings planned for October 2017. Following this consultation and after the Scientific Board has issued its opinion, the 2018 work programme will be submitted to the Board of Administrators in November 2017.

In addition to these theme-based orientations, the main policy orientations proposed for 2018 are shown here.

Regarding risk assessment, the Agency will strive to keep abreast of changes in consumption modes and habits, the development of new technologies, and the presence of multiple sources of contamination in the general environment or the workplace, all of which may expose people to risk.

ANSES will therefore be pursuing the work to find alternatives to neonicotinoids and to examine their impacts on health and the environment. The Agency will also publish the results of its Pesti'home Study assessing the domestic use of pesticides and biocides, an expert appraisal on a risk assessment related to nanoparticles in food, another on the risks related to the presence of chemical contaminants in babies' nappies and sanitary protection products, or again on herbicide-tolerant plant varieties.

It will also continue its work for the assessment of endocrine-disrupting substances. In addition, ANSES will continue to work with its French, European and international partners on all the major health challenges: air quality, endocrine disruptors, nanomaterials, radio frequencies, plant protection products, biocides, combating antimicrobial resistance, veterinary drugs, vector control, etc.

As for alerts and vigilance, the DAVS will set up the **strategic vigilance committee of the poison control centres; the corresponding Decree was published in June 2017**.

It will consolidate its role within ANSES as coordinator of the vigilance schemes that use data from the poison control centres and the RNV3P, and those used for phytopharmacovigilance, nutrivigilance and veterinary pharmacovigilance, and also as a provider of methodological and epidemiological support for the studies that use these data. It will establish a partnership with Inserm aimed at detecting weak signals by the automatic analysis of the data from the poison control centres and the RNV3P. It will continue publishing several issues a year of Vigil'Anses, and will set up a WG for vigilance regarding

species harmful to humans present in the environment. At the request of the Scientific Board, it will organise discussions for bringing greater consistency to the methodological criteria used for the analysis of the signals detected during vigilance activities. It will continue to coordinate the management of alerts by ANSES, in particular through the introduction of **SALSA, a web-based alert-management application.**

In the area of plant protection and biocidal products, ANSES will continue the work of improving its procedures for the assessment of MA applications, so that the related decisions can be issued more rapidly. The work with a view to the total digitisation of the application submission process will continue. At European level, ANSES will continue to be closely involved in assessing plant protection and biocidal active substances, and also with methodological research. **Regarding regulated products**, ANSES will continue to **provide support for the implementation of regulatory and legislative decisions to restrict the use of pesticides**, especially with the finalisation of its response to the formal request on the identification of alternatives to **neonicotinoid-based** plant protection products, their benefits, their risks and their impact on agricultural activities.

The Social Sciences, Expertise and Society Team was created to give greater visibility and a new impetus to the activities deployed by ANSES in this area in 2018. The team will continue and enhance its support for the Agency's activities, in addition to keeping a watch on societal issues and ensuring openness to society. Several research and development agreements involving research teams in the social sciences and concerning different themes (OELs, vaping, socio-digital analysis of scientific assessment, etc.) are in their starting phase and other partnerships will be developed.
An additional effort will be devoted to the **consideration of the socio-economic aspects** inherent to certain regulations (the EU Biocides Regulation, for example) or to certain formal requests received by the Agency (e.g. for alternatives to neonicotinoids) and to the working practices to be applied here, on both the organisational and methodological levels.

In the field of scientific communication and exploitation, to satisfy its different audiences ANSES needs to invest fully in its mission to support public policies by ensuring that it plays its role consistently, in all its major fields of competence, in order to accomplish its mission for information and outreach on a day-to-day basis, while consolidating its visibility and its reputation. Its communication policy exploits **a wide palette of tools**: scientific events and fairs, the publication of magazines and newsletters, documents posted on its websites, presence on social networks, relations with the media, etc.

Special commitments for 2018:

- continuation of the efforts to have all Opinions and Reports of international importance translated, the better to promote **the Agency's scientific production on the international scene;** the deployment of a **communication plan to exploit the work of the laboratories** (both research and analytical reference);
- **continuation of a proactive policy to distribute scientific magazines**: *EuroReference*, the *Bulletin de Veille Scientifique*, the *Bulletin Epidémiologique* on "Animal Health - Nutrition", Vigil'Anses, etc.).

Some of the main events planned for 2018:

- International symposium on the impact of climate change on emerging issues in animal health;
- Scientific seminar for ANSES's experts;
- Participation in the 35th National Congress for Occupational Medicine and Health;
- Annual scientific conferences on antimicrobial resistance in animal health;
- ANMV open day for stakeholders;
- Open days in the laboratories as part of the Science Festival (Fête de la Science);
- Annual scientific meeting on bee health;
- Publication of research results from the PNR EST;
- Participation in SPACE and the Paris International Agricultural Show;
- Meeting organised by the Dozulé laboratory (a European reference laboratory) of European NRLs in equine diseases.

In the area of research:

- Concerning the PNR EST, in 2018 ANSES will issue two calls for projects: one will be general, the other on the theme of radiofrequencies and health.

- At European level, 2018 will see the start of a major project coordinated by ANSES, **the One Health European Joint Programme (EJP) on the theme of foodborne zoonoses, emergences and antimicrobial resistance**. There are 41 partners in this EJP, from 19 Member States or EU Associated Countries. The principle behind the partnership is to associate two public health organisations in each participating country, one in human health and the other in animal health. In addition to coordinating the partnership, ANSES will be directly involved through the participation of its teams in the scientific projects and initiatives to be undertaken within the EJP.

In 2018, meetings and exchanges will continue with ANSES's partners, in particular with a meeting between scientists of the members of the "IC4Health" partnership (in France, ANSES and the French Public Health Agency), as well as the public health institutes of England (Public Health England), Norway (Norwegian Institute of Public Health) and the Netherlands (RIVM), and also with the BfR (Germany) and DTU-Food (Denmark) in the framework of the partnership between the three institutions.

The actions undertaken with the signatories of all the Agency's partnership agreements will be intensified, especially in the framework of the commitments under ANSES's future COP.

ANSES's actions at European and international level for 2018 and the following years will be in line with the priorities defined in the Agency's future COP and in its strategy document "ANSES 2025".

Concerning its laboratories, the Agency will continue the work undertaken in partnership with the Scientific Board in order to broaden its debate and strengthen **its strategic vision on the development of its scientific orientations for the period 2018-2022** following the collective assessment in 2016.

In this framework, the laboratories and scientific units will be expected to propose, with the support of the six Scientific Directors, **specific scientific orientations for this period of 2018-2022**, emphasising the synergies and key alliances envisaged at both internal and external levels.

More generally the **scheduled action plan** drawn up as part of the ANSES 2025 strategy as a result of the collective assessment of 2016 will be implemented. It will focus on both the strategic framework (identification and activation of the levers necessary to strengthen the cross-cutting functions, clarification and implementation of our partnership policy with the academic world as well as with the private sector, while ensuring that the Agency remains fully independent) and the means and tools (development of shared technological platforms, management and exploitation of our biological assets and our data, etc.).

ANSES will continue to provide its **support for building epidemiological surveillance platforms** for the **organisation and development of methodologies or tools**, to achieve greater efficiency in food safety and plant health.

Regarding reference activities, ANSES's teams will be kept busy in 2018 preparing possible French applications for the European Commission's calls concerning the granting of European Union Reference Laboratory (EURL) mandates, especially in plant health.

Work will continue in 2018 to **strengthen European cooperation in order to enhance the effectiveness of the NRLs in the Member States** in health matters, particularly through:

- the creation of bilateral (or even trilateral) projects or partnerships on tools identified in 2015 by our counterparts during the benchmarking initiative: surveillance and wildlife, microbiological strain collections, analytical methods, etc.;
- the commitment driven by ANSES for discussions with our European partners on how best to structure the group of organisations involved in reference activities that has been formed in the framework of the editorial committee of the EuroReference online magazine.

Modernisation of scientific equipment and facilities

As part of the preparation for its multi-year investment plan, ANSES will continue to pursue a reasoned property investment policy in 2018, which is necessary to secure its activities and modernise its infrastructure.

The first phase of construction work on new buildings in Ploufragan for studying the health and welfare of poultry will be completed, while work continues on the construction of a new building for the ANMV at Fougères. The Lyon Laboratory's property renovation project will be clarified, in order to respond to the health challenges of the new Auvergne-Rhône-Alpes region and strengthen its position in the Greater Lyon area. A real estate roadmap for the Maisons-Alfort site should be finalised, to achieve greater medium- and long-term synergy between the different facilities and teams at the site.

Furthermore, the **refurbishment and extension of the Boulogne-sur-Mer site of the Laboratory for Food Safety**, which will be completed in 2018, will bring the ANSES Boulogne-sur-Mer team and the Agri-food and Aquatic Products team from the Université du Littoral-Côte d'Opale under the same roof, in order to optimise joint funding and existing synergies in terms of the quality and hygiene of fishery and aquaculture products.

In terms of **scientific equipment**, the impetus for **acquisition and pooling** is continuing. This is vital for allowing the laboratories to conduct their research and reference missions effectively. This impetus seeks firstly to maintain the teams' analytical capacity (which implies the renewal of equipment) and secondly to ensure access to and control of modern equipment and technologies offering new potential: the reference laboratories need to propose new analytical methods that are more effective in terms of reliability and cost.

The process to harmonise and consolidate the reference activities of the Agency's laboratories, in order to improve efficiency, will continue in 2018, especially concerning the control of reagents and the introduction of training courses given by the reference laboratories.

In connection with a risk-based approach and the publication in late 2017 of the revised ISO 17025 standard on the competence of laboratories, an attempt will be made to **finalise work to pool the main components of the laboratories' quality management systems**, in order to achieve efficiency gains, synergy between entities, greater collective capitalisation and more flexibility when needing to implement new provisions.

Annex 1

ANSES Policy Orientations in Food safety and nutrition

1. General points on context and orientation

On 14 January, the **French National Food Council** (CNA) was set up by Guillaume Garot in a revised format. From the end of 2017, this "Parliament of Food" will start work to define a "diet favourable to health". ANSES will contribute to the work through its latest findings (in particular INCA[1] 3 and the consumption guidelines).

In addition, the **National Consultation on Food** (EGA) began on 21 July 2017. As well as improving incomes in the agriculture and food sectors, the EGA's mission includes organising a collective debate on a "healthy, safe and sustainable diet". ANSES will support the public authorities and offer all its expertise for this project, stated as a Government priority, by providing a transparent and independent scientific basis for the debates to come, through its work: total diet studies (TDS2 and Infant TDS), INCA 3, consumption guidelines, 2016 Ciqual table, and regular OQALI (Food Quality Observatory) reports on the food supply, its quality and trends.

In 2017, the Agency is also continuing its efforts with the **food chain surveillance platform (PF SCA)**. The first meeting of the Steering Committee, in which ANSES (DSP[2]) participated, was held on 28 June 2017 and served as a reminder of the importance of the Agency's work in schemes like this. With its laboratories' expertise and its collective assessment mechanism that enables it to maintain its independence in multi-partner surveillance platforms, the Agency is able to make proposals in its fields of competence through the examination of practical cases (e.g. work under way on *Salmonella* serotype Dublin) that mobilise its know-how in epidemiology, risk assessment and pathogen typing, related to animal health and food safety.

The establishment of the new DSP and six scientific directors for the three main fields (animal health, plant health and food safety) and three specific topics (epidemiological surveillance, antibiotic resistance, and exposure to chemical substances) is a significant new asset. Its aim is to ensure, in the fou s field, a greater **collective dynamic between research and reference laboratories** in entities dispersed across the country that deal with food safety: the Laboratory for Food Safety, including its site at Boulogne-sur-Mer, is of course a major player but there are also important complementary missions elsewhere, in particular Ploufragan, on pork and poultry products, epidemiology, and source attribution for infectious diseases, the Maisons-Alfort Laboratory for Animal Health (parasitology, etc.), Fougères (food toxicology, etc.), Lyon (antibiotic resistance and epidemiological surveillance), the Nancy Laboratory for Hydrology, etc.

The Agency's mobilisation and active contribution will continue at European and international levels, whether in the fields of risk assessment, research, reference or scientific and technical cooperation. The Agency will therefore continue its involvement in the work of the European (mainly EFSA, ECHA and the DG SANTE) and international institutions (WHO, OIE, FAO, etc.), as well as with its counterparts and partners in Europe (Germany, Denmark, Netherlands, etc.) and elsewhere in the world (Canada, United States, China, etc.). In particular, a conference on past, present and future challenges in food risk assessment, organised jointly by ANSES and its partners in Germany (BFR), Denmark (DTU-Food) and South Korea (NIFDS), will be held in Berlin at the end of November.

[1] Individual and National Study on Food Consumption (ANSES, July 2017)
[2] The new Strategy & Programmes Department

Lastly, the **general strategy for food safety and nutrition** is underpinned by general themes, already stated in 2017 (see the 2017 note), which are therefore not included here in full but remain major subjects:

* Extensive cross-cutting initiatives in the areas of chemistry and methodology for food, the environment and occupational health;

* Links between the Agency's different fields of competence created by cross-cutting approaches, in environmental and occupational health;

* An approach that takes greater account of specific features of the diet or particular sensitivities, and therefore of the characteristics and problems unique to different population sub-groups (children, pregnant and breastfeeding women, seniors, vegetarians and vegans, etc.).

2. Main progress in the field of food safety and nutrition in 2017

➢ **In terms of cross-cutting activities, whether or not specific to the field of food safety and nutrition, the year was marked by:**

- ANSES's continued involvement in the National Endocrine Disruptor Strategy (**SNPE**) and **ECHA**'s **classification of bisphenol A (BPA)** as a SVHC ("Substance of Very High Concern"), under the REACh Regulation, following the French proposal drafted by ANSES;

- Continuation of the **comprehensive debate on the overhaul of the system of official surveillance and control in food safety,** in the framework of the recommendations of the interministerial committee for the modernisation of public administration **(CIMAP)**[3], with the first opinions or deliverables (opinion on source attribution for infectious diseases, note on chemical surveillance/control plans), and the holding of in-depth mid-term discussions with the supervisory ministries concerned (29 June 2017);

- **Continued development of new approaches for the detection and characterisation/quantification of chemical or microbiological hazards** in order to offer increasingly effective methods (broad-spectrum methods for non-target detection, high-throughput PCR, digital PCR, high-throughput sequencing, etc.);

- The publication in January 2017 of the **first special issue of the *Bulletin Epidémiologique* on "Animal Health - Nutrition"** (a joint ANSES-DGAL publication) devoted to health surveillance of food. This special issue, which is to be published annually, presents the organisation and results of the main food surveillance schemes.

- The analysis of **guides to good hygiene practice** (GGHP): for cider and perry, and for meat in supermarkets and hypermarkets. As agreed with the supervisory ministries, ANSES has been tasked with verifying the coherence of the hazard analysis proposed by the applicant responsible for the GGHP with the production sector in question. ANSES has proposed significant improvements that could contribute to monitoring of the manufacture of the targeted food products.

➢ **In terms of activities related to water intended for human consumption (WIHC):**

- An opinion on the assessment of the safety and effectiveness of water filter jugs **used by individuals to treat tap water (effectiveness, guidelines, precautions for use)**;

- Several opinions on draft orders intended to **transpose European Directive (EU) 2015/1787 on the quality of water** intended for human consumption;

- An opinion on the project to **recycle overflow water** from the thickeners of the Clairfont and Pech David water treatment plants supplying the commune of Toulouse;

[3] In this regard see the 2017 Policy Orientations "Cross-cutting activities"

- Support for the formal request relating to ***Bacillus anthracis*** **on issues relating to water and its uses, including for WIHC**;

- Outside the field of WIHC but in connection with agri-food processes and the potential of process water to be a vector for biological hazards, an opinion on the use of the process based on high-energy-density light pulses (**pulsed light) to decontaminate water used to blanch vegetables** intended for canning.

Several other expert appraisals by ANSES will be published in 2017:

- Work on the benefits of continuing to treat water intended for human consumption (WIHC) with **orthophosphates, in order to limit lead dissolution**.

- Assessments of the health risks associated with **situations of contamination** of water intended for human consumption by chemical contaminants: perfluorinated compounds, manganese, carbon tetrachloride, etc.

In parallel, ANSES has been continuing its efforts with **formal requests and regulatory support** mainly on **products and processes for the treatment of WIHC and materials in contact with water, with around a dozen opinions or scientific and technical support notes produced, and work on asbestos under way.**

In addition, in 2017, **the Nancy Laboratory for Hydrology (LHN) developed its work programme in connection with the Ministry of Health** and the Risk Assessment Department concerning, in particular, data on the occurrence of contamination of water resources used for WIHC production and for recreational water:

- To ensure that it reflects the distribution of drinking water in France, approximately 1300 samples were analysed to screen for the presence of phthalates, haloacetic acids, chlorite, chlorate, perchlorate, bromate, iodide, iodate and an opportunistic bacterium, *Rouxiella chamberiensis*. The results on these classes of **non-regulated parameters** will be analysed in conjunction with the DGS and ANSES's DER;

- Work on methods of detecting **cyanobacteria** in bathing water;

- A national survey on the occurrence of certain **amoebae** of interest to health in bathing water.

➢ **In terms of activities associated with physico-chemical hazards in foods:**

- Establishment in spring 2017 of the Working Group on assessment of the risks associated with uses of **manufactured nanomaterials** (MNMs) in **foods (in particular, additives and FCMs);**

- An opinion on new toxicological evidence on potential cancer promotion by **nanoscale titanium dioxide** (E171, an additive used as a colouring and coating) in conjunction with the publication of an INRA-ANSES study (Bettini *et al., 2017*);

- An opinion on the **transfer of mineral oils** (known as MOA and MOSH) from recycled paper and cardboard to dry foods due to their presence in certain packaging;

- The first delivery of work on **control and surveillance plans relating to chemical hazards for the authorities**;

- Production of a scientific and technical support note on assessment of the risks of using category PT3 and/or 4 biocidal products on hatching eggs and, if these biocidal products are not authorised for food contact, on the need to exclude hatching eggs from human or animal consumption, following a request from the Directorate General for Food (December 2016);

- Finalisation of an assessment of the impact of revising the IESTI equation (in collaboration with the DGAL, EFSA, OECD and the *Codex Alimentarius*) on the establishment of MRLs for plant protection active substances;

- An opinion on toxic or edible **macroscopic fungi**, with the comprehensive updating of a positive list of edible fungi and the development of an original classification method;

- An intermediate report on a **request relating to the monitoring** of agricultural production around the Metaleurop (Hauts-de-France) **site polluted** by trace elements, in connection with local measurements and the sampling plan of the local monitoring services;

- An opinion with a collective expert appraisal report presenting the state of knowledge on the compound BMAA produced mainly by cyanobacteria and found in certain shellfish. Establishment of the WG on pinnatoxins (work 2017-2018);

- Finalisation of the "Kannari" study on dietary exposure to **chlordecone** (kepone) for the end of 2017;

- Lastly, **FCMs and improvers, as well as processing aids, enzymes and GMOs,** remain major subjects for assessment, and to which the Agency devotes significant resources (with a permanent WG, in particular). An increase in the number of formal requests concerning GMOs was noted in 2017;

- With regard to the **laboratories**, particular emphasis was placed on **establishing alternative methods to mouse bioassays** (in the field of marine biotoxins), and on **developing and validating analytical methods** to improve the monitoring of contaminants or residues (for example, veterinary drug residues in eggs). The development of a technique for identifying **microplastics** in the seafood sector is continuing. The end of the ANR **SOMEAT** project should be noted: it has helped produce many data on **chemical contaminants of meat**, with a view to conducting comparisons between **"organic"** and non-organic products.

➢ **In terms of activities related to biological risks in foods:**

- Confirmation of the acceptance in July 2017 of the project, coordinated by ANSES, for a **European consortium** to establish a "**European Joint Programme" (EJP) on foodborne zoonoses and emerging risks,** in line with the One Health concept, and mobilising Agency players in both food safety and animal health;

- Publication of a report presenting a **critical review of source attribution methods for foodborne infectious diseases,** describing which methods to implement depending on the public health issue to be addressed, the characteristics of the pathogen and the available data;

- The start of work and the establishment of the WG (February 2017) on **control measures for *Campylobacter*** in the poultry sector;

- Publication of an **opinion on *Bacillus anthracis* (anthrax**) that provides practical background information for local managers (ARS, DDPP[4]) in the context of the resurgence of sporadic outbreaks of bovine anthrax (questions on the management of fodder, water from private wells, exposure of agricultural and construction workers, or the risks of certain leisure activities such as swimming or picnicking); a scientific and technical support note from the Laboratory for Animal Health also provided information on the descriptive and analytic epidemiology of animal outbreaks in the area concerned in Meurthe-et-Moselle;

- An opinion on scrapie **in small ruminants** and its enzootic nature. This ultimately involved determining the risks inherent to a change to the list of specified risk materials from the carcasses of these animals, in connection with the conclusions already published by EFSA;

- An opinion on **EHEC (enterohaemorrhagic *E. coli*)**: virulence factors, evolution of pathogenic serotypes, methods and the impact on consumer protection of monitoring minced meat mixtures in industry;

[4] French Regional Health Agency, Departmental Directorate for the Protection of Populations

- With regard to the laboratories, continued development of genomics and greater deployment of **bioinformatics for the characterisation and monitoring of pathogens**, especially those involved in collective foodborne infection episodes; publication of work resulting from the Fish Parasites project (ANR), which provides concrete data on contamination (***Anisakis***, etc.) for both assessors and managers.

➢ **In terms of work on nutrition, 2017 was marked by the following:**

- Publication of work on the **nutrition recommendations of the National Health and Nutrition Programme (PNNS)** for the general population (men and women): a substantive scientific review of the dietary reference values, the deployment of a complex and multi-constraint computer tool, the extraction of different consumption scenarios taking these constraints into account (epidemiological, contaminant-related, etc.) and verification of their relevance;

- Publication of the first results of the **National INCA 3 Study** (individual and national study on food consumption) in July, followed by specific studies of different parameters dealt with in the questionnaires in 2017 and beyond;

- A very strong contribution by the teams on the questions of **additional nutritional labelling and the corresponding nutritional rating systems**: publication of an opinion on the **nutritional relevance of optional labelling**;

- The start of reporting work for the request related to **food allergies**, with a view to updating the existing documents already published by the Agency;

- In terms of **nutrivigilance,** an opinion on the specific risks of food supplements (FSs) for pregnant **women (iodine and vitamin D**); an opinion on the risks of FSs containing **spirulina**; on FSs intended for athletes (**to reduce body fat and increase muscle mass**). Lastly, the opinions on supplements for joint health and on melatonin are expected in autumn 2017;

- Following a major update in 2016 of the data on nutritional composition from the Ciqual table, a complete overhaul of the **Ciqual website** was carried out. At the same time, the European joint action on nutrition and physical activity (**JANPA**), which France has coordinated for two years, led to the publication of good practice guides, in particular for monitoring the food supply and food reformulations.

- The continuation of **substantive work on foods intended for special medical purposes** (eleven opinions were published between October 2016 and July 2017). The Agency regularly reviews the dossiers forwarded by the authorities with a view to identifying mismatches between the formulation, the target populations and the recommended directions for use of these foods for specific purposes.

4. Policy orientations for 2018 in the field of food safety and nutrition

➢ In terms of cross-cutting activities (physico-chemical and biological hazards):

Following the recent publication of the TDSs, opinions and reports on consumption guidelines and nutritional needs of adults, and the INCA study, ANSES now needs to reflect on the continuation of a number of these large-scale fundamental studies. These are invaluable tools for managers and also enable the Agency to carry out its expert appraisals (INCA consumption data, especially).

In particular, discussions have already started, internally and with the experts, on the strategy to be put in place for a new **TDS**. The desire is to focus more on already-identified risk situations (to verify changes in exposure), emerging phenomena and links with specific consumption typologies, and to be able to produce more regular results through a suitable breakdown of the work.

Similarly, the INCA 3 data open up a whole new field of investigation: in 2018 ANSES will begin considering the orientations and changes to make to an **INCA 4,** with a view to providing the supervisory authorities in 2018 with development positions for 2019 and beyond.

2017 and 2018 will gradually see the finalisation of the work to **prioritise microbiological and chemical hazards in order to optimise the resources for managing** food safety and foodborne risks (chemical and biological), for which certain elements have already been submitted (in June 2017, the review of methodologies of source attribution for infectious diseases, for example).

Also of note is the **methodological work on the quality of contamination data** and on the formats for transmitting the data to EFSA, carried out by both the assessment units and the laboratories (Dataquality project and work on the Contamine database; Qualiplan project in particular), with in addition resumption of the zoonosis data transmission activity carried out by the DGAL[5].

Lastly, a survey was conducted in 2017 in order to update the **consumption data on seafood products** from the CALIPSO study (2006). The corresponding database should become operational during 2018.

➢ In terms of activities related to water intended for human consumption (WIHC):

Several expert appraisal projects will be continued or undertaken following formal requests from the Agency's supervisory ministries:

- **Antibiotic resistance and the environment** (water and soil);
- Update of the 2006 work on cyanobacteria and cyanotoxins (WIHC and bathing water);
- Use of **alternative anti-scale** systems placed in drinking water distribution networks (finalisation in 2018);
- Determination of criteria of relevance for **pesticide metabolites** in water intended for human consumption (finalisation in 2018);
- **Disinfection by-products** in water (compounds or classes as yet undetermined) and assessment of the risks associated with the presence of these contaminants in WIHC;
- **Revision of the drinking water directive** at European level, which will require the Agency to provide the ministries with scientific and technical support in late 2017 and early 2018.

[5] Directorate General for Food

In addition, in 2018, regular work will take place on:

- Materials in contact with WIHC, especially in connection with the harmonised work being performed jointly by several European Union Member States;
- Products and treatment processes for WIHC: dealing with applicant dossiers and formulating guidelines. This type of request also concerns swimming pools.

Lastly, for 2018, regarding **reference**, the LHN is aiming primarily to develop new non-standardised analytical methods (explosives residues, pesticide metabolites and new emerging compounds). New alternative microbiological methods will be tested and verified. Then, with regard to **surveillance**, the LNH will work to determine occurrences of pesticides (parent compounds and metabolites) and emerging organic micropollutants (halobenzoquinones, explosives residues) prior to the health assessment, in order to produce a national-level review of environmental contamination of water resources used for the production of WIHC. With regard to **research**, the NRL will endeavour to understand the processes by which water resources and treated water are contaminated by emerging substances (in particular pesticides and their metabolites) and to study their behaviour in different systems (ponds, rustic filtration devices, water courses). Through an ongoing literature watch and the launch of preliminary studies using HRLC, one of the other objectives will be to identify compounds of interest in order to subsequently develop additional studies (e.g. on pesticide adjuvants). For the microbiology of water, research projects are under way on pathogenic Shiga toxin-producing *E. coli* and their occurrence in water and sediments.

- **In terms of activities relating to nutritional risks and benefits:**

- Continued work on the consumption guidelines, in connection with the updating of the PNNS, with **specific approaches for all populations**, beginning with **pregnant and breastfeeding women, and children under the age of three,** following questions that have been raised about the exposure of young children and foetuses. This same debate will also be **started at the same time for the seniors age group**, and work on an IR[6] relating to vegetarians and vegans is being considered. This activity is coupled with methodological work on acquisition and adjustment of the modelling tool used in the work on adults;
- Continuation of the efforts to update ANSES's work on **food allergies**: physiopathological mechanisms, new allergens, impact of prevention messages, etc.;
- Work to exploit INCA 3 data, already planned (IR on **physical activity and sedentarity**) or being considered (**inadequate intakes** of vitamins, minerals and three macronutrients);
- Work for an IR resulting from the initial discussions of the WG on Plants, on the risks associated with the **consumption of plants** and in particular on the risks of excessive iodine levels associated with the consumption of **seaweed** in foods (foods, fortified foods or food supplements);
- A critical scientific review of ANSES's activities in the past few years on assessment of the risks of **foods intended for special medical purposes**;
- An active contribution to the work proposed in 2017 by the Agency's Scientific Board on the **methodologies used in connection with reports** from the "monitoring, alert and vigilance" schemes and, in particular, in terms of the causality of the cases identified in nutrivigilance;
- Major work will continue to update the CIQUAL compositions database and exploit data from OQALI (nutritional section of the Food Observatory), making it possible to **monitor developments for**

[6] Internal request

each sector in the overall food supply and in recipes, including according to the market shares of the products in question;

- **A process of reflection with a view to making proposals for new contamination or consumption studies** that can respond to the recommendations made during previous expert appraisals, regarding the lack of suitable data: contamination and organic/non-organic compositions, specific consumption characteristics of the French overseas territories, etc.

➢ **In terms of activities associated with physico-chemical hazards in foods:**

- The Agency will continue assessing the risks associated with uses of **manufactured nanomaterials** (MNMs) in **foods** (in particular **additives** and food contact materials), work that was considered in 2016 and started in 2017. First of all, in 2017-2018, the Agency and the experts will focus on an analysis of the R-Nano database and a sector study;

- The debate on the **orientations and changes to make to a new TDS**;

- The gradual finalisation of the EUROMIX project (2019) on **the assessment of mixtures of compounds** and the progressive adaptation of the methodological proposals to the Agency's risk assessment work when possible;

- Participation, at the DGAL's request, in leading the work to draw up OECD Guidelines on setting MRLs in honey;

- Continued participation in work relating to the development of a database for predicting the metabolic profile of new compounds (METAPATH project, "plant metabolism" case study), in collaboration with the US-EPA, OECD, BfR);

- Publication of the results of risk assessment work based on data on **contamination of breast milk** from the Contalait programme (collaboration with the Paris Public Hospital System); finalisation of a study on body contamination levels based on PBPK-type predictive models;

- As announced in 2017, development of a strategy for prioritising heat-induced substances, as well as **calculation of aggregate exposure** (air/dust, contact, food) for phthalates and development of the associated methodology;

- An assessment of the risks associated with the presence of **pinnatoxins in shellfish**;

- With regard to the laboratories, in the field of **marine biotoxins**, cooperation with the BfR in a research project and continued development and adaptation of **chemical methods** and ***in vitro*** **tests on Neuro2A** (to replace bioassays). For **trace-elements, speciation work** is also continuing, with the long-term aim of refining certain exposure calculations (e.g. Cr VI and iTDS). For veterinary drug residues, the development of analytical methods and the extension of their scope of analysis will continue. More generally, establishment of the new cross-cutting function "exposure and toxicology of chemical contaminants" will seek to define and implement a shared strategy for the Agency in this matter.

➢ **In terms of activities related to biological risks in foods:**

- Work will take place on **source attribution for infectious diseases,** through the analysis of epidemiological data (including data on foodborne illness outbreaks), in order to identify the main risk factors. This will be done in a complementary way in the laboratories, with **molecular typing work** related to genomics developments and sequencing and exploitation of various strains (partnership with the NRCs concerned), but also with discussions on adapting the PF SCA to data collection for all subsequent attribution work**;**

- The finalisation of work on **control measures for *Campylobacter*** in the poultry sector;

- **The quantitative risk assessment related to *Salmonella*** in the swine industry;

- A planned **critical review of several GGHPs**. Various guides are likely to be examined by ANSES in 2018: delicatessen meats, minced meat, delicatessen foods in supermarkets and hypermarkets, cheese sellers/agers, butchers/offal sellers, *foie gras* and duck breast producers, etc.

Annex 2

ANSES policy orientations in environmental health

Preamble

Most of the work conducted in the field of environmental health is notable for the extent to which it necessarily interacts with the other major areas of the Agency's work, in particular food safety and nutrition, and occupational health; the orientation notes for these other areas should therefore also be read to fully understand the scope of this document.

1. General points on context and orientation

The environmental health policy orientations and the work programme for 2018 continue the work undertaken in previous years. For the most part, they seek to support the implementation of the Third National Environmental Health Action Plan (2015-2019). They are also in line with the orientations laid out in other strategic documents or national plans: National Health Strategy, National Research Strategy, National Strategy for Biodiversity, National Endocrine Disruptor Strategy (SNPE), National Nutrition & Health Plan (PNNS), Occupational Health Plan (PST), Cancer Plan, Micropollutants Plan to preserve water quality and biodiversity, National Climate Change Adaptation Plan, interministerial roadmap for controlling antimicrobial resistance, etc. These orientations should also be seen in the European context (regulation, research) and at an international level in the framework of networks of foreign partners and international organisations (follow-up to WHO-Europe's 6th Ministerial Conference on Environment and Health, held in June 2017 in Ostrava, Czech Republic).

Environmental health activities also revolve around several strategic observations that are detailed below.

The occurrence of the same contaminant in several different media (consumer goods, foodstuffs, dust, water, air, etc.) provides justification for taking into account various routes of human exposure (inhalation, food, skin) in an increasing number of expert appraisal studies related to chemical risk in particular. These situations lead the Agency to investigate the most exposed (e.g. in the workplace, etc.) and/or vulnerable population groups and the determinants of exposure. In this context, special emphasis is given to exposure likely to affect the pre- and post-natal development period, i.e. in pregnant women and young children. Special attention is also paid to contaminants potentially associated with serious or common pathologies such as cancers, allergies, and effects on health of endocrine disruption.

Expert appraisal work and support for research into risks that have generated strong scientific and social controversy will continue to feature prominently in the Agency's activities. These include health risks related to endocrine disruptors and nanomaterials, as well as risks potentially associated with certain emerging technologies. Dialogue with the stakeholders involved in some of these themes will continue in forums, to fuel discussions on the Agency's work.

Methodological work initiated in 2015, aiming to better characterise uncertainties and improve ways of assessing levels of evidence, was completed in 2017. It was conducted by a specific group of experts dedicated to methodology, working under the auspices of the Scientific Board. The identified approaches have been tested in several risk assessment studies: chemical substances, assessment of aggregated exposure to the same substance occurring in various media (air, food, water, consumer products, etc.), and physical agents (electromagnetic fields) in the general population and in the workplace when applicable. The work resulted in an Opinion by the Scientific Board and in the course of 2018 will be applied to operations carried out in the framework of the procedures for responding to the requests received by the Agency.

The membership of the seven expert groups working on the theme of "*Environmental Health*" was considerably renewed in 2017. It was important to renew the composition of the groups because this determines the range of skills the Agency can mobilise for risk assessment over the next three years, taking ethical issues particularly into account. In order to increase the effectiveness of its work, and to strengthen its cross-cutting flexibility, the scope of interest of some groups was redrawn, with the approval of the Scientific Board, to strengthen the coherence of the process for the production of health reference values: the committee for the assessment of chemical substances and the one for establishing occupational exposure limits (OELs) were therefore grouped together in a single committee dedicated to the establishment of health reference values.

The Agency started work on the mission entrusted to it in 2016 by the French Ministry of Health in preparation for the transposition into French law of Directive 2014/40/EU, also known as the Tobacco Products Directive. In particular, this new mission will involve assessing the hazards and where appropriate the risks related to chemical substances in **tobacco and smoking-related products, including those derived from vaping**. A permanent dedicated WG acting under the aegis of the Expert Committee on consumer products will begin its work in September 2017. In connection with this activity, the Agency will be taking part in a joint European initiative on tobacco with several other EU Member States.

Lastly, coordination regarding **vigilance on chemical products and substances** with the different structures involved (notably with the Poison Control Centres, RNV3P, and the Revidal-Gerda group) was strengthened in 2017, which will improve the efficiency of the Agency's expert appraisal work on consumer goods, e-cigarettes, etc.

2. Main advances in the field of environmental health for 2017

Activities relating to chemicals

- **National Endocrine Disruptor Strategy (SNPE)**

The conclusions of the expert appraisals on the following substances studied in 2016 under the SNPE were published in an Opinion in September 2017: triclocarban (CAS no. 101-20-2), tin sulphate (CAS no. 7488-55-3), dicyclopentadiene (CAS no. 77-73-6), RDP (tetraphenyl m-phenylene bis(phosphate)) (CAS no. 57583-54-7) and TMBPF (4,4'-methylenedi-2,6-xylenol) (CAS no. 5384-21-4).

The following substances are currently being studied as part of the work programme for 2017: homosalate (CAS no. 118-56-9), triphenyl phosphate (TPP, CAS no. 115-86-6), bisphenol B (CAS no. 77-40-7) and 2,2',4,4'-tetra BDE (BDE-47, CAS no. 40088-47-9 or 5436-43-1).

Bisphenol A (BPA) has again been the subject of studies by the Agency. Particular attention is drawn to the study assessing exposure via non-canned foodstuffs of animal origin, on the basis of contamination data collected at the request of ANSES. We should also note the decision by ECHA (June 2017), on the basis of a dossier submitted by ANSES, to identify BPA as a Substance of Very High Concern (SVHC) for its reprotoxic and endocrine-disrupting effects on human health, under the REACh Regulation.

Lastly, ANSES completed all its work on the **hazards, uses, exposure and regulations associated with polybrominated compounds** in connection with a request from the Directorate General for Health (2009) on about 30 Category 2 reprotoxic substances and/or endocrine disruptors.

In March 2017, the Agency organised an international scientific seminar jointly with the European Commission **on endocrine disruption of the thyroid gland by chemical substances.**

- **REACh and CLP Regulations**

It should be remembered that ANSES regularly undertakes Risk Management Option Analyses (RMOAs) for certain substances as part of the work protocol for the Agency's activities under the REACh and CLP Regulations. Further to these analyses, ANSES prepares the dossiers required to implement the recommended management measures (applications for harmonised classification, dossiers on the identification of SVHCs, restriction dossiers). In addition, ANSES's experts actively participate, as members and rapporteurs, in ECHA's technical committees (Committee for Risk Assessment and Socio-Economic Analysis Committee). In all these cases, ANSES provides its supervisory ministries, which have competence for these regulations, with supporting expertise, prior to the European meetings of the competent authorities. All these activities will continue in 2018.

Further to the analysis of 2-methoxyethyl acrylate, a **harmonised classification** in Category 1B was proposed due to its reprotoxic effects. Still on the subject of harmonised classifications, there is a French proposal to classify TiO2 as Category 1B carcinogenic by inhalation, and another proposal to classify DIOP, a phthalate, as Category 1B reprotoxic. ANSES's Opinion on the carcinogenicity to humans of glyphosate (9 February 2016) helped the Agency take a position as to the classification proposed by ECHA for this substance in mid-2016.

- **Health reference values**

The work on the production of health reference values is a permanent task for the Agency, which in 2017 led to the production of Toxicity Reference Values (**TRVs**) for compounds such as perfluorinated compounds, phthalates, benzene derivatives, ammonia and chloroaniline. The Agency has also pursued an intense programme for the production of Occupational Exposure Limits **(OELs)**, Biomarkers of Exposure **(BMEs)** and Indoor Air Quality Guidelines **(IAQGs)**. This autumn it will publish a roundup of its work, updating all the reference values pertaining to **formaldehyde**.

- **Pesticides: phytopharmacovigilance (PPV)**

Roll-out of the phytopharmacovigilance (PPV) scheme continued in 2017. At the junction of matters relating to human health and animal and plant health, it is of crucial importance for expert appraisal and risk assessment in environmental health. Its primary aim is to improve the relevance and quality of the information available to facilitate the detection of emerging signals associated with the uses or misuses of plant protection products; in this context, ANSES consolidates its relationships with the operators running surveillance or vigilance schemes who are its partners in phytopharmacovigilance. The Agency has also produced numerous summary sheets on substances of interest, as well as the initial analysis of data from specific reports. Initiated in 2015 in the framework of the Act on the Future of Agriculture, Food and Forests, the phytopharmacovigilance (PPV) scheme is designed to monitor and detect any adverse effects of plant protection products on humans, animals, crops, biodiversity and different environments, and the emergence of resistance to these products. This scheme enables the continual production of information and the detection of emerging signals for the benefit of risk assessment, the processing of marketing authorisation applications and the risk management missions performed by ANSES and the competent ministries.

In 2017, the organisation of the phytopharmacovigilance scheme was consolidated, in particular via:

- the publication of the regulatory texts specifying the operating procedures for PPV and organising the network of its partners (Decree no. 2016/1595 of 24 November 2016 and Order of 16 February 2017),

- the creation of a system for reporting adverse effects and the collection of the first reports. In order to facilitate the collection of this information, ANSES placed a reporting form on its website in early 2017, intended on the one hand for the professionals mentioned in Article L. 253-8-1 of the Rural and Maritime Fishing Code, and on the other hand for health professionals and individuals,

- the continuation of the study programme initiated in 2015 and 2016, in order to consolidate the existing networks, collect new data, or appraise the reports,

- the completion of the first analyses of the data available for the assessment of plant protection products on the basis of the information made available by the PPV partners (notably, data on the occurrence of substances in the different environments, cases of human or animal poisoning, and data concerning sales and use).

- **Biocides**

In the context of the movement of vector-borne diseases across French territory, ANSES has continued its work on Vector Control (VC). In particular, 2017 saw an assessment of the adulticide active substances that could serve as short-term alternatives to deltamethrin, as strong resistance to this substance has been observed in some *départements*. ANSES issued its first Opinion on the subject in February 2017. Another is expected in September 2017, on the possible use of certain active substances by derogation in the event of an outbreak of yellow fever in the French *départements* in the Americas.

At the end of 2016, ANSES issued an internal request to investigate resistance to antimicrobial biocides. The purpose of the work, carried out by a WG reporting to the CES Biocides, is to develop a method to assess the potential risk of the emergence of resistance and/or cross-resistance in bacteria as a result of the application of biocidal products with an antibacterial activity, and to propose a strategy for the management of resistance.

In addition, ANSES has continued its activity of processing regulatory biocides dossiers, whether for the assessment of active substances with a view to their approval at European level, or for marketing authorisation applications for biocidal products. This work is carried out in close collaboration with the authorities of the other European Member States: For example, following their assessment, several marketing authorisations were issued for insecticide products intended for the general public or professionals (products to combat cockroaches, ants, termites, bed bugs, etc.).

- **European programme for biomonitoring (HBM4EU)**

The Agency is closely involved in the implementation of the Joint European Project "Human Biomonitoring for EU (HBM4EU)" (2017-2021), which brings together more than a hundred organisations in 28 countries. The Agency is particularly involved in the definition and implementation of the method for prioritising chemical substances, and the definition of health guidance values for biomarkers of exposure to compounds considered to be a priority at European level (DEHP and DINCH in 2017).

- **Consumer goods**

Among the studies carried out, attention should be drawn to the question of the risks associated with mineral oil compounds capable of migrating into food from **recycled paper or cardboard packaging,** as well as the assessment of the safety of **water filter jugs**. Expert appraisals continued on the **safety of footwear and clothing textiles** (identification of sensitising/allergenic substances) and the **safety of intimate sanitary products and babies' nappies**.

- **Nanomaterials**

Based on a study report submitted by ANSES, the Ministry of Ecology published the fifth report on **the reporting scheme for uses of nanoparticle substances** in France. In response to specific requests, the Agency also provided partner organisations with data extracts. More generally, the Agency has taken the first steps in assessing the health risks associated with **nanomaterials present in food** and submitted an emergency Opinion concerning the **hazards of titanium dioxide**.

Activities relating to physical agents

- **Electromagnetic fields**

Two Opinions on exposure to electromagnetic fields emitted by **smart meters** have been published since the end of 2016. The Agency also published an analysis concerning the expected publication in the United States of a study on the potential effects of radiofrequencies by the *National Toxicology Program* (*NTP-NIEHS*). Specific studies relating to **electrohypersensitive** individuals are nearing completion following the release of the draft report for consultation in 2016.

- **Noise**

The Agency published a review of available knowledge on the **health effects of infrasonic and low-frequency noise produced by wind turbines**.

- **Other subjects**

In addition, the Agency published the results of its expert appraisal on the assessment of the health risks related to the **use of devices using physical agents** such as radiofrequencies, optical radiation and ultrasound intended for the **performance of certain aesthetic procedures** (lipolysis and hair removal). ANSES also commented on the recent Opinion of the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concerning **tanning equipment**. The state of knowledge relative to the risks induced by **new lighting technologies** will be the subject of a forthcoming publication.

Activities relating to water quality

In addition to the publication of the work on filter jugs, the Agency carried out an assessment of the **risks associated with the domestic uses of rainwater** (for washing laundry), which was also published in early 2017. This expert assessment concludes a cycle of work by the Agency on the various technological measures and developments implemented to address the health issues associated with occasional and/or sustained risks of water shortages. Several Opinions were also issued on draft regulations for transposing into French law the most recent amendments to the EU Drinking Water Directive. Support on issues related to water and its uses (bathing, occupational exposure, etc.) was provided in the framework of the work published on *Bacillus anthracis*. As part of its permanent mission, ANSES continued to provide regulatory support on products and processes for the treatment of water intended for human consumption and materials in contact with drinking water. Several Opinions are scheduled for the end of 2017 on situations relating to contamination of WIHC by chemical contaminants: perfluorinated compounds, manganese, carbon tetrachloride, perchlorates, etc. Moreover, an analysis of recent publications relating to the presence of asbestos in WIHC is in progress. 2017 will also see the completion of an expert appraisal on the **risks related to the**

treatment of water by orthophosphate used to limit the dissolution of lead in lead pipes carrying WIHC. The Agency will also soon be publishing its analysis of a study on the determination of thresholds for the management of cooling towers regarding the parameter ***Legionella pneumophila*** in cases where the q-PCR method is used.

Activities relating to air quality

ANSES has updated the state of knowledge relating to emissions induced by the decomposition **of Sargassum seaweed** in French *départements* in the Americas, thus extending its previous work on green algae. Several studies dealt with certain atmospheric pollutants (particulate matter) as well as the issue of corresponding **standards**. The autumn will see the publication of a documentary study on **purification devices for indoor air** and their impact on indoor air quality, as well as the publication of major work on the **monitoring of pesticides in ambient air** that will give rise to an exploratory monitoring campaign in the environment, funded by ANSES in the framework of its phytopharmacovigilance mission. The end of the year will see the publication of the state of knowledge on the risks induced by **pollen and mould in the French overseas *départements***, as well as the culmination of a study to assess the expected health benefit for the general population and certain categories of workers of wearing **anti-pollution masks**. In June 2017, ANSES published a report on the uses of materials suspected of emitting **elongate mineral particles (EMPs)** and their characterisation in the air and in materials (a sector study, with proposed measurement protocols). On the basis of ANSES's recommendations, exploratory studies are continuing to acquire the first emission and exposure data for EMPs concerning the general and working populations. In addition, the Agency carried out an assessment of the risks associated with airborne dust from the Mange-Garri storage sites, operated by **Alteo**. Lastly, the initial results of the **Pesti'Home study** on pesticides used in the home will be published.

The National Research Programme for Environmental and Occupational Health (PNR EST)

In 2017, in the framework of the National Research Programme for Environmental and Occupational Health (PNR-EST), ANSES issued three calls for projects: the first is general, covering a large part of the environmental and occupational health field, the second on "*Radiofrequencies and Health*", and the third on antimicrobial resistance. The selection process is under way and it is estimated that thirty projects will be funded for a total amount in the region of €5.8 M. As in previous years, at the end of 2017 the Agency will launch two calls for projects in 2018: one general and the other dedicated to radiofrequencies.

European and international activities

When carrying out its risk assessments, ANSES takes into account the work performed at European and international level, paying particular attention to its partners in Europe but also those in North America.
In March 2017, ANSES and the US National Institute of Environmental Health Sciences (NIEHS) signed a memorandum of understanding to strengthen their collaboration around a common mission: to better understand and anticipate the impacts of environmental phenomena on human health.
ANSES follows and contributes to several projects run by the WHO's Chemical Risk Assessment Network, which met for the first time at ANSES in 2014. ANSES participates in the definition of priorities and the planning of research in Europe on environmental health with its partners of the ERA-ENVHEALTH network and with WHO-Europe.

3. Policy orientations in the field of environmental health for 2018

Activities relating to chemicals

- **Endocrine disruptors (EDs) and/or reprotoxic substances**

The programme for the assessment of EDs and/or reprotoxic substances will continue in 2018. The list of substances that will be examined by ANSES in this context will be submitted for consultation in the

last quarter of 2017 during a meeting with several Thematic Steering Committees (COTs). It will aim to carry out preparatory Risk Management Option Analyses (RMOA) that may give rise to a proposal to identify endocrine disruptors as Substances of Very High Concern (SVHC) in 2018 or 2019. An assessment of the health risks related to a mixture of several phthalates taking into account exposure by ingestion and by inhalation will be launched in 2018, with a special emphasis on children. The Agency will respond to the public consultation planned by the European Commission on the Guidance Document for the Implementation of the Hazard-Based Criteria to Identify Endocrine Disruptors (EDs) in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012 currently being drafted by ECHA, EFSA and the JRC.

- **REACh and CLP Regulations**

Work on substances to be assessed under the REACh and CLP Regulations will include the re-assessment of substances listed in the Community Rolling Action Plan (CORAP) in past years, for which additional data have been obtained, such as methylparaben or MTBE. In order to obtain additional information, in particular on its nanoscale forms, titanium dioxide will be assessed. ANSES will evaluate several substances, including n-butyltin chloride (CAS no. 1118-46-3) and titanium dioxide (CAS no. 13463-67-7). The Agency plans to submit at least two SVHC proposals (identification of phenanthrene and pyrene as PBT/vPvB).
On the subject of classification, in addition to monitoring the proposals currently being examined, the Agency will submit several new proposals for the classification of chemical substances.

- **Health reference values**

Reference values will be established for the following substances:

- TRVs: NO_2, acrolein, trichloroethylene, ammonia, 4-chloroaniline, 3-chloroaniline, 2-chloroaniline, and 2.5-dichloroaniline;

- OELs: formaldehyde (update), cadmium and its compounds, inorganic lead and its compounds, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dust referred to as “without specific effects”, as well as an Opinion and Report covering 11 substances (namely trimethylamine, methylamine, n-butylamine, acetic acid, potassium hydroxide, methyl ethyl ketone peroxide, acetic anhydride, cyanogen chloride, chlorine, boron trifluoride and chlorine trifluoride);

- BMEs: BBP, DBP, DIBP, BPA and cadmium.

- **Pesticides: phytopharmacovigilance (PPV)**

In PPV, the Agency will continue the activities undertaken in 2017, in connection with the actions to coordinate ANSES’s health vigilance schemes, and also with those of its counterparts in Europe or North America. These activities will focus primarily on:

- completing the integration of its PPV partners and the introduction of any new partners, the consolidation of the descriptors received from surveillance and vigilance networks, and the initial work of comparing the results from the different compartments with a view to identifying emerging signals,

- continuing the deployment of the system for reporting adverse effects of plant protection products, analysing and processing reports and compiling a first feedback report,

- setting up ad hoc studies to generate new knowledge. In 2018, specific work will be carried out in partnership with the French Public Health Agency with regard to the exposure to pesticides of residents in agricultural areas (exposure of humans and the environment).

- **Biocides**

ANSES has received several applications for approval of new biocidal active substances, some of which are generated in situ, that it will assess in 2017 and 2018.

In addition, ANSES will remain very active in the assessment of biocidal products (for which the effectiveness and the risks must be assessed before an MA may be granted), whether actually assessing applications submitted to the Agency, or participating in work to improve the methods available for assessing these products, in particular by contributing to various European studies overseen by ECHA, as well as to international partnership projects. These studies mainly concern methods for assessing exposure and the risks to human health, and also their efficacy.

For the examination of MA decisions for biocides, the MA Monitoring Committee will be enlarged at the end of 2017, to enable it to deal with issues related to their use. The MA Monitoring Committee may therefore be called on to improve knowledge of practices, assess the applicability of certain restrictions or management measures, or inform ANSES of products addressing specific health or environmental issues (e.g. the control of mosquitoes that are vectors of debilitating diseases, veterinary disinfection in epidemic contexts, etc.).

- **Nanomaterials**

- The Agency will continue its **assessment of exposure to nanomaterials in food**, as stipulated by Action 36 of the PNSE3. This will consist in studying the food industry, describing the stakeholders involved and the amounts of nanomaterials handled, and identifying the nanomaterials involved, the uses, and the finished products. The issue of the use of nanomaterials in the food industry may then give rise to specific risk assessments for affected workers.
- The Agency will also continue its **management of the national portal for mandatory reporting** for the 2018 reporting year and its support for around 1500 reporting entities. The Agency will also process the reported data to produce an annual report accompanied, if necessary, by specific Agency work on emerging issues relating to the hazards associated with nanomaterials or their specific uses.

- **Consumer goods**

ANSES will complete its **work on substances found in clothing textiles and footwear** that can cause skin reactions (irritation or allergy) and also its work on **the safety of intimate sanitary products and babies' nappies**.

New activities relating to **tobacco and vaping products** will be developed in 2018. In particular, these activities will lead to the definition of a surveillance programme for the products present on the French market as well as to an initial assessment of the hazards and if appropriate the risks of the substances of interest identified.

➢ **European and international work on chemicals**

As part of the EU's HBM4EU project (H2020), the Agency will continue its work on the prioritisation of chemicals, in close cooperation with several EU bodies such as the European Environment Agency, UBA (Germany) and VITO (Belgium), and on the definition of health guidance values and biomarkers of exposure (bisphenols, perfluorinated products, etc.).

The Agency will continue its participation in the European EUROMIX project (H2020), which is developing a methodology for the assessment of cumulative and aggregate risk (taking into account multiple substances, routes and sources of exposure at the same time). The project is particularly focused on pesticides, mycotoxins, endocrine disruptors and heavy metals. The Agency will also continue to take part in a European project studying the modelling of human variability in toxicokinetic and toxicodynamic processes, financed by EFSA. The Agency will also participate in the EU's joint action on tobacco and vaping products.

As in previous years, ANSES will continue its participation in the WHO's worldwide network for the International Programme on Chemical Safety (WHO/IPCS), whose objective is to improve the assessment of chemical risk by promoting interactions between organisations.

Activities relating to physical agents

➢ **Electromagnetic fields**

2018 will see the completion of the work of updating the knowledge relating to the assessment of the exposure and effects on human health of **extremely low frequency** magnetic fields. This study, which concerns both the general and working populations, will supplement the work published recently by the Agency as regards the effects of these fields on animal health. In addition, several previous expert appraisals carried out on radiofrequencies had led the Agency to mention in its conclusions the issue of the development of **exposure limit values (particularly the Specific Absorption Rate, or SAR)** underlying French and European regulations. In this context, the Agency therefore intends to carry out a literature review on this issue. The Agency will monitor the progress of an ongoing **epidemiological study** on symptoms reported in the vicinity of relay antennas, which benefits from *ad hoc* funding. The conclusions of the collective expert appraisal on **electrohypersensitivity** are expected for early 2018. The large number of recent scientific publications, in particular on the effects on brain function, may also lead ANSES to continue its work in this area.

The Agency will continue to support the Cosmos-France study run by the International Agency for Research on Cancer (IARC), as part of the French contribution to the creation of a large cohort for the European Prospective Investigation into Cancer and Nutrition to collect data on the exposure of the population to electromagnetic waves and on their health.

➢ **New information and communication technologies**

The spread and the very significant increase in the multiple and regular uses of mobile communication devices (mobile phones, tablets, connected objects, etc.), together with the resulting changes in behaviour, raise many questions. ANSES will begin expert appraisal work to understand the issues and identify the potential impacts on health of these new technologies. The expert appraisal is intended primarily to conduct a review of the impacts that these **new information and communication technologies** can have on health (physiological disorders, mental health, etc.), and on social relationships (in the family, at work, at school, etc.). It will include a prioritisation stage with a view to assessing the potential health risks.

As an extension of the Agency's previous work on the question of stereoscopic vision, it is proposed to undertake a specific study concerning virtual and augmented reality, in particular through the use of **virtual reality headsets**. This study will concern both domestic and professional uses.

Activities relating to water quality

As part of its permanent missions, the Agency will continue its work on **chemical and microbiological risks** in water intended for human consumption (WIHC), whether risks related to regulated or non-regulated substances, which is a major and constantly evolving field (e.g. compliance issues for water resources (used for WIHC), water treatment processes, materials in contact with WIHC, health risk assessment on a contaminant or family of contaminants, etc.) as well as on the question of swimming pools.

Several expert appraisal projects will be continued or undertaken following formal requests from the Agency's supervisory ministries This will be particularly the case of work on **antimicrobial resistance** and the environment (water and soils) aimed in particular at producing a review of the state of contamination of the different environments by antibiotics and resistant bacteria, the updating of the Agency's expert appraisals of 2006 on **cyanobacteria and cyanotoxins** (in WIHC and water for bathing) likely to cause acute or chronic toxic effects in humans, the use of **alternative anti-scale technologies in WIHC distribution systems**, and an expert appraisal concerning the **by-products of water disinfection** (in WIHC and swimming pools).

2018 will see the publication of work regarding the **determination of criteria of relevance for pesticide metabolites in WIHC** (plant protection products or biocides), in order to address challenges in the local management of non-compliance when metabolites are found at levels above the quality limit. As a continuation of this work, ANSES proposes to obtain and analyse feedback on the question of quality thresholds for pesticide residues in water **(Vmax)**. The Agency will provide its supervisory ministries with scientific and technical support concerning the work to revise the **European Directive (EC) 98/83 on the quality of WIHC** planned for 2018. Further to work previously published on the **health risks related to medicinal products found in drinking water**, an expert appraisal is to be undertaken on diclofenac.

Activities relating to air quality

- **Outside air**

2018 will see the culmination of the considerable work undertaken by the Agency since 2016 concerning the **effects on health of particles in the ambient air as a function of their physico-chemical characteristics**. This expert appraisal takes into account the analysis of changes forecast in the emissions of various air pollutants, notably from road transport, in the short and medium term. These studies provide crucial support for decision makers with regard to the definition of the most relevant risk management strategies, particularly concerning particles, a critical issue in public health, and the impact of road transport technologies on air pollution. At the same time, the Agency will complete its work to identify emerging pollutants that should possibly be monitored specifically in the light of changes in their emissions and health issues. Lastly, two new initiatives will be launched in the area of surveillance: the question of the usefulness and use of individual pollution sensors and the question of the surveillance of mould in the environment.

- **Indoor air**

2018 will see the completion of a review of knowledge on **pollution transfers from outside to indoor air** in buildings and the resulting specific issues in terms of urban planning and development. Lastly, in 2018 the Agency will undertake an expert appraisal on the **methods and tools for assessing exposure of the population to settled dust in indoor environments**. In the long term, this innovative project aims to contribute to the establishment of guidance values for settled dust, considering that many compounds may be present in this matrix, for which it represents a source of significant exposure for the population, especially children.

Annex 3

ANSES Policy Orientations in Occupational Health

Preamble

This document will be supplemented by the detailed work programme in data-sheet form that will be discussed at meetings of the Thematic Steering Committees (COTs). Written in late summer 2017, this document also presents the most significant advances made in 2017, for information purposes. They are not representative of the annual report, which is only partial at this stage.

1. Points on context and orientation

This orientation note, and the 2018 work programme, were drafted in the context of the imminent publication of the first-year review of the third **National Occupational Health Plan** (PST 3, 2016-2020). ANSES will remain actively involved in its implementation throughout the entire duration of the plan. In this respect, the Agency is responsible for coordinating the implementation of several of its key actions.

The National Occupational Health Plan is organised around two main strategic themes, one of which seeks to prioritise primary prevention and the development of a culture of prevention. Measures have been introduced to foster this culture in essential areas such as information, training, risk assessment and the design of work environments. It thus permeates the actions carried out on risks identified as a priority, such as the continuation of efforts on several "conventional" risks, including chemical risk, and the anticipation of **emerging risks** (endocrine disruptors, nanomaterials, impact of digital technologies). For this reason, following on from previous years, the Agency will focus its expertise and support for research on occupational health issues, in particular on emerging risks and also on CMR risks.

For the past few years, the Agency has had to conduct **complex expert appraisals** in occupational health related to a specific profession or industry sector, or to the particular ways in which work is organised (sewer workers, exposure of agricultural workers to pesticides, risks associated with night work, etc.). In particular, the question of the assessment of cumulative risks or **multiple exposures** remains central and recurring in all of the expert appraisals.

This question is a major challenge for all those active in the field of health, safety and prevention. It is a challenge as regards knowledge of exposure, as well as a methodological challenge for risk assessment. These goals in particular require the Agency to develop knowledge and promote research on the characterisation and assessment of exposure in real work situations.

These occupational health orientations are especially emblematic of the Agency's work, and are coordinated with those of the other major themes addressed at ANSES, particularly environmental health and food safety and nutrition. In addition, the Agency will continue its involvement in studies and collaborations with institutions, committees and counterpart agencies at European or international level.

2. Main advances in the field of Occupational Health for 2017

After 2016, a year that was quite remarkable for ANSES in the area of occupational health because of the publication of several major studies, some of which had been under way for several years, 2017 was mainly devoted to continuing the expert appraisals under way, to ongoing activities, and to the implementation of the National Occupational Health Plan. This year, therefore, with regard to the PST 3, ANSES concentrated on coordinating and leading the plan's actions for which it is responsible: the "substitution" sub-action of Action 1.10, Action 1.11 on poly-exposure, Action 3.10 concerning the surveying of data in occupational health and safety, and Action 3.14 on the standardisation and strengthening of strategic planning of occupational health research. At European level, 2017 was marked by the discussion on the French proposal, prepared by ANSES, to classify titanium dioxide (TiO_2) in all its forms as a Category 1B carcinogenic. Ultimately, a classification in Category 2 was adopted after examination by ECHA's[7] Committee for Risk Assessment. This year also led to BPA being identified as a Substance of Very High Concern for its reprotoxic and endocrine disruptor aspects, based on ANSES's proposal.

Since 2005, ANSES has been responsible for the scientific expert appraisals needed for establishing occupational exposure limits (OELs) based on health criteria. In 2017, the Agency published several collective expert appraisal reports produced as part of this permanent mission[8]. A public consultation is planned for autumn 2017 on the assessment of the methods for measuring 27 of the 31 substances listed in Directive 2017/164/EU, which will enable this directive to be transposed into national law.

In September 2017, the Agency will present additional results from a measurement campaign of biological agents potentially found in sewer air, carried out by the Ile-de-France regional health insurance fund (CRAMIF). The results of this campaign confirm that the drainage network in which the sewage workers operate on a daily basis is an unhealthy environment, a finding that had already been noted in the analysis of data on exposure to chemical pollutants published in the Opinion of June 2016. The Agency has recommended a series of technical and organisational measures to reduce the exposure of these workers.

Lastly, in autumn 2017 the Agency is due to publish the results of two expert appraisals: on the risks associated with exposure of professionals working in fingernail care and decoration activities, and on improving the management of occupational risks induced by climate change.

3. Main work in the field of Occupational Health for 2018

- ***Occupational Exposure Limits (OELs)***

As part of its permanent mission, the Agency will continue its scientific expert appraisal work to formulate recommendations for atmospheric and biological limit values, as well as its contribution to the work of the EC's SCOEL[9]. This year, this activity takes place in the context of the renewal of four Expert Committees (CESs) that work specifically on questions of chemical assessment. The aim is to strengthen the consistency of the Agency's work on multiple reference values (TRVs, IAQGs, OELs, DNELs, etc.), which was previously carried out by different CESs, while avoiding tedious coordination work requiring numerous exchanges between these different committees. A new CES devoted to "Health reference values" has therefore now been entrusted with developing and validating the various reference values for which ANSES's expertise is sought (TRVs, OELs/BLVs/BRVs, IAQGs, DNELs).

[7] European Chemicals Agency
[8] The more recent ones include the Agency's recommendations on the setting of atmospheric limit values for trichloroethylene, di-n-butyl phthalate (DnBP), benzyl butyl-phthalate (BBzP), 2-ethoxyethanol (EGEE), 2-ethoxyethanol acetate (EGEEA) and n-butanol. In addition, this year, the Agency has also proposed biological limit values for hexavalent chromium, acrylamide, di-n-butyl phthalate and benzyl butyl-phthalate.
[9] The European Commission's Scientific Committee on Occupational Exposure Limits

In 2018, the OEL work already under way will be continued or published, in particular that on cadmium and its compounds, inorganic lead and its compounds, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), dust without specific effects, and an isocyanate. Moreover, in France, with regard to prevention of chemical risk in the workplace, the French Labour Code provides for the use of biological monitoring of exposure and biological limit values. ANSES is thus identifying biomarkers of exposure or of relevant effect in order to recommend biological limit values (BLVs) or biological reference values (BRVs) for the monitoring of occupational exposure to substances of interest; the substances concerned by this programme in 2018 include phthalates and BPA. This work will be carried out in connection with the European human biomonitoring project HBM4EU[10].

- ***Activities in the regulatory framework of REACh, CLP, plant protection products and biocides***

With regard to implementation of the REACh Regulation (Regulation (EC) No 1272/2008), assessment work as part of the Community Rolling Action Plan (CoRAP) will continue in 2018 on several substances, including TiO_2, for which data on occupational exposure will be examined systematically.

The placing on the market of plant protection products and biocides in the European Union is regulated at European level (Regulations (EC) No 1107/2009 for plant protection products and (EU) No 528/2012 for biocides).

Marketing authorisations for plant protection products and biocidal products are now issued by ANSES, on the basis of a scientific assessment of their risks to humans and the environment, and of their effectiveness, according to strict conditions and criteria defined in the aforementioned regulations and the various guidance documents that accompany them.

Whether for plant protection products or biocides, ANSES is required to verify applicants' recommendations regarding personal protective equipment (PPE), which must be included in the conditions of use for products placed on the market.

In 2018, ANSES will also continue its participation in European methodological work on the assessment of cumulative risks, the exposure of applicators and workers to plant protection products, and worker exposure to biocidal products, as well as on exposure scenarios in the context of REACh.

It will also develop the observation of worker exposure to regulated products and the possible health consequences, in particular in the framework of the phytopharmacovigilance scheme implemented by the Agency, in which the issue of occupational exposure is obviously crucial.

Lastly, like every other year, dossiers will also be prepared on proposals for harmonised classification (CLP Regulation), including one for methyl methacrylate.

[10] https://www.hbm4eu.eu/

- ***CMR substitution***

Support and assistance with substitution, especially that of CMR substances or endocrine disruptors, remains a priority action for the public authorities and the Agency, in the framework of the PST 3. This work falls under Action 1.10 entitled "Support companies in establishing efficient and effective prevention", and also relates to the Ecophyto 2 plan. ANSES has been entrusted with coordination and control of the sub-action aiming to support and assist substitution by less hazardous substances. It relies in particular on strengthening the effectiveness of the "substitution-cmr.fr" website, pooling good practices through the exploitation of existing data (international or European initiatives, standardised risk assessment documents sent to the DIRECCTE, fact sheets for assistance with substitution, etc.), and seeking opportunities for synergy with other European or international agencies.

In addition, as part of the examination of MA applications for plant protection and biocidal products containing a substance included in the list of candidates for substitution (plant protection products) or with certain hazard characteristics (biocidal products), a comparative assessment has to be carried out by the Member State for each use in the application.

Lastly, the Agency will continue its work to assess the benefits of formaldehyde regarding its use in certain industry sectors: pathological anatomy and cytology, embalming, as a processing aid in human food and animal feed, and also in the fish farming sector. The results of this work will, where appropriate, help strengthen enforcement of the substitution requirement in the sectors concerned.

- ***Endocrine Disruptors (EDs)***

The programme for the assessment of priority EDs or reprotoxic substances will continue in 2018 in the framework of implementation of the National Endocrine Disruptor Strategy (SNPE), which each year tasks the Agency with the re-assessment of substances to be examined as a priority, as well as the assessment of several other substances. The list of those to be investigated by the Agency under the SNPE is systematically subject to consultation in the framework of a meeting involving several Thematic Orientation Committees (COTs). Compared to previous years and thanks to the adoption of ED criteria, the goal is now to accelerate identification of endocrine disruptors (SVHC 57f) in the framework of REACh.

Starting from the premise that occupational exposure to endocrine disruptors is insufficiently characterised or taken into account, Action 1.12 of the National Occupational Health Plan seeks to enhance knowledge of occupational exposure to endocrine-disrupting chemicals. The Agency will obviously be mobilised for the implementation of this action.

- ***Nanomaterials***

The Agency will continue its work on the issue of risks associated with nanomaterials, which is also one of the priorities of the National Occupational Health Plan. Over the last few years, this activity has been pursuing three specific themes:

- Continued management of the national online reporting portal, "R-Nano", including exploitation of its data with publication of an annual report, accompanied where appropriate with specific studies by the Agency on emerging issues relating to the specific hazards or uses of nanomaterials.
- Monitoring of work relating to the regulatory framework for specific nanomaterials, in particular under the REACh Regulation, with the assessment of TiO2, particularly its nanoscale forms.
- Lastly, following a formal request from the public authorities, expert appraisal work is in progress on the risks associated with uses of nanomaterials in the food sector, including risks for the professionals concerned in this sector.

- ***Health risks for workers associated with waste recycling activities***

The waste management and recycling sector is booming, and the number of companies, and therefore workers involved, has increased sharply over the last few years. These workers are exposed to many types of pollution: hazardous materials and substances and biological agents, as well as organisational constraints. In view of these findings, several European or international studies have highlighted the need for priority actions to prevent the risks associated with the growth of the green economy, and the recycling sector in particular. ANSES decided to issue an internal request in 2016 to conduct an expert appraisal of the health risks for professionals in the waste management and recycling sector in France. The results of the first phase of the expert appraisal, which seeks to identify the sectors of interest in terms of health risks in light of the available data, are expected in the summer of 2018.

- ***Crystalline silica: update of knowledge concerning hazards, exposure and risks***

ANSES issued an internal request to update knowledge on the hazards and health effects of crystalline silica, and on the industries involved in its production and use, in order to identify new uses and exposure trends, and to conduct, if appropriate, an assessment of the risks associated with the exposure scenarios of greatest concern. A review of the main regulatory provisions relating to prevention/protection/compensation associated with exposure to crystalline silica will also be carried out. On the basis of this information, the Agency will also explore the feasibility and relevance of a proposal for harmonised classification and labelling at European level within the framework of Regulation (EU) No 1272/2008 (CLP) taking into account the work of the IARC, the regulatory context (carcinogenic classification of work involving exposure to crystalline silica in the framework of Directive 2004/37/EC) and discussions concerning the nanoscale forms of crystalline silica. The expert appraisal work should be completed in the first half of 2018.

- ***Expert appraisal relating to other forms of atypical working hours***

In the first phase of its expert appraisal on the health effects of atypical working hours, the Agency focused on the question of night shift work, for which data on the associated health risks were already available. In the second phase of the expert appraisal, the Agency will examine other forms of atypical working hours and the potential health effects associated with these forms of work organisation. An initial stage will involve defining the different categories of atypical working hours and their distribution, and identifying the industry sectors and professions concerned. Lastly, if the available data allow, the Agency will attempt to identify the potential health effects and constraints associated with the practice of these different categories of working hours.

- ***Exploratory study of occupational exposure and risk situations associated with biotechnology applications in industry***

An initial report by the Agency published in 2013 revealed that sectors using biotechnologies are experiencing strong growth, with more and more applications, and are affecting a growing number of activities, whether in research and development, or industrial production. According to the latest data published by the OECD in 2012, France ranks third in the world in this area, with nearly 2000 companies employing biotechnology processes. In this context, ANSES proposes conducting a review of the available data on the health risks associated with the use of biotechnologies. This review should also make it possible to identify for different sectors the nature and hazards of the biological agents handled, the situations liable to lead to exposure and even possible co-exposure, the number of employees concerned, the risk assessment methods, and the prevention and protection measures implemented.

- ***Occupational risks in the livestock sector***

French agriculture is organised around many different production systems, ranging from major crops and intensive farming throughout northern Europe, to Mediterranean, and then tropical production

systems in the overseas territories. Besides the production of greenhouse gases, livestock farming generates dust containing chemicals and/or biological agents, as well as gases, in particular ammonia, which can be harmful to human health. ANSES's expert appraisal of occupational exposure to pesticides in agriculture had in particular stressed the absence of systematic surveys of situations involving exposure related to the use of biocides in livestock farming. Regarding occupational health, even though means of reducing exposure are available and measures to raise awareness are already taken in livestock farms, the working conditions, in particular inside enclosed agricultural buildings, expose visiting workers, farmers or employees to a number of substances potentially posing a risk. Many epidemiological studies have also revealed respiratory problems among farmers (asthmatic symptoms, obstructions of the respiratory tract, chronic sinusitis and bronchitis, etc.). These observations have been confirmed by the data of the National Network for Monitoring and Prevention of Occupational Diseases (RNV3P), which show, for example, strong causality between exposure, mainly to organic dust, and respiratory diseases such as chronic obstructive pulmonary disease and asthma in pig breeders. Since 2002, ANSES's Ploufragan Laboratory has been studying the respiratory health of poultry farmers in France, in collaboration with the Agricultural Mutual Insurance Scheme (MSA). The AIRPOUL study, launched in 2005, has thus demonstrated that the dust in the henhouses of layers has a direct impact on the respiratory health of farmers. New epidemiological studies on respiratory risks have been carried out in poultry and duck hatcheries (AIRCOUV and PALMICOUV studies), poultry slaughterhouses (ACCROCH'AIR project) and chicken farms (AIRELEVEUR project). A project on occupational respiratory exposure in fattened duck holdings is being prepared.

ANSES plans to initiate a debate on the topic, and to document the health risks in a livestock sector considered to be of interest, mainly by assessing the exposure situations and sources for workers in the sector. Account will be taken of the economic and social dimension, which can have direct or indirect consequences on the exposures encountered.

- ***Integrative approach to the occupational health of workers employed in the cleaning and sanitation sector and in situations of multiple exposure***

Cleaning and sanitation workers perform their activities in every sector (private or public) and work in very varied environments. They are subject to multiple risk factors, whether physical (accidents, falls, excessive stress on joints, etc.), organisational (work load, night work, irregular or atypical hours, isolation), biological (risk of viral or bacterial contamination from contact with dirt), or chemical. Cleaners also use many cleaning products: scourers, descaling agents, detergents, degreasers, disinfectants, etc. that can contain potentially hazardous chemicals. They are particularly exposed to the risk of developing respiratory (rhinitis, asthma and asthma-like syndromes) and dermatological (dermatitis) disorders. The chronic risks associated with exposure to carcinogenic, mutagenic or reprotoxic substances are still only rarely documented. In its mid-mandate review, the Agency's CES on "Consumer items and products" expressed a wish to investigate more specifically the issue of chronic exposure to cleaning products. Cleaning work, practised predominantly by women, is therefore characterised by high exposure to multiple agents by people who are often in a precarious economic or social situation. Moreover, the medical monitoring of these workers is complicated by the activity itself, often involving multiple sites, multiple employers and multiple occupational health services.

The Agency therefore proposes initiating preliminary work in 2018 with the aim of investigating the risk factors to which cleaning and sanitation workers are subjected, and identifying the population categories concerned and the different exposure situations and factors, as well as their determinants. Particular attention will be paid to the reasons for any difficulties encountered in this characterisation. It will thus be necessary to shed light on the economic and social constraints associated with this sector in order to better understand the health issues (in the WHO sense). This preliminary work should help identify the situations and/or populations to be investigated as a matter of priority.

- ***Vigilance in occupational health and exploitation of RNV3P data***

The RNV3P data now routinely provide input for the Agency's expert appraisal work or that of its external partners. Data mining of the statistics in the national database is carried out regularly in order to identify reports to be exploited by the dedicated working group, some of which may be examined in depth in the framework of specific formal requests. Exploiting the RNV3P data also enables ANSES to assist in defining the work programme of the Commission on Occupational Pathologies of the Steering Committee on Working Conditions (COCT). Lastly, the RNV3P data will play a role in the debate planned by a key action of the PST 3, on improving the system of data management in occupational health, in particular to increase its operational capability for the benefit of those responsible for prevention. The RNV3P actively participates in and contributes to the work of the European MODERNET[11] network. In September 2017, ANSES will open the Occwatch platform, whose prototype was developed in the framework of MODERNET, and which will provide a forum for members of the European network, occupational health specialists, to share clinical cases identified as potentially significant in terms of emerging risks.

[11] MODERNET – "Monitoring Occupational Diseases and tracing New and Emerging Risks in a NETwork"

Annex 4

ANSES Policy Orientations in Animal Health, Welfare and Nutrition

Preamble

This document reviews some of the major work completed by the Agency in the field of **animal health, welfare and nutrition** in 2017 and proposes a few key themes for the 2018 work programme of the Agency's laboratories, French Agency for Veterinary Medicinal Products (ANMV) and assessment departments with regard to animal health, welfare and nutrition.
It is supplemented by the detailed work programme, which will be discussed at meetings of the Thematic Steering Committees (COTs) and the Scientific Board (CS) planned for October and November.

1. General points on context and orientation

Within ANSES, animal health, welfare and nutrition benefit from an organisation which is unique in Europe, combining risk assessment for animal health, welfare and nutrition, assessment and management of veterinary drugs, plant protection products and biocides, assessment of environmental and occupational health risks for humans, and laboratories carrying out research, analytical reference, surveillance and expert appraisal missions in animal health and welfare. This alliance between laboratories, animal models, practical experience in the field, expert appraisal and inspection activities in the field of veterinary medicine, which calls on many internal and external scientists, means that when required, the Agency can rapidly mobilise its resources in its areas of expertise. It enables ANSES to offer a comprehensive and systemic approach to issues of research and assessment in animal health, welfare and nutrition, taking into account farming systems and their consequences on animals, the health of professionals involved in animal production, food safety, and on the specific health risk posed by antibiotic resistance in veterinary medicine. It therefore provides the State with the science-based evidence that is essential for establishing and supporting the implementation of risk management measures in all these areas.

2. Main advances in the field of Animal Health, Welfare and Nutrition for 2017

Of all the actions carried out as part of the Agency's work in animal health, the following **highlights** deserve mention:

- **Emerging phenomena and animal diseases: research, reference, surveillance and risk assessment**

The end of 2016 and then 2017 were of particular concern in terms of emerging epizootic diseases, showing not only the ability of our animal health surveillance system to detect them, but also the fragility of our health status, which had previously been controlled:

- Serotype 8 of the **bluetongue** virus re-emerged in autumn 2015; this then continued through 2017.

- Three outbreaks of porcine epidemic diarrhoea due to the Indel strain (moderately virulent) were detected and investigated during 2017, and the circumstances of their introduction (mainly imports from other European countries) led the DGAL to respond to calls from professionals to classify the disease in Category 1 for hypervirulent strains and Category 2 for Indel strains.
- At the end of November 2016, almost a year to the day after the emergence of three **highly pathogenic avian influenza viruses** (H5N1, N2 and N9) of European origin, France was once again severely affected by an outbreak of highly pathogenic H5N8 avian influenza. This virus of Asian origin, very probably originally introduced by wildlife, caused an animal epidemic on an unprecedented scale in France, being responsible for more than 500 outbreaks, essentially located in the South West, in fattened duck holdings. ANSES's work, performed by its laboratories, the Epidemiological Surveillance Platform for Animal Health and the Risk Assessment Department, was able to confirm that this H5N8 did not possess the key determinants of pathogenicity for humans and to establish that at least two different viral strains have been circulating in France, one originating in a migratory flow in northern Europe and the other having previously circulated in Hungary and Croatia. The majority of the cases identified in poultry in the South West had originated from this "South-East" Europe strain.
- Several emergences of Q fever in the Deux-Sèvres and Indre-et-Loire *départements* during the summer of 2017 required the National Reference Laboratory (NRL) in Sophia Antipolis to work on the identification of animal strains.
- In all these emergences, the **mobilisation of the staff** at the NRLs concerned, the epidemiology units in coordination with the Epidemiological Surveillance Platform for Animal Health (ESA Platform), the Agency's sequencing platform, the DER's UERSABA Unit, experts from the CES on "Animal health and welfare" (SABA), and the Health Monitoring & Alerts Department, was key to responding effectively to the scientific management of these health crises.
- Also in the field of emerging phenomena, the Lyon Laboratory developed and validated a new veterinary vaccine approach against **Rift Valley fever**, thus supplementing the arsenal available to combat this major zoonosis in the event of its emergence on French territory.
- In the field of **bee diseases**, at the end of 2016 the Sophia Antipolis Laboratory celebrated 40 years in reference work dedicated to bee health, a truly cross-cutting field of activity at the Agency since it touches on both animal and environmental health, and includes missions to assess the risks associated with regulated products and veterinary drugs. This year, 2017, also saw the emergence of *Varroa destructor* on the previously disease-free island of Réunion, while work continued on the interaction of thiametoxam with chronic bee paralysis virus (CBPV), or black disease.
- Through its partnership with GDS France, ANSES's Niort Laboratory continued its reference work on IBR and BVD and undertook research on interference between the diagnosis of IBR and paratuberculosis, a disease for which the laboratory holds the OIE reference mandate.
- Also in the **area of wildlife and its interaction with the health of livestock animals**, in 2017 our Nancy Laboratory completed a project on oral vaccination of badgers against bovine tuberculosis by BCG. These animals are proven vectors in the persistence of this disease in suckler herds mainly due to the possible contact of grazing herds with badger setts. ANSES was also closely involved, through its risk assessment activity, in topics at the interface between wildlife and livestock, such as pestivirus in Pyrenean chamois, or brucellosis in Alpine ibex.
- The question of the **risk of introduction in France of lumpy skin disease,** which was the subject of a major report by the CES SABA in 2017, illustrates the synergies between the different ANSES entities, from the Health Monitoring and Alerts Unit, which called on the international monitoring carried out by the Epidemiological Surveillance Platform for Animal Health, through to the expert groups of the Risk Assessment Department, who were tasked with assessing the risk.
- ANSES's EURL mandate for equine diseases was renewed in May 2017 for a further five years. In the framework of this mandate, therefore, the Maisons-Alfort Laboratory for Animal Health will continue to work on West-Nile virus, glanders, vesicular stomatitis virus and more generally viral encephalitis of Equidae. The Dozulé Laboratory for Equine Diseases will continue its own reference

activities specifically on contagious equine metritis (CEM), dourine, equine viral arteritis (EVA), equine herpes viruses 1 and 4 (EHVs) and equine infectious anaemia (EIA).

- The Maisons-Alfort Laboratory for Animal Health, which in the autumn of 2016 gained a brand **new containment level L3 laboratory and insectarium** (the "iCube" laboratory), has positioned itself as a leader on the international scientific stage in particular on foot-and-mouth disease. The laboratory obtained its mandate as OIE Reference Laboratory on foot-and-mouth disease in 2015, and in late 2016 hosted the annual meeting of the network of OIE/FAO reference laboratories on foot-and-mouth disease, which brought together laboratories from Europe, Africa, Asia, and South and North America.
- Lastly, in the framework of its BIPAR joint research unit (ANSES, INRA, ENVA), in 2017 ANSES contributed to the development and implementation of a Web and smartphone application enabling members of the public to report tick bites. This first component of the Citicks project gives ANSES the chance to participate in citizen science, in line with the Agency's commitments regarding dialogue with its stakeholders.

➢ **Antimicrobial resistance**

- The main event of 2017 in the area of antimicrobial resistance will undoubtedly be the conclusion of the EcoAntibio 2017 plan and the launch of EcoAntibio2. The EcoAntibio 2017 plan is on track to achieve the reduction targets it had set for itself, which is remarkable in light of their initial ambition. The French surveillance network for antimicrobial resistance in pathogenic bacteria of animal origin (RESAPATH) has been one of the drivers of this plan and serves as a reference at European level. Similarly, the observatory on antibiotic uses in the animal production sectors has been one of the spearheads of this programme. These successes have led to RESAPATH becoming **leader of Action 39 of the interministerial roadmap,** which promotes at European level the development of coordinated surveillance of the major pathogens observed in veterinary medicine.
- The ANSES Lyon Laboratory is a partner in two of the international research projects being funded by the Joint Programming Initiative on Antimicrobial Resistance (JPI-AMR). The coordinator of ANSES's antimicrobial resistance unit also represents France within the JPI-AMR.
- The ANMV has been continuing the work it initiated under the EcoAntibio plan in the area of monitoring of antibiotic use and development of indicators. As such, in partnership with the IFIP (French Pork and Pig Institute), it developed and rolled out a computer application for managing data collected on antibiotic uses in the pig sector. This tool will help develop a more detailed analysis of antibiotic use and calculate individual indicators.
- The ANMV also finalised work for an internal request in response to Action 17 of the EcoAntibio 2017 plan, on the "*methodology for revising the dosages of older antibiotics*". The proposed methodology is based on a PK/PD (pharmacokinetics/pharmacodynamics) approach. It will then be possible to exploit this opinion at European level in the context of work on this topic that began this year at the EMA.
- Lastly, it has been an active participant in the European working groups of the EC and the EMA, in particular chairing the JIACRA inter-agencies working group (EMA, ECDC, EFSA), which has just published its second report. At the end of 2017, work on the assessment of "*alternatives to antibiotics*" will be presented. The CES on "Animal feed" will take this opportunity to describe its proposed method for assessing scientific publications on substances claiming, by their use, to reduce the dependence on antibiotics.

➢ **Veterinary medicinal products**

- In the vigilance sector, in order to facilitate the reporting of pharmacovigilance cases and in response to requests by veterinarians, who are the primary reporters of adverse effects, the ANMV published a new declaration form more suited to collective treatments, and launched a new more user-friendly electronic submission site. This new tool is connected to the ANMV's drug database and also enables users to create accounts, archive their reports, and attach files.

- In addition, the ANMV has set up a Monitoring Committee for Veterinary Medicinal Products, mainly in order to collect information on the uses of veterinary drugs (adverse effects, therapeutic shortcomings, etc.) and the context of these uses (impact of management measures, relevance of the proposed protective measures). This will give the ANMV a pragmatic and overall perspective of the issues surrounding the decision: context, economic and health impacts, drug availability, etc.

➢ **Animal welfare**

The Risk Assessment Department also received several formal requests (still being examined) in the field of animal welfare, relating to different species and issues, ranging from the stunning and slaughter of livestock animals to questions on the behavioural assessment of potentially dangerous dogs. The work on these formal requests will come to an end during 2018.

➢ **Partnership policy, European and international relations**

- The year 2017 was marked by the launch of "**Agri Food Transition**", the Carnot "Springboard" initiative supported by the ACT Food Bretagne federation, and for which ANSES is in charge of scientific management. The Carnot Springboard's first call for projects was a resounding success and will allow 10 research projects to be funded, including two shared by Carnot and CEA Tech.
- At European level, ANSES is particularly involved in **European research networks**, under the "One World, One Health" concept. As part of this, in 2017 the foundations were laid for the European Joint Programme (EJP) Co-fund on "One Health". This partnership project, half of which is being funded by the European Commission, is being coordinated by ANSES. It brings together around forty European institutes in human and animal health, and is focusing on research in the area of foodborne zoonoses, emergences and antimicrobial resistance. It was proposed to the European Commission in February 2017 and following a positive assessment, is expected to start in early 2018. ANSES will be involved both as coordinator and through the participation of its teams in numerous scientific projects and initiatives to be undertaken within the EJP.
- At European level, the ANMV has been heavily involved in work to revise the EU regulations relating to veterinary medicinal products. It has been a driving force for proposals regarding the amendments to the draft text put forward by the French authorities. At international level, the ANMV has supported the development of a laboratory for quality control of chemical veterinary medicinal products within the LANAVET in Garoua (Cameroon). The ANMV has been assisting this laboratory since 2013, with a feasibility study and the drafting of specifications for the acquisition of equipment. Practical training started at the ANMV in December for the LANAVET staff concerned and two inspectors from the Cameroon Directorate for Veterinary Services.
- **International collaborations** have flourished, for example in China, with the China Animal Health and Epidemiology Center (CAHEC) in the framework of the cooperation protocol signed for 2016 to 2020, focused on the surveillance and control of bacterial zoonoses, and with the Chinese Academy of Agricultural Sciences, during discussions in China with a delegation from ANSES's General Directorate.

3. Outlook for 2018

In the field of animal health and welfare, 2018 will see the implementation of the reorganisation of ANSES's scientific governance, taking into account the results of the most recent scientific assessment of the laboratories in 2016, based on six scientific departments focusing on the Agency's six cross-cutting strategic themes.

➢ **Activity that reflects the health events of 2017**

The emergence of new highly pathogenic avian influenza viruses in South-West France and the reintroduction of flocks after a long period of cleanout will mobilise our virology, epidemiology and risk assessment teams, who will be monitoring the repopulation of the restriction zone. Vigilance will be

necessary to avoid the influenza virus being reintroduced next winter from wildlife or a re-emergence of viruses that may have been able to survive in the environment. In this respect, application of the biosafety plan co-signed by professionals and the ministry will be decisive for preventing a new health crisis.

Successive health crises have underlined the need for rapid diagnostic methods, devolved to the farms to substantiate the clinical suspicions of veterinarians and accelerate the health decisions. In the coming years, ANSES will be developing and validating such methods and is already a partner of the European Vivaldi programme (**Error! Unknown document property name.**), which seeks to develop and validate such instruments for avian influenza and foodborne zoonoses in livestock farming.

The recent spread of African swine fever in Eastern Europe towards Slovakia and the Czech Republic should keep us alert to the possible emergence of this disease in France through the movements of wild boars, in particular.

- **Surveillance**

The establishment of a scientific department for epidemiology and surveillance, cutting across the Agency's different policy areas, by combining the Agency's teams responsible for reference activities and the epidemiology units, as well as the entities in charge of risk assessment, should be a key element in the definition of a reaffirmed Agency strategy for epidemiology research and contribution to surveillance.

ANSES will continue to take note of the needs of the DGAL and professionals, in order to maintain and develop scientific and technical support for the ESA Platform, both in terms of the general surveillance methodology and specifically on the health hazards considered by the platforms. It will continue its work for this platform, in particular on the definition and implementation of a surveillance scheme to anticipate possible emergences, as part of international health monitoring, in coordination with the Health Monitoring and Alerts Department and in the framework of deployment of the SALSA system.

Moreover, ANSES will continue the self-assessment process it initiated on the contribution of the laboratories and other entities to the surveillance schemes, on the basis of the benchmark adopted this year, with the aim of continuous improvement and greater efficiency in the mobilisation of teams to respond to issues of surveillance performance.

- **Analytical reference**

Work by the teams at ANSES, GDS France and regional laboratories, in support of the Directorate General for Food, should in 2018 lead to a strong regulatory framework for the **control of reagents and diagnostic kits by the national reference laboratories**. In particular, for each disease, this new framework should define the role played by the NRLs in the initial control of diagnostic kits and in their possible control batch by batch.

As was the case with the current year, 2018 will see our teams mobilised to prepare and defend their applications in response to calls announced by the European Commission for EURL mandates, with a key issue for France being the European reference mandate for foot-and-mouth disease, for which the call was issued in the spring of 2017.

- **Antimicrobial resistance**

Our work in monitoring antimicrobial use in animal production sectors and in antimicrobial resistance of pathogenic and commensal bacteria will continue, and activity on this subject in 2018 will be marked by the launch of EcoAntibio2 and the completion of the research programmes funded by the EcoAntibio 2017 plan. The activity of the scientific department for antimicrobial resistance will be especially dependent on the implementation of this plan.

The ANMV will continue its work at European level, in particular, on tools for monitoring the use of antimicrobials (ESVAC) and by chairing the AMEG (Antimicrobial Expert Group), which will soon be mandated by the European Commission to review the categorisation of antibiotics according to their

importance for humans and the risks of transmission of antimicrobial resistance from animals to humans. This work is particularly important because it has a clear impact on policies for the use of antibiotics at European level. At international level, the ANMV will continue providing its expertise as a collaborating centre to the OIE for the implementation of its global database. At national level, the ANMV will be pursuing its IT work to improve surveillance tools and their necessary adaptation to the various animal sectors (swine, veal, poultry and domestic carnivores). An opinion will also be issued on the adaptation of the sampling plan for surveillance of antimicrobial resistance of strains of *Salmonella* isolated from carcasses of cattle under one year of age at the slaughterhouse (Request 2017-SA-0140).

Moreover, as part of the environmental health chapter of the Environmental Conference's 2015 roadmap, ANSES is required (Measure 56) to conduct an expert appraisal to formalise knowledge on the mechanisms involved in the development of antimicrobial resistance in the environment. The expert appraisal will aim to conduct a review of current knowledge on the contamination of various environmental compartments (water and soil) by antibiotics and resistant pathogenic bacteria in France, and to determine the mechanisms underlying selection and transmission of antimicrobial resistance *via* the environment. This is a particularly cross-cutting request for ANSES, which will call on the different skills of its CESs and laboratories.

Lastly, under the leadership of the Interministerial Delegate for Antimicrobial Resistance, as part of the work of the Interministerial Committee for Health (CIS) planned for September, and under the One Health approach to this issue, ANSES will have a major role in the implementation of several national actions, on the animal component and in major strategic themes such as the appropriate use of antibiotics and possible alternatives, the surveillance of antimicrobial resistance in the different non-human compartments, and the planning of research in this area.

- **Animal welfare**

ANSES's research and expert appraisal activities relating to animal welfare rely on a research unit within the Ploufragan-Plouzané Laboratory and a dedicated working group of the CES SABA. In 2018, construction will begin on the first poultry barn of the future (broilers), which should, in collaboration with EFSA and the DGAL, enable the implementation of a research programme on welfare for broiler health. This fundamental multi-year project will initially revolve around a thesis project but will also be built with the partners of a future regional innovation laboratory (LIT Oustérel), to enable shared use of this equipment funded by the CPER (State-Region plan contract).

- **European partnerships**

At **European level**, 2018 should see the start of the **European "*One Health EJP*" project** mentioned above, which will mobilise many of ANSES's scientific teams as well as the "Strategy and Programmes" and "European and International Affairs" departments for its coordination. Collaborations with foreign partners are expected to continue (in particular via European twinning programmes in Serbia and Azerbaijan), while other envisaged cooperations may start with *ad hoc* actions.

- **Outlook regarding veterinary medicinal products**

An important feature of 2018 will be continuation of the **monitoring of negotiations on changes to European regulations for veterinary medicinal products**. The outcome of this reform is vital to the future activities of the ANMV. Another major event will have a great impact on the future activity of the ANMV and its European positioning: the exit of the United Kingdom from the European Union in March 2019. The United Kingdom makes a major contribution to European expertise (the UK alone is estimated to contribute around 30-40% of procedures) and it is now necessary to begin anticipating and mitigating its exit. To this end, the ANMV will be putting in place an action plan in order to adapt and to affirm its position at European level in the new agencies network model that is likely to emerge.
In addition, the ANMV will continue its work in the area of alternatives to antibiotics and new therapies, to achieve better regulatory visibility and define the content of the data to be provided.

Work will continue on developing the computer tools essential to the ANMV's activity and performance; the VIGIE project that involves putting in place a new long-term scalable national pharmacovigilance database will help optimise all operations to manage reports to the pharmacovigilance scheme. Similarly, the ANMV will continue the development of tools for analysing data on the use of antibiotics and calculating monitoring indicators. It will also pursue its discussions on the digitisation of processes and data.

Lastly, the ANMV will continue **its international activities**, particularly with Cameroon, Morocco and Thailand, as well as its expertise activities as an OIE collaborating centre.

- **Risk assessment**

With regard to risk assessment in animal health, the ranking of animal diseases found in the French overseas *départements* will enable the Agency to respond to a request from the DGAL, with a view to preparing specific categorisation for these French regions. This work should be published in 2018. The major health events of 2017 in the area of avian influenza will require the Agency to continue assessing risks in this area, in support of both the reform of poultry farming practices in the area of biosafety (the Guides to Good Biosafety Practices for professionals will be assessed by ANSES) and the debate on the surveillance of low pathogenic influenza viruses. Lastly, it should be noted that ANSES is now seeing a constant flow of formal requests from the authorities relating to health issues involving wildlife and its contacts with livestock animals. These requests are unique in that they require the use of comprehensive scientific approaches to animal health, calling on new disciplines in the expert groups, ranging from ecopathology to integrative biology and including the human and social sciences, which are vital for making sense of the divisions underlying these issues. In this framework, in 2018 ANSES will apply its expertise to the question of bovine tuberculosis and the role of wildlife in its maintenance and spread. Regarding bovine tuberculosis, France's new action plan will also see the authorities call on ANSES regarding other points requiring expert appraisal and risk assessment.

Major work by the CES on "Animal nutrition" (ALAN) on "*Animal feed and Salmonella in animal production*" will be completed in early 2018, providing the supervisory ministries with an unprecedented synopsis on this theme, both from the point of view of the bibliographic references and the analysis of the available databases. It should also be noted that the DGAL and the DGCCRF jointly approached ANSES with a formal request to assess microbiological hazards in animal feed, in order to gain scientific and methodological information in this area to provide guidance for the authorities' surveillance and control plans, which are currently mainly oriented towards chemical contaminants. Lastly, the CES ALAN's regulatory assessment activities, such as assessments of claims in animal nutrition, European dossiers on dietetic foods, and applications for authorisation to test new additives, will be affected by the rapid development of products designed to offer a response to the reduction in the use of antibiotics in livestock farming, regarding not only questions of safety for animals and humans, but also methodological challenges regarding the assessment of evidence of effectiveness. In 2018, risk assessment activity in the area of animal welfare will be marked by the completion of a major project on the issue of self-inspections in slaughterhouses, which required the collection and analysis of data from slaughterhouses on the stunning of animals of different species, but also the development of suitable methods for gathering experts' statements, with the aim of providing the authorities and professionals with operational information for their controls. In addition, many good practice guides for animal welfare are expected at the Agency for scientific assessment, not only for livestock animals, but also for pets.

Annex 5

ANSES Policy Orientations in Plant Health and Protection

Preamble

This document reviews some of the major work completed by the Agency in the field of **plant health and protection** in 2017, and proposes a few key themes for the 2018 work programme of the Agency's laboratories and assessment and decision-making departments working in this field.
It is supplemented by the detailed work programme in data-sheet form, which will be discussed at meetings of the Thematic Steering Committees (COTs) planned for October.

1. General points on context and orientation

France's agricultural and forest landscape is constantly changing under the pressures of increased frequency and volume of world trade, global climate change, and changes in crop management techniques (particularly in the context of the new agricultural policy that incorporates the concept of agro-ecology), as well as regulatory changes aiming to promote the use of biocontrol products and reduce the use of other plant protection products, both in number and quantity. Some of these factors may increase the risk of introduction of new pathogens and pests in France, while others may potentially lead to the emergence of new plant health issues. France also has considerable overseas territories, which are ecologically fragile and particularly exposed.

As in the areas of animal health and food safety, ANSES has expertise structures for risk assessment, and reference and research laboratories with analysis and monitoring capabilities it can mobilise rapidly to respond to emerging plant health issues. Plant health and protection are addressed in a cross-cutting manner at the Agency:

- With the support of the Strategy and Programmes Department (DSP) of the Research & Reference Division;
- As the national reference and research laboratory, the Plant Health Laboratory (LSV) performs missions in the field of plant health, on plant pathogens and pests (quarantine in particular), on invasive plants and detection of GMOs;
- The Lyon Laboratory, through its Resistance to Plant Protection Products Unit (RPP Unit), studies the emergence and development of pesticide resistance in populations of plant pests, and through its Unit for Coordination and Support for Surveillance (CAS Unit), it provides support for the development of activities relating to epidemiology and contribution to surveillance in the area of plants;
- The Regulated Products Assessment Department (DEPR) within the Regulated Products Division conducts assessments of the hazards and risks for humans, animals or the environment, as well as the agronomic benefits, of plant protection products and substances, fertilisers and growing media, and non-indigenous macro-organisms beneficial to plants that are introduced into the environment, in accordance with European and national regulations;

- The Market Authorisations Department (DAMM) within the same Regulated Products Division is responsible for marketing authorisations and permits (for parallel trade and experimentation) relating to plant protection products, fertilisers, growing media and their adjuvants. It receives the application dossiers and reviews the draft decisions. It also manages declarations of product testing and experimentation, the functioning of the MA Monitoring Committee, and product control and inspection activities;
- The Risk Assessment Department (DER) is a part of the Science for Expertise Division. Its scope encompasses the work of the Expert Committee (CES) on "Biological risks for plant health", with scientific and technical support from the LSV, and the work of the Phytopharmacovigilance and Observatory of Pesticide Residues Unit, which manages a scheme for detecting and monitoring the adverse effects of plant protection products on human health, fauna, flora and the environment.

A comprehensive approach to plant health and protection, which involves studying pathogen interactions between the plant and its environment, helps set the Agency's activities in the general health and economic context, while taking into account societal demands and risk assessment needs.

The Agency's mobilisation and active contribution will continue at European and international levels, whether in risk assessment, research and reference, or monitoring, surveillance and vigilance. The Agency will therefore be pursuing its involvement in the work of European and international institutions (mainly EFSA, ECHA and EPPO), as well as with its counterparts and partners in Europe and elsewhere in the world (Canada, United States, the countries of the Maghreb, etc.).

2. Main achievements in the field of Plant Health and Protection, and outlook for 2018

➢ Plant health: emergence, research, reference, surveillance and risk assessment

The health status of crops and the environment is constantly exposed to parasitic pressure and the threat of new pests. Alerts are regularly reported to the units of the LSV, most often concerning the detection of exotic insects. Some alerts have undergone research and risk analysis to help the DGAL put in place the appropriate means to manage them.

The alerts of greatest concern during the first half of 2017, and which will have a significant impact on activity in 2018, relate to:

- The observation of defoliation of apple orchards in the Auvergne-Rhône-Alps region, which seems to be due to infection by strains of *Alternaria.* Strains isolated from the apple orchards are currently being characterised in the Mycology Unit. This emergence is the subject of a formal request to determine the identity of the strains capable of causing this type of disease on apple trees, with a view to establishing the origin of the inoculum, and to assess the economic and environmental consequences of these diseases.

- Detection of an outbreak of *Phytophthora ramorum* in a plantation of Japanese larch (*Larix kaempferi*) in the Finistère *département*. In France, it is regularly detected in nurseries on rhododendrons and viburnums. In 2009, severe attacks on Japanese larch in South-West England were attributed to *P. ramorum*, and the disease has spread rapidly throughout the whole of the British Isles. In 2013, 16,000 hectares of larch trees had to be felled there. The detection on Japanese larch raises fears of an explosion of *P. ramorum* infections.

- The detection of many insects is regularly reported; some have undergone a risk analysis; this is the case with a borer (*X. compactus*) and the black peach aphid (*Pterochloroides persicae*) in peach orchards in the South East of France.

Several formal requests will be examined in 2018:

- Pest risk analysis for *Candidatus* Liberibacter sp., the agent responsible for huanglongbing (citrus greening disease);
- Formal request on strategies to combat the red palm weevil;
- Risk analysis for *Fusarium oxysporum* forma specialis *cubense* responsible for Panama disease, for the French overseas *départements*;
- Analysis of the risks relating to hairy caterpillars for human and animal health;
- Internal request on effluent disinfection methods in laboratories and experimental facilities handling regulated pests.

The work in progress to prioritise plant pests enables the DGAL to categorise these pests in accordance with the Act on the future of agriculture. This work required the design of an automated method for identifying the necessary information within databases, websites and scientific documents, gathering it all in a database and analysing it using a multicriteria approach in order to prioritise them. This tool and the associated data will provide a new prioritised list of pests for metropolitan France in 2018. A variant of this tool has been developed for the overseas territories. Once applied, it will assist with the prioritisation of risks in these various territories. This database will serve as a resource for analysing future plant health risks, anticipating unforeseen events and modelling invasions.

The teams of the LSV were also mobilised in 2017 to monitor the extension of certain outbreaks. The most significant example of this was characterisation of the emerging polyphagous bacterium *Xylella fastidiosa* (reference activities, support for the health authorities as part of crisis management, research projects seeking to obtain a better understanding of the bacterium's biology, vectors and control methods, technical and methodological support for surveillance, etc.).

In 2018, the LSV will continue its special partnerships with INRA and CIRAD for research projects relating to *Xylella fastidiosa,* tropical viral diseases, genetics of fungal populations and resistance to copper among phytopathogenic bacteria.

There will be many new challenges facing the LSV in 2018, such as:

- strengthening its influence through networks and partnerships at national, European and international level with, in particular, mobilisation to prepare a French application in response to the future European Commission call to grant one or more European reference mandates in plant health,
- continuing the gradual integration of innovative diagnostic techniques (barcoding in entomology, NGS and digital PCR in phytopathology and in GMO detection, in particular for the detection of unknown and non-targeted exogenous sequences, metagenomics in forest mycology, etc.),
- continuing its active involvement in implementing cross-cutting actions within ANSES in terms of reference missions (processes to transfer methods to accredited laboratories, organisation of inter-laboratory proficiency tests) and expert appraisal tasks,
- involvement in the establishment of an epidemiological surveillance platform for plant health, announced by the health authorities.

➢ **Resistance to plant protection products**

The RPP Unit studies the emergence and development of phenomena of resistance to plant protection products in the main agents of economic interest (fungi, pests, bacteria and weeds). It helps establish and implement the DGAL's biological surveillance plans in France concerning the "Resistance" component of the monitoring of unintended effects (UEs) of plant protection products. It also offers its

expertise to assessors (MA application dossiers for the DEPR) and risk managers (participation in the drafting of common technical notes on resistance as well as in the phytopharmacovigilance scheme). Regarding reference activities, the RPP Unit will be focusing on the development of methods to detect resistance to plant protection products, whether with bioassays or molecular biology. In particular, the unit will continue developments on the combinations *Drosophila suzukii*/organophosphates, *Dysaphis plantaginea*/flonicamid and *Phytophthora infestans*/CAA/QiI. More new themes are expected to be explored, such as the combinations *Sitobion avenae*/neonicotinoids, *Alternaria alternata*/QoI/SDHI and *Plasmopara viticola*/fluopicolide.

In terms of research, work will continue in collaboration with CIRAD La Réunion as part of the joint supervision of a thesis on biological invasion and hybridisation in the species complex *Bemisia tabaci* and their possible effect on resistance to insecticides. Work will also continue on resistance of *Myzus persicae* to insecticides, an important theme for the unit. Lastly, new projects on the development and use of new-generation molecular biology tools to detect resistance to ALS inhibitors in ragweed, and on the resistance of emerging pathogens in pome fruit orchards, are expected to be launched.

In the area of surveillance, like every other year, the RPP Unit will be taking part in the DGAL's Resistance surveillance plan (Guidance Note on unintended effects (UEs) including resistance). The list of themes to be studied under this plan will be defined in the fourth quarter of 2017.

➢ **Continual improvement in assessment methodologies for plant inputs**[12]

ANSES scientists involved in the assessment of plant protection products (PPPs) and fertilisers have worked extensively to develop or improve assessment methodologies. These studies have most often been undertaken in partnership with other organisations or in the framework of national, European or international working groups. Their purpose is not only to enhance the interpretation of assays used to determine chemical hazards, but also to construct detailed exposure scenarios and models used in assessing hypothetical risks and agricultural benefits. ANSES also funds specific studies to encourage the production of new knowledge needed for its expertise.

During the past year: as part of the implementation of the Act for the restoration of biodiversity, nature and landscapes, ANSES produced an initial opinion in response to the Ministry of Agriculture's formal request to conduct an assessment weighing up the risks and benefits of plant protection preparations containing neonicotinoids, compared with their chemical and non-chemical alternatives. This opinion presents the methodology developed to identify the alternatives to plant protection products containing neonicotinoids and comparing their effectiveness and operational capability. This interim opinion will, by the end of 2017, be followed by additional work on the identification, effectiveness and risks to health and the environment of alternative control methods, for all the existing uses of neonicotinoids, as well as on the impact of all the neonicotinoid active substances on human health.

Through its Regulated Products Assessment Department, the Agency has continued its support for the development of methods for assessing plant inputs, in particular by contributing to the formalisation at national level of a method of testing the effectiveness of biostimulants, and to the many methodological studies led in particular by EFSA, or conducted in the framework of international partnership projects. This work focused in particular on the methods for assessing the risks to human health (operators in charge of applying the products, workers, consumers, etc.) and the environment (contamination of media, risks to non-target species).

The coming year will see the continuation of this work: examination of the formal request on neonicotinoids (see above), or contributions to methodological work, in particular in the fields of:

[12] Only work involving the efficacy of plant protection products and their environmental impact is presented here. Work on public health risks is detailed in the "Food Safety and Nutrition " and "Occupational Health" documents. The issue of the transfer of MA decisions on plant protection products and fertilisers/growing media is also addressed elsewhere.

- assessment of the effectiveness of plant protection products (fungicides, insecticides, participation in the drafting at European level of a guidance document for the BAD – Biological Assessment Dossier);
- assessment of risks to human health (contribution to work on the establishment of MRLs in honey and hive products, assessment of aggregated and accumulated risks in the area of pesticides, production of data on operator exposure, etc.);
- assessment of risks to the environment and non-target species (methods for monitoring the impact of pesticides on earthworm populations, ecotoxicity tests for assessing the risks of fertilisers and growing media, etc.).

➢ **Phytopharmacovigilance (PPV)**

Initiated in 2015 in the framework of the Act on the future of agriculture, food and forestry, this scheme is intended to monitor and detect any adverse effects of plant protection products on humans, animals, cultivated plants, biodiversity or environmental media, and the emergence of resistance to these products. It enables the continual production of information and the detection of emerging signals for the benefit of risk assessment, placing products on the market and the risk management missions performed by ANSES and the competent ministries.

In 2017, the organisation of the phytopharmacovigilance scheme was consolidated; this included:

- publication of the regulatory texts specifying the operating procedures for PPV and organising the network of its partners (Decree No 2016/1595 of 24 November 2016 and Order of 16 February 2017),
- implementation of the system for reporting adverse effects and compilation of the first reports. In order to facilitate the collection of this information, in early 2017 ANSES published on its website a reporting form intended both for the professionals mentioned in Article L. 253-8-1 of the French Rural and Maritime Fishing Code, and for healthcare professionals and individuals,
- continuation of the programme of studies initiated in 2015 and 2016, in order to consolidate the existing networks, collect new data, or assess the reports,
- production of the first reviews of the available data for assessment of plant protection products based on the information made available by the PPV partners (in particular, data on occurrence of substances in media, human or animal poisoning cases, data on sales and use).

In 2018, the Agency will continue the PPV activities undertaken in 2017, related to the measures to coordinate ANSES's health surveillance schemes, and also those of its counterparts in Europe or North America. These activities will focus primarily on:

- completing the integration of its PPV partners and of any new partners, consolidating the descriptors received from surveillance and vigilance networks, initial work to compare the results from the different compartments with a view to identifying emerging signals,
- continuing the deployment of the system for reporting adverse effects of plant protection products, analysing and processing reports and compiling a first feedback report,
- setting up *ad hoc* studies to generate new knowledge. In 2018, specific work will be carried out in partnership with the French Public Health Agency with regard to the exposure to pesticides of residents in agricultural areas (exposure of humans and the environment).

➢ **Issuing of marketing authorisations**

The DAMM, which was set up on 1 July 2015 as part of the transfer to ANSES of responsibility for issuing marketing authorisations for plant protection products and fertilisers, has continued to implement processes and procedures for ensuring the admissibility of application dossiers and reviewing draft decisions. The DAMM is also responsible for handling informal appeals, in conjunction with the DEPR and the Legal Affairs Department (DAJ).

In 2016, nearly 3000 applications for authorisation or permits relating to dossiers for active substances were received. Nearly 2000 decisions were signed, and around 3000 declarations in the framework of the regulations on research and development testing were recorded and monitored.

The main objective is to process the application dossiers in optimal conditions, within the time limits and according to the regulatory requirements in force.
In this framework, the MA Monitoring Committee, introduced by the Act on the future of agriculture, food and forests and set up at the end of 2015, provides support to ANSES's Directorate General with defining and/or clarifying some of the management measures proposed in the decisions. At the end of 2017, its activity will be extended to the area of biocidal products.

Concerning the issuing of MAs, work is continuing in various areas, in order to structure, optimise and simplify procedures, with:

- the integration of activities in the broadened field of ISO 9001 certification, within a dedicated PR06 process,
- the finalisation of a major project, initiated in the autumn of 2015, to revise the application forms, with the publication on 30 June 2017 of a Ministerial Order laying down the composition of the dossiers relating to plant protection products, and the online publication of the revised forms accompanied by dedicated instructions,
- the implementation of new ways of managing applications when this involves the re-examination of preparations in an EU context,
- the success of the pilot phase of the D-Phy project to digitise MA applications, with the collaboration of the IPP Unit, for aspects relating to uses,
- the launch in March 2017 of an online service for reporting product testing and experimentation, leading to time savings and improved follow-up, for both reporters and managers.

Improvements were made to how the public is provided with information on authorisations, with data from the EPhy site being offered in open source form, dossiers being updated on a monthly basis, and the dedicated page on the ANSES website being overhauled.

The product inspection and control activities were established, with proposed working procedures (annual plan according to defined screening criteria, inspection report and method, etc.), and controls carried out in the distribution sector (sales for professional and amateur products). This work is carried out in close collaboration with the other State services, in application of a memorandum of understanding signed in December 2015.

In 2018, the DAMM will continue its work to optimise procedures and processes in order to reduce the time spent reviewing decisions.

The continuation of the D-Phy project to digitise MA applications and the launch of its Phase 2 should, over the next two years, improve how dossiers are examined when received.
An upgrade to the E-Phy site, which provides the public with data on authorisations, will incorporate parallel trade permits and offer several improvements for users. The information published in open source form will also be modified to take users' needs into account.
Regarding processes, priority will be given to establishing methods for managing data protection and a stabilised procedure for re-examining dossiers as required within the new EU framework (implementation of the provisions of Article 43 of Regulation (EC) No 1107/2009).
The scope and operation of the Monitoring Committee will evolve to take into account the activities relating to biocidal products, as well as the necessary coordination with the activities of the phytopharmacovigilance scheme and the Expert Committees.
Lastly, the inspection and control activities will be ramped up, with controls at sites where products are formulated.

At European level, the DAMM will continue its involvement in discussions and methodological coordination with the Member States of the South Zone (zonal assessment of products according to three geographical zones defined by Regulation (EC) No 1107/2009), as well as for all aspects related to the issuing of MAs (post-reapproval procedures, data protection, comparative assessment, etc.). Closer links with the entities in charge of decisions in the other Member States should also be developed in this framework.