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## La crédibilité de l'expertise scientifique. Enjeux et recommandations

Pierre-Benoît Joly, Catherine Dargemont, Francine Behar-Cohen, Jean-Marc Bonmatin, Marion Desquilbet, Christian Ducrot, Alain Kaufmann, Emeline Lagrange

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**Scientific Council of the French Food, Environment and Labour Safety Agency - Anses**

**Opinion on the report of the WG "Credibility of scientific expertise"  
from the Scientific Council**

In recent years, among the hundreds of opinions issued by the Anses, a few relating to regulated products have given rise to controversy and debate. In this context, the Agency's Scientific Council has mandated a working group (WG) to analyze the situation and make recommendations to strengthen the credibility of the Agency's expert opinions. It thus responds to the objective of permanent reflection stated by the Agency in its framework document on the methodology of collective expertise at Anses (June 2012) as well as to the objective of reinforcing scientific excellence, quality and independence of expertise (Anses Objective and Performance Contract 2018-2022).

The WG addressed the issue of the credibility of the expertise, i.e. the degree of trust it enjoys, based on a feedback approach on three case studies that have been the subject of controversy to varying degrees (glyphosate, SDHIs, neonicotinoids) and on an examination of the factors that determine the credibility of the expertise through a literature review and some 30 hearings. The data were examined along four lines: the discrepancy between the scientific knowledge available and that used for the three expert reports, the procedures, the discrepancy between the conclusions of the expert reports and the expectations of the stakeholders, and finally, the socio-economic impact of the implementation of risk management measures.

**MAIN RESULTS: SCIENTIFIC EXPERTISE AT THE HEART OF THREE MAJOR TENSIONS**

The results of this work shed light on three major tensions affecting scientific expertise in general.

Scientific expertise is subject to a first tension: on the one hand, the need to take into account the most advanced scientific knowledge and, at the same time, the need to rely on clear rules shared by all the actors concerned, so as to carry out a transparent, robust and reproducible risk assessment. This can lead to a discrepancy between scientific knowledge and the results of expert assessments, which is a source of public controversy.

The second tension refers, on the one hand, to the urgency of issuing certain opinions and, on the other, to the time needed to carry out a quality scientific expertise. The urgency may lead to adapting the usual codified rules of collective expertise to the time constraints

(plurality, capacity to analyze all available data, time for collective work, etc.). Their results may be fragile and therefore subject to challenge.

A third tension runs through the expertise. On the one hand, it leads to the need to separate risk assessment and risk management and, on the other hand, the need to put the results of the assessment into perspective with regard to the feasibility of management measures. This tension is

This is particularly true in situations of uncertainty, where, in application of the precautionary principle, it is necessary to qualify the uncertainty and the level of risk, and to implement proportionate measures. This requires, in particular, knowledge of the socio-economic impacts of the measures and the possible alternatives. A lack of clarity in the separation of assessment and management and a lack of transparency in the translation of advice into management measures contribute to the erosion of the credibility of the expertise.

## **RECOMMENDATIONS**

Concerning Anses, the Scientific Council emphasizes that procedural issues are already the subject of constant attention and efforts by the agency (expert groups bringing together scientists chosen for their expertise, subject to independence in the sector of activity considered). The same applies to relations with research (own research capacities, funding of programs supporting studies to fill knowledge gaps, coordination of the European Partnership for Risk Assessment of Chemicals (PARC)). At the international level, the agency is generally considered as one of the most advanced on these issues. Nevertheless, the Anses is subject to the tensions of expertise.

The lessons and recommendations from the three case studies analyzed by the WG are particularly relevant to situations in which there is high uncertainty and/or controversy among experts.

In order to limit the risks of expertise being called into question, the Scientific Council has formulated four groups of recommendations aimed at improving procedures, better informing the decision-making process, intensifying interactions with stakeholders and strengthening the separation of risk assessment and risk management within Anses.

### **1. IMPROVE PROCEDURES**

#### **1.1. Collectives of expertise**

- Encourage scientific diversity (multidisciplinary) as well as the dual presence of academic researchers and researchers familiar with the regulations
- Encourage the participation and renewal of experts
  - Encourage employers (universities, research operators, health agencies, expertise institutes...) to recognize scientific expertise in the evaluation of researchers/teaching researchers and agents, to facilitate the exercise of expertise (partial availability, publication assistance...) and to make visible the major role that expertise plays in the relations between scientists and society
  - Promote expert missions in the framework agreements between Anses and its partners, but also in the Research Alliances; develop new agreements if necessary
  - Use auditions as much as necessary when a specific skill is required

- Ensure regular renewal of the pool of experts to avoid the accumulation of mandates over time
- Strengthen the application of the rules of collective expertise
    - Clarify, for themselves and for the experts, the role of the expert group chairman, the expert coordinator and the Anses agents participating in these groups, in accordance with the new provisions of the internal regulations
    - Reinforce the training/information of experts and Anses agents on the rules, rights and duties of collective expertise and on their protection against media exposure
    - Ensure that discussions and minority opinions are recorded in the minutes of meetings
  - Refine the treatment of links of interest, in particular by applying the guidelines for the analysis of intellectual links proposed by Anses

## **1.2. Referrals and self-referrals**

- Systematize the possibility for expert groups to express their views on the formulation of questions and the timetable for dealing with them and, if necessary, plan discussions with the supervisory authorities to clarify the referral (subject, questions, deadlines and timetable for delivery, etc.)
- Informing expert groups of stakeholders' expectations expressed in Anses' dialogue structures
- To reserve the Emergency Collective Expertise Group (ECG) format exclusively for expertise that can be processed within a short timeframe, from the date of receipt of the referral
- Plan a long-term follow-up to ensure a continuous monitoring of knowledge on complex issues, where the health and/or media stakes are high
- Increase the use of self-referrals by the Agency in order to anticipate foreseeable problems

## **1.3. Scientific alerts**

- Formalize the treatment of scientific alerts and promote exchanges with the scientists who formulate them

## **2. BETTER INFORMING THE DECISION THROUGH THE EXPERTISE PROCESS**

- Systematically validate the selection of the literature taken into consideration with the groups of experts and develop a method for systematically screening for links of interest in the bibliographic journals used (conflicts of interest of authors and editors, funding of studies and scientific journals)
- Facilitate access to data contained in regulatory files
- Define a complete risk assessment grid, applicable in whole or in part depending on the situation, including risk assessment, qualification of the level of uncertainty (in accordance with the recommendations of the group "Accompanying the implementation of the Risk Assessment Methodology recommendations"), analysis of the economic and social impacts (CES "Socio-economic Analysis"), study of alternatives
- In the reports and opinions published by the Agency, systematically indicate: the level of uncertainty, scientific controversies (minority opinions, if any) and any discrepancies between the assessment carried out within the regulatory framework and the scientific knowledge produced outside the framework of the guidelines in force
- Use the recommendations resulting from the expert assessments in terms of knowledge improvement needs to prioritize funding for research projects (carried out by Anses laboratories or by external teams via research and development agreements or the National Environment-Health-Occupational Research Program), in particular to generate scientific data that will enable standards or assessment methods to evolve
- Collecting critiques and reservations from expert groups on regulatory frameworks for evaluation and increasing the Agency's role in the design of international guidelines (OECD, EU)

## **3. CONTINUE TO STRENGTHEN INTERACTIONS BETWEEN ANSES AND ITS STAKEHOLDERS**

- Continue to report to stakeholders on how their expectations have been addressed by the Agency
- For management decisions under the responsibility of the Anses, ensure the same level of clarification as that required for risk assessment
- Strengthen the links between Anses and operators/research organizations
  - Make research teams aware of the methodological prerequisites for taking their results into account in expert assessments
  - Raise awareness among Anses agents and experts of the issues related to the interactions between expertise, politics and society
  - Support an interagency initiative to analyze the mechanisms of ignorance production and their influences on regulatory frameworks

## **4. STRENGTHENING THE SEPARATION OF RISK ASSESSMENT AND MANAGEMENT AT ANSES**

- Attach all specialized expert committees to the "Science for Expertise" cluster

- Improve the clarity of the missions of the different entities of the Agency, particularly with regard to regulated products

In conclusion, the implementation of the proposed recommendations requires support with adequate human and financial resources.



# **The credibility of scientific expertise**

**Issues and recommendations**

## **REPORT of the working group of t h e Scientific Council of Anses**

**November 2022**

## **Suggested quote**

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Joly, P.B., Dargemont, C., Béhar, F., Bonmatin, J.M., Desquilbet, M., Ducrot, C., Kaufmann, A., Lagrange, E. (2022). The credibility of scientific expertise. Enjeux et recommandations - Rapport du Groupe de travail du Conseil scientifique de l'Anses, Maisons-Alfort: Anses, 134 p.

## **Key words**

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Scientific expertise; credibility; procedures; regulatory science; risk communication; agnotology; socio-economic analysis; uncertainty; precautionary principle.

## **Presentation of the speakers**

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Mrs Emmeline LAGRANGE - Hospital practitioner in neurology at the Grenoble Alpes University Hospital - Medicine - Neurology - Environment, Epidemiology - Neuromuscular diseases

## **ANSES SCIENTIFIC COUNCIL**

**PREAMBLE:** The expert members of the Anses Scientific Advisory Board are all appointed in a personal capacity, *intuitu personae*, and do not represent their parent organization

The work, which is the subject of this report, has been monitored and adopted by the Anses Scientific Council.

- **Scientific Council - [2020-2023]**

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*The quotes from the verbatims are anonymized and associated with generic categories, all of which are in the masculine form.*

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## Acronyms and abbreviations

AFSSA	:	French Food Safety Agency
AGG	:	Assessment group on glyphosate
AMM	:	Marketing authorization
APR-EST	:	Call for research projects - environment-health-work
ANMV	:	National Agency for Veterinary Medicines (Anses)
BfR	:	Bundesinstitut für Risikobewertung, German Federal Institute for Risk Assessment
GLP	:	Good laboratory practice
CDPCI	:	Ethics and Conflict of Interest Committee of the Anses
CE	:	European Commission
CES	:	Specialized expert committee
IARC	:	International Agency for Research on Cancer
COP	:	Contract of objectives and performance
COT	:	Thematic Steering Committee
CLP	:	Regulation No. 1272/2008 of the European Parliament on classification, labelling and packaging of chemicals and mixtures
cnDAspe	:	National Commission on Ethics and Alerts in Public Health and the Environment
DAMM	:	Directorate of Marketing Authorizations (Anses)
DAVS	:	Direction des alertes et des vigilances sanitaires (Anses)
DER	:	Risk Assessment Department (Anses)
DEPR	:	Directorate for the Evaluation of Regulated Products (Anses)
DiSSES	:	Social Sciences, Economy and Society Directorate (Anses)
ECHA	:	European Chemicals Agency
EFSA	:	European Food Safety Authority
GECU	:	Emergency Collective Expertise Group
GT	:	Working Group
INRAE	:	National Research Institute for Agriculture, Food and Nutrition the environment

Inserm	:	National Institute of Health and Medical Research
PARK	:	European Partnership for Risk Assessment of Chemicals
OECD	:	Organization for Economic Cooperation and Development
OFB	:	French Office for Biodiversity
GMO	:	Genetically modified organisms
NGO	:	Non-governmental organization
OPECST	:	Office parliamentary d'évaluation of choices scientific and technological choices
NRP-EST	:	National environment-health-work research program
REACH	:	Regulation n° 1907/2006 of the European Parliament and of the Council on the registration, evaluation, authorization and restriction of chemicals
EU	:	European Union

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Figure 2: Chronology of the SDHI case

Figure 3: A general lack of confidence in the ability of public authorities to protect people (Source: IRSN 2021 p.34).

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Box 1. Key lessons from the case studies

# Synthesis of the argument and recommendations

## Synthesis

### WG Terms of Reference

In recent years, the expert reports produced by the Anses (and in some cases the experts who contributed to them) have been contested and even violently attacked, directly or through the media. This situation, if not carefully managed, could threaten the credibility of the agency, particularly for the management of pesticide dossiers and for the planned transfer of the evaluation of genetically modified organisms (GMOs), another very sensitive dossier. In this context, the Working Group (WG) set up by the Anses Scientific Council was tasked with diagnosing past events, analyzing the various cause-and-effect relationships, and making proposals on the various possible ways to improve the situation.

By addressing these issues from a feedback approach and by mobilizing scientific knowledge on scientific expertise, this working group intends to contribute to the institutional reflexivity of the Agency and to strengthen its credibility. It thus meets the objective of permanent reflection stated by the Agency in its framework document on the methodology of collective expertise at Anses (June 2012) as well as the objective of reinforcing scientific excellence, quality and independence of expertise (Anses Objective and Performance Contract (COP) 2018-2022)

### Method

The credibility of expertise can be defined as the degree of confidence in it. Credibility is the result of a set of factors that manage to convince people of the accuracy of the expertise within a defined framework. As sociology and the history of science show, the credibility of expertise depends on many factors: institutional, social, procedural... but first of all on the rigor, impartiality and transparency with which it is conducted. In order to identify these different factors, the approach was conducted at two levels:

- The core of the analysis is the realization of case studies on the glyphosate, SDHI and neonicotinoid dossiers, allowing for feedback. These studies are based on a detailed analysis of the processes aimed at identifying the role of factors related to the conduct of the process;
- A more general approach, based on a literature review and interviews with agency managers and stakeholders, is also used. It aims to understand the factors related to (i) organizational reputation and (ii) stakeholder expectations. This general approach makes it possible to supplement or even extrapolate the case studies, in order to identify cross-cutting findings and recommendations.

## The three case studies

The choice of three cases (glyphosate, SDHI, neonicotinoids) was guided by the repeated criticism of the opinions issued and the intensity of the controversies and polemics generated by the glyphosate and SDHI assessments in different arenas (media, Parliament, non-governmental organizations (NGOs), administrations, etc.), which have damaged the agency's reputation - in contrast to the case of neonicotinoids, for which criticism of the agency's assessments has, on the contrary, been limited. These cases, which are rare but relevant for an in-depth analysis of the scientific credibility of the Anses, are not representative of the hundreds of opinions issued each year by the agency. Nevertheless, the analysis of such cases is timely and necessary when one is interested in the credibility of scientific expertise. Moreover, the intensity of the controversies and polemics makes it possible to collect a very rich material, which is essential for such an analysis.

In a transversal way, a heuristic framework was also mobilized. It includes four working theses:

- Thesis 1. Credibility is a matter of discrepancy between scientific knowledge and expertise
- Thesis 2. Credibility is a matter of procedures
- Thesis 3. Credibility is about the gap between expertise and the expectations of the concerned audiences
- Thesis 4. Credibility is about the socio-economic impact of implementing risk management measures

For each of the three cases, descriptive sheets were produced based on the collection of all available literature. This documentary phase was extended beyond the cases to cross-cutting themes by collecting a variety of sources. About thirty interviews were conducted with researchers (13), Anses officials (11) and various stakeholders (8). These interviews were processed in two phases:

- A double-coding of all interviews according to the four theses of the heuristic framework
- An analysis of the different hypotheses for each case (transversal elements, specific elements) based on the verbatim

## Results

### ***Neonicotinoids***

In the case of neonicotinoids, criticism of the Anses' expertise remained limited in the media and focused on the authorization of sulfoxaflor. The decision of the Nice court and the non-appeal of the Anses have extinguished the controversy. The absence of questioning of scientific credibility in this case is due to the integration of new scientific knowledge in the regulatory framework, even if the time required for the investigation is undeniably too long and the process is still incomplete. This integration tends to reduce the distance between the answers provided by the agency and the expectations of the various stakeholders. The weight of economic interests limits the integration process, both at the European level (little integration of knowledge in the guidelines) and at the French level (derogation granted to the beet industry). The content and lack of transparency of these decisions undermine the credibility of the expertise. Concerning the role of procedures, the mobilization of expertise predates the creation of the agency. The history of this case shows the procedural progress linked to the creation of the Anses compared to what prevailed before. Witnesses cite in particular the independence of the expertise and the scientific referencing of arguments. The possibility of self-referral, which is essential to investigate complex and uncertain issues, was also mentioned. It is therefore essential that the principles of impartiality and adversarial nature of the collegial expertise be strictly respected.

### ***Glyphosate***

The Anses has faced significant criticism concerning the expert assessments it has conducted on glyphosate. These criticisms are part of a context in which the regulatory evaluation of glyphosate has crystallized criticisms and strong expectations from civil society, but also from actors in the scientific and political worlds, and has become an emblem of expected changes, on a better consideration of the dangers and risks of pesticides, more broadly as regards agricultural production methods. The procedures play an essential role here with the restriction of the questions asked to the experts in the referrals, the modalities of functioning of an expertise in the form of Groups of collective expertise in urgency (GECU), the literature taken into account, the reading of the precautionary principle, the non finalization of a mandate entrusted to a group of experts. The gap between science and expertise also plays an important role, with the whole issue of the gap between the evaluations of the International Agency for Research on Cancer (IARC) and EFSA (European Food Safety Authority), strong criticism of the European regulatory expertise on glyphosate. They affect the Anses via the collectives of experts mobilized but also via the agency's activity, whether it is the legal ban on Roundup Pro 360 or the criticisms addressed to the Assessment Group on Glyphosate (AGG) consortium, in charge of the re-evaluation of the authorization of glyphosate. Finally, because of the importance of glyphosate's uses and the difficulties of doing without this active substance, the weight of economic interests appears to be an obstacle to the consideration of independent expertise.

### ***SDHI***

The Anses' management of the scientists' alert on SDHI was strongly criticized for the procedures implemented, both for the initial exchanges with the group of scientists and for various limitations related to the choice of a GECU format for the initial investigation of the alert (limited in duration, number of experts involved and their field of expertise, consideration of scientific literature). The gap between science and expertise also plays an essential role, since the alert concerns a gap between scientific knowledge on known toxicity mechanisms (mitotoxicity) and the regulatory framework for the evaluation of pesticides, which does not take these mechanisms into account. A strong involvement of different stakeholders from civil society, the political world and the scientific community, testifies to the discrepancy between the expectations of a broad assessment of the dangers and risks of pesticides and the narrow framework of regulatory expertise, which is also a source of erosion of credibility. Finally, the high economic stakes surrounding the use of SDHI in the agricultural sector appear to be a brake on the societal and political demand for a reduction in the use of pesticides.

### **Box 1. Key lessons from the case studies**

## **Main results: scientific expertise at the heart of three major tensions**

The results of this work shed light on three major tensions affecting scientific expertise in general.

Scientific expertise is subject to a first tension: the need to take into account the most advanced scientific knowledge while relying on clear rules shared by all the actors concerned, for the conduct of a transparent, robust and reproducible risk assessment. This can result in a discrepancy between scientific knowledge and the results of expert assessments, which is a source of public controversy.

The second tension refers, on the one hand, to the urgency of issuing certain opinions and, on the other, to the time needed to produce a quality scientific assessment. The urgency can lead to work that does not respect all the usual and codified rules of collective expertise (diversity of experts, access to all available documentation, time for collective work, etc.). Their results can be weakened and thus be the subject of contestation.

Finally, a third tension runs through the expertise. On the one hand, it leads to the need to separate risk assessment and risk management and, on the other hand, the need to put the results of the assessment into perspective with regard to the feasibility of management measures. This tension is particularly strong in situations of uncertainty, where, in application of the precautionary principle, it is necessary to qualify the uncertainty and the level of risk, and to implement proportionate measures. This requires, in particular, knowledge of the socio-economic impacts of the measures and the possible alternatives. A lack of clarity concerning the modalities for separating assessment and management and a lack of transparency concerning the translation of opinions into management measures are another source of erosion of the credibility of expertise.

## **Recommendations**

As far as the Anses is concerned, procedural issues are already the subject of constant attention and efforts by the agency (expert groups bringing together scientists chosen for their competence, subject to independence in the sector of activity concerned). The same applies to relations with research (own research capacities, funding of programs supporting studies to fill knowledge gaps, coordination of the European Partnership for Risk Assessment of Chemicals (PARC)). At the international level, the agency is generally considered as one of the most advanced on these issues.

However, the Anses is subject to the tensions of expertise. In particular, the gap between science and expertise is one of the most important factors in the erosion of credibility, and the Anses does not always succeed in reducing this tension. In particular, in the fields studied, compliance with a European regulatory framework does not allow for the rapid integration of new scientific knowledge, which is nonetheless relevant for risk assessment. In addition, expert reports from Emergency Collective Expertise Groups (GECU) have been challenged.

The lessons learned from the three case studies analyzed by the WG are particularly relevant to situations in which there are high uncertainties and/or controversies between experts. The WG's recommendations are in line with the continuous improvement of scientific excellence, quality and independence of expertise at Anses (Anses COP, 2018-2022). Some of these recommendations do not fall within the scope of the Anses' competences or means, but the WG considers that they should be implemented, as they refer to the Anses' direct environment, which must be considered.

## **Regulatory framework and new scientific knowledge**

The credibility of an expert scientific opinion (or of a decision based on an opinion) is all the stronger if the opinion is based on criteria deemed to be in line with the state of the art of scientific knowledge on the subject. Nevertheless, the risk assessment of regulated products imposes guidelines and standards. This can result in a gap between scientific knowledge and expertise, which is a source of public controversy and criticism of expert opinions. Limiting this discrepancy makes it possible to better inform the decision-making process and to limit the risks of challenges to the expertise.

**RECOMMENDATION 1** Systematically validate the selection of the literature taken into consideration with the expert groups and ensure that new scientific knowledge is taken into account

**RECOMMENDATION 2** Develop a method for systematically screening for links of interest in the bibliographic journals used (conflicts of interest of authors and editors, funding of studies and scientific journals) and define criteria for taking them into account

**RECOMMENDATION 3** Facilitate access to data in regulatory files

**RECOMMENDATION 4** Do not limit the risk assessment of products subject to regulatory constraints to expertise restricted to the regulatory framework (knowledge produced in accordance with regulatory frameworks and/or in laboratories governed by good practices (GLP), etc.), and provide for the possibility for expert groups to express criticisms and reservations about the regulatory frameworks of the assessment

**RECOMMENDATION 5** In cases where the referral requires the use of only knowledge generated according to existing guidelines, incorporate out-of-framework knowledge into a specific part of the body of the report and opinion

**RECOMMENDATION 6** Use the recommendations resulting from the expert assessments in terms of knowledge improvement needs to prioritize funding for research projects (carried out by Anses laboratories or by external teams via research and development agreements or the National Environment-Health-Work Research Program (PNR-EST)), in particular to generate the scientific data required to develop standards or assessment methods

**RECOMMENDATION 7** Increase the Agency's role in the design of transnational guidelines (Organisation for Economic Co-operation and Development (OECD), European Union (EU)) and dedicate additional resources to this mission

## **Procedures**

The credibility of scientific expertise is all the stronger when the expertise procedure has followed the golden rules (impartiality, transparency, plurality and adversarial process). Since its creation, the Anses has been committed to continuously improving its procedures, in particular through the creation of specifically dedicated WGs (WG Risk Assessment Methodology (WG RAM), WG Accompanying the implementation of RAM recommendations (WG ACCMER)). Our recommendations are fully in line with this continuous improvement process.

## **Referrals and self-referrals**

**RECOMMENDATION 8** Systematize the possibility for expert groups to express their views on the formulation of questions and the timetable for dealing with them and/or to supplement the expertise corresponding to the referral with additional elements in order to better inform the decision and, if necessary, provide for discussions between the expert groups and the supervisory authorities to clarify the referral (purpose, questions, deadlines and timetable for delivery, etc.).

**RECOMMENDATION 9** Increase the use of self-referrals by the Agency to anticipate foreseeable problems

**RECOMMENDATION 10** Provide for long-term monitoring to ensure continuous knowledge surveillance of complex issues with significant health and/or media implications.

## **Collectives of expertise**

**RECOMMENDATION 11** Foster scientific diversity

- Promote a balance between academic researchers and researchers familiar with the regulations
- Encourage multidisciplinary and, in particular, when relevant, the involvement of experts in the human and social sciences

**RECOMMENDATION 12** Encourage the participation and renewal of experts

- Encourage employers (universities, research operators, health agencies, expertise institutes...) to recognize scientific expertise in the evaluation of researchers/teaching researchers and agents, to facilitate the exercise of expertise (partial availability, publication assistance...) and to publicize the major role that expertise plays in the relations between scientists and society
- Include expert missions in the framework agreements between Anses and its partners; develop new agreements if necessary

- Develop interactions between Anses and research alliances (Allenvi, Aviesan) to raise the awareness of scientific communities to the expertise mission
- Protect and train experts from media exposure
- Make more systematic use of the audition format when a specific skill is required

**RECOMMENDATION 13** Refining the treatment of conflicts and links of interest

- Apply the guidelines for the analysis of intellectual connections
- Building the capacity to control IPR

**RECOMMENDATION 14** Strengthen the application of the rules of collective expertise

- Clarify the role of the expertise coordinator and of the Anses agents present in the expertise groups (provision of scientific information, coordination support, etc.)
- Set up internal training for expertise coordinators
- Clarify and strengthen the role of the collective chairman in ensuring compliance with the rules of collective expertise, including the role of Anses agents in the experts' discussions
- Establish a quorum for each collective meeting, not just for the adoption of the work
- Ensure that discussions and minority opinions are recorded in the minutes of meetings and facilitate the use of minority opinions throughout the expertise
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**RECOMMENDATION 15** Reserve the GECU format exclusively for expert reports that can be processed within a short period of time (typically less than one month from the date of receipt of the referral)

- Prefer a "classic" WG format (except for emergencies) for controversial subjects and/or subjects of scientific alert (with, therefore, a public call for experts)

### Scientific alerts

**RECOMMENDATION 16** Formalize the handling of scientific alerts

- Report in a precise and argued way on the treatment of a scientific alert
- Adopt a scientific alert analysis grid that identifies potential gaps in current guidelines and ways to improve them

**RECOMMENDATION 17** Consider scientists carefully when they issue warnings

- Facilitate their access to data and knowledge exchange
- Integrate them as early as possible in the expertise process (in groups/at hearings)

## Interactions of the Anses with its stakeholders

Concerning interactions with stakeholders, the comparison with other agencies, especially internationally, is generally advantageous for Anses, which has taken many initiatives to open up to society (Thematic Steering Committees (TSC), Dialogue Committees, etc.). The WG encourages the continuation of this approach.

**RECOMMENDATION 18** Inform, internally and in expert groups, of the expectations of stakeholders expressed in Anses' dialogue structures (dialogue committees, COT, inter-COT, phyto platform)

**RECOMMENDATION 19** Continue to report to stakeholders on how their expectations have been addressed by the Agency

**RECOMMENDATION 20** In the reports and opinions published by the Agency, systematically indicate: the level of uncertainty, the scientific controversies (minority opinions if any) and any discrepancies between the assessment carried out within the regulatory framework and the scientific knowledge produced outside the framework of the guidelines in force

**RECOMMENDATION 21** Support an interagency initiative to analyze the mechanisms of ignorance production and their influence on regulatory frameworks

## Precautionary principle and the evaluation/management link

Scientific expertise provides the decision-maker with the necessary arguments to act in a proportionate manner, which requires a necessary qualification of the level of uncertainty, which can be improved in the current procedures of the Anses, and an integration of the socio-economic analysis in order to evaluate the effects of the proposed measures.

**RECOMMENDATION 22** Define a complete risk assessment grid applicable in whole or in part depending on the situation, including risk assessment, qualification of the level of uncertainty (in accordance with the recommendations of the group "Accompanying the implementation of the recommendations of the Risk Assessment Methodology"), analysis of the economic and social impacts (CES "Socio-economic Analysis"), reversibility of damage, analysis and study of alternatives

**RECOMMENDATION 23** For management decisions under the responsibility of the Anses, ensure the same level of explicitness as that required for risk assessment

## Organization of the Anses

Anses carries out risk assessment and, in some cases, risk management missions in a range of fields and for a range of products governed by national, European or international regulations. The organization of the Anses into divisions, effective in 2017, and in particular the structuring of risk assessment and management missions for regulated products, and risk assessment for non-regulated products, is still perfectible. The separation between assessment and management is not clear to some stakeholders.

**RECOMMENDATION 24** Attach all ESCs to the "Sciences for Expertise" cluster

**RECOMMENDATION 25** Improve the internal and external readability of the missions of the Agency's various entities, particularly with regard to regulated products

**RECOMMENDATION 26** Strengthen links between the Agency and operators/research organizations

- Make research teams aware of the methodological prerequisites for taking their results into account in expert assessments likely to lead to changes in regulatory standards
- Raise awareness among Anses agents and experts of the issues related to the interactions between expertise, politics and society

### **Cross-cutting recommendation**

**RECOMMENDATION 27** In conclusion, the implementation of the proposed recommendations requires support with adequate human and financial resources.

# 1. Context, purpose and modalities of the expertise

## 1.1 Context

In recent years, some of the expert reports produced by the Anses (and sometimes the experts who contributed to them) have been contested, or even violently attacked, directly or through the media. Although the cases that pose a problem are numerically marginal, it is feared that their impact on the agency's reputation may weaken its credibility and the scope of its opinions.

## 1.2 Purpose of the referral

This study aims to provide a better understanding of the factors that condition the credibility of expertise and its challenge, in order to identify predictable factors and provide avenues for improvement.

By addressing these questions from a feedback approach and by mobilizing scientific knowledge on scientific expertise, this working group intends to contribute to the institutional reflexivity of the agency and to the reinforcement of its credibility

### 1.2.1 Processing methods: means implemented and organization

In this context, the Scientific Council (SC) of Anses has created a working group on the credibility of scientific expertise. The mandate of this WG is to *"analyze the different factors and scope of the destabilization of the credibility of the scientific expertise produced by the Agency based on three case studies in the field of plant protection products: SDHI, glyphosate and neonicotinoids"*.

The work of this WG was regularly presented and discussed in the SC. The report takes into account the observations and additional elements transmitted by the members of the SC.

This work is the result of an interdisciplinary group of researchers with complementary skills.

## 1.3 Prevention of the risk of conflicts of interest

The Anses analyses the links of interest declared by the experts before their appointment and throughout the work, in order to avoid the risk of conflicts of interest with regard to the points dealt with in the expertise.

The declarations of interest of the experts are published on the website <https://dpi.sante.gouv.fr/>.

The Anses identified a major link of interest in Mr. Bonmatin's declaration of interest concerning the specific case of neonicotinoids. In view of the manageable nature of this major link, a deferral measure was adopted: Mr. Bonmatin did not participate in the writing of the neonicotinoids case.

# 2. Heuristic framework and methodology of the WG

## 2.1. Issue

### 2.1.1. Complex factors and environment to be considered to understand the credibility of scientific expertise

In the terms of reference of this WG, credibility of expertise is defined as the degree of confidence in it. Credibility is the result of a set of factors that convince people of the accuracy of the expertise within a defined framework. As sociology and the history of science show, the credibility of expertise depends on many factors: institutional, social, procedural... It depends first of all on the rigor, impartiality and transparency with which it is conducted. Nevertheless, the basic axiom of our work is that the credibility of a scientific statement is not equivalent to its validity. Of course, the two are generally linked, but there are many situations where one believes statements that are false or where one does not believe statements that are true<sup>1</sup>.

As Shapin (1995) points out, the factors that influence scientific credibility (not scientific expertise) are numerous and there is no exhaustive list of them. Among the factors most frequently mentioned in the literature, he cites (Shapin 1995: 260):

- the plausibility of the claim
- the reputation (reliability) of the procedure used to produce the result
- the importance and multiplicity of witnesses
- accessibility and replicability of the phenomenon
- the ability to impute bias to the researcher making the claim
- the reputation of the researcher and his/her institution
- the reputation of the researcher's allies
- the estimated costs of the implications of the claim
- a set of characteristics of the researcher (class, gender, age, race, religion, nationality...)
- the level of expertise (competence) of the researcher, taking into account also the means by which this expertise is known and recognized
- the researcher's behaviour and the way in which he or she communicates the claim
- the details of the lives of those evaluating the claim and their knowledge of the lives of those making the claim
- (...)

Shapin's argument concerns the credibility of scientific statements. The difference with the credibility of expertise is that, while for scientific statements the main part is played in the scientific field, for expertise, the arenas of credibility are much more diverse, starting with the traditional media, social networks, politics,

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<sup>1</sup> In science, and even more so in scientific expertise, the question of truth and falsehood is obviously not so simple and clear-cut. This does not detract from this statement.

In addition, the historical dimension of expertise and the multiple arenas in which it is inscribed must be considered.

**To put it another way, thinking about the credibility of scientific expertise, in this case that of the Anses, cannot be done without analyzing the Agency's place in :**

**a) a historical trajectory and context**

**b) an environment, with its multiple actors, spaces and levels - an environment with which Anses interacts, by which it is influenced, which it influences in return.**

### **2.1.2. Specific questions posed by regulatory science**

Scientific expertise is subject to a strong tension between, on the one hand, the need to take into account the most advanced scientific knowledge and, on the other hand, the need to rely on clear rules that are known to all the actors concerned, in order to carry out a transparent, robust and reproducible risk assessment. Regulatory science" is at the heart of this tension. It is therefore necessary to define the concept and to clarify its relationship to so-called academic science. Indeed, regulatory science is more or less institutionalized depending on the country and is not subject to a stabilized definition. We propose to provide an overview based on a synthesis of social science research (notably : Boubal and Jouzel 2019, Camadro et al. 2018, Joly 2016, Borraz and Demortain 2015).

Boubal and Jouzel (2019) define regulatory science as the specific form of recourse to expertise practiced by the agencies in charge of controlling the risks of industrial products and activities. They specify that, for academic researchers, it refers to the coexistence of scientific and political considerations in the work of agencies in charge of risk assessment. For Camadro et al. (2018), the term covers all scientific activities that produce the knowledge used to develop, support, or adapt public health and environmental regulations. According to Borraz and Demortain (2015), regulatory science is a set of scientific assessment activities that participate in the taking of legal measures to frame industrial activities and products (authorization, withdrawal, setting of presence or exposure thresholds, labeling of drugs, cosmetics, certain foods or chemicals, etc.).

Different regulatory bodies around the world use the concept of regulatory science, giving it different meanings (Camadro et al. 2018). For the Japanese Medical Device and Pharmaceutical Agency, regulatory science is an estimation science, which aims to estimate the social impact of scientific and technological advances, regulate and adjust them, and functions as a bridge between science and society by providing patients with new scientific knowledge. In the United States, the Food and Drug Administration defines it as the science that develops new tools, standards and approaches to evaluate the safety, efficacy, quality and performance of all products regulated by this agency. The European Medicines Agency considers it to be the range of disciplines applied to the assessment of the quality, safety and efficacy of medicines, informing regulatory decision making throughout the life cycle of a medicine: it encompasses medical science (basic and

and social sciences, and contributes to the development of standards and regulatory tools.

The modalities of articulation between agencies and the academic world vary throughout the world and according to the subject. Boubal and Jouzel (2019) describe, in broad strokes, a professionalization of regulatory scientists in the United States, with the scientific community encouraging the development of research in regulatory science, whereas in Europe recourse to academic expertise remains more ad hoc for the purposes of assessing and managing risks induced by industrial development - the modalities of articulation between agencies and the academic world may present different subtleties depending on the precise context (see also July 2016 on these differences).

Irwin et al (1997) propose a framework for analysis by introducing the concept of the "regulatory pentangle". This framework is composed of five categories that indicate the various activities included in regulatory science, which can be carried out by scientists, public experts or industrial actors:

- Academic research on topics that may have regulatory relevance;
- Development and validation of regulatory tests so that products can be analyzed for potential hazards and risks;
- Regulatory compliance testing by industry, often in collaboration with various scientific departments, as required by regulatory authorities;
- Further investigation of test results showing non-compliance with regulations, to identify if the results are false positives, or if there are special circumstances that suggest the result is not relevant to the risk assessment;
- Compiling the regulatory assessment package for review.

While regulatory science is practiced within institutions that make public and discuss the knowledge produced, it is largely based on data that remain private, which limits public expertise. Thus, a significant part of the data produced by firms is not made public. Moreover, under the pretext of protecting intellectual property rights and business secrecy, precise elements of the composition or manufacture of products may not be disclosed, making analysis of the data produced limited.

Moreover, regulatory science requires a large upstream infrastructure that is largely private (Borraz and Demortain 2015):

- The production and interpretation of data are governed by guidelines developed in expert committees;
- Good Laboratory Practice (GLP) codes, which dictate quality assurance requirements for regulatory testing provided by private companies, condition the knowledge generated;
- The development, performance and interpretation of the tests are based on experience that is essential for toxicologists and scientists.

The development and maintenance of this infrastructure is transnational, invisible, dominated by private interests and controlled by relatively closed collectives. The rules and norms that frame regulatory assessment are defined in "invisible colleges" of scientific experts working in regulatory agencies, research organizations or companies. These invisible colleges are built both by the professional circulation of scientists interested in regulatory issues, their activities as scientific advisors or consultants for private actors, and their participation in various organizations bringing together experts from different backgrounds (professional associations, learned societies, intergovernmental bodies ...) (Demortain 2011). Among these organizations, one can note the particular role of science lobbying organizations, which decline the usual techniques of lobbying in the world of science and scientific experts. One example is the International Life Science Institute, a nonprofit organization funded by large agribusiness, agrochemical, chemical, and petroleum companies, whose activities include promoting regulatory science methods that benefit industry (Demortain 2020).

In order to change the guidelines and standards, some academic laboratories carry out studies using innovative techniques and methods, with exposure times and methods not constrained by regulatory texts, on models that are relevant but not recognized or validated by certain stakeholders involved in the regulatory approach. This work, even if it is deemed relevant by peers (*peer review*) and published, is not easily taken into account either in hazard and risk assessments or in the revision of limit values, either because exposure data are insufficiently described for the regulator, or because the number of repetitions of the experiments is deemed arbitrarily low (note that GLP does not stipulate any explicit obligation of reproducibility, *cf.* decree 2006-1523 of 4 December 2006).

In addition, international recommendations, aimed at researchers, indicating the methodological prerequisites for the inclusion of studies in expert assessments and institutions that evolve standards, are advocated and are beginning to be published (Ågerstrand et al 2017, Ågerstrand et al 2018). Similar steps are being taken to conduct non-regulatory preclinical studies for highly innovative therapies (Vestergaard et al 2013). In addition, groups of researchers are publishing strategies for assessing endocrine disruptor toxicity (Lupu et al 2020). A documented publication shows that the application of regulatory values such as GLP can defeat regulatory agencies (Myers et al 2009).

## 2.2. Theses retained by the WG

Given the wide variety of factors affecting the credibility of scientific expertise, it is proposed here to rely on four theses inspired by the Anses colloquium on the credibility of scientific expertise<sup>2</sup> and the bibliography. The focus on these four theses does not exclude the factors mentioned above. However, it allows us to build a heuristic framework necessary to study the three selected cases (glyphosate, neonicotinoids, SDHI).

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<sup>2</sup> International online symposium "Credibility of scientific expertise and public decision making", 20 January - 9 February 2021, Anses.

### 2.2.1. Thesis 1. Credibility is a matter of reducing the gap between scientific knowledge and expertise

**Main statement:** The credibility of an expert opinion (or of a decision based on an opinion) is all the stronger when the expertise procedure has allowed to take into account all relevant scientific knowledge, including recent knowledge. Discrepancies are a source of controversy between scientists and of criticism of expert opinions by the various stakeholders.

**Sources in the literature:** various analyses of the differences and relationships between "academic science" and "regulatory science" (see above).

**Examples:** See the examples given in the General Inspectorate report on environmental health (Lavarde et al. 2020).

**Levers for action:** evolution of the guidelines for expertise, evaluation grid of the scientific references taken into account in the expertise, possibility for expert groups to express criticisms and reservations on the regulatory frameworks.

#### Derived statements:

- Expertise loses credibility if it is perceived as limited to a regulatory framework that ignores important academic knowledge
- An expert opinion loses credibility if it indiscriminately cites articles written by employees of firms or financed by firms that have an interest in influencing the regulation of their products in their favor

### 2.2.2. Thesis 2. Credibility is a matter of procedures

**Main statement:** The credibility of an expert opinion (or of a decision based on an opinion) is all the stronger if the expertise procedure has followed the golden rules (impartiality, transparency, plurality and contradictory)

**Sources in the literature:** theories of legitimacy, procedural approaches to expertise, analyses on judicial expertise .<sup>3</sup>

**Examples:** founding documents of European expertise, dominant culture in the agencies, separation between risk assessment and risk management.

**Levers of action:** definition and implementation of procedures, quality management.

#### Derived statements:

- The participation of stakeholders upstream of the expertise contributes positively to its credibility because it allows witnesses to be brought on board to ensure that it is carried out properly
- A committee made up of experts with relevant skills, without major conflicts of interest and with a variety of views on the subject of the expertise contributes positively to the credibility of the opinion given by the committee
- The reputation of the body contributes positively to the credibility of scientific expertise (Carpenter 2010)

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<sup>3</sup> See the work of O. Renn on risk governance.

### **2.2.3. Thesis 3. Credibility is a matter of reducing the gap between the expertise and the expectations of the concerned audiences**

**Main statement:** The credibility of an expert opinion (or a decision based on an opinion) is stronger the more it corresponds to the expectations of the different audiences involved. There are two very different interpretations of this thesis:

- Some consider that it is a matter of cognitive bias or confirmation bias: credibility would then be all the weaker if the expertise goes against the spontaneous beliefs of the population. Conversely, an opinion would be all the more credible if it confirms these beliefs. In the age of the Internet and social networks, this phenomenon would explain the cognitive bubbles and the propagation of "infokes". Attitudes towards vaccination and vaccines are often taken as an example.
- The other interpretation, more generous to the publics and stakeholders, suggests that the credibility of an opinion is stronger the more the framing of the problems corresponds to their concerns; in other words, that the opinion considers the problem in the way the publics and stakeholders see it, and answers the questions they have.

Various scientific works support one or the other of the two interpretations. It is not a question of settling this controversy or taking sides. The investigation will be attentive to both positions without necessarily opposing them because each one can shed some light on phenomena whose complexity must be understood.

The fact remains that, depending on the interpretation, the levers are different:

- In the first case, it is generally considered that adequate communication and better education on scientific issues are likely to solve the problem by orienting beliefs and expectations.
- In the second case, it is considered necessary to set up broad debates upstream of the expertise, to encourage participation and consultation with the stakeholders in the definition of the questions. We pay attention to the plurality of views in the expert committees. Citizen science and participatory research approaches may be implemented (Houllier et al. 2017) in order to involve the people and territories concerned in the production of knowledge in risk assessment.

### **2.2.4. Thesis 4. Credibility is about the socio-economic impact of implementing risk management measures**

**Main statement:** Expert advice (or a decision based on advice) is more debated the higher the estimated impact of implementing management measures, or conversely, the higher the health impact of not implementing them appears to stakeholders.

**Sources in the literature:** regulatory capture theory, organizational denial, agnotology

**Examples:** Numerous examples in the analyses of Dedieu and Jouzel, but also in the report *Late Lessons from early warning* of the European Environment Agency which highlights that in many cases, proven scientific knowledge has not been implemented given the socio-economic impact

**Levers for action:** Better highlight the costs of the *status quo*; accelerate research on alternatives

**Derived statements:**

- The socio-economic analysis allows us to objectify the economic stakes and the obstacles that need to be removed
- Alternative development is an essential function for good risk governance

These four theses have been added to during the course of the investigation. Initially, the two versions of thesis 3 were the subject of two separate theses; the current thesis 4 was added at the very beginning of the survey. Apart from these changes, the analysis conducted by the WG did not lead to the addition of new theses. Rather, it led to the development of specific reflections on the precautionary principle and the structure of the Anses regarding regulated products.

### 2.3. Survey techniques

The originality of this report lies in the collective investigation method that was implemented with the support of the Anses. The working group is composed of eight scientists from different disciplinary backgrounds (cell biology, chemistry, ophthalmology, neurobiology, veterinary science, sociology, economics) who themselves have diverse experiences of the practice of collective scientific expertise, at the Anses or in other organizations. The group has co-constructed the heuristic framework presented above.

The members of the group conducted about thirty interviews which constituted the core of the survey work. For each case, the interviews were preceded by the preparation of descriptive sheets based on the collection of all available literature: secondary and primary sources (agency opinions, press articles, main scientific articles, court decisions). This documentary phase was extended, beyond the cases, to cross-cutting themes by collecting a variety of sources: reports from parliamentary or administrative bodies, expert reports, internal Agency documentation on expert procedures, reports from the Agency's Committee on Ethics and the Prevention of Conflicts of Interest (CDPI)...

The interviews were conducted using the semi-structured interview method. The group used an interview guide consisting of three parts: one part on the interviewee's experience with the subject matter of the work, one part focused on the case(s), and one free-form part addressing the broader issue of scientific credibility. As is customary with this method, the interview guides listed the topics to be addressed and included follow-up questions used only when necessary. At the end of the interview, the group gave the interviewee the opportunity to add points about scientific credibility that had not been addressed and to make suggestions for improvement.

The interviews were systematically conducted by videoconference. They lasted between 1h30 and 2h00 and were systematically recorded and transcribed. Three or four members of the WG usually took part, which made it possible to conduct the interviews with a diversity of views and skills. The interviews were then double coded, taking up the four theses of the heuristic framework in order to carry out the transversal analysis.

The panel of interviewees includes external scientists who have participated in the Agency's collective expertise (members or presidents of CES, WG or GECU), Agency staff and stakeholders (politicians, journalists, industrial representatives, whistleblowers, etc.). These people were selected on the basis of:

- their participation in the expert work on the three cases studied
- their transversal knowledge, relative to these three cases and/or to the different issues of scientific expertise
- their involvement in the public or political problematisation of these three cases

We began the interviews with the people who had worked directly on the selected cases. Then, a "snowball" logic was used to identify other people to interview.

## **2.4. A few points of reference on the expertise activities of Anses**

For a proper understanding of this report, a preliminary presentation of the main expert assessment activities carried out at Anses is necessary. They are listed in Table 1, which distinguishes between risk assessment exercises or more general approaches and external referrals or self-referrals, and whether these activities concern regulated or unregulated products. As will be seen, an important distinction is made between products for which the Anses has both an assessment and management mission and those for which, given the strict application of the principle of separation of assessment and management, it only has an assessment mission.

Objects	Time frame	Institutional format/framework	Coordination	Realization	Productions (public)
Health risk assessment (HRA)	Non-emergency	Referral, self-referral	Risk Assessment Directorate (RAD), Regulated Products Evaluation Directorate (RPED), National Veterinary Drugs Agency (NVDA)	Specialized expert committee(s) Group Working Group (WG) <sup>4</sup>	Notice Report <sup>4</sup>
	In emergency			Emergency Collective Expertise Group Expertise Group (GECU)	Notice Report
ERS	Regulatory deadlines	Authorization of setting on the market, approvals	DER	CES GT <sup>4</sup>	Notice
		Implementation of REACh regulations	DER	CES	Notice European report
		Implementation of regulations / inputs plant inputs, biocides	DEPR	CES	European report Notice <sup>1</sup>
Other expertises outside of ERS	Non-emergency	Referral, Self-referral	DER DEPR ANMV Laboratories Direction des alertes et des vigilances sanitaires (DAVS) DiSSES (Direction sciences sociales, économie et société)	Anses teams	Notice Report <sup>4</sup>
Scientific and technical support (AST)	Non-emergency	Studies, development of tools...	All entities	Anses teams CES if the AST accompanies a HRA	Note, synthesis, base of data... <sup>5</sup>

**Table 1. Overview of scientific expertise modes and productions at Anses**

<sup>4</sup> Possible but not necessary.

<sup>5</sup>Published unless otherwise specified in the framework.

Depending on these situations, the constraints on these activities are very different. These are important elements that will also condition the credibility of the expertise.

Table 1 also indicates that, depending on the case, three different types of committees are in charge of collective expertise: the ESCs, the WGs and the GECUs. These committees have different compositions and operating rules. We will come back to this later.

To complete these points of reference, it should be added that the institutional affiliation of the committees may also vary (see Figure 1). The ESCs are generally attached to the Risk Assessment Department (DER) of the Science for Expertise Pole, which corresponds to the need for strong interactions between science and expertise. Nevertheless, two ESCs are exceptions:

"Plant protection substances and products, biocontrol" and "Biocidal substances and products".

We will see that these characteristics, which are not necessarily legible even for the scientists involved in the expertise, also have an influence on the conditions of realization of the expertise.

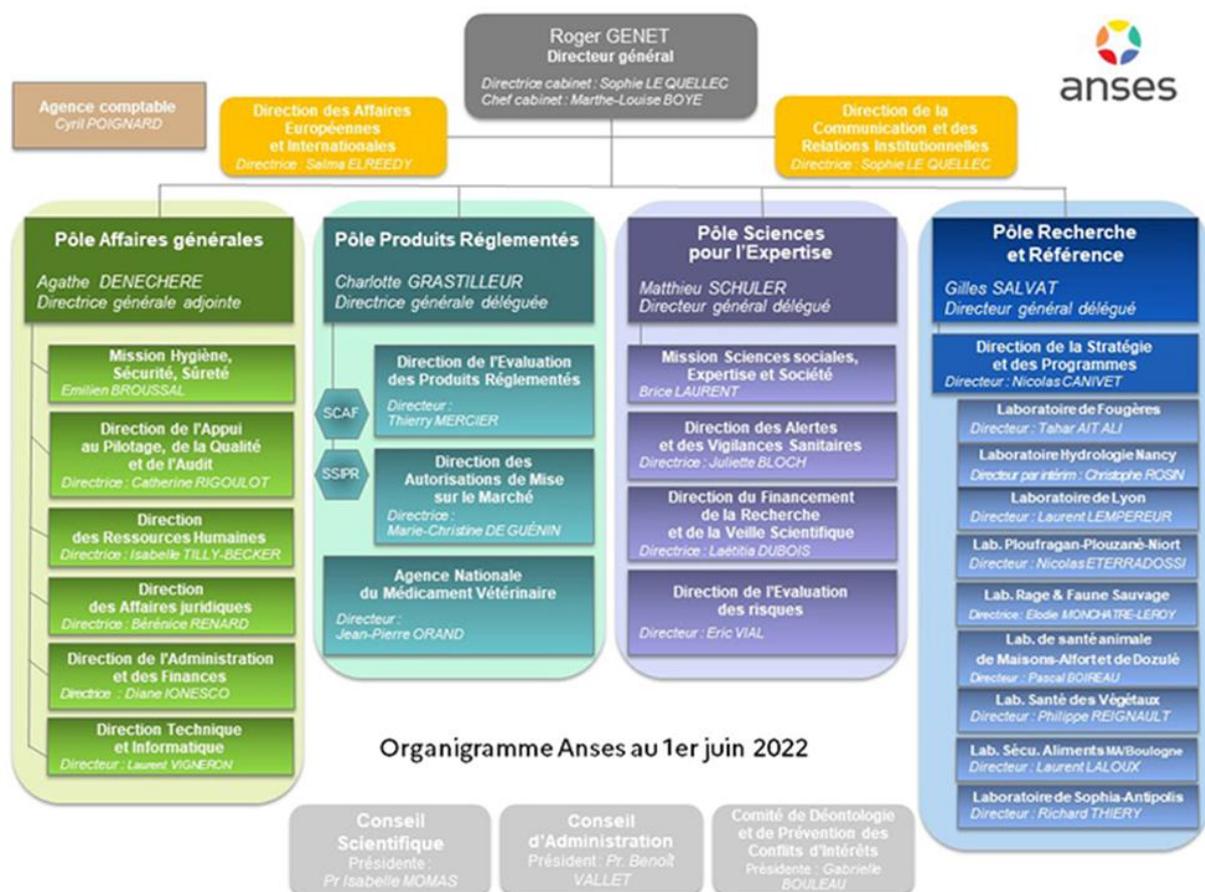


Figure 1: Anses organization chart as of June 1, 2022

## 3. Presentation of the case studies

The three cases analyzed (neonicotinoids, glyphosate, SDHI) were chosen for different reasons, notably because the opinions of the Anses have been intensely discussed and, sometimes, strongly criticized. They are therefore not at all representative of the hundreds of opinions issued each year by the agency. Nevertheless, the analysis of such cases is timely and necessary when one is interested in the credibility of scientific expertise. On the one hand, the intensity of the controversies and polemics makes it possible to collect very rich material, which is indispensable for such an analysis. On the other hand, in public arenas (media, parliament, mobilization of associations, general inspection reports, etc.) reference to the Anses is very often linked to these cases. Thus, even if they are rare, they have an effect on the public image of the agency.

In this section, we present the three case studies. The narratives of these cases are based on a processual analysis conducted using secondary sources and a set of focused interviews.

### 3.1. Neonicotinoids

#### 3.1.1. A coalition of stakeholders emphasizes the importance of knowledge not considered in the regulatory framework

In 1994, French beekeepers observed and reported sudden and alarming signals in the behavior of honeybees, ranging from failure to return to the hives to mortality observed in front of and in the hives, and this particularly in the vicinity of sunflower fields.

These troubles coincide with the introduction of a new insecticide, Gaucho®, marketed by the firm Bayer from 1991 and used in France since 1993. This insecticide, whose active substance is imidacloprid, is not used for spraying but for coating sunflower seeds. The alert of the beekeepers and the financial impact on the beekeeping production and the essential role for the pollination of many crops oblige the public authorities to launch studies in 1997-1998 (Steering Committee "Gaucho" of the Ministry of Agriculture, in consultation with Bayer). These studies do not allow any conclusion but they raise serious suspicions supported by scientific knowledge. As a result, the Gaucho® treatment was suspended for the first time in 1999 for all sunflower crops, in the name of the precautionary principle. In addition, the beekeeping unions raised awareness and encouraged public research to take up these issues in order to conduct more in-depth exposure and toxicology studies.

Over time, the progression of scientific knowledge in three complementary fields has challenged the risk assessment as it had been carried out until then:

- Demonstration of the importance of chronic low-dose exposures (Suchail et al. 2001)
- High exposure levels compared to previous results (Bonmatin et al. 2003)

- The need to take into account the synergies between molecules and between biotic and abiotic agents in the toxicological analysis (CST report of the Ministry of Agriculture 2003).

In view of this new knowledge, the Ministry of Agriculture suspended the Gaucho treatment for maize in 2004, while the fipronil-based Regent® treatment (a phenylpyrazole also a systemic insecticide) was suspended for all crops at the end of 2004. The Ministry issues new marketing authorizations (MA), in particular for the Cruiser® treatment based on another neonicotinoid (thiamethoxam) for rapeseed (2008). These authorizations will also be withdrawn.

The accumulation of scientific knowledge used by stakeholders, the increasing judicialization, the constitution of coalitions (environmental associations and beekeepers, researchers, elected officials, but also agricultural unions, seed companies, agrochemical industries and even the Ministry of Agriculture at certain times), accompanied by intense media coverage, have highlighted the need to rethink the risk assessment and management system. The scientific method underlying the regulatory assessment of risks to bees must be improved, in particular the development of new eco-toxicological tests, the treatment of multi-causality, the quality criteria of studies, the consideration of multiple exposures at low doses, and all this in the dimension of a family of products, in this case neonicotinoids. Indeed, until now, when a product was banned, it was generally replaced by another of the same family or with the same modes of action, which only shifted the problem.

### **3.1.2. Europe takes over**

As Arnold (2018) reminds us, in 2011, the European Commission (EC) asked the European Food Safety Authority (EFSA) to assess, before any marketing, the quality of the evaluations on the risks that pesticides represent for bees. In particular, it asked to assess the environmental assessment system, which was then based on the recommendations of *the International Commission for Plant-Bee Relationships*, an organization close to the plant protection companies.

Following this request, an EFSA working group drafted a scientific opinion in 2012 noting that the toxicity of pesticides placed on the market had not been properly assessed. Several key aspects had not been taken into account: toxicity on larvae, long-term effects on colonies, chronic toxicity on adults, sublethal toxicity (the fact that bees may become disoriented after exposure to an insecticide, not returning to their hive and dying quickly) (EFSA 2012).

Since the late 1990s, the effects of these products on bees have thus not been properly assessed before they were placed on the market. A new guide for the assessment of these risks to honeybees and wild bees was published by EFSA in 2013 (EFSA 2013)<sup>6</sup>. Nearly ten years after its publication, this guide is still not adopted at the European level. According to the representation of the producers of the pesticides concerned, the tests

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<sup>6</sup> <https://efsa.onlinelibrary.wiley.com/doi/pdfdirect/10.2903/j.efsa.2013.3295>

This EFSA report proposes guidelines for the assessment of risks to bees. But these have not been implemented by the Member States (interview with an expert, 10 June 2021).

proposed would not be robust and reproducible enough. Presumably, the economic pressure is strong. Under the influence of industrialists considering that the implementation of these guidelines would lead to the removal of a large number of authorized substances, several countries voted against the adoption of this guide and have reportedly asked EFSA to make the guidelines more flexible (OPECST 2019).

Specifically concerning neonicotinoids, EFSA concludes unambiguously that insecticides of this family are dangerous to the health of bees. It suspends the use of three of the six molecules on the market for honey crops. Fipronil is also suspended. In 2018, the member states of the European Union extend the ban on the three neonicotinoids and fipronil for all outdoor crops; treatments are now only allowed under closed greenhouses. Moreover, scientific findings extend the deleterious impacts of neonicotinoids to many other species, invertebrates (e.g. beneficial insects), vertebrates (e.g. birds) and even humans.

### **3.1.3. The contribution specific of the Anses as evaluator and manager**

The Agency has played an important role in building the knowledge base needed to better assess the complex effects of insecticides on bee health<sup>7</sup> :

- Between 2012 and 2015: Expertise on the effects of co-exposure of bees to different stressors and their respective roles in the phenomena of weakening, collapse or mortality of bee colonies.
- 2015: Expertise on the prioritization of bee diseases.
- 2016: Expertise on the risks posed by insecticides based on substances in the neonicotinoid family.
- 2018: Recommendations to strengthen national provisions imposing restrictions on the use of plant protection products during periods when crops are attractive to these insects.
- 2019 : Recommendations for strengthening risk assessment methods for plant protection product marketing authorization applications.

On this basis, and in consideration of the decree of 20 November 2021 on the protection of bees and other pollinating insects, the Anses has implemented a more comprehensive risk assessment than required by current European regulations, with additional toxicity tests in laboratories, "flight back" tests, and tunnel tests (Anses, undated information note ).<sup>8</sup>

Since 2015, the Anses has also been in charge of the management of plant protection products, and therefore in charge of issuing MAs. In France, the ban on all neonicotinoids was enacted in 2016 by the law for the reconquest of biodiversity, taking effect in September 2018 and without possible derogation after 2020. An amendment of 2018 (EGAlim law) had also been added to ban in France any molecule with the same mode

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<sup>7</sup> <https://www.anses.fr/fr/content/santé-des-abeilles>

<sup>8</sup> [https://www.anses.fr/fr/content/note-d information-on-risk-assessment-for-bees-and-other-insects](https://www.anses.fr/fr/content/note-d-information-on-risk-assessment-for-bees-and-other-insects)

action than the five neonicotinoids targeted by the 2016 law. The Anses was then asked to study alternatives to neonicotinoids and the agency submitted a report, which was voluminous and well argued, in 2018.

In 2017, the Anses issued a MA to the insecticides "Transform" and "Closer" based on sulfoxaflor. This decision may be surprising because, according to the Agency, this active substance, although related to neonicotinoids, is registered by the European Commission. These MAs will be cancelled by the Court of Nice by a decision of November 2019. The Court will consider that the risk assessment by the Anses is not consistent with the precautionary principle :

*"It follows from the precautionary principle enshrined in these provisions that, where there is uncertainty as to the existence or extent of risks, protective measures may be taken without having to wait for the reality and seriousness of these risks to be fully demonstrated" (...)*

*"The conclusions of the evaluation on the marketing authorization application published by Anses on June 26, 2017, state the dangerousness of the products "Transform" and "Closer" for auxiliary fauna and pollinating insects when used under cover. In addition, the European Food Safety Authority noted high risks to bees and bumblebees when using sulfoxaflor in its reports published on March 11, 2015 and February 26, 2019. While Anses and Dow Agrosciences argue that the use of the insecticide is accompanied by risk mitigation measures, such as the absence of application of the product during the flowering period, these measures cannot be considered sufficient since they are general in scope and are not accompanied by any obligation for users of the product. Under these conditions, the existence of a risk for pollinators must be considered as a sufficiently plausible hypothesis in the state of scientific knowledge.*

(Decision of the Court of Nice of 29/11/2019)

As the government has decided to ban the use of sulfoxaflor and flupyradifurone, two plant protection substances with the same mode of action as neonicotinoids, in application of the EGalim law, the Anses will not appeal the judgment of the Nice court<sup>9</sup> .

Following the pressing demand of the sugar beet industry, which experienced production losses in 2020, the government proposed and passed an order, in early 2021, which again authorizes the treatment of beet seeds with the neonicotinoids imidacloprid or thiamethoxam. The authorization is renewable for three years, while research proposes alternatives for this crop. There was a lot of media and legal controversy about this derogation for sugar beet, but no scientific controversy. The socio-economic impact will have been the reason for a scientific expertise and stabilized and concordant national and European regulatory procedures. Nevertheless, such derogations concern several countries of the European Union (EU). The Anses report submitted in June 2021 identifies some 20 alternatives to neonicotinoids for this particular crop, of which four or five are considered operational<sup>10</sup> . The government has therefore proceeded with this authorization

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<sup>9</sup> <https://www.anses.fr/fr/content/jugement-du-tribunal-administratif-de-nice-l%E2%80%99anses-retire-put-on-permissions-0>

<sup>10</sup> <https://www.anses.fr/fr/content/des-solutions-alternatives-aux-n%C3%A9onicotino%C3%AFdes-to-fight-ya-nice-in-themselves>

without waiting for the Anses evaluation, which suggests that political and economic considerations prevail.

### 3.1.4. Reflection on the integration of new knowledge

The case of neonicotinoids is considered rich in lessons regarding the integration of new knowledge into the existing regulatory framework, even if this integration is very slow (Maxim, van der Sluijs 2013, Arnold 2018) and remains fragile. This is essential because the gap between scientific knowledge and the regulatory framework is one of the main sources of criticism of expertise for regulatory purposes.

If we follow David Demortain's analysis, this rather singular case has more to do with extrinsic characteristics than with elements directly under the control of the Anses:

*"The singularity of the restrictions applied to neonicotinoid products in France is that they were decided by actors who were not the usual and designated risk assessors or managers in the regulatory space. Existing bureaucracies, in this case, were placed at the center of a space that was completely reconfigured by the rise of an advocacy coalition demanding a ban on neonics.*

*(...) The knowledge resulting from the research did not only circulate among the usual actors in the regulatory space. It was produced in relation to this broader mobilization, which was deployed over time and took as its object the successive chemicals of the neonicotinoid class. The coordinated restrictions of all neonicotinoids thus result from a reversal of the routine and closed functioning of the regulatory space and the production of a standard regulatory science that structurally ignores low-dose, chronic, and sub-lethal problems. A fragile, and in fact reversible, outcome of the politics of knowledge that is at the heart of environmental policy."*

(Demortain 2021, our translation)

### 3.1.5. Lessons from the case concerning the credibility of scientific expertise

Criticism of the Anses' expertise has been limited in the case of neonicotinoids. They focused on the authorization of sulfoxaflor. The decision of the Nice court and the non-appeal of the Anses have extinguished the controversy.

We hypothesize that these limited criticisms can be explained by the ability to integrate new scientific knowledge into the regulatory framework (Thesis 1), although, as various observers note (Maxim, van der Sluijs 2013, Arnold 2018), the time frames are unquestionably too long and the process remains unfinished.

This integration tends to reduce the distance between the responses provided by the agency and the expectations of the various stakeholders (Thesis 3). The strong investment in the study of the effects of co-exposures allows the production of relevant systemic knowledge to understand and anticipate the problems affecting pollinators. The weight of economic interests (Thesis 4) limits the integration process, both at the European level (non-integration of knowledge in the guidelines) and at the French level (derogation granted to the beet industry). The content of these decisions and the lack of transparency undermine the credibility of the expertise.

It is therefore thesis 1 that plays an essential role here. Concerning the role of procedures (Thesis 2), the mobilization of expertise predates the creation of the agency. The history of this case thus shows the procedural progress linked to the creation of the Anses. The witnesses cite in particular the independence of the expertise and the scientific referencing of the arguments put forward. The possibility of self-referral, which is essential to investigate complex and uncertain issues, is also mentioned. It is therefore essential that the principles of independence and adversarial process be strictly respected.

## **3.2. Glyphosate**

Glyphosate is a non-selective herbicide (it kills most plants to which it is applied at an effective dose). It was first marketed in 1974 by the company Monsanto and became publicly available in 2000. It is currently one of the main pesticides sold in the world, with an annual global market estimated at more than 4 billion euros, and a very wide use, mainly in North and South America, to eliminate weeds, after harvesting crops and on crops of genetically modified plants tolerant to glyphosate. In France, the use of alternatives to glyphosate can lead to significant additional costs in certain situations. In the European Union, a classification of glyphosate as a suspected carcinogen (class 1B of the CLP regulation, relating to the classification, labelling and packaging of chemical substances and mixtures) would have significant economic repercussions, since it would lead, according to European regulations, to a ban on this active substance.

The evaluation of the dangers and the conditions of the authorization of glyphosate have crystallized strong tensions. They have been the subject of strong mobilizations in the scientific, political, media and civil society spheres. This background is first recalled. It allows us to contextualize the opinions of the Anses on this active substance, which are then presented, before providing information on the reactions they have provoked.

### **3.2.1. The context**

The reflections on the active substance glyphosate are born in a particular context on the political level (file of deputies, empty National Assembly during votes, phone calls to or by experts on Monsanto / Bayer in session ECHA (European Chemicals Agency) or EFSA (European Food Safety Authority)), societal (nucleation of social networks, aggressive practices of the firm to place favorable content in the press and on the Internet, false advertising, false petitions ...) with discrimination of authors and scientists considered as opponents - including those of the IARC (International Agency for Research on Cancer, agency of the World Health Organization) like Christopher Portier or Christopher Paul Wilde on social networks.

Concerns about the product were reported as early as 2000 by associations that filed a complaint for false advertising on the labeling of products formulated with glyphosate. A 2012 Anses scientific watch note calls for verification in other studies and on other models of knowledge regarding the possible endocrine disrupting effects of glyphosate (Crettaz 2012).

While in 2015, the IARC declared glyphosate genotoxic, carcinogenic to animals and probably carcinogenic to humans (Group 2A) (IARC 2015), the German agency BfR, in charge of examining the dossier for the renewal of the authorization of glyphosate for Germany, the reporting Member State, concluded that there was no sufficient evidence of carcinogenicity to humans. The BfR does not propose a classification of glyphosate in terms of carcinogenicity or mutagenicity. However, it identifies a concern about the toxicity of glyphosate-based preparations, particularly with regard to genotoxicity. On this basis and on the proposal of EFSA, the Commission renews the authorization of glyphosate, but only for a period of five years, until 2022.

As early as 2015 an alert was launched by Christopher Portier and several scientists (Portier 2015) on the evaluation of glyphosate conducted by the BfR, and an open letter was sent in 2017 to the President of the European Commission (Portier 2017). In the same year, an expert report commissioned by the NGO Global 2000 (Weber 2017), which was widely reported in the press, showed that long passages of the BfR's glyphosate assessment report were identical to the application for renewal of glyphosate registration sent to the European authorities by Monsanto.

Also in 2017, glyphosate was at the center of the "Monsanto Papers" affair, revealed in France by the newspaper *Le Monde* following access to internal documents of the firm made public by the American justice system in the context of trials (Foucart, 2017; Foucart, 2018; Horel and Foucart 2017b and 2017c). This case shows the strategies deployed by Monsanto to denigrate the IARC's work on the carcinogenicity of glyphosate. It also highlights the firm's practice of "ghostwriting", which consists of having scientists sign scientific articles, written by employees of the firm, agreeing to put their names to them in exchange for payment. Some articles later known to be

"It also shows older strategies within Monsanto to minimize the risks of glyphosate: a scientist paid in the 1980s to review data considered problematic by the EPA; a scientist paid in the 1990s to review data considered problematic by the EPA; a scientist paid in the 1990s to review data considered problematic by the IARC. It also shows older strategies within Monsanto to minimize the risks associated with glyphosate: a scientist paid in the 1980s to re-examine data considered problematic by the EPA; another scientist carrying out a consultancy in the late 1990s that concluded against glyphosate, and was not taken into account by the firm that had commissioned it. These various elements are taken up in the 2019 report of the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), which recommends improving the transparency of evaluation work by the agencies by making available to the public all of the data contained in the files submitted to the evaluation agencies in order to allow for a citizen's counter-expertise, by making the links of interest transparent and by controlling the links of interest declared within the framework of strong ethical obligations weighing on the agencies' personnel and experts (OPECST 2019).

Another attack on the European evaluation of glyphosate is taking place in 2020. The NGO PAN Europe reveals that a German laboratory implicated in fraud conducted numerous tests of the 2017 glyphosate reauthorization dossier (PAN Europe 2020).

At the same time, four ministerial departments (risk prevention, health, labor, research and innovation) and the Ministry of Agriculture and Food) commissioned Inserm for a collective expertise report on pesticides and health to be published in July 2021 (Inserm 2021). The Inserm Collective Expertise Pole attached to the Thematic Institute

Public Health is coordinating this work. This work is based on more than 5,300 documents, mainly from the scientific literature available in the first quarter of 2020. The expert opinion concludes that there is an increased risk of non-Hodgkin's lymphoma with a medium presumption of a link, and evokes an increased risk of multiple myeloma and leukemia with a low presumption. It considers that mutagenicity tests on glyphosate are rather negative, while genotoxicity tests are rather positive, which is consistent with the induction of oxidative stress. Experimental carcinogenesis studies in rodents show excess cases, but are not convergent. It mentions other mechanisms of toxicity (intergenerational effects, disruption of the microbiota, etc.) that it would be interesting to consider in the evaluation procedures. The report concludes by stressing the importance of periodically re-evaluating knowledge in the field of pesticides and health, and the need to further study and integrate the indirect effects of certain pesticides on human health through effects on ecosystems and social and economic aspects, in order to inform decision-making when developing public policies.

Anses is participating in the re-evaluation process of glyphosate<sup>11</sup>, whose current authorization expires at the end of 2022, in a consortium of four reporting Member States (France, Hungary, the Netherlands, Sweden), the Assessment Group on Glyphosate (AGG). The draft assessment report on glyphosate delivered by this consortium in June 2021 considers that glyphosate does not meet any of the criteria for a ban (including carcinogenicity). The large number of comments received during the public consultation on this draft report led to a delay in the European assessment, which is expected to be concluded in June 2023 (EFSA 2022a). Among the many comments received during the public consultation, several were from Inserm following its 2021 assessment and contradicting some of the conclusions of the assessment report of the consortium of Member State rapporteurs (Foucart 2022).

In 2021, two reports by two toxicology researchers for the NGO SumOfUs asserted the unreliability of the vast majority of genotoxicity studies relied upon by BfR, EFSA, and ECHA experts during the last evaluation of glyphosate in 2017 and during the ongoing authorization renewal process (Knasmueller and Nersesyan 2021; Nersesyan and Knasmueller 2021). These reports were made possible by two rulings of the Court of Justice of the European Union on March 7, 2019, which, when seized by Members of the European Parliament and a toxicology consultant for NGOs, ordered EFSA to provide access to industry-derived files on the genotoxicity of glyphosate, which had previously been placed under the seal of industrial secrecy (CJEU 2019a and 2019b). According to these reports, the industry-derived data did not comply with the OECD guidelines that are supposed to frame regulatory testing. According to cnDAspe (Commission nationale de la déontologie et des alertes en matière de santé publique et d'environnement), *"this conclusion is likely to mislead the public serious doubts about the impartiality of the experts from the agencies that gave their opinion on this dossier. Far from responding to these concerns, EFSA refused to publish the names of the experts from the Member States involved in this scientific evaluation and their statements of interest"* (cnDAspe 2022a).

In the same year, the cnDAspe recommended harmonizing the conflict of interest management systems within the agencies responsible for risk assessment in the context of the review

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<sup>11</sup> Reassessment process still underway as this report is adopted (November 2022).

of pesticide registration applications by recommending the development of a set of common minimum rules (cnDAspe 2022b). A new front is opening up in the controversy surrounding the European reauthorization procedure for glyphosate, with scientists pointing out that a 2001 industrial study showing neurotoxic effects of a glyphosate salt was not communicated to European authorities, contrary to regulatory requirements (Mie, Rudén 2022). These scientists suggest a retrospective check of the lists of studies performed by testing laboratories against studies submitted to regulatory authorities to examine the completeness of data submitted to authorities. They also suggest that future toxicity studies be commissioned by the authorities rather than by companies, to improve the authorities' oversight of existing data and to avoid economic conflicts of interest affecting the reporting of study results and conclusions.

### 3.2.2. Opinion of the Anses

#### 3.2.2.1. 2015 GECU and 2016 Anses opinion on the comparison of IARC and BfR opinions on the carcinogenicity of glyphosate

In March 2015, the Anses was asked to clarify the discrepancy between the IARC and EFSA opinions on the carcinogenicity of glyphosate. It created a GECU of four experts, attached to the CES "Plant Protection Substances and Products, Biocontrol"<sup>12</sup>, and assigned it two missions (Anses 2016a):

- "Identify whether the elements presented by IARC and BfR are such as to support a proposal to modify the classification of glyphosate for carcinogenic properties, to inform the position of Anses during the upcoming public consultation in the framework of the classification procedure by ECHA" (report requested for December 16, 2015) ;
- "Identify whether the results of the genotoxicity studies in the BfR assessment projects are sufficiently robust, and whether these results should lead to additional studies on formulants and/or glyphosate-based formulations" (report requested by March 22, 2016).

For the first part of the referral, the GECU met twice. Its report mentions that

*"Given the time frame for responding to the request, GECU was unable to consult the reports of regulatory studies and/or all published articles that were used by the BfR and IARC to support their conclusions. This report identifies important differences in the bodies of studies considered by the two agencies:*

- IARC relies on articles published in the open literature (*peer review*) with a critical analysis of the quality and validity of the methods and results presented;
- The European evaluation procedure is based on regulatory studies generally conducted according to the principles of good laboratory practice (GLP) and subject to OECD guidelines. These studies are rarely published in peer-reviewed journals.

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<sup>12</sup> Here named CES Phyto.

Thus, it notes:

- The large body of regulatory data is not considered by IARC, except for those that have been published;
- A high number of published studies are not considered by the BfR (lack of precision on the material used, non-conformity of the protocol with experimental standards, lack of raw data...)
- Given the format of the available glyphosate database, the BfR assessment is based on a broad spectrum of validated studies rather than a key study for each item;
- The lack of sufficient qualitative and quantitative data on impurities in the batches of glyphosate tested, either in a publication or in a regulatory study, generally calls into question the acceptability of the results and the proposed conclusions.

The GECU will conclude along the lines of the European expertise (Anses 2016a): *"In conclusion, taking into account, on the one hand, the time limits for the investigation and, on the other hand, the very large number of*

*In view of the large number of studies and publications available, the working group's analysis was based exclusively on the reports of the European and IARC evaluations and not directly on the reports of studies conducted according to the guidelines, which incorporate raw data, as well as on the published scientific literature. Consequently, it is not in a position to give an opinion on a classification in category 2 or on the absence of classification within the meaning of Regulation (EC) No 1272/2006. On the other hand, the working group considers that the analysis conducted shows that the level of evidence of carcinogenicity in animals can be considered as relatively limited and does not allow, within the meaning of Regulation (EC) No 1272/2008, to classify glyphosate (active substance) as a category 1B carcinogen.*

". In its opinion of February 9, 2016, the Anses repeated this conclusion.

### 3.2.2.2. Lack of advice on the second part of the 2015 GECU mandate on glyphosate-based formulations

The second question put to the GECU experts, concerning glyphosate-based formulants and preparations, will not result in an opinion or a decision by the CES Phyto, thus justifying the abandonment of the draft report, which will be denounced in an article in *Le Monde* (Foucart 2021a). However, the 2016 Anses opinion indicated that the agency was continuing its work by setting up a working group on the risks associated with co-formulants present in all plant protection products, with priority given to glyphosate-based products and the re-evaluation of products combining glyphosate and tallowamine, products for which compliance with the requirements set out in Article 29 of Regulation (EC) No. 1107/2009 is a major issue. In July 2016, the Anses proceeded to withdraw 132 marketing authorizations for glyphosate-based products following the identification of concerns regarding the co-formulant POE-Tallowamine (Anses 2016b). In contrast, the second GECU report, on glyphosate-based formulations, will never be published. This will lead *Le Monde* to consider that the Anses has buried a report on glyphosate (Foucart 2021a). In a message addressed to the members of its boards (Board of Directors, Scientific Council, Ethics Committee), the Agency's DG will state: *"This additional expertise, announced in the February 2016 opinion and mentioned in CES in September 2016, was not finalized in this form due to the*

*consideration of the question posed in other scientific and regulatory frameworks. While there was no scientific deliverable duly finalized and endorsed by a group of experts in accordance with Anses expertise procedures - which could explain why the experts contacted by Le Monde were unable to respond to the journalist's request - I would like to emphasize that this subject, on which we have remained very vigilant, has well taken up and educated through other channels."*

### 3.2.2.3. Roundup Pro 360 herbicide approved in 2017, overturned in court in 2019

After its 2016 opinion, the Anses continues to authorize commercial glyphosate-based herbicides. On March 6, 2017, it authorized the marketing of Roundup Pro 360. This decision was annulled by the Administrative Court of Lyon in 2019 *"in application of the precautionary principle defined by Article 5 of the Charter of the Environment"*, on the grounds of *"suspected carcinogenic potential"* and the Anses was called into question for *"error of assessment with regard to the precautionary principle"* (Administrative Court of Lyon 2019). The opinion of the Anses of 2016 is mentioned in the judgment. This decision will be confirmed by the Administrative Court of Appeal of Lyon in 2021, according to which *"[a] plant protection product that disregards the requirements of the precautionary principle cannot benefit from a marketing authorization"* (Administrative Court of Appeal of Lyon 2021).

### 3.2.2.4. 2018 GECU and 2019 Anses opinion on the terms of reference for a study on the carcinogenicity of glyphosate

Following the controversies over the carcinogenic classification of glyphosate, the Anses received a referral in March 2018 from the Ministers of Ecological and Solidarity Transition, Solidarity and Health, and Agriculture and Food, to establish the specifications for a study on the carcinogenicity of glyphosate (Anses 2019a). The referral letter mentions that the glyphosate hazard study will follow a study protocol *"based on European or international guidelines."*

The Agency is setting up a GECU made up of five members, including two Europeans outside France, to work on these specifications. It met three times, from September to December 2018, and presented its report in February 2019 to the CES Phyto. A hearing of Roger Genet at the National Assembly reports that *"[t]he quality of some of the studies in the assessment was deemed to be improvable and an approach to distinguish both epigenetic and genotoxic effects was proposed."* The report is finalized in March 2019 and the Anses opinion published in July 2019. It may be noted that the report cites without comment an article then known to be "ghostwritten" by Monsanto, without questioning whether its content may be favorable to that firm's interests (Brusick et al. 2016), to support the assertion that one test (the *in vitro* comet assay) is considered to have low weight in a weight-of-evidence approach.

To meet these specifications, the agency is launching an international call for applications during the summer of 2019, closing on October 15, 2019. The agency will receive only two proposals (Anses 2020a) and will select one, that of a consortium coordinated by the Pasteur Institute of Lille, while offering to fund part of the project proposed by IARC with the unsuccessful consortium.

The selection of a consortium coordinated by the president of the GECU and including two of the four other members of the GECU will lead to a written question on the ethics and independence of the procedure by the deputy Mrs. Delphine Batho on June 9, 2020 (National Assembly 2020). The reproaches formulated are nourished:

- The specifications were written by a GECU expert, who applies for and wins the tender, which is contrary to ethical principles and the rules of public procurement;
- This same expert participated in the CES Phyto which deliberated on the GECU report
- He was also one of the experts on the 2015 GECU on the comparison of IARC and BfR opinions on the carcinogenicity of glyphosate, which presented the risk of a lack of impartiality.

This initiative is relayed by an article in *Le Monde* (Horel, Foucart 2020) which also argues that the specifications of the Anses on the carcinogenicity of glyphosate would favor the candidacy of the members of the GECU, and would include scientifically unjustified and questionable requirements:

- The requirement of GLP conditions for the *in vivo* genotoxicity test would favor the laboratory of the GECU president. It is presented in the *Le Monde* article as the only public laboratory approved in France for this purpose; in reality it is a private foundation. The list of test facilities controlled by Cofrac in accordance with the principles of Good Laboratory Practice (GLP)<sup>13</sup> confirms that only private laboratories are GLP certified for toxicity and mutagenicity studies and that only the Institut Pasteur Lille laboratory works in the framework of public expertise.
- The DNA breakage methods required in the specification would favor the candidacy of some GECU members. It can be noted that in the specifications, their description is supported by the citation of two publications of which two GECU members are co-authors.
- The Cell Transformation Assay required in the specification would favor the application of a GECU member and would be scientifically questionable as probably not sensitive for a low dose pesticide. It can be noted that eleven publications cited in the section describing the Cell Transformation Assay requirements have a GECU member as a co-author.
- Two cell lines required in the specification are linked to GECU member laboratories and would not allow for the study of lymphomas and blood cancers highlighted in epidemiological studies of farmers in relation to glyphosate.

An article published by *Libération* in July 2020 questioned various links of interest of the GECU president during his career with pesticide industrialists (Massiot 2020). The Anses, quoted in the article, indicates that it has taken into account and analyzed the links of interest included in the declaration of interest of this expert according to the Agency's analysis grid for links of interest, which is public and validated by its ethics committee, and has qualified these links as minor.

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<sup>13</sup>[https://www.cofrac.fr/fileadmin/user\\_upload/cofrac/Liste\\_des\\_installations\\_d\\_essais\\_controlées\\_par\\_le\\_Cofrac\\_2022-05-31.pdf](https://www.cofrac.fr/fileadmin/user_upload/cofrac/Liste_des_installations_d_essais_controlées_par_le_Cofrac_2022-05-31.pdf)

This challenge led to the withdrawal of the consortium in July 2020 (Anses 2020b). The IARC in turn withdrew in October 2020, which was covered in an article in *Le Monde* questioning the requests of the Anses, which the IARC considered unacceptable ("*glyphosate will have to be supplied by the Glyphosate Renewal Group and the protocol transmitted to the latter*") (Foucart 2021b). In the end, no study will be launched.

#### 3.2.2.5. Anses participation in the European re-evaluation of glyphosate

In June 2021 the four member states of the EU Glyphosate Assessment Group (AGG) (France, Hungary, the Netherlands, and Sweden) deliver their assessment report, which proposes no new classification for glyphosate, whose marketing authorization expires on December 15, 2022. The four Member States present an 11,000-page evaluation report and conclude that no further classification as a carcinogen is warranted. Their work is now in the hands of the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) who will have to finalize the risk assessment. Their conclusions, expected at the end of 2022, have been postponed to mid-2023 and will serve as a basis for the European Commission to propose, or not, the renewal of the herbicide to the EU Member States (EFSA 2022a; EFSA 2022b). The assessment group proposes that the active substance be classified as H318 ("Causes serious eye damage"), and H411 ("Toxic to aquatic organisms, causing long-term adverse effects").

### **3.2.3. The lessons of the glyphosate case concerning the credibility of scientific expertise**

The Anses has faced significant criticism concerning the expert assessments it has conducted on glyphosate. These criticisms are part of a context in which the regulatory evaluation of glyphosate has crystallized criticisms and strong expectations from civil society, but also from actors in the scientific and political worlds, and has become an emblem of the changes expected more broadly on a better consideration of the dangers and risks of pesticides (Thesis 3).

Thesis 2 plays an essential role here with the restriction of the questions asked of the experts in the referral, the modalities of operation of an expertise in the form of a GECU, the questions concerning the literature taken into account, the positioning in relation to the precautionary principle and the non-finalization of a mandate given to a group of experts. Thesis 1 on the role of procedures also plays an important role; fueled by the discrepancy between the IARC and EFSA evaluations, the European regulatory expertise on glyphosate is strongly criticized. Criticism affects the Anses via the groups of experts mobilized, but also via the agency's own activities, whether it be the legal ban on Roundup Pro 360 or criticism of the AGG consortium in charge of re-evaluating the authorization of glyphosate.

Finally, because of the importance of glyphosate uses and the economic costs of alternatives to the use of this herbicide, thesis 4 on the influence of economic issues is also quite relevant.

## **3.3. SDHI**

### 3.3.1. Summary of the case

In October 2017, Pierre Rustin, research director at the CNRS and specialist in mitochondrial diseases related to SDH (succinate dehydrogenase, complex II of the mitochondrial respiratory chain) dysfunction, contacted the Anses by email after having fortuitously discovered with various colleagues the existence of a family of fungicides, SDHIs (succinate dehydrogenase inhibitors), which act on target fungi by blocking their SDH. Genetic mutations that cause partial blockage of SDH are the cause of human diseases such as encephalopathies and cancers. The group of scientists wonders how the scientific knowledge on SDH was taken into account when these pesticides were authorized.

Although the scientists did not have this information when they contacted Anses, it turns out that SDHIs represent an important commercial and agronomic issue, in a context where some fungicidal active substances are losing their effectiveness due to the development of resistance in pathogen populations, and where other active substances are banned.

Exchanges took place with the Anses, which notably transmitted certain dossiers on authorized SDHI active substances to the group of scientists and encouraged them to apply for the Anses' Call for Environment Health and Work projects (APR-EST). However, a real dialogue did not take place during these first exchanges. The Anses representatives consider that the elements on genetic diseases related to a deficit of SDH activity do not provide evidence of toxicity under conditions of exposure to SDHI that are punctual, partial and fluctuating over time. Scientists are unfamiliar with the regulatory assessment framework for pesticides and note in regulatory dossiers that SDHI toxicity to mitochondria is not tested during approval procedures. Moreover, their letter of intent to the RPA EST Anses is rejected. They contacted their research organizations (CNRS, INSERM, INRAE) to inform them of their alert, but these institutions did not support their approach. They published a *preprint* in March 2018 (Bénil et al. 2018). They then decide to make a public alert through an op-ed published in *Libération* on April 15, 2018. In addition to the known effects of SDH blockage due to genetic mutations, the op-ed also exposes that cellular respiration and the SDH enzyme function in the same way in all living species, and questions how SDHI pesticides could have been put on the market with the assurance of having no impact on human health and ecosystems.

Three days later, the Anses announced the constitution of a GECU. In the weeks and months that followed, environmental NGOs took up the case, with a dossier from Générations Futures<sup>14</sup> and a petition from Pollinis<sup>15</sup>. The scientists were heard at the National Assembly by the parliamentary commission of inquiry on industrial food<sup>16</sup>. The opinion of the Anses, following the work of the GECU, published on January 15, 2019, concludes that the information and scientific hypotheses given by the whistleblowers do not provide evidence in favor of a health alert that would lead to the withdrawal of authorizations for

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<sup>14</sup> <https://www.generations-futures.fr/actualites/boscalid-sdhi/>

<sup>15</sup> <https://www.pollinis.org/publications/pollinis-demande-le-retrait-immediat-des-fongicides-sdhi-en-waiting-for-their-evaluation/>

<sup>16</sup> [https://www.assemblee-nationale.fr/dyn/15/comptes-reports/cealimindu/115cealimindu1718005\\_report#](https://www.assemblee-nationale.fr/dyn/15/comptes-reports/cealimindu/115cealimindu1718005_report#)

marketing of plant protection products containing SDHI (Anses 2019b). It recommends that knowledge of the hazards of SDHIs, exposure to these products and the risks that may arise from such exposure, and the strengthening of regulatory risk assessment mechanisms be further developed. It notes that these issues will be shared at the European level.

The group of scientists regretted various limitations of the GECU report in a letter addressed to Anses and later made public on a website created at the initiative of two scientists of this group, Pierre Rustin and Paule Bénit<sup>17</sup>. He argues that data on the use and presence of SDHI residues are incomplete and insufficiently questioned, that the importance of mitochondrial diseases in public health is not taken into account, and that epidemiological and biomonitoring data are lacking despite worrying signals. He questions the composition of the group of experts, which does not include any specialist in mitochondrial physiology, diseases associated with mitochondrial function impairment or cancer pathology. Finally, he regrets that the knowledge of the mode of action of SDHI, of their capacity to inhibit the human enzyme as well as that of other living organisms, and of the pathologies linked to the blocking of SDH in humans, does not lead to the application of the precautionary principle.

In June and July 2019, while the NGO Pollinis is preparing a petition for the European Commission, MEPs, and EU member states, research funding is granted for work on SDHI. Two are granted by the Anses on a project to characterize the toxicity mechanisms of SDHI fungicides and on a project to explore the data of the national registry of hereditary paraganglioma linked to a mutation of SDH, to specify the evolution of the incidence of this pathology and to carry out a case control study. The other one is granted by the French Office of Biodiversity (OFB) in the framework of the Ecophyto 2 plan.

The fall of 2019 is marked by the release of a book by journalist Fabrice Nicolino, opening a campaign on SDHIs by the movement "We want poppies," a movement of which he is the president and which calls for a ban on all synthetic pesticides in France (Nicolino 2019). In his book, the journalist describes in particular the tense meeting of the group of scientists with the GECU and other members of the Anses in June 2018, and also questions the links of interest of a member of the GECU with actors in the agricultural and agrochemical world.

Also in the fall of 2019, the SDHI alert appears for the first time in the European review procedure for an application for authorization of a fungicide in this family, pydiflumetofen. The EFSA peer-review document on this active substance cites the alerters' preprint (EFSA 2019). The issue of diseases that may be linked to SDH inhibition is presented in general terms by France, the rapporteur Member State on this dossier. The experts note that a concern and a relevance for humans cannot be excluded. But the assessment of these issues is considered inconclusive, due to lack of data and validated methodology to address the issue.

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<sup>17</sup> <http://endsdhi.com>

The preprint of the collective of scientists leads shortly after to a publication in the journal PLOS One (Bénil et al. 2019). This will be the subject of a communication by the CNRS<sup>18</sup> but also of a counter-analysis video by the Union des Industries de la Protection des Plantes (UIPP) in January 2021<sup>19</sup> and of a counter-publication by authors from BASF in February 2021 (Kamp et al. 2021).

The cnDAspe is issuing an opinion in November 2019 following a report on possible risks related to SDHI fungicides (cnDAspe 2019). It considers that the situation constitutes an alert due to the dangers not taken into account in the European regulation on pesticides and calls for dedicated funding due to the substantial uncertainties remaining on the risks that would be induced in humans. It also considers that the Anses has treated the report communicated to it by the research team in a reactive and thorough manner. Anses officials are the subject of a (non-public) hearing by the National Assembly's environmental health study group in November 2019.

In January 2020, the daily newspaper *Le Monde* published an article by 450 scientists, supported by ten scientists specializing in mitochondrial diseases, deploring the denial of scientific data and calling for a halt to the use of SDHIs in open environments. A hearing on SDHI took place a few days later at the OPECST. In its conclusions, the OPECST considers that the work of the group of researchers raises interesting points, some of which need to be validated and deepened, but do not seem sufficient to legitimize a health alert commensurate with the fears expressed in the press. He recommends that the toxicologists responsible for establishing guidelines at the international level take up the potential mitotoxic effects of phytopharmaceutical substances (OPECST 2020).

In January 2020, three associations, the movement "We want poppies", Générations Futures and France Nature Environnement, asked the Anses to cancel the marketing authorizations of three SDHI-based fungicides. They announce a legal action if the agency does not respond within two months. Also on the judicial front, a ruling was made on Voxan, a fungicide containing three active substances including an SDHI (fluxapyroxad). It follows a lawsuit filed by a beekeeper who had rented his hives to pollinate a farmer's rapeseed field and whose bees had suffered a high mortality attributed to the treatment of a neighboring field with this fungicide. The judgment rendered in June 2020 was in favor of the beekeeper. In February 2021, the BASF firm was dismissed from a lawsuit seeking to overturn this earlier judgment. In the meantime, Voxan has lost its registration, following the withdrawal of marketing authorizations in France for another active substance contained in the product, epoxiconazole. Part of the media coverage of this bee loss and the subsequent ruling referred to the SDHI scare<sup>20</sup>.

In February 2020, Anses launched a call for applications for a WG on SDHI, which began work in October 2020 and is expected to publish its work by the end of 2022. In October 2020, two new projects are funded by the ANR and the Foundation for

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<sup>18</sup> <https://www.cnrs.fr/fr/les-fongicides-sdhi-sont-toxiques-pour-les-cellules-humaines>

<sup>19</sup> <https://www.youtube.com/watch?v=BQL9da6qENw>

<sup>20</sup> For example: <https://france3-regions.francetvinfo.fr/occitanie/ariege/foix/ariege-victoire-apiculteur-justice-recognized-poisoning-his-millions-bees-1842402.html>

<https://www.leparisien.fr/environnement/pesticides-un-apiculteur-obtient-la-reconnaissance-de-l-intoxication-of-his-bees-18-06-2020-8337723.php>

Medical Research and are in addition to projects previously funded by the OFB and Anses. They fund a consortium of French researchers in chemistry, toxicology, ecotoxicology, epidemiology, medicine, agronomy, economics, sociology and history, which aims at an integrated assessment of the toxicity and ecotoxicity of mitochondrial toxic pesticides and their regulation<sup>21</sup>.

In December 2020, the report of the parliamentary commission of inquiry on the evaluation of public environmental health policies recommended, with regard to the Anses and based on the example of SDHI, that the evaluation of hazards and risks be entrusted to scientists who meet the standards of the scientific method, so as to impose regulatory frameworks that are truly protective of the health of living beings and of the environment (Toutut-Picard, Josso 2020)

On June 30, 2021, the Inserm expertise on pesticides and health addresses the case of SDHI and devotes a chapter to it (Inserm 2021). It describes the lack of epidemiological data and the potential endocrine disrupting effect shown in some animal models. She discusses the regulatory basis for considering tumors observed in rodent tests as irrelevant to humans and concludes that research is needed to improve the assessment of the carcinogenic potential of SDHIs, and more generally of non-genotoxic active substances.

In november 2021, following its 2019 opinion on SDHI reporting, the cnDAspe will issue an opinion on "alert management of chemical risk" (cnDAspe 2021) on the basis of a report that it had commissioned from a group of experts. The opinion includes various recommendations on the methods of questioning or monitoring the scientific expertise of the competent agency, a clarification of the criteria leading the agency to update or not the risk assessment, transparency on the data taken into account in the updating of the risk assessment, publication of the recommendations addressed to the government, and a new procedure for the examination by the European competent authority of a recourse to safeguard clauses by a Member State, as well as an improvement in the quality of the public debate on chemical risk through the training of professional actors.

In June 2022, Pollinis' petition was submitted to the European Commission. Also in June 2022, EFSA publishes a peer review of the SDHI active substance isoflucypram (EFSA et al. 2022). It notes that the active substance could be tested in vitro for its potential to inhibit SDH but does not require it and considers that the toxicological assessment conducted by the petitioning company corresponds to the current regulatory requirements.

Some SDHI fungicides were marketed as early as the 1960s (Pesticide Property Database, Lewis 2016), but SDHIs have mostly entered the crop protection market since the early 2000s, with a "SDHI wave" of new active substances (Leadbeater 2015; Phillips 2020) intentionally developed to achieve greater biological efficacy (Rheinheimer 2019; Coqueron et al. 2019). Currently 27 SDHI active substances (23 fungicides, one fungicide and nematocide, and three acaricides) are identified by the Fungicide and Insecticide Resistance Action Committees (FRAC 2022

IRAC 2022). In the European Union, four of them have been banned since 2002, two have been banned in 2021 and 2022 respectively, eleven are authorized and four are in

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<sup>21</sup> Holimitox Scientific Network, <https://holimitox.fr/>

The last six have not yet entered the EU authorisation procedure (EU Pesticides Database 2022). SDHIs represent a significant share of the pesticide active substances under review for EU authorization (a total of 64 active substances, many of which are biocontrol products). The value share of SDHIs in the global fungicide market increased from 2% in 2004 (Krämer et al. 2007) to 8% in 2015 (Jeschke et al. 2019).

SDHIs are therefore of great interest to the agricultural world, where they are often used in products or crop management programs that combine active substances from several families, particularly to limit the development of resistance. In addition, production methods that rely more on natural regulations and less on synthetic inputs allow a reduction in the use of fungicides, but do not necessarily exclude them.

It can also be noted that strobilurins, an even more important family of fungicides (20% of the market in 2015, Jeschke et al. 2019) are also substances with mitochondrial toxicity, which in turn target complex I of the respiratory chain. The question of mitochondrial toxicity posed by the group of scientists thus concerns a broader field than just SDHIs.

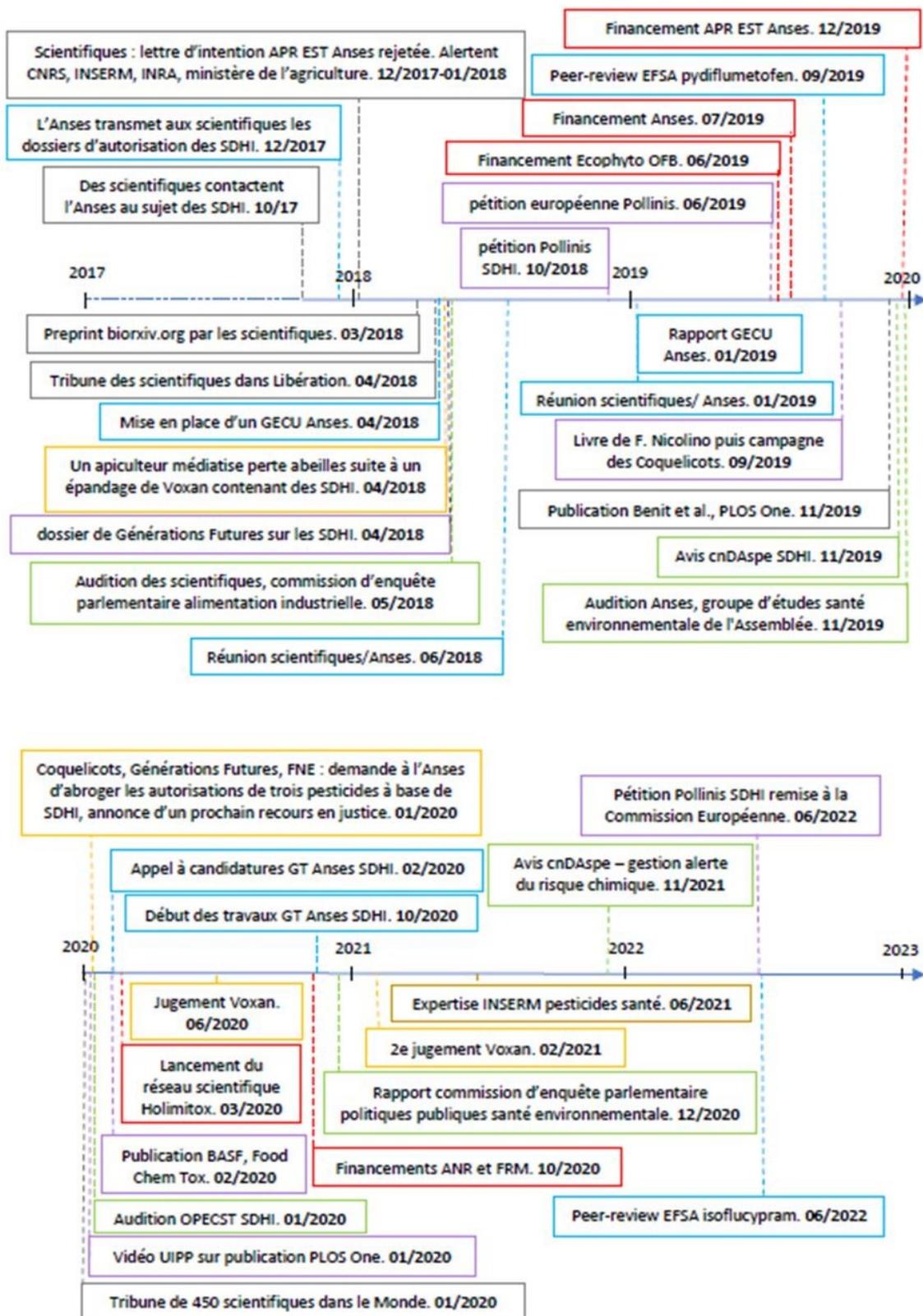


Figure 2: Chronology of the SDHI case

### **3.3.2. Lessons from the case concerning the credibility of scientific expertise**

The management of the SDHI scientists' alert was strongly criticized under thesis 2 (procedures), both for the initial exchanges with the group of scientists and for various limitations related to the choice of a GECU format for the initial instruction of the alert (limitations in the duration, the number of experts involved and their field of expertise, the consideration of the scientific literature).

Thesis 1 (mismatch between academic knowledge and regulatory expertise) also plays an essential role, since the alert concerns a mismatch between scientific knowledge on known mechanisms of toxicity (mitotoxicity) and the regulatory framework for evaluating pesticides, which does not take these mechanisms into account.

The strong involvement of different stakeholders from civil society, politics and science testifies to the relevance of thesis 3 with strong expectations for a better assessment of the hazards and risks of pesticides.

Finally, thesis 4 (on the impact of economic issues) is also illustrated by this case, given the increasing use of SDHI as a fungicide, which is in conflict with social and political demands to reduce pesticide use.

## 4. Thesis 1. Integration of the evolution of scientific knowledge in a science framed by regulations

The hearings have consistently shown that, compared to other European agencies, the Anses has a certain advantage in terms of its links with the academic world and the mobilization of scientific data. It also benefits from the framework of the health expertise charter on the management of experts' links of interest and from ethical rules that allow a better distance with the bearers of interest than in other European agencies. However, as is also the case in other European agencies, some of the agency's work may be criticised: it is perceived as insufficiently integrating the state of scientific knowledge, or as being too favourable to the interests of private companies, or as being too subject to political pressure.

The Agency is obliged to comply with national, European and international regulatory frameworks when it examines applications for marketing authorizations for regulated products for which it is responsible for risk management at the French level, or when it participates in European evaluations of marketing authorizations managed at this level. However, on a certain number of subjects within the scope of Anses' missions, the regulatory framework is increasingly questioned as being out of step with the state of the art of scientific knowledge. The Anses is not exempt from criticism when some stakeholders consider that the assessments comply with regulatory frameworks that are too narrow. This situation is encountered in our case studies, for example, with the legal cancellations of the MAs that the agency had granted to Roundup Pro or sulfoxaflor. It is also found in the current evaluation of the renewal of the European authorization for glyphosate, for which the Anses is participating in the consortium of rapporteur Member States, and which was the subject of numerous comments during the public consultation phase.

As for its risk assessment mission outside of these national or European authorization procedures, the Anses is not obliged to comply with regulatory frameworks; it may have the latitude - sometimes limited by the scope and timeframe of the referrals - to broaden the spectrum of scientific opinions issued, including by integrating elements that may go against regulations and/or suggest regulatory changes. Anses has also been criticized for its risk assessment mission, for example when it dealt with the alert on SDHI, or following the non-finalization of the second part of the mandate given to a GECU on glyphosate in 2015, concerning glyphosate-based formulations. In this case, it is the agency's capacity to use methodological references that deviate from the regulatory frameworks that is called into question, and its independence in relation to a political order.

Finally, the Anses has a role to play in discussions and working groups on the evolution of regulatory frameworks and guidelines at the European and international levels. Regulations evolve according to scientific knowledge, but with a time lag that is sometimes very significant (several decades) and that can cause sometimes irreversible damage to the health of individuals and the environment. This time lag is difficult to reduce because the evaluation methods

The regulatory framework and the normative values associated with it are European and depend on international guidelines, notably those established by the OECD. This discrepancy is not only temporal, but also conceptual, and raises questions about the level of certainty that scientific data must provide in order for the guidelines to evolve. Bringing the regulations closer to the state of knowledge therefore requires a continuous evolution of standardized evaluation methods and standards at the European or international level, which requires a significant and long investment in the bodies concerned, with no guarantee of success. Even if significant efforts are made (see in particular the role of Anses in the European PARC program), the Agency's investment in the evolution of international and European regulatory frameworks can sometimes be considered insufficient, as illustrated by the case study on SDHI.

## **4.1. Regulatory science and structuring of knowledge mobilized in scientific expertise**

This section shows both the importance, and the difficulty, of striking the right balance between academic and regulatory science at all levels of expertise, and of paying attention to the implications of possible biases in the scientific knowledge mobilized in the expertise.

### **4.1.1. The documentary base mobilized in the expertises**

The literature base used in the scientific assessments is a central point that emerges from the case studies.

The methodological framework for the mobilization of bibliographic sources in expert assessments has developed considerably in recent years at the Anses. The "Risk Assessment Methodology" WG (MER WG) attached to the Agency's Scientific Council has made various proposals to structure the evaluation of the weight of evidence and the analysis of uncertainty in the agency's expert assessments (Anses 2016c, 2017a and 2017b). The WG

The successor group "Accompanying the implementation of the recommendations of the MER WG" (ACCMER WG), which also reports to the Anses Scientific Council, has developed an internal methodological guide for the planning of expert assessments, uncertainty analysis, literature review, and evaluation of the weight of evidence (Anses 2022, forthcoming) based on this work. In particular, this work establishes a reference method for literature review in expert assessments. It corresponds to a systematic review of the literature on the most important data in the realization of the expertise, i.e. those whose impact on the result of the expertise is significant. The assessment of the importance of the data is left to the unit and the group in charge of the expertise. The flow chart of the method and its different steps are detailed in the report of the ACCMER WG (Anses 2022, forthcoming) and in various internal Anses documents.

The expert assessments at Anses are carried out using the data available at a given date (scientific literature, data from surveys, reports from other agencies, results from experiments carried out in the context of registration dossiers, etc.), which are identified, selected, evaluated and summarized by Anses experts and agents as part of the first stage of the assessment.

This methodology, well detailed in the reports of these WGs, is not repeated here, the objective being rather to present the problems identified during the analysis of the cases that it does not cover. Indeed, the case studies highlight several blind spots in this approach, which can impact the quality of the expertise.

#### **4.1.2. Links of interest in the affiliations of the authors of the articles or their funding**

As mentioned above in the presentation of the glyphosate case study, an article then known to be "ghostwritten" by Monsanto employees (Brusick et al. 2016) was cited in the 2019 GECU report, without specific comment. Beyond this particularly emblematic case, the same report cited several publications with authors affiliated with private companies (industry or private testing and contract research firms, including in several cases a signatory of the previous publication

"The report was also published in a publication funded by the Glyphosate Task Force (an industry platform for producers of glyphosate-based herbicides).

These remarks on this report illustrate a more general problem: the Anses does not currently have a methodology or recommendations for analyzing the links of interest in the literature and contextualizing a publication financed by a firm with an interest in a regulation that is favorable to it, or co-authored by employees of this firm. However, industrialists can influence the scientific literature mobilized for the constitution of guidelines or, further downstream, for the work of internal experts or groups of experts in the agencies, as analyzed in the scientific and journalistic work on the merchants of doubt. The extent of this phenomenon is difficult to document precisely, apart from cases where company archives are made public during legal proceedings.

This influence can take the form of private funding of research whose methodologies aim to underestimate the risks of the products of the companies concerned, or to put forward alternative causalities to the risks of these products, in order to artificially maintain open controversies (Oreskes and Conway, 2010; Proctor, 2012). It also involves the creation of scientific journals, an example of which is the journal *Regulatory Toxicology and Pharmacology*, an official publication of an association dominated by scientists who work for industrial trade groups and consulting firms (Michaels, 2008). For example, Velicer et al. (2017) document this journal's ties to the tobacco industry and their consequences, arguing that "[t]he significant representation of other industries with an interest in regulatory science (chemical, pharmaceutical, food, as well as lawyers representing industry) on the editorial board raises similar concerns for research of broad interest range of other industries". This influence can also come through the underwriting of scientific papers by employees of private companies that are signed by other scientists, or ghostwriting, as documented in the Monsanto Papers (Horel and Foucart, 2017c).

Transparency on conflicts of interest in the scientific literature has improved, with more and more scientific journals requiring the declaration of conflicts of interest in author affiliations or study funding. This gives the possibility to exercise more vigilance on this type of influence in the expertise. But this is not the case for all

journals, nor for older scientific articles, and this obviously does not allow the detection of *ghostwriting*.

On the other hand, in various fields, the situation of industrialists is sufficiently favourable for the production and interpretation of knowledge to converge with their interests without them having to deploy strategic intervention. This is what is analyzed in the work on "*undone science*," which focuses on the nonexistence of certain knowledge resulting from an unequal distribution of power in society (Hess, 2016). From another perspective, work on the institutionalized production of ignorance emphasizes that the institutions in charge of risk assessment are dependent on the forms of knowledge that are most compatible with their modes of action, which induces selection effects of the available knowledge, and leads to the ignoring of some (Jouzel, 2019). Finally, Boullier and Henry (2021) show situations where expertise depends on unpublished industrial data. More generally, they analyze the structural forms of influence of private actors on the knowledge mobilized in public expertise, which the current problematization in terms of the management of conflicts of interest of experts tends to make invisible.

Vigilance on the funding or authorship of studies was recommended in a 2016 opinion of the Anses Ethics Committee on the exploitation of scientific literature (CDPCI Anses 2016). In particular, the following extracts can be cited:

*"Several researches, in various fields, have shown that full or partial funding of the study by industry or service sector actors influences the published results. A statistical analysis of the studies shows a significant overrepresentation of results favorable to industry when the research received funding from them."<sup>22</sup>*

(CDPCI Anses 2016, p.4)

*"The efforts made by the Anses to prevent the risk of conflicts of interest have mainly focused on the appointment of experts and the conditions of their participation in expert assessments. However, the use of bibliographic tools for expertise purposes (bibliographic files and databases, criteria for the thematic selection of publications, choice of journals, etc.) also constitutes a major risk of exposure to conflicts of interest, which is not mentioned in the Agency's normative documents on the*

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<sup>22</sup> The CDPCI report cites the following publications: CAMPBELL E. G. et al. 2007. Institutional Academic-Industry Relationships, JAMA, 298(15):1779; CAMPBELL E. G et al., 2007. A National Survey of Physician-Industry Relationships. NEJM, 356(17):1742; LESSER L. I. et al. 2007. Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles. PLOS Medicine, 4(1):e5 - 0041; KRIMSKY S. 2010. Combating the Funding Effect in Science: What's Beyond Transparency? Stanford Law and Policy Review (21)1:101; MAXIM L. and ARNOLD G. 2012. How conflicts of interest can influence research and expertise. Hermes. 64:48-59; BAS- RASTROLLO M. et al. 2013. Financial Conflicts of Interest and Reporting Bias Regarding the Association between Sugar-Sweetened Beverages and Weight Gain: A systematic Review of Systematic Reviews. PLOS Medicine.10(12); DIELS J. et al. 2011. Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products. Food Policy. 36:197-203; Union of concerned scientists. 2012. Heads They Win, Tails We Lose - How Corporations Corrupt Science at the Public's Expense. Feb.

*ethics of expertise<sup>23</sup>. This risk, which has only recently been understood, concerns both the status of authors of publications, peer review arrangements, and the source of funding for journals, as previously reported."*

(CDPCI Anses 2016 p.12)

In this report, the Anses CDPCI recommended the creation of a WG on "Evaluation and methodology for processing bibliographic sources" attached to the Anses Scientific Council and to the Technical Committee on Referrals, whose mission would be to *"develop an analysis method on the quality of bibliographic sources, the detection of practices the mechanisms of institutional regulation, the relevant period for taking into account publications (how far back?), in order to encourage the Agency's experts to be more vigilant in the constitution and selection of bibliographies*

(CDPCI Anses p.13). It called for the development of methodological guides on the minimum conditions that must be met by a study to be retained in the framework of an expertise, including the consideration of links of interest in the articles, and encouraged *"the identification of obstacles and biases encountered by experts in the development of bibliographies in support of expertise in order to build a memory of these incidents, accessible to subsequent practitioners" and a "monitoring function on the development and the growing potential of data collection, processing and analysis tools (knowledge of the state of the art in science, controversies, modes of perception of weak signals...), detection of influences" (ibid.).*

In addition to the work of the MER WG (which the ACCMER WG followed), this CDPCI Anses report called for international standards relating to ethics and good practices in the field of publications to be taken into account, in particular the principles established by the Committee on Publication Ethics<sup>24</sup>.

The analysis of the case studies shows that these recommendations are still relevant. In addition to the inclusion of links of interest in articles, this can be added to the need to do so for journals. As an example, the *Regulatory Toxicology and Pharmacology* journal mentioned above, for which industry influence is documented in academic work, is cited without specific comment in the reports of the two glyphosate GECUs (Olson et al. 2000 in Anses 2016a; Annys et al. 2014 in Anses 2019a).

#### **4.1.3. Consideration of emerging scientific hypotheses and recent data**

In essence, very new scientific data are generally not yet replicated by other groups when the question arises as to whether they should be considered for risk assessment. However, they should not be discarded because they can

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<sup>23</sup> The CDPCI Anses (2016) report cited these documents: Code of Ethics for Expertise (Nov. 2012), Fundamental Principles and Key Points of Collective Expertise (Nov. 2012), Note de cadrage sur la méthodologie de l'expertise collective (Feb. 2012), Quality Management Manual (version b of Aug. 25, 2014). The risk of exposure to conflicts of interest through the use of bibliographic instruments for expertise purposes is also not included in the current versions of these documents.

<sup>24</sup> [https://publicationethics.org/files/Code\\_of\\_conduct\\_for\\_journal\\_editors\\_Mar11.pdf](https://publicationethics.org/files/Code_of_conduct_for_journal_editors_Mar11.pdf)

constitute warning signals. On this subject, the CDPCI Anses recalled the principles of impartiality, transparency, plurality and adversarial nature of health expertise set out in Article L.1452-1 of the Public Health Code and formulated the following recommendations in the aforementioned 2016 opinion:

*[It is essential to look for any studies that contradict the dominant results. Identifying minority or emerging scientific hypotheses and taking them into account in the assessment is a necessary condition for drawing up an inventory that reflects as accurately as possible the state of knowledge at the time of the assessment and, if necessary, inviting more in-depth studies to be carried out.]*

(CDPCI Anses 2016 p.15)

*"Care must be taken to ensure that the selection criteria...are not so rigorous as to exclude any study that does not conform to mainstream thinking.*

(CDPCI Anses 2016 p.12)

Such recommendations are still valid. When quantitatively assessing the level of evidence provided by the various documents included in the literature base, they call for the inclusion of articles whose level of evidence may remain low due to their novelty, as long as the methodology used to produce the results is well described.

The CDPCI (Anses 2016) recommendations can be extended to studies that are consistent with mainstream thinking but critical of regulatory approaches. Again using the example of the 2019 GECU report on glyphosate as an illustration, it shows that the choices in the specification were not situated with respect to the academic literature about the controversy over the carcinogenicity of glyphosate following the classification discrepancy between IARC and EFSA. Thus, for example, the publication by Portier et al. (2016) on the comparison of IARC and EFSA assessments of glyphosate carcinogenicity, signed by 96 mostly academic authors, was not cited. It is important that critical knowledge on regulatory assessments be taken into account in Anses' expert assessments.

It is also essential to have the ability to incorporate important recent knowledge, even published after the initial literature search. An example is the publication by Simon-Delso et al. (2018), showing chronic toxicity effects of an SDHI substance on bees that are not considered in regulatory procedures. Released near the beginning of the SDHI ECWG work, it is not cited in their report.

#### **4.1.4. Consideration of academic scientific results obtained outside of GLP guidelines and standards, including when analyzing the risks of regulated products**

For risk assessment evaluations, whether they are carried out in the context of a marketing authorisation or outside such a framework, the interviews highlight the need to allow experts to explore the literature without any a priori restrictions, and in particular

not to be limited to publications and studies that comply with good laboratory practices and guidelines, which are the most usable in a regulatory framework.

*"In terms of regulatory science and academic science, I think that's the crux of the problem. This is something that should be better explained to policymakers. Again, there is confusion, including in the scientific community. That's what's terrible. I realized in working on these glyphosate stories that for the broader scientific community or the medical community, a regulatory opinion is a scientific opinion. It's an opinion in which we've implemented a strategy of exploring the literature looking for what might explain what we're seeing in the real world or these kinds of things. That's a scientific approach. It's obviously not and it's so shocking."*

(journalist)

*"Everything that is a scientific study that can be looked at within the framework of a specific expertise, including regulated products, must be for me. Afterwards, if it is not retained for this or that reason, it must be said, traced and made transparent. But, in my opinion, one cannot say: "I exclude this study" without giving precise and valid reasons. When the BfR at the time, in the first glyphosate expert report that I re-read, rejected the epidemiological studies because they did not respect the Klimisch criteria, I had serious doubts. For an epidemiological study, by definition, the Klimisch criteria do not apply, even if we can try to transform them. There are published methodological references that can be used in these circumstances. For me, it is clear that if there are studies, other than GLP studies or industrial studies, that are useful, that could be useful in a regulatory assessment, they should be used."*

(Anses manager)

The scientists involved in the collective expertise must remain free to choose the references to be considered and must remain independent in their reasoning, questions, observations and analyses, without interfering with the regulatory issues. When the questions put to the experts are limited to the regulatory framework in force, a proposal emerged from several interviews: to allow the experts to give complementary points of view outside these regulatory frameworks as long as they are supported by solid scientific arguments. These additional points of view could be given separately in the opinion, in addition to the response limited to the strict scope of the referral:

*"Secondly, when we are a state agency, we are always free to have prerogatives with a scientific dimension. We are always able to provide an answer to the question that the government asks. Then, it is possible to add an additional chapter saying that we have been questioned on certain data and to present our answer. On the other hand, it is also possible to say that one should be careful because other data are not based on the framework mentioned. It is possible to say that this data is about this and that. It is quite possible, not to go outside the framework, but in the response given to the government, to draw their attention to the fact that another view of the situation exists, from a strict scientific point of view, than the framework that the government has set."*

(political leader)

This proposal is also consistent with the following recommendation from the Anses Ethics Committee in 2021:

*"This disjunction between regulatory and academic science - always temporary but often long-lasting - is recognized as one of the causes of public distrust. In the name of transparency on the one hand, and contradictory science on the other, the addition of certain results of academic science, convergent although not yet totally validated, should be mentioned as a track to follow and at least serve as an alert to deepen the subject within a time limit to be fixed."*

(CDPCI Anses 2021 p.6)

For risk assessments carried out in the context of marketing authorizations, we can thus recall this excerpt from a judgment of the European Court of Justice (CJEU, 2018): *"On the other hand, this does not mean that the relevant scientific literature should not be taken into account in the context of a review under Article 21 of Regulation 1107/2009. [Unless otherwise specified, the decisions that the Commission is called upon to take under this Regulation must always take into account the latest scientific and technical knowledge more recent"*. The practical implementation of this recommendation within the framework of MA procedures continues to be debated.

The long excerpt from the interview reproduced below illustrates the topicality of the criticism of the practice of excluding articles from the academic literature in the context of the European review procedure for the authorization of glyphosate.

*"Now that I've been fortunate or unfortunate enough to be interested in these issues for a while, I sometimes spot a paper in the literature. Sometimes there are critical papers. We know they are very important papers. I wonder how they will take this paper into account in the next European re-evaluation. There is one example that I find very amusing. It's a paper that came out in 2019 or 2020 by Swiss researchers. They did an experiment on humans to find out how much glyphosate we were actually exposed to. Strangely enough, it's an open question that we don't really have an answer to. We can measure what comes out in the urine. Then we do a bit of a messy calculation to see what that corresponds to in terms of oral exposure. We come up with a result. The basis for these calculations are regulatory studies done on rats. So researchers did the experiment on humans to see if it was the same in rats as in humans. That was published. Unfortunately, they didn't find the same result at all. There is a difference of a factor of 20 on average, and as much as 50. We take in on average 20 times more glyphosate than the regulatory agencies think. We can take it any way we want, but it's a subject. So I had fun looking through the thousands of pages of the glyphosate renewal report to see how we took that study into account... The study in question is crossed out with a stroke of the pen, saying, "We didn't look at everything that came out in all the excreta of the people who were sampled. That's not reliable. So we're not going to take that into account. I was interested in how biomonitoring experts talk about this study in their own work, because this study has been cited a lot since it was published. Indeed, the experiment had never been done. It was replicated by Swedes who found the same result. There is not even the objection that they are the only ones to have done this study. They were the first to do it, but it has been replicated by other teams who find a result that matches. Explicitly in the scholarly literature, there is a whole paragraph in the latest journal on population exposure to glyphosate in which the researchers say, "We finally have a human toxicokinetic and impregnation study of glyphosate. That's great. This should definitely be considered in the next re-evaluation." The*

*The result is a line in a table. When we object to the regulators that they don't take the scientific literature into account, they immediately say, "Oh, but we don't. We have taken everything into account. We have taken everything into account. You have to see how poorly the work is dismissed out of hand. You are the best people to know that all studies have their limits. As soon as there is the slightest limitation, the study is dismissed without further ado, even if you have 50 papers that point in the same direction. That's a huge problem."*

(journalist)

It can also be noted that the Anses staff of the Regulated Products Unit do not make much use of the Anses service for scientific resources. We have not found the explanation for this surprisingly low use. This is certainly an avenue that needs to be explored.

#### **4.1.5. Access to the details of the regulatory data**

It also seems necessary for experts to have access to the details of the regulatory data that they consider useful for their analysis (including studies presenting the raw data) and to have the time and means to analyze them.

To give an example, during the GECU work on the comparison of IARC and EFSA opinions on the carcinogenicity of glyphosate (Anses 2016a), a letter to EFSA from about 100 scientists detailed various criticisms of the assessment conducted by EFSA and BfR (Portier et al. 2015, which later led to the publication Portier et al. 2016). One example is the unpublished study by Sugimoto (2017), whose observed trends in tumor incidence were rejected by the BfR on the grounds that the maximum observed response was within the range of historical control data. This study was challenged by Portier et al. (2015) because of the use of historical controls from a different mouse line than the mice tested. In contrast, it was cited without comment in the 2016 GECU report. When asked about this, one expert responded:

*"You're putting words in my mouth. It doesn't tell me anything, but I can tell you something else. If we had access to the raw file, we would have seen it. I remember that I criticized an active ingredient in this way. There were two cancer studies, and they had used the controls from one study to make the calculations for the other. At the time, we were defending the files at the EU, I went to York and I told the British: "I don't agree with this amalgam of data". They told me: "You are looking in the corners and we did not notice it". So you have to look precisely. It's possible that they misused the historical controls, because there are rules for using them. These are the historical witnesses from the same lab, which cover a period of less than five years. Invoking historical witnesses is not enough, and is inadmissible if the batch of witnesses covers a period that extends beyond five years. You have to dig to see all this."*

(expert)

As another example, the question of access to data also arises for the second part of the mandate of this expert group, on glyphosate-based formulations, which did not result in the publication of an opinion:

*"The GECU had begun to answer the second question, looking at what method could be used and what tests could be done very easily. However, I had stressed that in order to interpret the data, it seemed to me essential to have the compositions of the formulations and not only the representative formulation. And then if we want to say something useful, it is*

*In particular, to look at the composition of the formulations on the market, to be able to say if it is valid or not, or if we should rather test for this one or that one, depending on what we know about the co-formulants. The answer is simple: we never have access to the co-formulants. I have never seen them. So we asked for details but they were not available. I was puzzled by this lack of information, and it seemed unnecessary to continue to answer this kind of question. If the compositions are not accessible why ask such a question?"*

(expert)

Anses agents provide valuable assistance to expert groups for literature reviews. Anses' support could be strengthened to facilitate access to the data in the regulatory dossiers requested by the experts, or to clearly explain the reasons why these data could not be provided.

#### **4.1.6. Time to analyze the collected data in detail**

Mobilizing and analyzing the literature in detail requires time, which is not always available, due to constraints often experienced by the agency. On this subject of the need for time for a detailed analysis of studies, feedback from experience may be interesting to mobilize (for example, the case of an expertise outside the Anses with a public sponsor, for which the group of experts had negotiated two two-year post-docs). Another idea that emerged from the interviews is to anticipate subjects that we know will be sensitive, in order to arrive with a background if a somewhat urgent request arrives. In particular, having time is not possible in GECUs, so the analysis may remain on the surface on some points.

#### **4.1.7. Ability to return to literature reviews with different lexical queries as the expertise progresses**

Like the questions asked in the referrals, the subjects taken into account and explored in the framework of the expertise may change as the expertise progresses. Limiting the questions to those that are too narrow exposes us to the risk of overlooking important fields of knowledge for a relevant risk assessment.

#### **4.1.8 Work carried out in Anses laboratories or in academic laboratories and funded by Anses**

Another important subject is the consideration of the recommendations of the expert assessments, in terms of the need to advance knowledge, in order to prioritize either research funding by the Anses (through research and development agreements or within the framework of the PNR-EST), or research in the Anses laboratories. One point in particular is the interest in generating scientific data to develop standards or assessment methods.

Anses does not appear to have been proactive in conducting work in its laboratories to clarify the appropriateness of the regulatory assessment mode for SDHIs, even though the SDHI GECU had made numerous recommendations on this topic (Anses, 2019b).

*"On very specific and particular issues, the Anses laboratories eventually need to have a little more money and flexibility to approach the subject. Let me give you an example. One of the Anses laboratories is working in 2022 on*

*Paraquat. Paraquat has been banned since 1969 in Switzerland and in France since a certain date. We still have laboratories of the Anses working on paraquat. It is money badly used. The Anses laboratory that works on paraquat should work on SDHI. We asked very concrete and direct questions about SDHI. We brought answers. We could relocate people to a research topic".*

(scientist)

The question also arises as to the means available to Anses for such work. The Anses has the possibility of launching studies conducted by mutual agreement with research teams, notably in the form of research and development agreements. However, it does so with limited means, which can be an obstacle. In 2021, the Ethics Committee of the Anses recommended increasing the resources of the Anses to finance such complementary studies:

*"Part of the difficulties encountered by the agencies comes from public doubts about the reliability or completeness of the data. However, constrained by the regulations, the Agency can only act on the margins by refusing a marketing authorization or by requesting confirmation studies from manufacturers each time the data seem to be fragile or incomplete, which it already does. But it would also be appropriate to finance additional independent research when the petitioners' results are not in line with the results of academic research. The concerns of civil society about current agricultural production methods, relayed by several parliamentary reports, should make it possible to justify to the legislator an increase in the resources of the Agency, whose competencies are constantly being expanded. It is essential, from a deontological point of view, that the Agency be able to finance such complementary studies and that its staff work in optimal conditions.*

(CDPCI Anses 2021 p.5)

## **4.2. Role of Anses in establishing guidelines**

The case studies highlight the inadequacy of current guidelines for assessing the toxicity of pesticides on bees (neonicotinoids), the failure to take into account the effects of mitochondrial toxicity in the regulatory assessment of pesticides (SDHI), as well as various alerts on the conditions of marketing authorizations for pesticides. For example, in the glyphosate case study, the existence of fraud in a laboratory that is GLP-accredited (PAN Europe 2020), or the failure of a company to comply with its obligation to submit all known data on the toxicity of its product (Mie, Rudén 2022).

Several hearings emphasized that France should lead efforts at the European and international levels to change the European regulatory framework and reduce the differences with scientific knowledge; in particular by investing in the construction of guidelines at the OECD. Among the other French actors that could have an impact on this issue, the Anses could play a more proactive role in changing regulatory methods.

*"We had made a proposal on the mobilization of European and OECD levers under the aegis of the General Secretariat for European Affairs. I don't remember who said it earlier, but in France, the experts didn't seem to us*

*have a great deal of appetite to position themselves on everything that is done at the OECD level or in the implementation of methods at the European level. This is something we regret. On the OECD side, we tried to see a little more clearly, but it was a real black box. We were not able to find out who was sitting in the different bodies and how they worked. But we realize that some of the methods of expertise are derived from the discussions at the OECD. (...) I believe that for the credibility of the expertise, there is a real need to go upstream, to invest more in everything that concerns methods, guidelines, definition of good laboratory practices at the OECD and that people sit on the committee. I understand that this is very long, that potentially seven years of working groups have to be done and that it is not necessarily very gratifying, including in professional terms. I don't know how it should be organized, but for me, the Anses would have an essential role to play, to contribute to the animation of the pool of experts who will sit in all these method definition bodies."*

(Inspector General)

This is what is proposed in the General Inspections' report of 2020 "Health-Environment: research, expertise and public decision making", under proposal 27, of high priority: *"Establish, under the aegis of the SGAE [General Secretariat for European Affairs], a roadmap for mobilizing European (and OECD) levers that is shared between the various administrations, the organizations concerned (in particular the Anses), the Permanent Representation to the European Union, and the ministers' offices concerned"* (Lavarde et al. 2020, p. 4).

A more proactive involvement in the European and international bodies that develop guidelines and regulatory frameworks, and greater transparency in the functioning of these bodies, appear to be central. The Anses could play an important role in this process, not only to better take into account scientific knowledge on the toxicity and ecotoxicity of products, but also to improve the current limitations of the European authorization procedure (possible fraud in GLP-accredited laboratories, subtraction of data on the toxicity of their products by the companies, etc.)

## 5. Thesis 2. Procedural issues

Since the end of the 1990s, scientific expertise has been the subject of a series of reforms aimed at increasing its quality and restoring confidence, with, in particular, in France, the Law of 1 July 1998 on health security. This law defines the main lines of the reform: implementation of the separation between expertise and management, delegation of expertise to specialized agencies -independent authorities, several of which were created by the 1998 law, others will follow- which rely mainly on external expertise, obligation of transparency and communication with the public and stakeholders. These reforms therefore establish several "fundamental principles" that constitute the foundations of expertise: competence, independence and transparency.

The production of procedures is part of this framework. It can be identified by a series of texts. Without attempting to be exhaustive and limiting ourselves to France, we can give a few points of reference. The AFNOR NF X 50-110 standard of May 2003 "*Quality in expertise - General competence requirements for expertise*" aims to "improve the control of points having an impact on the product of expertise and to allow, if necessary, a recognition of the capacity to conduct expertise". It defines expertise as "the set of activities whose purpose is to provide a client, in response to a question, with an interpretation, an opinion or a recommendation that is as objectively founded as possible, based on available knowledge and demonstrations accompanied by professional judgment. This standard indicates in particular that: "The quality of an expertise depends on the competence, independence and probity of the experts, and on the expertise process itself, the transparency and justification of which are increasingly required." The standard is supplemented by several fascicles detailing recommendations for its application (FD X 50-046: 2010, FD X 50-046: 2011).

Anses is firmly committed to this movement and actively contributes to the development of the doctrine, its implementation and its continuous improvement. The Anses expertise process is under quality assurance, with an ISO 9001 certification, including

- The fundamental principles of the agency's expertise
- The regulatory requirements of the decree on health expertise (decree 2013- 413)
- The normative requirements of the NFX 50-110 standard

The internal corollary is that various stages of the process are documented or framed by documents attached to the realization process. The work on procedures is therefore quite considerable and aims at a continuous improvement of expertise.

## 5.1. Preparation of the referral

A referral is a request for expertise leading to an opinion from the Anses, issued by an authority or an authorized legal entity, on clearly identified points within the Agency's fields of competence.

The applicant may or may not be one of its supervisory ministries, public establishments of the State, associations approved at the national level in the fields of environmental protection, quality of health and care of patients, consumer protection, as well as associations providing assistance to victims of work or occupational diseases represented in the Asbestos Victims' Compensation Fund, trade unions, professional and interprofessional organizations. The Agency also has the power to refer cases to itself.

To respond to the referral, the agency mobilizes a collective scientific expertise that meets the principles of impartiality, transparency, plurality and adversarial debate, as defined by article L. 1452-1 of the Public Health Code. It is part of *"all the activities having to provide a client, in response to a question, with an interpretation, opinion or recommendation, as objectively based as possible, developed from available knowledge and demonstrations supported by professional judgment"*. (NF X50-110 standard).

The referral must therefore allow the full expression of scientific knowledge: *"Science is the basis for public decision-making by producing reliable benchmarks that allow the various options available to the decision-maker to be evaluated"* (Benoit Vallet, Chairman of the Board of Directors of the Anses)

The drafting and the outlines of the referral are mentioned in some interviews as a fundamental step that conditions the quality of the whole process. The question posed by the referral must not only enlighten the client in his decision making but also have a certain "value" for the experts and the stakeholders of the company. It is this value that generates motivation and commitment to the agency, from the moment the experts are called for. However,

*"Sometimes the questions that, for example, guardianship wants answered are not necessarily the questions that society or society's stakeholders are asking."*

(Anses manager)

*"Several people contacted me and said they would no longer participate in the working group because they felt they were not being used."*

(expert)

Or again, in the case of the glyphosate carcinogenicity referral, where the framework and deadlines were very restrictive:

*"I would never have gone there."*

(expert)

The wording of the question must therefore be clear and unambiguous to allow the experts to produce relevant scientific benchmarks.

*"It is very clear that the principal sometimes plays on ambiguity to give himself the means to get around it"*

(political leader)

*"Sometimes the questions appeared ambiguous or too general. One of the suggestions we made to the Agency was to be able to discuss the text of the referral beforehand to better target the possible response.*

(expert)

The clarity of the referral makes it possible to better decide on the knowledge that can be mobilized to see to what extent the knowledge that corresponds to the regulatory framework must be supplemented by academic knowledge.

The need to go beyond the question posed in the referral was frequently mentioned. For several interviewees, the committees must be able to complete a referral that they consider restrictive, both in terms of the state of the art of scientific knowledge and the regulatory and methodological framework.

*"There is nothing to prevent us from saying: 'In connection with your answer, without it being directly the question asked, we take the liberty of pointing out this or that'"*

(political leader)

*"Not addressing certain aspects can be abusive in relation to the mandate of the expertise. Experts also have their autonomy. This is also good. A compromise is bound to take place somewhere between the sponsor and the experts."*

(expert)

A poorly formulated referral with too narrow a scope may be perceived by the experts as an injunction or an intention to restrict the expertise intellectually and interpreted *a posteriori* by certain observers as a desire to influence the expertise and the risk assessment.

*"The department will therefore be tempted to direct its referral in a direction that suits it for reasons that are not necessarily scientific.*

(political leader)

In some cases, referrals can be a wait-and-see or problem-avoidance strategy, which can undermine the agency's credibility.

*"There are obviously many ways for the opinion seeker to influence. They can change the scope of the question. We see cases where the answer comes in and you can say in hindsight that it was the wrong question. At the time it was formulated, no one was moved by it."*

(political leader)

The drafting of referrals in a negotiated partnership between the client, the agency and, as far as possible, the expertise groups seems to us to be necessary in order to *ultimately* produce an expertise that is useful to the client and scientifically founded.

*The "scoping paper" (...) defines the perimeter of the question, saying what is included and what is excluded, to avoid embarrassment. There must first be a dialogue between the agency and the client so that it is not just an order received, but a dialogue is established until there is agreement that the question makes sense and is good."*

(political leader)

*"In our group, we really had latitude. It wasn't total. That's okay, but it was important and it allowed us to rephrase questions that we thought were relevant or not relevant to get our heads around the issue. I think the agency really respected that."*

(expert)

It thus appears, for all the interlocutors, that the drafting of the referral is the first element that conditions the future credibility of the expertise produced. It must be the subject of increased attention, involving the experts as much as possible, which is not a problem for ESC referrals.

Self-referrals are described as a comfortable way of exercising, a facilitating anticipation of debates, both by the experts of the CES, WG, GECU and the managers of the agency. Thus, the Anses has used its capacity to take on certain questions on its own initiative, to evaluate the co-exposure of bees to stress factors, playing its role of prospective intelligence, monitoring and scientific development.

*"On the one hand, the working group formed was multidisciplinary and balanced; on the other hand, the material conditions (means, support and duration) were adapted to the questions asked. Finally, from the beginning, the questions could be broadened by the experts as much as needed to provide answers and recommendations relevant to all stakeholders."*

(expert)

*"It's to integrate the agency into its role, much more in a normal life, anticipating issues, rather than grabbing it like a firefighter."*

(stakeholder)

## **5.2. Composition of committees and selection of experts**

### **5.2.1. A panel of quality, multidisciplinary experts from different professional backgrounds**

The evaluation groups, whether they are CES, WG or GECU, are made up of experts appointed by Anses according to specific procedures. The NFX50-110 standard defines an expert as "a person whose competence, independence and probity are such that he/she is formally recognized as suitable to carry out expert assessment work".

The appointment of experts for the ESCs and WGs follows a call for applications published on the Anses website, advertised and managed by the Agency's expertise support department, in conjunction with the scientific coordinator of the group of experts and the head of the Anses unit concerned, according to

procedures that allow the traceability and transparency of the selection methods. It should be noted that the applications of experts for the ESC are also presented, discussed and validated by the Scientific Council. The selection criteria are traditional - competence, scientific excellence, complementarity, practice of expertise (a prerequisite that is not indispensable but often taken into consideration), independence (analysis of the Public Declaration of Interest, see below).

On the other hand, the appointment of GECU experts is carried out without a call for tenders. The Anses may call upon experts already appointed to Anses evaluation bodies, or from the list of competent persons (persons who have applied for calls for tenders but have not been selected but whose competence in a given field has been identified), or from any other scientific personality. The emergency nature of the GECUs has sometimes justified the appointment of experts whose competence in the subject matter may have been questioned *after the fact*, thereby undermining the credibility of the expertise produced.

*"We were also challenged by who these rapporteurs were, who had worked on this topic and the fact that no one had expertise in mitochondrial diseases. The report had been looked at in terms of the value and use of these pesticides."*

(expert)

The disciplinary diversity of the experts in the teams is a guarantee of the credibility of the expertise and is the subject of constant attention by the Anses departments. While the need for complementary scientific skills is obvious to all, the representation of human and social sciences (sociology, epistemology, economics, law, etc.), which are able to detect and decipher rhetorical and socio-economic phenomena, particularly in difficult contexts (heated scientific debate, high economic stakes, etc.), must not remain marginal.

*"By this I mean that I have not made a complete examination of all the forms and modalities covered by this notion of expertise meeting the AFNOR quality standard, but it seems to me that it is very heterogeneous. It is very heterogeneous in terms of ambition, in the number of experts and in the diversity of disciplines, between an emergency expertise between four toxicologists and a very multidisciplinary expertise like the one I participated in on the exposure of agricultural workers to pesticides. There was history, epidemiology, ergonomics, sociology and toxicology."*

(expert)

*"From my perspective, the people who have best understood what has happened on the neonicotinoid issue, for example, and who have described the socio-economic phenomena at work, are often people from the humanities and social sciences. They are often historians of science. These are people who were used to seeing this kind of rhetoric coming into the public debate and this kind of intervention on literature and research to muddy the waters, to find alternative causalities and fund what is interesting to fund rather than research on toxins, varroa mites, parasites and viruses."*

(journalist)

In addition, the balance between academic experts with strong expertise in their scientific field and researchers who are better trained in regulatory constraints and collegial expertise practices is a real difficulty, starting with the Anses staff in charge of

the composition of the committees. Ensuring this balance is indeed essential in order to articulate in a fruitful way the necessary knowledge of the formal and even regulatory procedures of expertise and the possibility of integrating the most recent knowledge when it is relevant.

A third, well-known tension is between the requirement of competence and the requirement of independence of experts.

*"I came to this kind of expertise very late, but I was always told that if we don't have any contact with the industry, we don't know how it works, especially in the drug industry. So we would be bad experts. If we refuse to take on independent groups the people who know the pharmaceutical industry well, as soon as they declare their interests, we will have no experts. I am now involved in the Anses expertise and then in others, but it is a job. It is not the job of a researcher. It's another job. I didn't know that."*

(expert)

Finally, it is important to ensure that the pool of experts is regularly renewed in order to avoid relying on a population that is too narrow and made up of researchers who are no longer active on the science fronts. The agency is particularly active in identifying new experts and helping them learn the practices of collegial expertise. This is a real challenge. It is all the more important because the competence specific to collective expertise activities is acquired through learning by experience in different roles in committees.

*"Then, the scarcity, the involvement, as an expert, you have a hunger that is inexhaustible. You get involved, you get involved, and afterwards, I've won other collectives. I always talk about collectives."*

(expert)

### **5.2.2. The pool of experts: difficulties in recruitment, attractiveness, commitment**

The multidisciplinary nature of expert committees and the establishment of a fruitful dialogue based on mutual trust between experts are the basis of collective expertise, provided, however, that the commitment of each is similar. However, the regular presence of experts within the collectives is not systematic. This lack of commitment can not only harm the quality of the debates, but can also lead to significant biases in the expertise due to a lack of competence in a given field or, on the contrary, favour a minority position and thus give an angle of attack to opponents. The attendance and commitment of experts are absolutely essential in small groups, such as the GECUs, which work under time constraints.

*"I discovered this world where most of the experts in the group did not work much, it must be said. It was finally a chance, because those who wanted to work (4 or 5 people) could work on scientific bases ... One of the negative aspects was that some people did not come much. So there was an overload of work for the others. This is always a problem. I would like to say one thing: You have to exclude the people who don't come."*

(expert)

To facilitate and improve the presence of experts, it is essential that the mission of scientific expertise (Code de la recherche Article 411-1) be better recognized and publicized by employers (research organizations, universities...) but also explicitly taken into consideration in the evaluation of researchers and teacher-researchers.

Like what is done with certain research organizations (such as INRAE or Inserm), the Agency could, within a framework that is either formal (agreements) or informal (participation and interventions in the Alliances and France Universities events, for example), make research institutions aware of the absolute necessity of voluntary involvement of scientists in the Agency's work as a guarantee of the credibility of scientific expertise. Expertise is a crucial mission for researchers in the dialogue between science and society.

Such voluntary action would undoubtedly limit the shortage of expertise in certain fields from which the Anses suffers.

The direct solicitation of laboratories and experts upstream of calls for tenders, a common practice at Anses, increases the range of applications, scientific and methodological expertise, and analysis angles. In this respect, we can mention the proactive approach of the Anses' Social Sciences, Expertise and Society mission, which was successful in setting up the new "Socio-economic Analysis" ESC launched in 2022, with the identification and contact of many laboratories and researchers likely to apply and institutional leaders in the disciplines concerned.

In addition to the national pool, international experts could be mobilized as suggested by an Agency official:

*"On specific subjects such as those related to controversial pesticides, there would certainly be an interest in having this type of peer review by undisputed researchers at the international level, especially since an outside view is often useful in principle anyway. Or of course to be able to integrate these scientists in the working groups when possible."*

(Anses manager)

An essential element in the attractiveness of the expertise mission is the respect and protection of the expert. In particular, it is necessary to ensure the confidentiality of the debates as laid down in the rules of procedure (Article 8) and not to divulge the names of the experts before the publication of their report and the opinion of the agency to protect them from pressure. The appointment of scientific integrity and ethical integrity referents can only benefit the respect of the rules of expertise.

*"If we want to make him work quietly and serenely, he must not be subjected to immediate pressure, and therefore we do not disclose the names of experts before the publication of their report and the opinion of the agency to protect them from these pressures which can be very strong today"*

(Anses manager)

*"I have not been protected. So I'm careful. I was educated a bit with INRA about the media. If there is something, I immediately warn the hierarchies. I don't really feel targeted. Many journalists ask me questions. I am careful if I feel that things are getting out of hand."*

(expert)

Finally, it is important to respect the expertise and opinion of all the experts and therefore to record divergent opinions and minority opinions in the minutes of the meetings, and even in the expert report (articles 6 and 11 of the rules of procedure), in order to avoid a feeling of frustration, useless investment and discouragement.

### 5.2.3. Dealing with conflicts and links of interest

Historically, before the reforms of the 1990s, the choice of experts could be the result of influence struggles rather than scientific competence. Thus, the Gaucho steering group, organized by the Ministry of Agriculture in 1998, included stakeholders, whether representatives of the companies or the Ministry of Agriculture. Since then, the procedures put in place by the Anses to appoint experts are much more rigorous and aim to guarantee, as much as possible, the independence and impartiality of the experts.

*"The supposed influence of private actors on public expertise and decision-making has led to the implementation of ethical and transparency rules.*

(Lavarde et al. 2020 p.36)

*"We are constantly improving the ethics of our collective expertise on conflict and interest review. We sometimes have links that are problematic. We have very rigorous procedures.*

(Anses manager)

The application of Article L1452-2 of the Public Health Code and the Health Expertise Charter established by Decree No. 2013-413 of May 21, 2013, involves "examining the links of interest for each section of the public declaration of interest (DPI) filled out by the expert, using the guide for analyzing declared links of interest" (Anses Procedure Anses/PR1/2/01). The Anses guide for the analysis of declared interests<sup>25</sup> specifies the boundary between major links of interest (i.e. of high intensity), leading to the exclusion of the persons concerned from the expert groups or to the adoption of deferral measures depending on the dossier concerned, and minor links of interest (i.e. of low intensity), which are *a priori* compatible with participation in the expert group. The major links of interest are essentially links with a company or an organization likely to be penalized or to benefit from the work of the expert group: professional activity; participation in a decision-making body; individual remuneration for consultancy work; significant individual remuneration for scientific work; provision of significant material resources; intervention with individual remuneration or payment of travel and subsistence expenses; holding of a patent; research contracts representing a significant part of the team's resources. The analysis of the declared links covers a retroactive period of five years. The Agency clearly considers that any major interest with regard to the missions of the group of experts or to the theme to be assessed is a reason for exclusion, even if it means restricting its pool of experts.

In the summary of its work for the period 2011-2016 (CDPCI Anses 2017), the Ethics and Conflict of Interest Committee of the Anses raised the paradox of the missions of researchers who are encouraged by their organization to work with the private sector

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<sup>25</sup><https://www.anses.fr/fr/content/guide-danalyse-des-int%C3%A9r%C3%AAts-d%C3%A9clar%C3%A9s>

in order to contribute to innovation and to participate in expertise excluding links of interest classified as major:

*"The CDPCI did not encounter any particular difficulties in answering the specific questions it was asked concerning the material links of interest declared by the experts. However, at a more general level, it was unable to avoid noting the paradox to which expertise is subjected. On the one hand, the greatest rigor is demanded in the choice of experts without conflicts of interest; on the other hand, researchers and teachers - researchers who constitute the bulk of the pool of experts - are strongly encouraged to work with or for industry with the legitimate aim of transforming theoretical knowledge into progress for societies.*

(CDPCI Anses 2017 p.30)

Nevertheless, this analysis of IPR alone is undoubtedly not sufficient in view of the issues of scientific credibility. Several avenues for improvement were proposed in the joint report of the Inspections générales (Lavarde et al. 2020), which concern, on the one hand, provisions relating to the supervision of benefits ("anti-gift" provision) and, on the other hand, adapted controls of IPR that are currently only declarative.

Finally, the IPR does not address the problem of interests that are more than five years old or that are assessed as minor, but are sometimes considered problematic by some members of the public. There are two opposing views on the treatment of minor interests, one inclusive, the other exclusive. In the first case, as suggested by Philippe Roqueplo in his book *Entre savoir et décision* (Roqueplo, 1996), one would seek to mobilize all the interests involved in carrying out an adversarial appraisal, on the model of a trial. In the other case, the principle of independence will be strictly applied, which is more or less easy depending on the field. The Anses, having to implement the principle of independence, must manage the tension between competence and independence.

Roqueplo's position was inspired by a broad analysis of interests. Basically, a researcher is never independent of his own interests, starting with the interest for his field of research, which he often advocates. He then considered that the expertise must highlight the philosophy of action and the reference values that will condition the interpretation of the available knowledge. From this point of view, one should certainly not limit oneself to individual links of interest with the industry. In this sense, Henry and Boullier (2021) point out that, regardless of individual ties of interest with industry, some experts internalize the consequences of their expert work on economic activities and have a representation of their work that incorporates the need not to disturb the economic status quo too much. This is certainly an important point that requires great vigilance on the part of the Agency. However, it is certainly necessary to go further, as other interests than those of the industry can obviously be internalized by the experts. This leads to the question of "intellectual ties of interest", which was the subject of a recent opinion by the CDPCI. The opinion identifies the difficulties of recruiting experts without intellectual ties of interest and the risks of the operational implementation of this notion. As already indicated, the participation of SHS in committees can contribute to the objectification of the field of interests specific to a given subject and such objectification can help expert collectives to deliberate in knowledge.

These difficult questions, which are crucial for the credibility of the expertise, will have to be the subject of further work.

### **5.3. The GECU: an inappropriate forum for assessing uncertain and controversial issues**

The Anses' internal regulations stipulate that, in case of emergency, the Director General may decide to set up an emergency collective expertise group (GECU). For example, in the event of an avian flu epidemic, the Ministry of Agriculture refers the matter to the Agency for risk assessment and the measures that should be implemented. Given the urgency of the situation, the provisions governing the GECU are more flexible than those for the ESCs and WGs. For example, the members of the GECU are appointed by the Director General of the Agency without a call for candidates or the opinion of the Scientific Council (unlike the ESCs) and without the opinion of the ESC presidents concerned.

In two of the cases studied, the agency created GECUs to mobilize expert advice. In the case of glyphosate, the objective of the first GECU was to identify whether the evidence presented by IARC and BfR supports a change in the classification of glyphosate as a carcinogen; a second GECU aimed to develop the terms of reference for a study on the carcinogenicity of glyphosate. In the case of SDHI, the objective assigned to the GECU was to determine whether the alert launched by a group of researchers provided evidence of exposure and risks that had not been taken into account in the evaluation of the fungicidal active substances concerned.

While the establishment of a GECU is fully justified in the case of an urgent need to act, for example in the case of avian flu, this formula poses a problem in the case of issues characterized by uncertainty or controversial questions. This assessment is the subject of a strong consensus among the persons heard who expressed their views on the subject.

First of all, in order to untangle these difficult problems, it is essential to produce a quality, contradictory, rigorous and transparent expertise that takes into consideration all the arguments, that hears the contradictory positions, that evaluates them by mobilizing all the necessary disciplines. This is essential in order to clearly identify the residual uncertainties, the points of disagreement and the areas of ignorance.

*"The first point that seems important to me, on controversial and difficult subjects, is to take the time to build and maintain the quality of the expertise".*

(Anses manager)

This in-depth work is all the more justified as new and uncertain knowledge is likely to call into question the rules of expertise as set out in the guidelines. In the cases studied, it can be seen that this challenge is not at all obvious, as it potentially shakes up not only economic interests but also established certainties, paradigms and organizational routines... Not all new knowledge requires changes in the rules of risk assessment. Nevertheless, it is certain that the GECU format cannot provide satisfactory answers to the questions that arise when dealing with controversial subjects.

The setting up of a GECU is justified by the pressure that the agency is under from its supervisors or more generally from its environment.

*"On timelines, put yourself in the shoes of the public policy maker. The state needs to have a scientific agency that can answer these questions quickly. It's inescapable."*

(political leader)

But these very tight deadlines are incompatible with the time needed to produce quality expertise.

*"Deadlines and time pressure like we have had (...), with ministries asking for work to be delivered within deadlines that are often difficult for us, almost impossible sometimes if we wanted to do a real collective expertise with all the scientific rigor and transparency that this implies, because it takes time."*

(Anses manager)

This situation of paradoxical injunction has several negative consequences. First of all, it creates a real dissatisfaction for the experts involved, given the impossibility of doing the necessary work to shed light on difficult questions.

*"When you're asked to do something urgently, it's impossible to do something well, especially on a subject like this, it seems to me."*

(expert)

*"The GECU had only a few weeks at its disposal, which led it to restrict itself to the IARC's summary document, which summarizes its position in 40 pages, but without having the time to analyze the details of the studies. We also took the synthesis of Germany, which was the rapporteur Member State and had produced a large volume (...) With a GECU of a few weeks, what can you do? You can't go through the file, you can't go through the publications."*

(expert)

For subjects on which there is disagreement, the constraints of a GECU mean that either the various experts in the controversy are not included, with the risk of strong polemics on the report (as in the case of SDHI), or they are sought to be included, and it is then difficult to produce a quality report within the time allowed.

*"I thought the GECU I attended was really messed up. It was useless. It was kind of a gratuitous dud. They brought together people who didn't agree with each other and the Anses got into a whirlwind."*

(expert)<sup>26</sup>

It can also be noted that the first GECU on glyphosate and the GECU on SDHI each included only four experts, while the second GECU on glyphosate included only five experts. This limited number of experts makes it difficult to conduct a pluralistic and contradictory expertise.

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<sup>26</sup> Let us recall that the Anses decided to interrupt the process and not to publish the report, which provoked a conflict with the newspaper *Le Monde* following the article by S. Foucart who pointed out that the Anses had "buried the report" (see glyphosate case).

But even more seriously, the use of a GECU for such problems can put the Anses in a difficult situation, expose the experts concerned to public accusations and, *ultimately*, contribute to the erosion of the credibility of the expertise. Some actors go further and consider that the choice of treatment of these problems by GECUs is dictated by an intention. In the case of the Glyphosate GECU, the aim is not to call into question the BfR's evaluation.

*"In the absolute for glyphosate, I told you earlier that it was a way to sit on the IARC decision. That is why this report was commissioned. That is also why it was requested that it be rapid".*

(political leader)

How to get out of this situation?

First of all, it can be observed that the interpretation of urgency is flexible. For the head of a GECU:

*"The emergency collective expertise groups are usually for tomorrow. And even then, tomorrow is sometimes a bit late. The term GECU from Anses a few months away has always surprised me. I consider that it is no longer an emergency. (...) Either we assume that it is an emergency group, and it will respond in a few days. It will be easier to assume the uncertainties. Or it is a permanent group.*

(expert)

In cases of self-referral (e.g., SDHI) where the agency is not constrained by external deadlines, it is certainly possible to better adjust the mechanism to the case at hand. However, even in the two GECUs set up in response to a ministerial referral, the response times were long, more than six months, which suggests that it would have been possible to set up a WG.

On some topics, it also seems feasible to better anticipate requests. For example, the classification of glyphosate by the IARC was known with certainty since 2015. Several experts consider that a working group on the issue should have been set up much earlier. One of them indicates that he alerted the CES Phyto on this subject without success.

## **5.4. Implementation of the expertise: the collective work**

### **5.4.1. Animation and coordination of expert groups**

#### **5.4.1.1. The role of the President of the body, a determining personality**

The Anses rules of procedure for the bodies specify that *"the chairman of the expert group leads the debates and deliberations. To this end, he is supported by the coordination. In the conduct of discussions, he/she ensures that the principles of collective expertise are respected and promotes an open and respectful exchange of views.* The chairman ensures that the opinions of each expert are respected, that all opinions are substantiated and justified, coordinates the work of the group of experts and the Anses scientific coordinators (referral amendments, invitations to Anses or external experts, etc.) and organizes the drafting of the

evaluation report. The choice of the chairman of the group of experts, who is responsible for leading the discussions without imposing his personal vision, is therefore crucial.

*"All the groups that worked best were the groups where there was good facilitation, linked in particular to the abilities of the scientific chairs and coordinators, where everyone knew their role well and was fully invested in the expert work."*

(Anses manager)

*"There are people who are more or less persuasive. There are people who can successfully dominate a group in terms of consensus building. It's a really tricky issue."*

(political leader)

#### 5.4.1.2. Anses staff and their participation in the group: a pastoral management function

The coordination of the groups is also an important factor in the smooth running of the expertise. In this respect, the Anses internal regulations (2021), which govern the expertise bodies, specify in article 4: *"When the group of experts is formed, the Agency specifies the units and agents responsible for coordinating the expertise. The coordinator thus designated ensures that internal procedures are respected. It provides the group of experts with administrative support and a scientific contribution to the work (bibliographical research, analysis of articles, methodological proposals, modelling, statistical analyses, etc.) by*

The expertise coordinators have a crucial role to play as collectors of data and publications, which are transmitted in whole or in part to the experts for analysis. In particular, the expertise coordinators have a crucial role as collectors/screeners of data and publications, transmitted in whole or in part to the experts for analysis.

However, during the interviews, it appeared that the supervision of the expert groups by the Anses is sometimes a source of tension and the coordination function is not always understood.

*"They [the coordinators] need to be familiar with what a scientific coordinator is. It's not a task force expert."*

(Anses manager)

*"Every year we have a meeting with our expert committee chairs, and unanimously they are very appreciative of the role of our scientific coordinators and the help they provide to the experts."*

(Anses manager)

However, there is a lack of understanding of the coordination function of the group of experts between the Anses, which considers that it does not steer the groups of experts but tries to help them, and certain experts who, while recognizing an indispensable secretariat and benevolent steering, sometimes feel hindered in their thinking, and stakeholders who do not always understand the difference between coordination that aims to respect procedures and intrusive steering.

Even more worrying, some experts deplore intrusive and conflicting relations with Anses agents.

*"During our initial meetings during the first year, we had not only the presence of Anses agents from the risk assessment directorate, who provided the scientific secretariat for our work, but also their colleagues from the regulated products directorate. They had conflicting relations with certain experts. It was all quite painful. I would not say that they overstepped their function, but we had the impression that the Directorate of Regulated Products was listening to what we were saying. It was a little uncomfortable because there were latent conflicts that were starting to get pretty real between some of the experts."*

(expert)

It is therefore important that the rules of procedure for coordinating expertise be made known to everyone (Anses agents and experts) and be strictly applied. In particular, some experts observe that Anses agents do not systematically introduce themselves, do not mention the unit to which they report, or even their directorate (DER or DEPR), and are sometimes more numerous than the experts.

#### **5.4.2. The contradictory opinion within the group or the minority opinion: a statutory obligation of the agency to be trivialized**

The adversarial principle is one of the basic principles of collegial expertise and conditions the quality of expertise in uncertain and controversial situations. The opinion of the council of ethics and prevention of conflicts of interest of the Anses (Opinion 2017-1) relating to the application of the principle of adversarial approach in expertise: relevance and traceability of minority opinions, was translated into the internal regulations for expertise bodies in 2021, which specifies that *"any member may state a position divergent from the conclusion and/or recommendations adopted by the group of experts. In this case, the divergent position is accompanied by an argument. The divergent positions are discussed by the expert group before the adoption of the expert report. Divergent positions are subject to traceability."*

The implementation of the adversarial principle is delicate and depends on a number of elements

For example, if a specific skill is only covered by one member of the group of experts, there is sometimes a risk that his opinion will be misunderstood by the other experts and will therefore be in the minority. It is therefore necessary to avoid this situation and to bring the opinion of the Ethics Committee and the rules of procedure to the attention of the experts during the information sessions so that each expert may, if necessary, express a minority opinion. Trivializing such a procedure will certainly make it less conflictual.

*"X, on the other hand, did not agree with me at all. He was much closer to the German BfR. At the time, I said that I would not sign the report if we did not find a consensus. I was confronted with Anses officials who pushed for consensus. They did not want one of the experts, and moreover the president, not to sign the report."*

(expert)

In addition to the regulatory aspect of minority opinions, the analysis of uncertainties and the weight of evidence, as recommended in the internal methodological guide for the planning of expert assessments (Anses, forthcoming), the uncertainty analysis, the literature review and the evaluation of the weight of evidence recently produced following the report of the Working Group on Risk Assessment Methodology, will make it possible to avoid overly binary expert conclusions and thus to better take into account the differences in position within the committees. The aim is to implement these recommendations very quickly, as a priority on sensitive subjects, and thus respond to the criticisms recently made by the OPECST in its 2019 report.

## 5.5. The necessary formalization of treatment of alerts

An alert can be defined as the reporting of a potentially serious threat. The treatment of alerts is particularly difficult when taking them into account requires changes in existing cognitive or organizational frameworks. It is then a "weak signal" in the sense of a signal that is difficult to take into account within existing cognitive or organizational frameworks. This is also referred to as a "black swan" (Taleb 2012). Such signals have a particular property: retrospective predictability. *In hindsight*, when/if the threat has been realized, it seems obvious; we then wonder why we did not act sooner and look for those responsible. However, not every report is a real threat. The challenge for the organizations involved is to sort out the issue by minimizing the risk of rejecting a report when there is a real threat while limiting the risk of spending time dealing with false alarms.

For Anses, alerts can be of different natures, including alerts from vigilance and surveillance systems and alerts from the scientific community as well as from other expert institutions. It is this second type of alert that was discussed in the interviews, particularly with regard to SDHI, and which is the focus of this section.

The analysis of the SDHI case shows that the alert launched by scientists has led to accusations against the Anses, relayed by journalists and activist groups, particularly between 2018 and 2020.

Let's first go back to the elements of the diagnosis. The temporal dimension is the fundamental element.

*"I regret that in this SDHI affair, there was not enough time for a calm debate, and that repeated pressure, sometimes at the limit of what is tolerable, was put on the agency before we could even start working on the subject. But I am not blaming one person or another specifically. It is simply an observation about the way society works today, where it is becoming increasingly difficult to take the time to develop expertise in a context of precaution.*

(Anses manager)

This pressure on the agency is very strong as soon as the alert is public (in this case an article in *Libération*) and becomes an issue for various political, media and other actors.

associations. The sociology of whistleblowers shows that publicity generally constitutes a recourse when the actors involved feel that their appeal is not really taken seriously by the institutions concerned (Chateauraynaud and Torny 1999). In the case of SDHI, the interviews show that two elements were at play: the forms of communication and the differences in the framework of interpretation.

On the side of the scientists who gave the alert, all the people interviewed consider that they have not been listened to, not taken seriously, or even that they have been denigrated.

*"For me, it was pretty impressive. I'm telling you this as I experienced it. We were in a structure with a very large table. There were the Anses experts on one committee and us on the other. There were nine of us, with microphones and screens. This hearing began with Pierre Rustin's presentation, which we had worked on together. Some experts were laughing or denigrating what Pierre Rustin was presenting. They showed signs of irritation and anger. At the end of the forty-minute presentation, we began to be bombarded with derogatory remarks and denigration of all the evidence we were presenting. It was very difficult for all of us. We were being scolded. Every piece of knowledge we put forward and concern we had was denigrated in a pretty violent way."*

(scientist)

On the GECU side, the memory of this sequence is very different:

*"We received the whistleblowers once. We had agreed with Anses that it would be interesting to meet in a room rather than answering each other or bickering through reports. That meeting was tense, but I personally did not feel any extreme tension either. On the other hand, this meeting was later described by the whistleblowers as a very unpleasant time for them. Quite honestly, I did not experience it that way. I'm a diplomat who likes to cut corners and doesn't like conflict. I can tell you that there was no conflict in that meeting."*

(expert)

On the side of the agency, an official recalls its will to establish a dialogue with the scientists concerned:

*"We may have done it in an awkward or discourteous way. I did not witness the initial exchanges. The emails I saw from Roger Genet were definitely not discourteous or comminatory. Mr. Genet is not a discourteous person. He is the one who got involved in asking for this."*

(Anses manager)

One politician who listened to the recording of the meeting described it this way:

*"It is very striking to see that there is initially an exchange of data. Very quickly, the meeting turned into a face-to-face meeting between the Anses general management, its representatives and the scientists who had issued the alert and referred the matter to the Anses. The dialogue turned into a mess between an administration that says that the regulation is not based on this, but on such and such elements, and scientists who are in a scientific discussion."*

(political leader)

Such a discrepancy is not exceptional in alert situations. But in this case, it is indicative of a communication problem fueled by differences in vision. The whistleblowers

alerters are the spokespersons of a potentially serious problem, identified on the basis of their scientific knowledge. They have high expectations of the institutions.

*"We figured that if they didn't have evidence on the likely mitotoxicity of SDHIs, our dispatching an emergency panel of experts could allow the use of these pesticides to be suspended while we review the dossier and the expertise is conducted. We were really in a naive mode. Given the level of concern we had, we were waiting for this reaction.*

(scientist)

The institutions are in a logic of application of the rules of which they are guarantors.

*"This is a special element. We received the whistleblowers with whom we were able to exchange. We have seen what our respective writings tell us. We each had our own vision. We are certainly each right in our own channel, but the channels do not talk to each other. We are right in our regulatory logic and they are right in their societal and political logic.*

(expert)

*"I am not hiding from the fact that we are hiding behind the regulatory argument. Today, in the light of the scientific knowledge on both sides, if we bring what the whistleblowers bring to us to the European community, will it ban these products? Our answer is no, because we are a group of experts, essentially toxicologists. We know the regulatory processes. But we don't have among our experts people who have political dimensions or dimensions of "how can we change a regulation?" So we only answer that question from the one small angle that we can answer: does the current state of regulation, which we also don't think is perfect, mean that this new data means that this substance should or could be banned? Our answer is that based on the 2018 data, it should not. You can see that three or four years later with more data, it's still not the case."*

(expert)

This difference in framing therefore amplifies the communication problem. For the group of scientists, the literature shows that the mitotoxicity of a class of fungicides massively used in the environment can lead to a series of deleterious effects in terms of human or environmental health. It is necessary to take this effect into account in the marketing authorization tests. Initially, the agency responds within the framework of existing regulatory processes and questions the weight of evidence, the measurement of exposure ... A dialogue of the deaf is thus established.

This diagnosis leads to the formulation of several recommendations, some of which are supported by the actors interviewed.

As noted in other sections, the best antidote to the tyranny of urgency is anticipation.

*"And then, to anticipate. When we know that there are opposing experts on this or that subject, regardless of the militant nature of certain experts on one side or the other, when we know that there is going to be lively scientific debate or other issues, we must to incorporate it into the work group, whether we like it or not. (agency manager)*

Second, a GECU should be avoided as much as possible as a false good solution to complex and uncertain problems.

*"On SDHI, if we had it to do over again, we might try not to go through a GECU. But the problem was that there was so much pressure, both from politicians and activists, that we really couldn't do it any other way. Ideally, of course, we would have been able to set up the working group from the outset, as we did in the second stage, where we were able to include in the working group people who were initially in the group of whistle-blowing scientists, in order to be sure that contradictory opinions could be expressed if necessary. But it was not possible because of the time constraints at the beginning". (agency manager)*

Third, to form a GECU, one of the whistleblowing scientists should have been invited as a member<sup>27</sup>.

*"In the SDHI group, there are scientists who had worked with Pierre Rustin on this. They had to be included, they met all the scientific and ethical criteria. Even though scientific debates can be heated and difficult to manage in a working group, it is essential that contradictory positions be expressed when they exist." (expert)*

Fourth, better knowledge sharing with whistleblowing scientists would have avoided some of the tensions and misunderstandings.

*"The dossiers [for certain SDHIs] were sent to us and they quickly became gibberish for us. Some of the dossiers are several volumes long and each one is several hundred pages long, and Pierre Rustin, who was not a toxicologist, could not understand them. So I started to work with him on the files, knowing that it was a bit complicated for me too. [...] I was quite surprised that we were told to look at the files, but that there was no particular follow-up. We didn't have a window or a person helping us. We could have expected someone to explain the files to us and help us decode. They could have looked with us to see these mitochondrial effects that we had identified, and the consequences that we know about human health". (scientist)*

A complementary point concerns the role of other institutions. There is certainly a need to improve the dialogue between scientific bodies and agencies so that the differences in culture and role are better understood on both sides. The question arises as to the role of third-party organizations such as cnDAspe, on which the comments received are discordant.

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<sup>27</sup> See also the CDPCI report on sensitive issues.

## 6. Thesis 3. The gap between the expertise and the expectations of the concerned audiences

Let us recall that this thesis is subject to two different interpretations:

- Some consider that scientific credibility is a matter of cognitive bias or "confirmation bias": credibility would then be all the weaker if the expertise goes against the spontaneous beliefs of the population. Conversely, an opinion would be all the more credible if it confirmed beliefs.
- The other interpretation suggests that the credibility of an opinion is all the stronger if the framing of the problems corresponds to the concerns of the publics concerned; in other words, if the opinion answers the questions that these different publics are asking.

The first interpretation is often justified by a conception according to which mistrust of science is on the rise, and science is considered by a large part of the population as a mere opinion. This interpretation, which is a true belief, is fed every time a scientific controversy or a conspiracy theory emerges.

It is important to remove any doubt from the outset and avoid starting off on the wrong track. Trust in science is and remains very high. On the other hand, trust in the authorities in charge of protecting people against risks is different. The question of the credibility of expertise lies at the heart of this paradox.

### 6.1. The paradox of credibility: trust in science but mistrust in the role of public authorities

Politicians, the media and certain scientific organizations frequently assert that our society is marked by a mistrust of science. This preconceived idea is all the more obvious as it is associated with the idea that we have entered a "post-truth" society. However, such a belief is contradicted by the facts. While there are many signs that France is a society marked by mistrust (Algan and Cahuc 2007), science is one of the institutions for which the level of trust is maintained at a very high level. Surveys conducted since 1972 by Daniel Boy of the CEVIPOF have consistently shown this. In his most recent study (Boy 2021), science comes in third place among institutions ranked according to their trustworthiness, with 78% of favorable expressions, behind medical personnel (87%) and hospitals (81%), but far ahead of the red lanterns, the media (28%), social networks (17%) and political parties (16%). The study coordinated by Michel Dubois confirms this very high level of confidence: in 2020, 84% of French people say they have "very much confidence" or "rather confidence" in science. Although there has been a slight decrease since the beginning of the 2000s, this decrease does not increase distrust of science, which remains stable; it is in fact the proportion of undecideds that is increasing (Bauer et al. 2022).

The results are very different when the French are asked about the level of trust they have in the authorities to protect people. The barometer of the Institut de

The results of the IRSN survey on the perception of risks and safety show that the level of confidence is low and varies according to the subject. The highest level of confidence concerns the ability of the authorities to protect individuals from AIDS. At the bottom of the list are endocrine disruptors (16%), pesticides (17%) and nanoparticles (17%) (Figure 3).

These survey data should be taken with caution, given the limitations of declarative measures, the influence of survey administration conditions on the results, and more broadly, attempts to objectify "risk perceptions". For example, the IRSN barometer (2021) mentions that a change in the wording of the question on trust in the authorities caused a drop of thirty points. Added to this is the vagueness and ambiguity of the definition of trust, which further weakens its measurement.

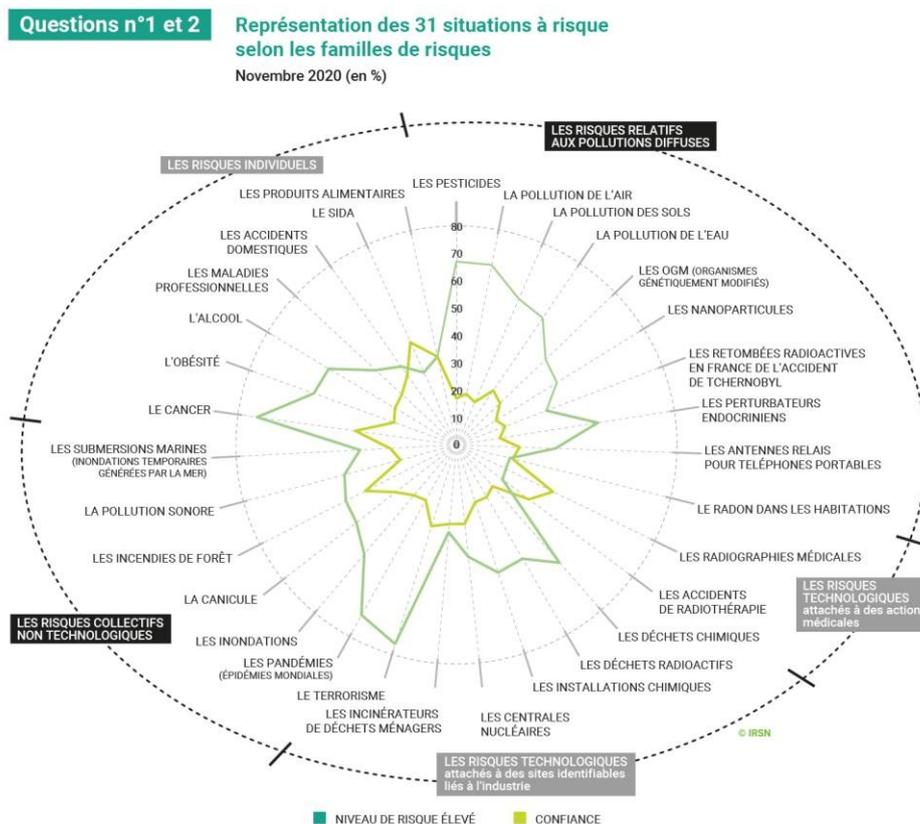


Figure 3: A general lack of confidence in the ability of public authorities to protect people (Source: IRSN 2021 p.34)

However, given the number of studies and the diversity of methods used, two results can be retained: (i) general confidence in science is high; (ii) confidence in the authorities to protect populations from technology-related risks (among them, those related to pesticides) is low.

Between trust in science and distrust in public authorities lies the heart of our subject: the question of trust in scientific expertise. The IRSN barometer (2021) indicates that the main qualities expected of a scientific expert, competence (34%), honesty (26%) and independence (20%), are strongly questioned by the respondents.

These indicators, while useful, are far from sufficient to provide a complete picture. While public authorities rely on science and science is widely trusted, why is it that mistrust of the authorities is so high, especially for certain risks? In the other sections, we were interested in the process of producing scientific expertise. Here, we address the question of its reception from the point of view of the people interviewed, who come from different sectors and worlds. Such an approach could be supplemented by additional investigations, using other methods such as closed questionnaires or focus groups aimed at directly grasping the perception and attitude of the publics concerned. Nevertheless, the qualitative results obtained from interviews with experts and stakeholders provide an original and interesting perspective.

## **6.2. Recognition of the agency's work to build trust**

### **6.2.1. Various interlocutors underline a discrepancy between the quality of the Anses' work and the criticisms it receives**

Among the various stakeholders interviewed, many are surprised at the discrepancy between the intensity of the criticism and the quality of the agency's work. The efforts made are emphasized, both from the point of view of the quality of the collective expertise and the interactions between science and expertise, as well as the implementation of the principle of transparency and dialogue with stakeholders. Particular mention should be made of the role of the Agency's Ethics and Conflict of Interest Committee, which has produced various opinions and reports on subjects related to this report and which plays an important role in the continuous improvement of the Agency's work. The comparison with other agencies, especially international ones, is therefore generally advantageous for Anses.

*"When we went to the European or international level, French expertise is still very well recognized, both on an institutional level, in its contribution, and on a level of capacity to create scientific research or support for the implementation of very useful regulations, even though the issues are very numerous, very complex and there is this principle of separation of risk assessment and risk management."*

*"Our object of astonishment is that we had the feeling that in public opinion, the work of the Anses could be stigmatized on certain subjects, even though the methodological conditions of transparency, prevention and ethics were more respected by the Anses than they could be by third parties."*

(Inspector General)

*"This is one of the things that has always struck me: the Anses, which is really the agency that has put forward, anticipated and integrated these questions that are not easy for it, both on plant protection products and others, is finally the agency that is most criticized. (...) To my knowledge, there is no agency on the subject of plant protection and even on others that has dialogue committees, possibilities to interact directly. Today, any company that requests an appointment with the agency, that appointment is traced. You can have the content of the appointment, the same thing for the HATVP [Haute autorité pour la transparence de la vie publique]. Yet, it is still in France that the level of media spikes in relation to these issues you mentioned is by far, but really by far, the most sensitive."*

(stakeholder)

Several interlocutors from outside Anses also indicate that on several occasions, the agency has played a pioneering role in the implementation of evaluations that have led to the banning of certain products. This pioneering role, which is probably explained by the importance of the efforts mentioned, should in principle reinforce the reputation of the Anses and its credibility.

## **6.2.2. Stakeholder dialogue structures - an internal communication problem?**

The Anses has long been a signatory to the charter on opening up its expertise to society. Thus, in addition to the various measures to ensure the transparency of its expertise, the Anses has taken several initiatives to involve different stakeholders in its work - without, however, co-producing expertise. Thus, stakeholders are regularly heard by the WGs in the framework of the Agency's collective expertise. Similarly, several dialogue committees have been created, quite systematically on subjects considered sensitive: nanomaterials, radio frequencies, and, very recently, biotechnologies. A platform dedicated to plant protection products has also been set up. The aim of these mechanisms is to inform stakeholders about the scientific work carried out by the agency while gathering their expectations and questions. Since its creation, the agency has set up five thematic orientation committees (COT) covering its main fields of activity. These consultative bodies are intended to support the Board of Directors in expressing needs in terms of risk assessment and research, and in defining the Agency's strategic orientations, by bringing to its attention the dominant concerns of civil society in Anses' fields of competence. Beyond the stakeholders, we should also mention the recent launch of reflections and projects around participatory research within the Agency's laboratories.

The establishment of structures for dialogue with stakeholders is rarely mentioned in the interviews. When it is mentioned, it is generally to emphasize the importance of these initiatives for the credibility of the expertise.

*"For a few years now, there has been what is called the inter-COT, where there is a desire for transversality within the agency, in the interaction with the stakeholders. This is perhaps already a first step, but I think we could do more on contextualization. (...) I was saying earlier that, very early on, there was this expression, the stakeholder dialogue committee that explained how the process was going to unfold. In this committee, I think any stakeholder, by the way, can raise questions and therefore ask for this or that point to be clarified."*

(stakeholder)

*"For example, on the subject of electromagnetic fields and mobile telephony, we discussed methodological issues with the members of our dialogue committee and regularly reported on the stages of our work. Not giving results, but saying from the outset how we are going to work, how we select or analyze the bibliography, for example, is very important for the stakeholders so that they can give their point of view, and also provide elements that they consider important for the expertise and which would not have been taken into account by the experts."*

(Anses manager)

One of the people we spoke to likened the efforts to open up to society to those aimed at integrating the social sciences, two distinctive characteristics of the Anses.

*"In my opinion, one of the two major trademarks of the agency in terms of the renewal of expertise practices over the last fifteen years is its openness to civil society and the social sciences. I say fifteen years because I trace this back to the Afsset, which was somewhat of a pioneer in these matters. (...) These are virtues and I think that we must persist in this direction."*

(expert)

Nevertheless, these positive assessments are not shared by all. This is notably the case of an expert who regularly participates in the work of the agency and says that he does not understand the real usefulness of these forums.

*"I think there are institutionalized discussion forums. We say that because they exist, public debate exists, but we see that they are not effective in practice. They either need to be changed or they need to be better publicized."*

(expert)

### **6.2.3. Two obstacles: media coverage of controversies and totemic subjects**

For several of the people we spoke to, expert opinion and health agencies are faced with two major difficulties in establishing the credibility of their opinions. On the one hand, certain forms of media coverage are considered to be capable of distorting the messages of expertise. This may result from the media's preference for sensationalism, sometimes reinforced by the mobilization of certain stakeholders:

*"This never stays in the scientific sphere. When you want to destabilize, you open the newspaper, the TV and so on, the opponents of the system never stay in the scientific sphere (...) when you see people who are systematically criticizing the system or attracting attention, sometimes by exaggerating, it never stays in the scientific sphere. To make analyses that are a little shortened, sometimes even completely distorting the scientific studies by cherry picking for analyses that are more media-friendly, unfortunately, that is the daily bread."*

(stakeholder)

*"It's not just related to that. It's also related to the activism of social movements that is spreading. It is also linked to the evolution of the media space which is more and more receptive to this type of alert. It will seek more to deploy critical information around science in general, the environment and health in particular."*

(expert)

The role of the media is pointed out by several interlocutors, including journalists who are aware of the effect of focusing on certain subjects, which does not always correspond to the precise hierarchy of health or environmental problems.

*"I also understand that there is a kind of journalistic premium on what's wrong. We're more interested in the problems and the trains that don't arrive on time than we are in the trains that arrive on time. It's a bit structural. I understand that some critics were wrong. It's normal that there are some. I am fully aware that there are also many things that are going very well at the Anses and that are done in an irreproachable manner. This is part of the problem, in the same way as when we focus on one product or class of products and everything else is a bit lost. We probably give the public a not-so-accurate view of the hierarchy of health issues. I think we can really be blamed for that. We need to hear it and try to respond. I think it's a real problem."*

(journalist)

Nevertheless, it is also the very structure of what some call "scientific-media-political controversies" that needs to be better understood. Several interlocutors point to the central role of "collusion" between the different parties (one could also say coalitions, which may have a more appropriate meaning), including the scientists involved.

*"These are scientific-media-political controversies. (...) Why did it become a controversy? Do you think it just happens? A journalist who says: 'Here, I'm going to go and look at the calls for tender of the Anses, to see if there aren't things that I can go and scratch a little.' Don't you think that this comes from collusion between certain scientific teams and the political world? (...) The other part can be true too. It is not because there is a scientific-media-political collusion that a controversy is 'false'. There may be some truth, or even all of it (...) But the Anses has been attacked."*

(expert)

This question is particularly sensitive when dealing with what can be called totemic subjects. Certain risks and certain substances that are the subject of controversy in the public arena and in the scientific world are caught in a kind of impasse. They constitute emblems and points of fixation that are very strongly invested by the actors, in the image of what we find in the field of health with homeopathy for example. Under these conditions, it is very difficult to make progress in a case, regardless of the scientific data that is produced:

*"Can we really today in France and perhaps even elsewhere, work serenely in total detachment? What we had tried to do on highly controversial subjects like this one? Can we do that? I don't know, but I'm afraid not. Because here, we were sure and certain that we didn't care about glyphosate anyway. We said to ourselves what we want to show is: are there any holes? As I told you earlier, are there any gaps in these regulations, phytosanitary and others? That was almost our only ambition. And glyphosate was somewhere the textbook case. That's it (...) I think we don't look enough at the context of these controversies."*

(expert)

*"Glyphosate is not a sensitive issue per se. It is a sensitive name. (...) There are contradictory presumptions about this molecule. It remains that my conviction as a citizen is that glyphosate reminds us of Monsanto. It reminds us of glyphosate-resistant GMOs. There is a pathos behind this molecule. It is a chemical molecule that has a toxicity, but beyond its toxicity, there is a pathos that makes it impossible for us to say anything about glyphosate either way without being shot at like rabbits. I can't do much about it."*

(Anses manager)

Added to this is a sense of uneven play expressed by several experts whose work has been publicly questioned.

*"Then, as an ultimate response and deterrent weapon, one of the whistleblowers said that if this happened, they would take this to the newspapers and attack us. All this work is possible, but it creates a clear asymmetry with us who must never have worked with an industrialist, or we hang. We are not allowed to respond in the media, but I don't want to either. We must also have declaration of interest forms that are public and accessible to all. Where whistleblowers have helped answer their whistle, they present themselves as meek lambs who have no conflict of interest, which is totally false."*

(expert)

*"The most difficult thing is the controversy, because it is quickly poured into the media field. In this field, we have an asymmetrical fight. We do not have the same weapons as our "competitors". We don't want to use the same ones either."*

(expert)

Hence, sometimes, a disillusioned feeling.

*"When you can't attack the expertise, you attack the experts. That's right."*

(expert)

#### **6.2.4. How to improve risk assessment communication?**

In many interviews, we collected various suggestions for improving risk communication.

##### **6.2.4.1. Communicate on the issues and benefits**

For a long time now, discussions on risk communication have pointed out that, since risk is never zero, it would be necessary to indicate the expected benefits in order to enlighten the public concerned. In our interviews, this idea was mentioned by a representative of an industry.

*"What I have observed throughout my career is that there is indeed a problem of lack of knowledge, perhaps, or of issues that are not fully understood. Let me explain: why are there plant protection solutions? Because there are plant health problems. And I think that this is totally, not evaded but, in any case, not at the same level as if we were talking about animal health, for example. I'm staying with the comparison here because human health is something else again. But between animal health and plant health, there is absolutely not the same perception".*

(stakeholder)

*"To go further, I think that this contextualization and this explanation of the meaning and the need for plant health, again, is not within the intrinsic competence of the Anses. I think it should be more in the competence of the Ministry of Agriculture, for example, and the investment should perhaps be more important. Anses could, in my opinion, complement this approach of the Ministry of Agriculture more."*

(stakeholder)

Such a proposal raises the question of socio-economic assessment, in addition to risk assessment, a subject that has been very strongly developed by Anses.

#### 6.2.4.2. A drafting of notices that does not hide the difficulties of risk assessment

The practices used in drafting Anses opinions are assessed in fairly contrasting ways. On the one hand, some stakeholders recognize the general quality of what is done while making suggestions for improvement.

*"I don't think it's poorly explained. I think the communication from Anses is relatively clear. They are keen to make a statement in common language that describes things to us a little bit. I just think that from the point of view of the decision maker, these opinions are often taken as the revealed truth. It's all the stuff we've been talking about since earlier about the limits of regulatory science and the fact that an expert opinion doesn't take into account a variety of parameters because that's the way the regulations are. I think all of that should be more explicit and come earlier in the Anses texts."*

(journalist)

On the other hand, some of the actors involved in these issues regret the institutional drafting, which they feel deviates from the expert data and seeks to reassure different audiences, which is not its role.

*"Here, the discrepancy between what the international scientific community says about pesticides or other examples of synthetic chemistry and what the agency says jeopardizes the agency's credibility. I am thinking of cases where the agency comes before parliamentarians, with a discourse of relativizing risks in order to reassure them (...) It endangers its credibility on the scientific level (...) Citizens today want a discourse of truth, clinical, cold and without judgment. (...) The data must remain data. It is not a question of wanting to alarm or reassure. We must provide the data and the comparative tools that allow us to understand them. That's all."*

(political leader)

The difficulties of risk communication are pointed out by some interlocutors who doubt the ability of the general public to understand technical data. For example:

*"The IARC has classified meat as carcinogenic. Behind this, I speak in terms of credibility: what do you want to tell Mrs. XXX by saying "glyphosate is category 1, it must be avoided" - it is true that this must be reserved for professionals, and especially not for the public - and at the same time "meat is also classified as category 1, but it is not forbidden". So there is a whole rhetoric, behind it, of explanation. These oppositions that we have, in my opinion, are destructive for the expertise. (...) I simply wonder if, in the advice we give every day, we need to have these experts behind us. I did not see any statistician in the other groups. Secondly, does the public understand all this? Because when we talk to them about uncertainty, I don't really know... They also expect concrete proposals. You have to be binary with the public: "it's toxic/not toxic," or "we don't know, so we're careful."*

(expert)

It should be noted that there is a fairly extensive literature on the issue of risk communication and that the considerable efforts of certain international organizations (e.g., the IPCC and EFSA) are enriching experience and good practices.

Nevertheless, independently of communication aimed directly at the general public, the question arises of the methods used to produce the reports and opinions that are published. In the interests of a culture of credibility, the group endorses the suggestions that go in the direction of great transparency in the drafting of opinions in order to inform about the level of uncertainty, scientific controversies and possible discrepancies between the assessment produced within the regulatory framework and the available scientific knowledge.

- Telling the gaps between the science and what is taken into account by the regulations

*"I find that a very clear roadmap laying out this diagnosis and saying, 'We're in this, and that's where some of the disconnect with public opinion comes from, depending on whether people are more interested in listening to expert scientists in the field or saying they trust the regulations.'"*

(Inspector General)

- Be transparent about necessary simplifications and default assumptions

*"At the European level, the commission says: 'Since we won't be able to test all the cocktails, multi-exposures, etc., we adopt a precautionary factor of x to be defined and we shoot everything down.' This is not particularly scientific, but at least it is pragmatic. Maybe we need to get away from the idea that the regulations allow us to do everything and say, 'Since they don't, I'll find palliatives'."*

(Inspector General)

- Clearly state the limits of the risk assessment and be transparent about what is not taken into account

*"There are sometimes frailties in the products of expertise that could be assumed by the agency. I think it would be simpler to say that what we did on SDHI may not be very satisfactory, but it corresponded to a certain type of expertise. It was an emergency expertise that we wanted to do quickly. After all, why not? That can be understood.*

(expert)

*"I think that if we really want to move things forward, every regulatory opinion or expertise on plant protection products should start by listing everything that is not taken into account in these opinions. I am talking about the fact that adjuvants are not taken into account in the marketing authorizations of active substances. I am talking about the fact that the chronic effect of adjuvants is never tested. I don't understand how this is possible. (...) If we are going to make opinions to introduce or reformulate expert reports, we should say all this in the preamble so that these people who vote for the laws are not convinced that there is no problem and that we should go ahead."*

(journalist)

### 6.3. Too narrow a scope of expertise

The discrepancy between scientific knowledge and guidelines is frequent and constitutes one of the elements that taints the credibility of scientific expertise. This point has been established by various works, including the OPECST report (2019) and the CDPCI note (2021) (see also Demortain 2021).

The OPECST report (2019) on confidence in the productions of health agencies develops in detail the case of bees. In 2012, EFSA issued a scientific opinion pointing out major weaknesses and gaps in the methodology for assessing the risk of pesticides on bees, not taking sufficient account of chronic toxicity, sublethal effects, larval toxicity and the multiplicity of sources of exposure. EFSA then published a proposal for a new guidance document for the assessment of pesticide impacts on bees in 2013, aiming to replace the 2002 guidance document, which was considered insufficiently demanding.

The OPECST report states that:

*"Member State experts sitting on the SCoPAFF refuse to validate the 2013 EFSA document, believing in particular that some studies are unfeasible (the protocol for the return to hive study to investigate the possible effects of pesticide residues on bee behavior is not applicable because the results would not be reproducible). A study carried out at the request of plant protection product manufacturers indicates that the application of the new guidance document would lead to the questioning of 82% of the authorized substances, for which a risk assessment of a higher level than that which exists today would be necessary, which could require the production of new data (residue analyses, field trials, tunnel trials, etc.).*

(OPECST 2019, p.108)

One of the thirteen recommendations in this report is that the guidelines be updated regularly:

*"#5 Encourage regular updating of guidelines so as not to delay the adoption of new methods and sensitive and reliable tests."*

(OPECST 2019 p.162)

The CDPCI report (2021) discusses this issue at length, observing that, in principle, the gap between expertise and academic science should be minimal because, since 2009, regulations require agencies to take into account recent advances (the last ten years of research from academic science). Nevertheless, the report notes that the agency sorts articles according to the weight of evidence provided, which leads to "dismissing interesting research that cannot meet the standards in terms of materials, good practices or methodologies, required by the regulations but beyond the reach of many academic laboratories."

This analysis leads to the following CDPCI recommendation:

*"This disjunction between regulatory and academic science - always temporary but often long-lasting - is recognized as one of the causes of public distrust. In the name of transparency on the one hand, and contradictory science on the other, the addition of certain results of academic science, convergent although not yet totally validated, should be mentioned as a track to follow and at least serve as an alert to deepen the subject within a time limit to be fixed."*

(CDPCI 2021 p.6)

This limited evaluation framework corresponds to what François Dedieu, a sociologist at INRAE, has called the "invisible cognitive architecture" (Dedieu 2022). Thus, for pesticides, the evaluation focuses on acute risks (and ignores more diffuse risks), proceeds molecule by molecule (no evaluation between several molecules) and is based on the belief in controlled use (for example, confidence in the use and effectiveness of protective equipment - one will put on protective equipment). This invisible architecture rests on three pillars: a) the history of regulatory science, which imposes a form of discreet hegemony of regulatory toxicology on the production of knowledge in this field; b) the tacit arrangement between actors who are a priori opposed (ministry and industry, and even certain NGOs) and who finally agree - for different reasons and to varying degrees - not to question the protocols of regulatory science; c) cognitive: assimilation of "regulatory science" to academic science, which in principle limits its contestation. In the interviews, these issues of the narrow framing of risk assessment were raised in different ways.

### **6.3.1. A critique of case-by-case evaluation**

Several stakeholders, parliamentarians and scientists consider that the case-by-case risk assessment is totally insufficient.<sup>28</sup> We mentioned this above in relation to communication. Here we point to the problem of credibility.

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<sup>28</sup> The need to go beyond case-by-case assessment echoes the research on the exposome that was the subject of a report and opinion of the Anses Scientific Council, adopted in September 2022. It should be noted that a more global approach may also lead to questions about the production system

*"I do not believe that the problem of credibility of the Anses is linked to the expertise. I think it is linked to the collapse of biodiversity in France. For me, this means that the expert assessments have not worked for 30 years. We can then ask ourselves why these expertises have not worked. Why the Anses or its predecessors were not able to see the catastrophe coming ? This is really the cause of the decredibilization of the Anses."*

(scientist)

*"When I talk to people around me, the reason agencies have lost credibility is because of the reality people see. It is now described and admitted. It's hard for people to accept. It completely calls into question our safety agencies and how they operate. This has been true for drugs. It's been true for pesticides and for many things that have made something substantively problematic in the expert assessments."*

(scientist)

*"As you know, the field is vast, the cost of inaction is increasingly documented, there are disturbing characters of environmental effects on health, it is a growing concern for citizens."*

(Inspector General)

This discrepancy appears to be one of the factors eroding credibility. It is obviously linked to the limits of the regulatory framework but also to the practices of the Anses. In some cases, the agency has been able to take on cross-cutting issues on its own (e.g. work on bee health), which has led it to question guidelines that ignored important dangers. The capacity for self-referral is an essential element in shifting this strong constraint.

### **6.3.2. Too much influence of the regulatory framework on risk assessment**

As mentioned above, the narrow framework associated with the case-by-case assessment is also due, for regulated products, to a selection of knowledge through the prism of the regulatory framework (guidelines, GLP, etc.). The difference in the evaluation of the carcinogenic potential of glyphosate (between IARC and BfR) is due to the fact that the bodies of reference used were not the same. This point is also well illustrated by the case of SDHIs. As the GECU chairman points out, the issue of mitochondrial toxicity was dealt with within the current regulatory framework when it was precisely the adequacy of that framework that was in question:

*"The question here was more whether the French regulation, which is a copy and paste of the European regulation (we can't do what we want), means that these substances should be banned today under the current regulation. The answer is no. This leads to this distortion between societal and political aspirations that I can share. (...) I think that this group of whistleblowers has played its role. It was right to do so and it has posed*

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(e.g. intensive agriculture vs. agroecology in the case of pesticides) which, for the Anses, can lead to the integration of socio-economic analysis.

*good questions. (...) We simply answered them on what we could do today with the regulatory and scientific tools we have, and what we could do better if we had other tools. Their societal and political will does not fit into the framework of our exercise, which is regulatory and scientific. I think the conflict arose from this difference of opinion and way of looking at the issue."*

(expert)

### **6.3.3. The influence of industry groups on regulatory frameworks**

As various articles have highlighted (e.g. Abraham & Reed 2002), the OPECST report (2019) notes the influence of industrial actors on the definition of guidelines and points to the importance of hybrid organizations such as the International Life Science Institute (ILSI). Funded by industry, it organizes meetings between researchers from public organizations and the companies involved and influences the development of evaluation methods (OPECST 2019, p. 98).

Various interlocutors mention the weight of "lobbies", particularly on the guidelines. This is the most plausible explanation for the non-adoption of the guidelines on the evaluation of pesticides proposed by EFSA in 2013 in the European regulatory framework. Several interlocutors gave this explanation, which is also found in the OPECST (2019) report cited above.

According to one parliamentarian, agencies such as the Anses, despite the procedures implemented, would be more vulnerable to the strategies of "merchants of doubt" formed by certain industrial groups. This is the reason why this type of agency is less credible.

*"In my speech that you were referring to a few moments ago, I quoted this amazing report from the WHO. In the 2000s, they make a statement saying that they have discovered and acknowledge that they have been infiltrated for decades by tobacco industry advocates. Their decisions have been influenced by well-placed people on committees and by doubts instilled here and there. They have been influenced and weakened from what they should have been. In itself, the WHO is such a sincere institution. It is not structurally something that defends this or that interest. There are so many representatives, interests and people, and then it's an easy target. If you are a smart lobbyist, you will write on your agenda that you will have to put someone you know well and trust on this or that panel of the WHO or the Anses. It is much more complicated to infiltrate the laboratories of Inria or Inserm.*

(political leader)

It is not only the implementation of risk assessment that is problematic but, upstream, the definition of the rules of the game of assessment. While much attention has been paid to implementation, this second aspect, although strategic, has received much less attention.



# 7. Thesis 4. Socio-economic impact of the implementation of risk management measures

Thesis 4 addresses the question of the socio-economic impact of implementing risk management measures. The hypothesis is that an expert opinion, or a decision based on an opinion, is all the more discussed when the estimated impact of the implementation of management measures is high, or, conversely, when the health impact of not implementing them seems high in the eyes of the stakeholders. In addition, the interviews conducted also allowed us to discuss the way in which the Anses takes up this question of socio-economic impact and takes it into account in its work.

## 7.1. Socio-economic issues mentioned in the case studies

In all three case studies, the agronomic and economic stakes appear to be very high and the industrial lobbies are very active and powerful. Several interviewees addressed this issue, each in their own way. As an illustration, here are some excerpts from the interviews:

*"We don't touch pesticides. The Ministry of the Environment is not strong enough to counter the Ministry of Agriculture.*

(expert)

*"These important molecule-producing [countries], not to mention Germany, rarely vote for regulations that will cost money and take molecules off the market for their major manufacturers."*

(Anses manager)

In the case of glyphosate, a journalist describes the multiple and cascading effects that a ban in France would have, which puts the issue of the political decision on such a subject in a systemic and international context, as these products have acquired an important place in intensive agriculture:

*"[...] If you do that, all the agribusiness sectors in Europe will have very big problems. For example, if you ban glyphosate in Europe, you will be pretty much obliged to put in place mirror measures, otherwise there will be a riot in the countryside. If you do this kind of thing, if you put in place mirror measures and you ban the import of glyphosate-treated soybean meal because it's "Roundup ready" that we grow in Argentina or on the plains of the Midwest, what will happen? It will make the price of a kilo of pork much higher. It will completely hamper the work of animal husbandry, which depends on these imports. You will make an absolutely impossible mess at the WTO. You'll start an unmanageable situation from an economic and geopolitical point of view."*

(journalist)

In another interview, it was emphasized that it is important to be concerned about the health of plants if we want to be able to produce and feed the population, elements that tend to be hidden by people who only consider the undesirable effects of pesticides, hence the importance of considering both the risks and the benefits related to the use of pesticides.

*Part of the problem comes from this, because we have completely lost the notion of "what it can be used for", including in public opinion, where, when we raise these types of questions, it is "Ah, you don't have product A, you take product B", "It's not a big deal if there is X less production", etc. We have lost the notion of the importance of solutions, the health of plants and therefore the elements in terms of production factors that can provide an answer, whatever they may be. We have lost the notion of the importance of solutions, of the plant health issue and therefore of the elements in terms of production factors that can provide an answer, whatever they may be, once again. I'm talking about phyto products, but the question of benefit-risk analysis can be asked in a global way."*

(stakeholder)

*"I think that this same effort [via the dialogue committees], including vis-à-vis stakeholders, should be made in terms of raising awareness of the plant health issue to perhaps contextualize the implementation of these products that will ultimately be validated with a benefit-risk analysis. If we don't understand the risk, we can't understand the benefit. This aspect, for me, could contribute, if not to credibility, at least to understanding the meaning of the work that is required of agencies. I think that was an important point."*

(stakeholder)

On the side of the actors who criticize the use of pesticides, the stakes of public health and ecosystem health explain the strong mobilization of NGOs and scientists to get things moving. On the subject of SDHIs, for example, several testimonies show the impatience of scientists to have these products banned:

*"152 preparations are sold with thirteen molecules. They are sold supposedly because they are better for this or that. It's a complete lie sold to farmers."*

*"We saw that the use was exponential and that the number of dossiers submitted for the authorization of substances was also increasing. [...] We felt that this was dangerous. [...] There was the fact that we had to play for time and that the Anses could have taken preventive action on the basis of the solid knowledge we had launched."*

*"Mr. X said that there had to be a ban or nothing. [...] X went into a somewhat extreme analysis."*

*"When you get daily emails from activist scientists wanting the Agency to deliver results without delay that are their own, it's pretty unpleasant, and sometimes very difficult for our young scientists to live with."*

(Anses manager)

## 7.2. Points of view on the positioning of Anses in the conflicts on pesticide issues

It is generally agreed that the reforms of the 1990s, of which the Anses is the heir, have profoundly improved the functioning and credibility of expertise. Although the creation of the Anses has allowed a great advance on the question of the credibility of scientific expertise, it nevertheless appears that it has not completely settled the question in the eyes of several of the people interviewed. They point out several limitations to the work of the Anses in producing an independent expertise in the face of the enormous socio-economic stakes that exist on the themes that concern our case studies. A first argument raised by several interviewees is that the Anses is instrumentalized by the political power to do nothing:

*"If I may, I always use the example of March 22 or 23, 2015. The World Health Organization, based on the work of IARC, announces that several substances are now recognized as probable carcinogens. Several substances are involved, including glyphosate. It is very interesting to note that on the same day that this information is made public, we see two government communiqués for two different substances. There is a release on malathion. It is on the same list as glyphosate. I believe that malathion had already been taken out of use in France, but it had been temporarily reauthorized under very special circumstances. A press release from the Minister of Health said that malathion was banned immediately. A few hours later, a joint press release from the Ministry of Health, the Ministry of Ecology and the Ministry of Agriculture said that the government had taken note of the IARC opinion on glyphosate. This explains why it is asking the Anses to conduct a new study [...]. The credibility of the expertise and its independence at the Anses depends on this technique of evasion by political leaders.*

(political leader)

This view is supported by another interview:

*"I think it's clear that this is the case. When we look at the latest case with SDHIs, the expertise is being used as a delaying tool. The warning was given in 2017. We are in 2022. Let's meet here in ten years. I have absolutely no doubt that all these products will be banned. But in the meantime, we have experts working. They write reports that are useless. That's systematically the case."*

(journalist)

A second criticism made by some stakeholders is that the Anses censors itself in situations of uncertainty and in the face of the underlying economic stakes:

*"It [Anses] may censor itself for various reasons. One reason is that it evaluates and sees for itself the implications that its evaluations may have. I'm thinking of things that can cause great embarrassment to the government, to the powers that be and to the economic world. She can be restrained in her opinions.*

(political leader)

*"The financial stakes are so huge, it's so politically complicated, that I think it's very difficult for them to do their job properly. I don't blame them, but I think it's very difficult. The pesticide vendor lobby, I'm not making that up."*

(scientist)

Some interviews also mention a conflict of issues within the agency. The fact that the same agency is responsible for both the "food" and "health and environment" domains automatically creates a conflict between health and economic issues.

Within this complex framework of action, it should nevertheless be noted that one expert interviewed reports that the Anses has a rather good reputation in terms of integrity compared to other European organizations in the sector:

*"We were hearing in the CES Phyto that France is more of a state considered tough at the European level. [...] Anses has a reputation for fighting long and stubborn battles."*

(expert)

### **7.3. The challenges of integrating socio-economic assessment into risk analysis**

The Anses COP 2018-2022<sup>29</sup> recommends that a reflection be initiated to develop socio-economic analysis in the Agency's work. It provides for "*mobilizing human and social sciences in expertise as needed*" in three frameworks: shedding light on the objects of scientific and sociotechnical controversy that the Agency must frequently face; conducting or evaluating impact studies of management options required by the regulatory framework; and the need in certain referrals to evaluate the impact of measures recommended by the Agency.

For this type of work, the Agency has been able to rely on the Social Sciences, Expertise and Society Mission, which became the Social Sciences, Economy and Society Directorate (DiSSES) in 2022. In particular, the reflections carried out since the COP was drawn up, notably the internal scientific and technical support report "Socio-economic analysis: assessment and perspectives for Anses" (Anses, 2020c), have led to the strengthening of this last dimension. An ESC dedicated to socio-economic analysis has also been created.

Socio-economic analysis is used in a regulatory context for the evaluation of chemicals falling within the scope of the REACH Regulation<sup>3031</sup>. In

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<sup>29</sup> <https://www.anses.fr/fr/system/files/ANSES-COP2018-2022pp.pdf>, page 1.

<sup>30</sup> As a reminder, although they are subject to the REACH regulation, chemicals are not included in the list of products designated by the Anses as "regulated products", for which the Agency has an ad-hoc definition.

<sup>31</sup> In the regulatory field, if the Reach Regulation (EC) 1907/2006 appears to regularly mobilize socio-economic analyses, other regulations can also be mentioned despite lesser uses: Biocidal Products Regulation (BPR) (EU) N°528/2012; Plant Protection Products Regulation (EC) n°1107/2009; analyses of the phytosanitary risk within the framework of the European Regulation n° 1143/2014 on the prevention and management of the introduction and spread of invasive alien species, adopted on 22 October 2014.

As part of its activities, the REACh ESC may be required to assess the socio-economic impacts of the measures envisaged in the context of the restriction proposals drawn up by the Anses for the French competent authority. The experience of this ESC shows the usefulness of combining a risk assessment with a socio-economic analysis of the impacts of this risk and the measures to manage it, while highlighting certain limitations of this exercise, in particular because of the asymmetry of information for the public assessor, who has to rely on data mainly from stakeholders (such as industry).

Outside the regulatory context, Anses is progressively developing socio-economic analysis around three types of questions (Anses 2020c):

1. Analysis of the determinants of exposure and health effects, to contribute to health risk assessments: behaviour of sub-populations particularly exposed for socio-economic, demographic or cultural reasons; approaches to inequalities and vulnerability; analysis of sectors, production processes, the construction and structuring of markets;
2. Economic or socio-economic evaluation of the impact of an agent (physical, chemical, or biological, or even of a work organization) or of an activity, in terms of health, environmental or organizational burden: this involves evaluating (not necessarily quantitatively) the pathologies associated with an exposure factor and the associated direct, indirect or intangible costs (i.e., not responding to market logic like the impacts on quality of life)<sup>32</sup> ;
3. Evaluation of one or more options for action intended to reduce or prevent health or environmental impacts deemed undesirable, within a regulatory or non-regulatory framework (e.g. information measures, standards, etc.).

With regard to the third type of question concerning the evaluation of options for action, the objective is not to replace a decision that is the responsibility of public decision-makers with a solution given by science. Socio-economic analysis is a matter of evaluation, not management. On the contrary, it is a matter of clarifying the terms of the debate and the possible options, of explaining the different scenarios or possible worlds, in order to make the diversity of possible definitions of the problems and the solutions understandable. To do this, the Socio-Economic Assessment must gather all relevant qualitative and quantitative data. It also integrates, in qualitative form, effects that cannot be quantified. This can lead to multidimensional analyses that cannot be reduced to cost-benefit analyses.

The issue of policy options also implies a broader understanding of alternatives, including not only those that replace one product with another, but also systemic alternatives—for example, in agriculture, non-chemical alternatives of the order of redesigning production systems with the modification of

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<sup>32</sup> It is noted that a socio-political point of view was adopted in the conduct of this type of exercise, as this is the only way to account for the diversity and heterogeneity of certain impacts.

of agronomic practices. However, the analysis of alternatives is not only based on socio-economic approaches: it must be multidisciplinary.

The Anses' voluntary and consistent commitment to the integration of socio-economic analysis can change the framework and practice of risk assessment, as has already been suggested by various international and European proposals (Anses 2020c). For this to happen, the involvement of the Social Sciences, Economy and Society Directorate, right from the start of the referral process, is essential. In this respect, several pitfalls may appear. The first is the methods used to answer the questions posed, given that certain aspects can only be addressed qualitatively and that data from very different metrics must be taken into account. A second difficulty is that of access to data to estimate the parameters studied, the precision, reliability and opposability of the data, and the possible biases in their measurement. Thus, the construction/stabilization of methodological milestones for studying and taking into account socio-economic issues, fully considering the uncertainties in the results obtained, is necessary.

## **8. Anses bodies and organization: questions raised by the structure of Anses concerning regulated products**

In our interviews, in addition to the four theses, two themes came up frequently: the organization of the agency regarding regulated products and the precautionary principle. These two themes are the subject of these last two chapters.

Anses carries out risk assessment and, in some cases, risk management missions (issuing or withdrawing marketing authorizations) in a range of fields and for a range of products governed by national, European or international regulations. Some of the products subject to regulatory frameworks are distinguished by the agency under the *ad-hoc* term of "regulated products". These regulated products include all products for which the Anses issues and withdraws marketing authorizations (MA): plant protection products and biocides, fertilizers and crop supports, veterinary drugs. They also include plant protection and biocidal active substances, and non-indigenous macro-organisms useful to plants, for which the agency has risk assessment missions, but for which it does not manage authorizations (authorizations that are managed at the European level for plant protection and biocidal active substances, and by the Ministry of Agriculture for non-indigenous macro-organisms useful to plants)

Other products for which the Anses has a risk assessment mission without a risk management mission are not included in the regulated products: this is the case, for example, for chemicals subject to the REACH regulation, whose authorization is managed at the European level.

The structuring within the agency of the missions of risk assessment and management of regulated products, and of risk assessment of non-regulated products, raises various questions and may generate various problems, which were mentioned during the interviews conducted for this work.

### **8.1. A new institutional structure that partially segments the activities related to regulated products**

The main characteristics of the institutional structure of the Anses in relation to regulated products are as follows (for more details, please refer to the decision on the organization of the Anses, Anses 2019c). The agency includes a "Regulated Products" division and a "Sciences for Expertise" division (see Figure 1 p.38).

- The "Regulated Products" division is composed of the MA Directorate (DAMM), the Regulated Products Evaluation Directorate (DEPR) and the National Veterinary Medicine Agency (ANMV).
  - The DEPR carries out the evaluation of the dangers, risks and effectiveness of regulated products, including, if necessary, for the files of applications for marketing authorization. It also issues opinions and recommendations to the competent authorities in its fields of competence. Three specialized expert committees are attached to it, the CES "Plant protection substances and products, biocontrol", "Biocidal substances and products" and "Fertilizers and growing media", as well as a permanent working group "Macro-organisms useful to plants" (Anses 2021a)<sup>33</sup>.
  - The MAH decides on marketing authorizations and permits for experimentation and parallel trade for regulated products for which the Anses provides risk management, based on evaluations conducted by the DEPR (Anses 2021a).
  - The ANMV is responsible for the MA of veterinary drugs, the monitoring of adverse drug reactions, the control of pharmaceutical establishments and the market of veterinary drugs.
  
- The "Sciences for Expertise" division includes the Risk Assessment Department (DER), the Health Alerts and Vigilance Department (DAVS) and the Social Sciences, Expertise and Society Mission (Misses).
  - The DER is responsible for the evaluation of nutritional and health benefits and risks related to food and for the evaluation of risks related to health-environment, occupational health, animal health, nutrition and welfare and plant health. It also carries out the evaluation of chemicals in the framework of the European chemical regulations REACH and CLP. The ESCs that do not depend on the DEPR or the DiSSES are attached to it. Some of its expert appraisals concern regulated products: for example, the 2021 Anses opinion on health reference values for chlordecone (Anses 2021b), for which the expert appraisal falls within the scope of the "Evaluation of physico-chemical risks related to food" (ERCA) and "Health Reference Values" CES.
  - The DAVS is in charge of a transversal mission within the Agency, related to health monitoring, alert and vigilance. This mission may therefore include regulated products.

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<sup>33</sup> See also <https://www.anses.fr/fr/content/appele-candidatures-d-experts-scientists-for-constituting-committees-of-experts>

- Finally, DiSSES, which is responsible for developing and coordinating the contribution of social sciences to the Agency's expertise activities, also works to encourage and strengthen interactions with stakeholders - here too, including on regulated products. The ESC The "socio-economic analysis" section is attached to it.

## **8.2. A reorganization instituting a functional separation between evaluation and management**

Historically, the organization into divisions within Anses, effective in 2017, follows the transfer of the management of marketing authorizations for plant protection products, fertilizers and crop supports and adjuvants, which was transferred from the Ministry of Agriculture to Anses in 2015 - a transfer that Anses had not requested. At that time, fears were expressed, particularly within the agency's Scientific Council and Board of Directors, about the consequences of such a transfer in terms of the quality, independence and, more broadly, the credibility of its evaluation. In response, a new institutional arrangement was put in place, distinguishing between the responsibilities of evaluation (taken on by the DEPR) and decision-making (taken on by the DAMM), which were then grouped together in the same "Regulated Products" unit

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*"On the regulated products side, we have done what was recommended at the time by the Agency's Scientific Council, i.e. we have completely separated the evaluation from the decision. This is an extremely important point. That is to say, when the evaluation is done, the Director of Evaluation on the regulated products side signs his opinion and then the decision is taken. But on the side of the Directorate of Marketing Authorizations that makes the decision, there is no right of review of correction or modification of any kind of the opinion that has been taken by the Directorate of Evaluation of Regulated Products."*

(Anses manager)

According to the report of a 2017 inspection mission, this division of responsibilities then appeared satisfactory to Anses board members (Belet et al. 2017).

## **8.3. An institutional arrangement that raises questions and concerns**

However, this structuring can be problematic in several respects. First, for regulated products, the distinction between risk assessment and risk management is not clear to various Anses contacts.

One scientist describes his interactions with the agency this way:

*"The people I talked to at Anses [...] covered both assessments and allocations, all the time. That's the only thing I can say. There may be a separation that I don't know about. I feel so much like there isn't. Whether you ask questions about management or evaluation, it's always the same person who has answered me. [...]. I was not told that I should see another person for MAs. [...] I never had one person to talk to when I asked about toxicity and assessment or MA. [...] I can't answer any more. This then comes down to the opacity of the Anses. It is not normal that I cannot answer these questions. It reflects the fact that although I have been in contact with Anses for four years, I still do not know who decides what, who does what or how it is organized. I should know, but I don't."*

(scientist)

A journalist interviewed confirms this lack of clarity in his exchanges with the agency, and wonders about the possibility of a *structural* separation between risk assessment and risk management, beyond the functional separation put in place:

*"There is never a distinction [...]. We never know which part of Anses is responding to us. We never know if it is the response from the MA point of view or the risk assessment point of view. We don't have that detail. [...] I think that any Anses agent who answers any question from a journalist on phyto topics giving rise to MAs issued by Anses is influenced in his way of communicating by the double hat of his administration. I don't think they can split into two. I am absolutely convinced that the risk assessment is carried out with the following thought in mind: "At the end of our work, will we have to ban this product? I think that's the thought that's going on in the back of my mind. I don't have the evidence to say so, but it's definitely something that seems obvious to me. I think that this dual competence has somehow contaminated the work of the Anses, at least on the issue of phytosanitary products, which I follow a little more closely than the others."*

(journalist)

In this line, the weight of regulatory frameworks in the risk assessment of regulated products also raises questions. An expert scientist from an Agency WG thus notes:

*"[...] The transfer of pesticide marketing authorization to the agency in 2015 has not done it much good in terms of credibility of expertise. It seems to me to give too much weight to this regulatory science part of the agency. It was probably already not the most open, but in my opinion it has become even more strained with the political responsibility for product approval. As an expert, I felt it in the WG. [...] It is still against the wind of the history of the separation of risk assessment and risk management. The agency has made its arrangements and put in place a formal distinction. I'm not sure how it works, or how effective it is, but this setup is not great. It's not great. There's too much in the hands of the agency here."*

(expert)

Other limitations or constraints that may affect pesticide risk assessments were expressed during the interviews, even when these risk assessments are not conducted in a marketing authorization review setting:

- Lack of diversity in the disciplines and skill areas used for assessment
- The weight of regulations, particularly European regulations, which are themselves constrained by international guidelines
- The tightening of the examination of the questions pertaining to a risk assessment of pesticides, respecting the constraints of the European regulatory framework without underlining its limits
- A lack or weak consideration of academic knowledge that may call into question the authorization of products and the regulatory frameworks that led to this authorization.

The weight of the regulatory frameworks in the expert assessments of regulated products can be illustrated by the ambiguity of the missions of two ESCs attached to the DEPR - the ESCs for "Plant Protection Substances and Products, Biocontrol" and "Biocidal Substances and Products" - as formulated in the calls for applications issued by the Anses in 2019 for the renewal of these two ESCs. On the one hand, in each of these calls for applications, it was specified: "*[t]he Anses implements an independent and pluralist scientific expertise to provide the competent authorities with all the information necessary for public decision-making, both at national and Community level*". On the other hand, these two calls for applications suggested that the ESCs' missions were restricted to a regulatory framework:

- CES "Plant protection substances and products, biocontrol": "*The Agency's mission is to evaluate, within the framework of Regulation (EC) No. 1107/2009 on the market of plant protection products, the risks and the interest for plant production of products based on chemical substances (of natural or synthetic origin) or microorganisms and to propose conditions of use for these products* "
- CES "Biocidal Substances and Products": "*The CES "Biocidal Substances and Products" is to assist Anses on the scientific and technical levels in the framework of its mission to evaluate biocidal substances and products according to the procedure defined in Article R522 of the Environmental Code.*"

Thus, the ambiguity of the missions of these two ESCs is to reconcile, on the one hand, the implementation of an independent and pluralist scientific expertise, and on the other hand, the description of a mission constrained by a regulatory framework. However, discrepancies between the state of scientific knowledge and the regulatory framework frequently occur. It is to be feared that this structuring and the culture of these ESCs condition limited possibilities to integrate relevant scientific knowledge not covered by the regulations. This question also emerges from an interview with a member of the "Plant Protection Substances and Products, Biocontrol" ESC.

*"You were talking about neonicotinoids. What has always surprised and shocked me is that, for example, the effects of neonicotinoids on bumblebees and solitary bees were never taken into account because the regulatory framework did not require it. However, there were many scientific publications showing that bees were very affected by neonicotinoids. [...] This question was often raised in the ESC. But the answer was logical: the guidelines only ask to look at the effect on bees. The bees had large colonies with recovery abilities, etc. You know this better than I do. It's a malaise that has always existed. [...] It is the way the ESC works and the way we work that makes us look only at the regulatory framework. [...] These were the rules of the game. [...] This is how we operate in this ESC. [...] The way in which the Anses will make its decisions and write its opinions is defined by this framework."*

(expert)

At the same time, the DEPR also has the task of proposing changes to regulatory frameworks and guidelines. One may therefore wonder whether this mission is sufficiently developed within the DEPR and whether it has the means to do so, and whether it is sufficiently promoted in the expert groups. A scientist who chaired an expert assessment covered by the "Regulated Products" Unit described the concrete difficulty of going beyond regulatory logic in expert assessment work:

*"As experts, if we participate in this expert work, we have to accept the regulations as they are. That's a pretty sensitive point. I'm not sure how we can influence the regulations. [...] Our expert panels don't really have a mandate to go beyond the regulatory difficulties that we have. We have to deal with the regulations as they are. If we don't want to do that, we don't participate in the panel. We participate in panels on other topics. So working in this group is implicitly accepting to work with the tools we have. Otherwise, you quit and say you don't want to work with these tools. But my firm belief is that they should not be dismissed so quickly. They are asking good questions about regulatory toxicology."*

(expert)

Some of the concerns expressed here are consistent with the recent report of the Inspectorate General on research, expertise and public health in the field of health and the environment (Lavarde et al. 2020). This inspection mission suggests that a working group involving all stakeholders be set up with the aim of proposing a renovation of the reference framework for risk analysis. It paid particular attention to the case of the Anses:

*"Indeed, the gradual diversification of its missions has made the Anses not only a risk assessment and, in part, risk management institution, but also a research operator in distinct fields. From the outset, and with each transfer, the question of its identity and positioning as a health agency has arisen. Ten years after the creation of the Agency, a reflection on the positioning of the Anses could be carried out within the framework of a broader reform of the governance of health and environment. Several options could be considered, including confirmation as a multi-purpose institution in charge of various missions (research, evaluation, risk management), or refocusing on its expert missions with the question of maintaining veterinary laboratories within it."*

(Lavarde et al. 2020, p. 62)

## 9. The setting in implementation of the precautionary principle by the Anses

As mentioned above, the questions raised by the consideration of the precautionary principle were mentioned several times by different interlocutors. These questions are also complex and directly related to the credibility of scientific expertise.

### 9.1. From conceptions different of principle precautionary principle

The history of the precautionary principle is well known (Godard 1997, Kourilsky and Viney 2000). It emerged in the 1970s as a legal principle designed to guide public action in situations characterized by the possibility of serious and irreversible damage when its occurrence is not known with certainty. It is therefore a principle of action in situations of uncertainty, codified by various European texts, in particular the European Commission's communication of 2 February 2000, and introduced into the French Constitution in 2005 (Article 5 of the Charter of the Environment), the highest level of the hierarchy of norms.

*"When the realization of a damage, although uncertain in the state of the scientific knowledge, could affect in a serious and irreversible way the environment, the public authorities will take care, by application of the precautionary principle, and in their fields of attribution, to the implementation of procedures of evaluation of the risks and to the adoption of provisional and proportionate measures in order to avoid the realization of the damage.*

(Constitutional Act No. 2005-205 of March 1, 2005 on the Charter of the environment)

The precautionary principle has always been the subject of controversy. At the first Earth Summit in Rio de Janeiro in 1992, the Heidelberg Appeal, signed by many scientists, denounced "the emergence of an irrational ideology that opposes scientific and industrial progress and harms economic and social development"<sup>34</sup>. The precautionary principle is thus accused of creating "a context that is detrimental to innovation and growth"<sup>35</sup> and of contributing to the French "decline"<sup>36</sup>. Closer to home in France, in 2015, a group of deputies lobbied to introduce into the normative order an "innovation principle," supposedly to counter the precautionary principle and defend new value-creating activities.

While it is certain that in rare circumstances the precautionary principle may have been misused as a requirement for proof of safety, here we confine ourselves to the definition of positive law, both the legislative and regulatory texts and the decisions of

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<sup>34</sup> The historian François Jarrige points out that the initiative leading to the Heidelberg Appeal was supported by the big oil companies whose strategic interests were threatened. He considers this to be one of the manifestations of the strategies of the merchants of doubt highlighted by Naomi Oreskes and Erik Conway.

<sup>35</sup> See Attali, J. (2008). Report of the Commission for "the liberation of French growth", XO Editions, La Documentation française, pp. 91-92.

<sup>36</sup> Gallois, L. (2012). Pact for the competitiveness of French industry. Report to the Prime Minister, p.39.

justice. Legally, it constitutes and, in the vast majority of cases, is used as a principle of action leading to proportionate and reviewable measures to avoid plausible though uncertain dangers.

*"In the block of constitutionality, it means precisely that in the face of a threatening disaster, it is the duty of the government to take measures to act to avert the disaster. So it is not a matter of restraint, but of action."*

(political leader)

As shown in the famous report by the European Environment Agency, *Late Lessons from Early Warnings: The Precautionary Principle* (EEA 2001), history shows us that in many circumstances, our institutions have been unable to listen to weak signals, i.e., to take into account information that could have made it possible to prevent poorly known dangers. This is the problem of "black swans", which is well documented in the literature (Taleb 2012) and to which we will return. What about health agencies in general and the Anses in particular?

## 9.2. Precaution and proportionate action: in search of a multi-criteria grid

The interviews express quite clearly the diversity of positions on the precautionary principle. For some scientific experts, the precautionary principle is clearly a risk management issue. It is therefore not within their competence. For example:

*"The precautionary principle, I don't get involved. For me, it's politics, so it's not my department. I think we have to be very clear about the scope of what we are saying. I always start my sentences with: "With the current state of knowledge, we can say this, this and this and not this."*

(expert)

Or again:

*"The precautionary principle is not really our role. As experts, our role is to assess hazards. If we know the exposure, we can do risk assessment. (...) Precaution is not the role of experts, but of risk managers. We are here to give arguments."*

(expert)

If we take for granted this argument of the separation between scientific and political evaluation, it is necessary that scientific expertise gives the decision-maker the necessary arguments to act in a proportionate manner. This requires, first of all, the necessary qualification of the level of uncertainty. The experience of the IPCC is cited as an example:

*"It took 30 years for the IPCC to learn to overcome this and to write in precise language what the terms 'likely' and 'certain' mean. When you look at the literature on the early days of the IPCC (...), you see that in the early meetings of the IPCC, the scientists explode among themselves when they wonder what terms and phrases to use to describe the problem."*

*"They destroyed themselves before they knew what language to use. The language that the IPCC uses comes across as a bit heavy-handed, with italicized words like "very likely. They describe the level of certainty and uncertainty. In the Inserm report (2021) on glyphosate, the conclusion was changed from "unlikely" to "moderately likely". On a scale of three, with "not very," "medium," or "very likely," they said that after reviewing everything, they were moving it up one notch from "not very" to "medium likely. I think that's the kind of approach we need to have now."*

(political leader)

Some of those interviewed went further. On the one hand, in order for there to be proportionate action, it is necessary to clearly define what O. Godard had called the "level of plausibility of the risk".

*"The precautionary principle remains a principle of action, of proportionate action according to the levels of evidence and uncertainties on the subject studied. Hence the importance of analyzing them clearly. Our role is to inform the choices of decision-makers, to ensure that their actions take these elements into account."*

(Anses manager)

Or:

*"We can give our area of uncertainty in CES Anses."*

(expert)

However, the level of plausibility of the risk is only one of the elements. As Bernard Chevassus-au-Louis, then Chairman of the AFSSA Board of Directors, suggested, it is necessary to develop a multicriteria grid. This sentiment is expressed by both agency officials and experts:

*"The dimensions of risk that will be used to make precautionary recommendations. (...) A whole bunch of criteria that I think are useful to take into account in relation to the precautionary principle, and in recommendations that the Agency would make on sensitive health risk topics."*

(Anses manager)

*"There are both criteria for applying the precautionary principle, but once you think there is a precautionary principle, there may be criteria for saying what level of action we are going to take."*

(expert)

Aware of the need to develop adequate methodologies to assess the plausibility of the hypotheses, the Anses initially mandated a Working Group

"In 2017, this report served as the basis for the recently produced internal methodological guide for expert planning, uncertainty analysis, literature review and weight-of-evidence assessment, also known as the ACCMER report. The purpose of this guide is precisely to put into practice and deploy uncertainty analysis and weight of evidence in expert groups. It is desirable that the ANSES should now focus on implementing these evaluation methodologies as quickly as possible, but also consider the acceptability of damage, observability, the level of irreversibility, the availability of alternative solutions, etc. As we can see, this is pushing towards an interdisciplinary expertise that takes into account socio-economic criteria in a broad way.

Concerning this question of the boundary between risk assessment and risk management, the case of plant protection products is specific in that the agency has this dual competence. An Anses official indicated that proportionate action is the principle followed and that this sometimes leads to restrictions that go further than those of other European agencies:

*"Whenever we can issue specific recommendations in relation to the precautionary principle, we do so. Afterwards, for regulated products, there are marketing authorizations. Decisions are taken on marketing authorizations or on the withdrawal of marketing authorizations. On a certain number of phytosanitary products, we have been precursors, far ahead of other European countries, in particular in trying to have them withdrawn under the precautionary principle in relation to certain study data."*

(Anses manager)

However, this view is not corroborated by other direct or indirect evidence collected by our working group.

### 9.3. Reducing precaution to risk assessment?

The calibration of risk management measures in uncertain and controversial situations is a delicate and sensitive matter. The choices made by Anses are not free of criticism:

*"If there is one constant on the three issues I have observed in the recent period between neonicotinoids, SDHIs and glyphosate, it is that there is a real problem of understanding the precautionary principle."*

*"(...) On the precautionary principle, Mr. Genet replies:*

*On the precautionary principle' - I always insist on the fact that he says that - 'when there is uncertainty, we carry out a risk assessment. This is the basis of the work we have done on each product'.*

*This is not the precautionary principle. The precautionary principle obviously consists of research, but provisional measures are also taken to prevent damage from occurring. This is the precautionary principle. There is a real gap in the precautionary principle.*

(political leader)

In addition, there is a structural argument. The agency's behaviour in a situation of uncertainty is very dependent on its perception of the room for manoeuvre linked to its relationship with the supervisory authorities and the regulatory framework, organized by European texts. This may explain why the agency makes very little use of the variety of possible measures to act in a proportionate manner (reductions in use, reinforcement of preventive measures, etc.), because of its aversion to the risk of appealing against decisions likely to lead to distortions of competition. Finally, the Agency is also criticized for not taking weak signals into account.

*"The Anses and its expertise are used by successive governments and politicians as a n appeal to do nothing. The classic example is that we have a serious scientific alert on a subject, not so much debatable or with tangible elements that give rise to scientific publication in scientific journals with reading committees and peer reviews. In order to do nothing and to draw no consequences in terms of public policy from this scientific war, the government is going to refer the matter to the Anses and ask it to conduct a counter-study to the independent study published in a peer-reviewed scientific journal. (...) Their classic tactic is to ask for additional evidence or evidence that invalidates the first assessments made."*

(political leader)

This question of the calibration of measures is therefore essential. It can be added that it remains very opaque and not very readable. The General Inspectorate report on environmental health raises this issue (Lavarde et al. 2020). While much progress has been made on the transparency of risk assessment, the lack of information on the reasons taken into account in the choice of measures leaves room for all sorts of speculation on the interplay of interests, particularly economic ones, that weighed on the decision. This lack of transparency in turn affects the credibility of the expertise.

## **9.4. The Anses in trial, in the name of precaution**

In the recent period, the Anses has been condemned twice by administrative courts:

- The judgment of the administrative court of Lyon of January 15, 2019 annulling the decision to market Roundup Pro 36
- The Nice Administrative Court's ruling of November 29, 2019 canceling the marketing authorizations for the insecticides "Transform" and "Closer" based on sulfoxaflor, an active substance approved by the European Commission.

This second judgment is motivated by the precautionary principle as provided for in Article 5 of the Charter of the Environment and in Article 191 of the Treaty on the Functioning of the European Union. The Court emphasizes that, even in cases of uncertainty about the harmful consequences of a product, the precautionary principle must be applied:

*"Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty about the risks to human or animal health or the environment posed by plant protection products to be authorized in their territory.  
(...)"*

[Furthermore, "a correct application of this principle presupposes the identification of the potentially negative consequences of a product and a complete risk assessment based on the most reliable scientific data and results the most recent international research. When it proves impossible to determine with certainty the existence or extent of the alleged risk because of the insufficient, inconclusive or imprecise nature of the results of the studies conducted, but the likelihood of actual harm persists should the risk be realized, the precautionary principle justifies the adoption of restrictive measures."

(Decision of the administrative court of Nice of November 29, 2019)

The precautionary principle therefore implies action, since uncertainty "*must not delay the adoption of effective and proportionate measures*". In this way, article 5 of the Charter of the Environment mentioned above requires public authorities to implement risk assessment procedures and to adopt provisional (as they will evolve according to the progress of knowledge) and proportionate measures (no doubt depending on the degree of uncertainty).

In a ruling dated July 12, 2021, the Council of State validated the provisions of Decree No. 2018-675 of July 30, 2018 banning neonicotinoids :

*"Neonicotinoids have adverse effects on bee health, both for acute toxicity and for so-called sublethal, i.e. long-term, effects, and severe adverse effects on non-target species that provide ecosystem services including pollination, as well as adverse effects on aquatic invertebrates and, through the food chain, on birds." [...] "Neither the circumstance that limited and temporary derogations from this ban have been granted on two occasions by the French authorities... nor the circumstance that other Member States have not adopted comparable regulations" can justify the use of neonicotinoids."*

(Council of State decision of July 12, 2021)

Despite this ruling, the government responded positively to the request for a derogation from the ban on the use of neonicotinoids to favor the sugar beet sector; thus, the law n° 2020-1578 of December 14, 2020 relating to the conditions of placing on the market of certain phytopharmaceutical products in case of sanitary danger for sugar beets. This law, validated by the Constitutional Council, establishes a temporary exemption to the use of neonicotinoids. Until July 1, 2023, joint orders of the Ministers of Agriculture, Environment and Health may authorize the use of sugar beet seeds treated with neonicotinoids or with substances producing the same effects.

With regard to the first judgment concerning the authorization of Roundup Pro 36, the administrative court of Lyon relied on the same reasoning. In a ruling dated June 29, 2019, the Lyon administrative court of appeal rejected the petitions of Bayer Seeds (formerly Monsanto) and Anses<sup>37</sup> .

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<sup>37</sup> See the judgment and the summary of the case on ALYODA.EU, the case law website of the Administrative Court of Appeal of Lyon.

Referring to the controversies surrounding IARC's evaluation of the carcinogenicity of glyphosate, the ruling concludes:

*"(...) All of these elements were such as to support the hypothesis of a risk of damage to the environment, linked to the use of glyphosate but also to the association of it with other co-formulants in preparations, likely to cause serious harm to health, at the date of the contentious decision, and justified, in spite of the uncertainties remaining as to its reality and its scope in the state of scientific knowledge, the application of the precautionary principle.*

(decision of the administrative court of appeal of Lyon of June 29, 2019)

The reception of these judgments by the agency's managers is mixed, to say the least, which indicates a difficulty on the part of the agency in recognizing the competence of the courts concerned to interpret the precautionary principle, which, it should be remembered, is enshrined in the French Constitution.

*"I do not know who is more credible between a judge, a lawyer and a group of experts to say that we have exceeded the precautionary principle or not. I wonder about a certain judicialization of scientific expertise. I wonder about the fact that the judiciary is taking over scientific expertise. I am not saying that we are perfect in our collective expertise. There are always things to improve.*

(Anses manager)

*"It seems to me that the judiciary is not the best guarantor of scientific expertise. We can hear scientific experts in court, but in the end it is lawyers and judges who choose who they hear. We try to choose panels of experts who do not carry an interest or an opinion supported by anything other than science."*

(Anses manager)

Or:

*"So, what is my opinion on the Lyon court? For me, it is an opinion issued by an administrative court, political and not scientific, the precautionary principle being in the very methodology of the agency. The problem is to anticipate this kind of situation. I think that this is your problem too (...)*

*"The problem was not one of substance. For me, it was a problem of form. They relied on that."*

(Anses manager)

It should be noted that the position of the judge confronted with scientific uncertainty is particularly delicate since he is exposed to two contradictory criticisms: either that of ignoring the state of scientific research, or, *a contrario*, that of substituting himself for the scientists without having the legitimacy to do so. In fact, the administrative judge mainly refers to "the current state of scientific knowledge" to justify the absence of consensus or scientific certainty and, consequently, to allow the public entity to continue to carry out the activity in question. The two above-mentioned judgments invoking the precautionary principle are, in this context, particularly noteworthy and should benefit from an in-depth analysis by the Agency.

This is all the more true since, in a pragmatic way outside the field of plant health, in certain evaluation files such as the long-term risks of infantile leukemia and exposure to low-frequency electromagnetic fields, we note that the Anses has been able to use the principle of

precaution, as early as 2010, on the basis of a cluster of concordant presumptions. This attitude was confirmed in 2019 with a recommendation not to establish new schools near very high voltage lines.

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November 15, 2022

# 10. Bibliography

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