



Scientific Board of the French Agency for Food, Environmental and Occupational Health & Safety – ANSES

Opinion of the Scientific Board on the report by the working group on "Credibility of scientific expert appraisals"

Over the last few years, among the hundreds of opinions issued by ANSES, some relating to regulated products have led to controversy and disagreement. In light of this, the Agency's Scientific Board mandated a working group (WG) to analyse the situation and make recommendations for enhancing the credibility of the Agency's expert appraisals. This therefore meets the objective of ongoing deliberations stated by the Agency in its framework document on the collective expert appraisal methodology applied at ANSES (June 2012), as well as the objective of strengthening its scientific excellence and the quality and independence of its expert appraisals (ANSES 2018-2022 Goals and Performance Contract).

The WG addressed the issue of the credibility of the Agency's expert appraisals, i.e. the degree of trust it enjoys, based on feedback from three case studies that have been controversial to varying degrees (glyphosate, SDHIs and neonicotinoids) and an examination of the factors determining the credibility of expert appraisals through a literature analysis and around 30 hearings. The data were examined according to four themes: the divergence between the available scientific knowledge and that used for the three expert appraisals; the procedures followed; the divergence between the expert appraisal conclusions and the expectations of stakeholders; and lastly the socio-economic impact of putting risk management measures in place.

MAIN FINDINGS: SCIENTIFIC EXPERT APPRAISALS SUBJECT TO THREE MAIN SOURCES OF TENSION

The findings of this work shed light on three main sources of tension affecting scientific expert appraisals in general.

The first source of tension to which scientific expert appraisals are subject is the need to consider the most advanced scientific knowledge while at the same time relying on clear rules shared by all the players involved, so as to carry out a transparent, robust and reproducible risk assessment. This can lead to a divergence between scientific knowledge and the results of the expert appraisal, which can give rise to public controversy.

The second source of tension relates on the one hand to the urgent need to issue certain opinions, and on the other to the time needed to conduct a high-quality scientific assessment. The urgency of the situation may lead to the usual codified rules of collective expert appraisals

(plurality, ability to analyse all the available data, time for collective work, etc.) being adjusted to fit the time constraints. This may lead to fragile results that are therefore subject to challenge.

A third source of tension runs through the expert appraisal, which requires risk assessment to be separated from risk management, while at the same time needing to contextualise the assessment results with regard to the feasibility of the 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 then implement proportionate measures. This requires knowledge of the socio-economic impacts of the measures and the possible alternatives. A lack of clarity about the way in which assessment and management are separated, and a lack of transparency on how opinions are translated into management measures help to erode the credibility of expert appraisals.

RECOMMENDATIONS

Concerning ANSES, the Scientific Board stresses that the Agency is already devoting constant attention and efforts to procedural issues (expert groups bringing together scientists chosen for their skills, subject to their independence in the sector in question). The same applies to its relationship with research (own research capacity, funding of programmes supporting studies to bridge gaps in knowledge, coordination of the European Partnership for the Assessment of Risks from Chemicals (PARC)). Internationally, the Agency is widely regarded as being at the forefront on these issues. However, ANSES is subject to the tensions affecting expert appraisals.

The lessons and recommendations from the three case studies analysed by the WG are particularly relevant to situations where there are major uncertainties and/or controversy among experts.

With a view to limiting the risk of expert appraisals being called into question, the Scientific Board has formulated four groups of recommendations aimed at improving procedures, shedding greater light on the decision-making process, increasing interactions with stakeholders, and reinforcing the separation of risk assessment and risk management within ANSES.

1. IMPROVE PROCEDURES

1.1. Expert groups

- Encourage scientific diversity (multidisciplinarity), as well as the dual presence of academic researchers and researchers familiar with regulations
- Promote expert participation and renewal
 - Encourage employers (universities, research operators, health agencies, expert appraisal institutes, etc.) to recognise scientific expert appraisals when assessing researchers/teacher-researchers and other staff, facilitate the implementation of expert appraisals (by making staff partially available, providing assistance with publication, etc.) and raise awareness of the major role played by expert appraisals in relations between scientists and society
 - Promote expert appraisal missions in the framework agreements between ANSES and its partners, as well as in research alliances; develop new agreements if necessary
 - Use hearings as often as necessary when ad hoc skills are required
 - Ensure regular renewal of the pool of experts in order to avoid an accumulation of mandates over time

- Strengthen application of the rules of collective expert appraisals
 - Clarify, for themselves and for the experts, the roles of the expert group chairperson, expert appraisal coordinator and ANSES staff participating in these groups, in accordance with the new provisions of the Agency's internal regulations
 - Strengthen the training/information of experts and ANSES staff on the rules, rights and duties of collective expert appraisals and on their protection against media exposure
 - Ensure that discussions and minority opinions are documented in the minutes of meetings
- Refine how personal interests are addressed, in particular by applying ANSES's proposed guidelines for the analysis of intellectual ties

1.2. Formal requests and internal requests

- Systematically enable the expert groups to express their views on the formulation of questions and the timetable for responding to them and, if necessary, provide for discussions with the supervisory authorities to clarify the request (subject, questions, deadlines and timetable for submission, etc.)
- Inform the expert groups of the stakeholder expectations expressed in ANSES's dialogue bodies
- Reserve the Emergency Collective Expert Appraisal Group (GECU) format exclusively for expert appraisals that can be completed within a short time frame, from the date of receipt of the formal request
- Arrange for long-term follow-up to ensure continuous monitoring of knowledge on complex issues where the health and/or media stakes are high
- Increase the Agency's use of internal request in order to anticipate foreseeable problems

1.3. Scientific alerts

- Formalise the handling of scientific alerts and encourage exchanges with the scientists issuing them

2. SHED GREATER LIGHT ON DECISIONS THROUGH THE EXPERT APPRAISAL PROCESS

- Work with the expert groups to systematically validate the literature selection taken into consideration and develop a method for systematic screening of personal interests in the deployed literature reviews (conflicts of interest among authors and publishers, funding of studies and scientific journals)
- Facilitate access to the data contained in regulatory dossiers
- Define a complete risk assessment grid, applicable in whole or in part depending on the situation, which includes the risk assessment, qualification of the level of uncertainty (according to the recommendations of the internal working group on "Support in implementing the recommendations of the risk assessment methodology"), an analysis of

the economic and social impacts (Expert Committee on "Socio-economic analysis"), and a study of the alternatives

- In the reports and opinions published by the Agency, systematically indicate the level of uncertainty, the scientific controversies (minority opinions, if any) and any divergence between the assessment carried out within the regulatory framework and the scientific knowledge produced outside the framework of the applicable guidelines
- Use the expert appraisals' recommendations on areas requiring improvements in knowledge to prioritise funding for research projects (carried out by ANSES laboratories or by external teams via research and development agreements or the National Research Programme for Environmental and Occupational Health), in particular to generate scientific data that can be used to develop standards or assessment methods
- Ask the expert groups to provide their criticisms and reservations on regulatory frameworks for risk assessment, and increase the Agency's role in developing international guidelines (OECD, EU)

3. CONTINUE INCREASING INTERACTIONS BETWEEN ANSES AND ITS STAKEHOLDERS

- Continue reporting to stakeholders on how their expectations have been taken into account by the Agency
- For management decisions that are the responsibility of ANSES, ensure the same level of clarification as that required for risk assessment
- Strengthen the links between ANSES and research operators/organisations
 - Make research teams more aware of the methodological prerequisites facilitating the use of their findings in expert appraisals
 - Make ANSES staff and experts more aware of the issues surrounding the interactions between expert appraisals, policy, and society
 - Support an inter-agency initiative to analyse mechanisms of production of ignorance and their influence on regulatory frameworks

4. STRENGTHEN THE SEPARATION OF RISK ASSESSMENT AND RISK MANAGEMENT AT ANSES

- Place all expert committees under the Science for Expertise Division
- Improve the clarity of the tasks performed by the Agency's different entities, particularly with regard to regulated products

In conclusion, implementing the proposed recommendations requires support in terms of adequate human and financial resources.