

## CODE OF ETHICAL STANDARDS FOR EXPERT APPRAISAL BY THE FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH & SAFETY

following discussions by the Board of Administrators on 29 November 2012

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### PREAMBLE

**Professional ethical standards** cover all the rights and obligations governing the activities and behaviour of those working in a given profession, within the framework of the rights and obligations defined by law. They apply collectively and are of a compulsory nature. They are based on values accepted across society and their proper respect guarantees the identity and credibility of the profession concerned in the eyes of that society, by ensuring full transparency in the relationship between the profession and its users or customers, whether public or private.

**A code of ethical standards** is a single document containing the full set of standards describing good professional practice, organised in a logical manner, taking as its basis certain general or partial legal principles and expressing them in the form of rules for correct conduct. A set of ethical standards also has an educational role, explaining the reasons for a legal framework and making sure that it is suited to a particular context which, in this case, means the ethical standards governing expert appraisals at ANSES.

**The code of ethical standards governing expert appraisals at ANSES** is an aspect of the general *principles of independence and impartiality* of good administrative behaviour, required of *any person holding public authority or discharging a public service mission*. Together with the principle of *keeping risk assessment separate from risk management*, these principles have been reaffirmed and reinforced in texts applying specifically to agencies in the field of public health and are intended to be applied across the entire field of environmental and occupational health.

The principles on which the Agency's expert appraisal practices are founded are based on Ministerial Order no. 2010-18 of 7 January 2010 establishing the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) classified under Articles L. 1313-1 *et seq.* of the French Public Health Code (CSP), in particular with the possibility for the Agency to set up Expert Committees (CES) to support it in its tasks, under the terms of Article L. 1313-6 of the CSP.

The provisions of Act no. 2011-2012 of 29 December 2011 on the strengthening of health protection with respect to medicinal and health products lay down the rules for transparency regarding relationships of interest for application to the Agency's expert bodies and personnel under the conditions described in Decree no. 2012-754 of 9 May 2012 on the public declaration of interests and transparency regarding public health and safety.

The Code is designed to guarantee the integrity, intellectual probity and impartiality of the ANSES expert appraisal system, to foster transparency within the expert bodies and encourage the individual responsibility of other people participating in these proceedings. By striving to avoid inappropriate or illegal behaviour, its purpose is to provide the basis for public confidence in the process of expert appraisals in the areas of health and the environment.

## **Article 1: Purpose**

The purpose of this Code, given the nature of ANSES as a public institution, the texts by which it was established and its Internal Rules and Regulations, is to define and specify its ethical standards in order to ensure, via the multiplicity of sources used, the impartiality and objectivity of its expert appraisal and the independence of its decisions and opinions, to facilitate dialogue with its supervisory ministries and the professionals involved, and to ensure that its operations are transparent for the general public.

## **Article 2: Scope**

This Code of Ethical Standards applies to all expert appraisals carried out under the responsibility of ANSES, and may also be extended to cover partners contributing to expert appraisals under contract.

### **TITLE I: GENERAL ETHICAL STANDARDS APPLICABLE TO ANSES EMPLOYEES AND EXTERNAL CONTRIBUTORS**

**Article 3:** ANSES employees and external contributors are required to comply with the general regulations applicable to civil servants laid down in Act no. 83-634 of 13 July 1983 defining the general status of state employees and describing the obligations incumbent on them, and Act no. 93-122 of 29 January 1993 concerning the prevention of corruption and guaranteeing the transparency of financial affairs and public procedures, as laid down in Article L. 1313-10 of the CSP.

## **Article 4: Obligation of impartiality**

In view of the obligation of impartiality and the principle of neutrality applying to public servants, ANSES employees and external contributors must not participate in any matters that may involve their personal interest, even indirectly.

They must not have any involvement likely to compromise their independence, in their own name or through third parties, in the companies or institutions with whom the Agency has to deal<sup>1</sup>.

Taking unlawful advantage of an interest is punishable by five years imprisonment and a fine of €75,000 and is defined in Article 432-12 of the French Penal Code as *“the taking, receiving or keeping of any interest in a business<sup>2</sup> or business operation, either directly or indirectly, by a person holding public authority or discharging a public service mission, or by a person holding a public electoral mandate who at the time in question has the duty of ensuring, in whole or in part, its supervision, management, liquidation or payment.”*

## **Article 5: No-gifts policy**

As specified in Paragraph 1 of Article L. 1451-2 of the CSP, persons required to file a public declaration of interests (PDI) may not receive gifts or gratuities in money or in kind, of any nature, either directly or indirectly, offered by companies providing services or producing or selling products reimbursed by mandatory social security schemes. This provision applies to companies operating within the sphere of competence of the Agency.

## **Article 6: Confidentiality<sup>3</sup>**

The obligation of confidentiality includes:

- professional secrecy, imposed in order to protect individuals, with infringements punishable under the Penal Code; this particularly concerns information regarding medical secrecy, industrial and commercial secrets and national defence, according to the conditions and sanctions laid out in Articles 226-13 and 226-14 of the Penal Code;

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<sup>1</sup> Articles L.1313-10 I, L.1451-1 and L.1452-3 of the CSP.

<sup>2</sup> "Business" is used here as a generic term to cover all forms of legal entity.

<sup>3</sup> Articles L. 1313-10 and L.1451-1 I of the CSP and Article 26 of Act no. 83-634 of 13 July 1983 on the rights and obligations of civil servants.

- discretion, requiring ANSES employees and external contributors not to divulge information or indications concerning their missions, imposed in order to protect ANSES and to ensure that its services function correctly; those infringing this rule are liable to disciplinary action.

Professional secrecy and discretion cover any information that may come to the notice of ANSES employees and external contributors in the performance of their duties, including not only information entrusted to them directly but also anything they may have seen, heard or understood<sup>4</sup>.

The fact that other people may already be aware of the information revealed does not affect their confidential and secret nature. ANSES employees and external contributors can therefore only be released from this obligation of professional discretion by express decision of ANSES or by legal procedures.

#### **Article 7: Obligation to exercise discretion**

Without prejudicing the application of the provisions of Article L.1451-1-1 of the CSP specifying the conditions for transparency regarding expert appraisal, public statements on subjects related to the Agency's missions must not adversely affect its interests nor bring it into disrepute.

ANSES employees and external contributors must exercise extreme restraint when expressing opinions and abstain from any critical remarks that by way of insult or inaccuracy might be damaging to the public service in which they work.

#### **Article 8: Guarantee of protection**

ANSES's Internal Rules and Regulations guarantee professional protection of its employees and external contributors under the same conditions as those provided by the regulations governing civil servants. Under their provisions, ANSES ensures the defence of its employees and contributors against threats, violence, blatantly illegal acts, insult, defamation or offensive comments to either themselves or those close to them, to their persons or their possessions, in the exercise of their functions.

#### **Article 9: Rules concerning the State Ethics Commission**

ANSES employees, whether civil servants or contract workers, who have been employed continually for at least a year, when leaving their positions either temporarily or permanently, are subject to the regulations<sup>5</sup> concerning the exercise of private activities.

##### **9.1: Bringing issues before the Commission**

Employees wishing to exercise a private activity must inform ANSES in writing at least one month before temporarily or permanently leaving their positions.

Prior to the employee taking up the intended activity, ANSES then places the issues before the Ethics Commission if said employee has been responsible:

- either for signing contracts of any type, or expressing an opinion on such contracts, with the private company that they wish to join;

- for proposing decisions concerning operations, or expressing an opinion on such decisions, carried out by the private company that they wish to join.

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<sup>4</sup> Without prejudicing the application of the provisions of Articles L.1451-1-1 and R.1451-6 of the CSP specifying the conditions for transparency regarding expert work, although group meetings, the opinions expressed in such meetings, the fact that a report has been forwarded, the tenor of its conclusions and the working procedures, among other details, are covered by confidentiality requirements, they are nonetheless covered by an obligation of discretion. This obligation prohibits ANSES employees and external contributors from mentioning the above details in public, in order to avoid compromising the smooth operation of the Agency and, more generally, the government departments with which it works. ANSES employees and external contributors may not infringe this obligation either at the request of their own line management nor that of any third party (persons from outside the Agency and not authorised to have knowledge of its operating procedures).

<sup>5</sup> Decree no. 2007-611 of 26 April 2007 amended with regard to the exercise of private activities by public employees or employees without tenure who have temporarily or permanently left their positions, and to the Ethical Standards Commission.

This requirement applies for the three years after employees leave their positions.

## - **9.2: An opinion from the Commission**

The Commission is requested to issue an opinion on whether the functions exercised within ANSES are compatible with whatever gainful activity the interested party wishes to practice, whether salaried or not, in a private company or other organisation, or a public organisation operating under the regime of private law in a competitive sector, or as a professional self-employed activity.

Employees are also subject to the provisions of Article 432-13 of the French Penal Code prohibiting them from practising any activity on behalf of certain of the companies with which they may have been in contact in the course of their functions, for a period of three years after leaving their positions.

## **TITLE II: EXPERT APPRAISAL ACTIVITIES AT ANSES AND ADDITIONAL RULES ON ETHICAL STANDARDS, SPECIFIC TO THOSE PARTICIPATING IN EXPERT APPRAISALS**

### **Article 10: Guidelines for expert appraisal activities**

Expert appraisal activities at ANSES comply with the principles of impartiality, transparency, plurality and adversarial debate specified in Article L.1452-1 of the Public Health Code.

Health risk assessments are carried out collectively by expert groups to ensure the possibility of open debate and the recording of any dissenting opinions.

To apply these principles, ANSES organises and defines the operating procedures for its expert appraisal activities, particularly by means of documents specifying the internal quality system for collective expert appraisals, in compliance with the requirements of the NF X 50-110 Standard.

### **Article 11: Selecting experts**

Successful expert appraisal depends on the selection of suitable experts.

ANSES proceeds by public calls for applications, ensures that the experts chosen possess the necessary competence and independence and strives to avoid any bias or discrimination in its choices.

ANSES takes steps to ensure professional pluralism in its expert bodies and regularly renews their members.

### **Article 12: The Agency's independence and impartiality in its contractual partnerships**

In order to ensure its independence and impartiality, ANSES sets a framework for its contractual relationships with private partners.

This partnership policy requires that special attention be given to contracts (service or research contracts). New or renewed contracts include specific standard clauses indicating that contractual obligations cannot contradict obligations resulting from the legal and regulatory requirements to which ANSES is subject, especially as regards risk assessment and marketing authorisations for veterinary medicinal products.

ANSES undertakes not to make partnership agreements under conditions likely to raise conflict of interest issues or to call into question the independence of the work it carries out and the opinions it publishes.

All exploitation contracts are examined, to ensure that the intended exploitation is the best solution in terms of public or animal health and the general interest, and is not likely to compromise the independence of ANSES. Under no circumstances may these contracts lead to remuneration for the Agency based on turnover by the partner in France or Europe, wherever the Agency has influence.

Partners for such contracts are chosen on the basis of objective and fully disclosed criteria. For this purpose, the Agency follows a procedure involving calls for expressions of interest.

ANSES takes great care to preserve:

- its scientific assets: licences for use (non-exclusive where possible) are preferred to contracts granting the permanent transfer of rights;
- fair and equal relations with the contractual partner: limited contract duration and the inclusion of exit clauses, in the event of total or partial absence of exploitation, for example;
- the financial aspects of the contractual cooperation: a fixed price, independent of actual commercial exploitation, is systematically preferred to payment of royalties. The price is calculated with a view to ensuring that the contract will be financially balanced.

### **Article 13: Independence and impartiality of those performing expert appraisals**

Persons participating in expert appraisal activities and therefore subject to obligations of impartiality must not deal with issues in which they have a direct or indirect interest, nor uphold any personal interest. They must act independently of all outside influence, consider only the assessment criteria of their own scientific disciplines, base their conclusions and their judgements on an objective analysis of all the data of which they have knowledge, and give particular attention to uncertain or contradictory data.

Persons participating in expert appraisal activities must consider whether the conditions under which they perform their mission enable them to perform it in total impartiality. If they have personal relationships with individuals or legal entities active within the field of their mission that could prevent such impartiality, or if they have had such relationships in the past, they must verify that these facts are not of a nature to bias their appraisal (whether positively or negatively), and in the event of uncertainty notify the Agency.<sup>1</sup> The most important aspect of this case is less any real bias that might result from these elements than perception by third parties of possible bias. The least suspicion, based on facts such as disputes between two people or the expression of certain positions in the past, would be enough to suggest a lack of impartiality.

### **Article 14: Public declaration of interests**

Members of expert bodies and employees of ANSES whose positions appear on the list drawn up by the Director General in compliance with Article 9 of the Agency's Internal Rules and Regulations must complete a written declaration of interests. This requirement also applies to persons invited to contribute their expertise to the aforementioned collegial bodies who are not members of these bodies.

In compliance with Article L.1451-1 of the CSP, they may not take part in the work, discussions or voting of the bodies to which they have been appointed until their public declaration of interests (PDI) has been completed. It must be updated in compliance with the regulations in force, as laid down by the Agency's Internal Rules and Regulations. It mentions relationships of interest of all kinds, whether direct or through an intermediary, held by the declarer, currently or during the five years before taking up his or her position, in companies, institutions or consultative bodies whose activities fall within the Agency's field of competence or that of the collegial body of which he or she is a member. The obligation to inform formalised by this declaration covers all interests, relationships or facts liable to give rise to conflicts of interest or incompatibility between the missions of individuals participating in the Agency's expert appraisal and their outside activities.

### **Article 15: Prevention and management of conflicts of interest for people participating in expert appraisal activities**

ANSES collects the public declarations of interest of people participating in expert appraisal activities in compliance with Article 14 of this Code of Ethical Standards. ANSES records the analysis of the declared relationships of interest carried out before each CES meeting, depending on the agenda, and identifies any risk of conflict of interests.

If any potential conflict of interests is identified regarding the case to be examined, the expert concerned is excluded from participating. Under the terms of Article L.1451-1 of the CSP, the expert cannot take part in the work, the discussions or the voting of the body to which he or she belongs.

However, work conducted by an expert with a conflict of interest may be taken into account, under the terms established by the Agency, especially by means of a hearing. However, this expert may not participate in any phase of the examination of the issue.

#### **Article 16: Transparency and traceability of decisions**

In accordance with Articles L.1451-1 and R.1451-2 of the CSP, PDIs submitted to ANSES are published, with the exception of specific details involving family relationships, sums of money collected and reported financial interests.

Publication complies with Article R.1451-3 of the Public Health Code, according to procedures specified by the Agency's Internal Rules and Regulations.

Although it guarantees the confidentiality of information covered by industrial, commercial and medical secrecy, ANSES publishes all its reports, opinions and recommendations and the methods used to reach them. It thus helps improve the sharing of available scientific knowledge and pursues the principle of reaching out to civil society.

In the event of disagreement between experts after the discussion phase, the Agency gives full expression to dissenting positions in the published Opinions.

ANSES is responsible for maintaining traceability of the expert appraisal process and conserving all items related to the expert appraisal work through to the finished product, including the Opinion, irrespective of whether a decision has been reached.

To this end, and in compliance with the provisions of Articles L.1451-1-1, R.1451-6 and R.1451-7 of the CSP, a full sound recording of the meetings of Expert Groups is made, in accordance with the procedures specified in the Agency's Internal Rules and Regulations, together with written minutes posted on the Agency's website, also in accordance with the procedures specified in the Agency's Internal Rules and Regulations. The minutes include the agenda, a record of the discussions, the details and explanations of voting, and any dissenting opinions.

#### **Article 17: Personal approach to the mission**

Experts carrying out missions for ANSES are appointed personally (*intuitu personae*); i.e. they may not delegate their authority to anyone else and must express themselves in their own name.

Experts have total freedom of scientific expression during working sessions.

#### **Article 18: Competence and "best efforts"**

In the context of their missions, and with due consideration for the resources available, experts must make their best effort to focus on the mission and carry out the tasks involved. They must take care to record a thorough account of the methodology followed, the sources used, hypotheses advanced and individuals questioned. They must comply with the Agency's quality standards.

This obligation applies to the resources engaged and not to the results obtained. As long as an expert can demonstrate that they made their best efforts and complied with the above-mentioned procedures, no blame can attach to them for having arrived at an erroneous conclusion.

ANSES experts must not accept an offer to work on a case for which they are not or do not consider themselves to be competent. If, while carrying out a mission, an expert is confronted by a question beyond the scope of his or her competence or falling within a different speciality, he or she must inform ANSES and assist the Agency in deciding how to proceed: suggest the appointment of another person, or cancel the mission that he or she lacks the competence to complete.

### **Article 19: Expression of personal opinions**

Except by prior written agreement from ANSES, experts may not exploit their status as experts for the Agency on any professional document for commercial use (offers of service, letterhead or business card).

Experts must refrain from publicly taking any position or acting in any way that might compromise the dignity of their functions or that of the public service with which they work. Experts may not speak in the name of ANSES, including concerning his or her missions, unless duly authorised.

Experts undertake to distinguish between information validated by ANSES and their own stated positions, which in no way commit ANSES. When speaking in their own names, experts must not leave any doubt as to the fact that they are not speaking on behalf of ANSES, for which they are carrying out an expert appraisal.

### **Article 20: Public appearances**

Under the provisions of Paragraph 2 of Article L.1451-2 of the CSP, persons mentioned in Article 14 of this Code of Ethical Standards who have links either with companies and organisations producing or exploiting health products or with consultative bodies concerned with such products, or with companies and organisations operating within the Agency's sphere of competence, must ensure that the public is aware of such links when either participating in a public event or in printed or audiovisual media concerning such products or the company's activities.

Such information may be conveyed either in writing, in the case of an article for publication in the press or on the Internet, or in writing or orally at the start of an oral presentation, in the case of a public appearance or a communication intended for the audiovisual media.

The Agency may dismiss anyone failing to respect these provisions.

## **TITRE III: SANCTIONS**

**Article 21:** Failure to abide by these provisions will lead to application of the sanctions specified in ANSES's Internal Rules and Regulations.