Press Kit

New missions for ANSES in the area of biocidal products

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Press release

New missions for ANSES concerning biocidal products

ANSES is today broadening its sphere of competence by taking over management of marketing authorisations (MAs) for biocidal products and responsibility for declarations to the biocidal products inventory (SIMMBAD). The Agency will build on the organisation it set up in July 2015 to issue marketing authorisations for plant protection products, while taking account of the specific features of the European regulation governing biocidal products. This regulation, applicable since 2013, seeks to ensure a high level of protection for humans, animals and the environment. **In gaining these new missions, the Agency strengthens the integrative approach it has adopted in the area of chemical risk, with the aim of safeguarding consumers and the environment.**

Biocidal products are mixtures or preparations consisting of active substances, to be used for domestic or industrial purposes with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Biocidal active substances and products are governed by a European regulation (EU No 528/2012), which has been in force since 2013 and aims to harmonise the placing on the market and use of these products in Europe. The main purpose of this regulation is to ensure **a high level of protection for humans, animals and the environment** by only placing on the market those biocidal products that are effective and do not entail unacceptable risks.

Until now, the Agency had been in charge of assessing biocidal active substances and products. Today, the Ministry of the Environment, which was previously responsible for issuing, withdrawing and amending MAs for these products, is transferring these tasks to the Agency.
Acquiring these new missions complements and strengthens the integrative approach adopted by the Agency in the area of chemical risk, with the aim of safeguarding consumers and the environment.

To carry out its new missions, the Agency will build on the organisation it set up on 1 July 2015 in the framework of the transfer of responsibility for MAs for plant protection products, fertilisers, growing media and adjuvants.

The Agency has also developed **guidelines**, which were submitted for public consultation in June, describing the criteria enabling it to exercise its power of judgement and thus reach individual decisions, on the basis of the scientific assessment of the MA application dossiers, carried out in compliance with the regulations.

The MA decisions taken will be made public *via* **a registry of decisions** accessible from the ANSES website. Lastly, the **Monitoring Committee,** created in the framework of the transfer of MAs for plant protection products, will have its sphere of competence broadened to include biocidal products. It can thus be consulted on the conditions under which the decisions will be taken, in particular on the management measures associated with the MAs, but also on the health and environmental benefits of the different biocide solutions available and the possible socio-economic impact of restrictions or prohibitions on the use of these products.

What are biocidal products?

Biocidal products are mixtures or preparations consisting of active substances, used for domestic or industrial purposes with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. These products, some of which are part of everyday life, include disinfectants, insecticides and other products to eliminate, destroy or repel fungi, bacteria, viruses, *etc.* The active substance found in the biocidal product can be a chemical compound or derived from a micro-organism exercising its biocidal action on or against the harmful organisms.

There are 22 types of biocidal products, divided into four groups:

- Disinfectants (human or animal hygiene, disinfection of surfaces, disinfection of drinking water, *etc.*),
- Preservatives (for products during storage, wood preservatives, construction material preservatives, *etc.*),
- Pest-control products (rodenticides, insecticides, repellents, *etc.*),
- Other biocidal products (embalming fluids, antifouling products, *etc.*).

Biocidal active substances and products are covered by a European regulation (EU No 528/2012) which aims to harmonise the placing on the market and use of these products in Europe.

The main purpose of this regulation is to ensure a high level of protection for humans, animals and the environment by only placing on the market those biocidal products that are effective and do not entail unacceptable risks. The measures it establishes are mainly designed to prevent long-term effects: carcinogenic or reprotoxic effects, or the effects of persistent, bioaccumulative and toxic substances.

How is the placing on the market of biocidal products regulated?

European Regulation (EU) No 528/2012, which came into force on 1 September 2013, follows on from European Directive 98/8/EC aimed at harmonising the regulations of the Member States of the European Union and ensuring the unity of the single market. The main purpose of this regulation is to ensure a high level of protection for humans, animals and the environment by only placing on the market those biocidal products that are effective and entail acceptable risks.

The Regulation is implemented in two phases:

- an **assessment of the biocidal active substances** leading to an approval regulation if the active substance fulfils the conditions for approval of **European** Regulation (EU) No 528/2012. The European Commission has drawn up a positive list of active substances approved at EU level.

- an **assessment of the products** (containing the approved biocidal active substances), which may lead to a national (valid only in the country that has issued the authorisation decision) or EU marketing authorisation (valid in all the countries of the European Union).

The making available on the market of a biocidal product, after authorisation under Regulation (EU) No 528/2012, requires an approval regulation to have been issued by the European Commission for all the active substances it contains.

Approval of active substances

Active substances are substances or micro-organisms (including viruses and fungi) exercising a general or specific action on or against harmful organisms.

The European regulation provides for an assessment of the biocidal active substances leading to a list of approved active substances at European level. This assessment is therefore the first step in the authorisation process.

The assessment of the active substances is carried out from three angles:

- assessment of the hazard intrinsic to the active substance;
- assessment of the exposure of humans, animals and the environment for certain proposed uses that are representative of the product-type;
- assessment of the substance's effectiveness.

The approval of an active substance therefore depends on the conditions of its use and, consequently, on the exposure of users and the environment. The approval of active substances is therefore specific to a product-type.

Provisions have been made in Regulation (EU) No 528/2012 to ensure a high level of protection, in particular the implementation of criteria relating to exclusion (Art. 5) and substitution of active substances (Art. 10), according to their hazard properties. In addition, adapted assessments are conducted for substances generated *in situ* or nanoparticle substances, to take account of their specific features.

Certain active substances **cannot be approved**, in particular:

- active substances classified as category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, in accordance with the CLP (**C**lassification, **L**abelling and **P**ackaging), or meeting the criteria to be classified as such,
- endocrine disruptors,
- substances that are PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative).

Waivers are possible if the risks are negligible (very limited exposure), if the active substance is essential for public health or environmental reasons, or if a ban would generate disproportionate consequences for society.

The availability of alternatives to the use of these substances is also taken into account when deciding whether or not to approve them.

Approval regulations and non-approval decisions are submitted to a vote by all the countries of the European Union in the framework of the Standing Committee on Biocidal Products, chaired by the European Commission.

Marketing authorisations for biocidal products

Once an approval decision has been made for all of a product's active substances for the product-type concerned, the product must obtain a marketing authorisation.

The data to be submitted in the MA application dossiers are defined in Regulation (EU) No 528/2012. In accordance with the regulations, the applicant must in particular provide:

- a dossier on the product,
- a proposed summary of product characteristics, which specifies in particular the uses of the product, as well as the conditions of use and associated management measures,
- a dossier for each active substance.

All these data enable ANSES to assess the effectiveness, and the hazards and risks associated with the use of the product for both humans and the environment. The conclusions of ANSES's assessment enable it to decide whether or not to authorise the placing on the market of the biocidal products.

The procedures for marketing authorisation by mutual recognition

In order to harmonise the European market and simplify the authorisation procedures for making products available on the market, the assessment of a biocidal product can be shared between the Member States concerned. In this case, the decision and, where appropriate, the authorisation conditions, are harmonised.

These procedures are known as "mutual recognition procedures". An application for mutual recognition may be made in several Member States at the time of submitting the first MA application on the European market. In this case, the mutual recognition is known as "simultaneous".

Mutual recognition can also be requested after a marketing authorisation has been granted by a Member State. In this case, the mutual recognition is known as "sequential".

New missions for ANSES as from 1 July 2016

At national level, ANSES coordinates the assessment of the hazards, risks and effectiveness of biocidal active substances and products for which application dossiers have been submitted in France, in accordance with the criteria defined by the European regulations. Marketing authorisations (MAs) are then issued on the basis of this scientific assessment of the effectiveness and risks of the products. Since 1 July, in application of the Act of 2 December 2015 concerning various provisions for adapting to European Union law, ANSES has also become responsible for issuing, withdrawing and amending MAs for biocidal products, in accordance with European Regulation (EU) No 528/2012, a mission that was formerly the responsibility of the Ministry of the Environment. The Agency also has responsibility for declarations to the biocidal products inventory (SIMMBAD). This same Act also discontinued "transitional[1]" MAs with effect from 3 December 2015. To carry out its new missions, ANSES will build on the organisation it set up in July 2015, for marketing authorisations for plant protection products.

An organisation guaranteeing independence and transparency

The Agency has been working for several months on the conditions under which these new missions will be implemented, relying on the organisation set up to issue decisions relating to plant protection products, for which it has been responsible since July 2015, and taking into account the specific features of the European regulation governing biocidal products.

The organisational arrangements for managing the issuing of marketing authorisations for biocidal products have to take into account the specific features of these products:

- a very broad field of products and uses,
- very tight regulatory deadlines,
- a European procedure that simultaneously addresses issues relating to assessment and management, and in which mutual recognition is predominant.

The regulatory procedure for assessment and authorisation of biocidal products is very similar to that in force in the area of veterinary medicinal products. Great importance is attached to collegial review between Member States, and harmonisation of conditions of use and management measures before the decision is made.

It was therefore important to define terms that preserve the independence of the assessment, while at the same time safeguarding the Agency's ability to effectively support its positions in assessment and management in the framework of the European procedure. Thus, two separate departments of the Agency are involved: the Regulated Products Assessment Department and the Department for Market Authorisations.

[1] MAs issued by the Ministry of the Environment according to national procedures, which concerned certain products for professional use (certain disinfection, rodent control and insect eradication uses). For these MAs, ANSES issued opinions on effectiveness and proposed a classification according to the CLP Regulation, but did not conduct a risk assessment.

The competences retained by the Ministry of the Environment

The management competence of the State and in particular the Ministry of the Environment, in conjunction with the Ministries of Health, Labour, the Economy and Finance and Defence, will continue to be exercised on:

- the **definition of acceptable risks**, on the basis of which ANSES will conduct the assessment and make a decision (guidelines, guidance documents, approval of active substances at European level);

- the **definition of general rules in the interest of public health or the environment** (the Act of 2 December 2015 concerning various provisions for adapting to European Union law strengthens the legal basis for taking such general supervision measures);

- the **possibility of temporary waivers** to authorise by ministerial order the placing on the market or use of a prohibited biocidal product (under the conditions laid down in Article 55(1) of the European regulation): these provisions enable emergency situations to be managed in the absence of any duly authorised treatment solution and have been used in recent years for vector control (epidemics of dengue or chikungunya) or control of the Asian Hornet;

- the possibility of **waivers** to preserve national defence interests;

- **enforcement of application of the rules** in primary production and among distributors.

- **Assessment of products and management of their marketing authorisations**

The dossier is assessed by a reference Member State. Following the assessment, if the product is deemed to be sufficiently effective, and if it does not present unacceptable risks to humans and the environment, this Member State prepares a product assessment report and may issue a MA. On this basis, applications for MA may be examined in other Member States according to the mutual recognition procedure.

In France, assessments of the risks and effectiveness of the products are carried out by ANSES, whether for the first assessment or for a mutual recognition procedure. For each application for a national MA (first MA or mutual recognition), the Regulated Products Assessment Department conducts the scientific risk assessment and prepares a synthesis document formalising the findings of the assessment. This document (called the "Assessment conclusions") indicates, for each claimed use, whether the effectiveness and the risks to animal health, human health or the environment are considered to comply with the requirements of the regulation. If necessary, management measures to ensure an acceptable risk are proposed. This document is then submitted for validation to the Expert Committee on "biocidal substances and products".

The draft decision, containing the summary of product characteristics, is prepared on the basis of the assessment conclusions.

In some cases, a further examination of the dossier or a series of dossiers raising a similar question may be carried out by the Monitoring Committee.

The **Monitoring Committee,** created in the framework of the transfer of MAs for plant protection products, has had its sphere of competence broadened to include biocidal products. The MA Monitoring Committee can thus be consulted on the conditions under which the decisions will be taken, in particular on the applicability of the management measures associated with the MAs, but also on the health and environmental benefits of the different biocide solutions available and the possible socio-economic impact of restrictions or prohibitions on the use of these products.

The entire Assessment Report, including the draft decision, amended where appropriate with observations from the review by the Monitoring Committee, is brought to the attention of the other Member States for discussion and harmonisation of conditions of use, before any decision is taken by ANSES.

ANSES publishes on its website the decisions relating to the MAs for biocidal products, recording them in a register. ANSES also publishes the conclusions of the assessment for each product that undergoes a scientific expert appraisal.

ANSES has developed **guidelines** specifying the principles adopted for issuing MA decisions. These guidelines describe the criteria enabling the Agency to exercise its power of judgement and thus reach individual decisions, on the basis of the scientific assessment of the MA application dossiers, carried out in compliance with the regulations.

In accordance with Articles L. 120-1 and L. 120-2 of the French Environmental Code, the Agency's proposed guidelines were submitted for public consultation from 30 May to 20 June 2016, in order to collect comments from the public, for examination before validation and publication of the final guidelines.

ANSES, biocidal substances and products in figures

The implementation of Regulation (EU) No 528/2012 in Europe has resulted in the number of MA dossiers increasing over the years, as the examination of the active substances has led to their approval at European level. The table below illustrates the gradual increase in the number of applications received in France.

For the Agency, 2015 saw a great deal of work to prepare for its new missions, in a context in which the assessment and authorisation scheme was gaining momentum, given the growing number of approved active substances.

Fifteen dossiers for a first MA for biocidal products were finalised in 2015. While the number of dossiers processed in 2014 slowed abruptly due to the entry into force of the new European regulation (this phenomenon was observed everywhere in Europe), the number of dossiers received at ANSES has been growing steadily over the last few months. Thirty applications for a

first MA for products or families of products were received in 2015 and are currently being examined.

In 2015, France was in third place in Europe in terms of the number of dossiers submitted for a first MA, which shows the recognition of the capacity of the ANSES teams to take part in the assessment of biocides within the community of Member States. This position is also reflected in ANSES's close involvement in the assessment of active substances.

The average time taken to process dossiers for a first MA for biocidal products continues to fall (15 months in 2013, 12 in 2015) and is approaching the target aimed at in the Agency's goals and performance contract (11 months).

Number and type of MA application dossiers for biocides received between 2012 and 2015

APPLICATION TYPE	2012	2013	2014	2015
1st MA: initial application	15	20	4	30
1st MA: minor/major amendment	2	31	10	27
Mutual recognition	52	88	46	82
Administrative requests	63	88	25	119
Other: R&D notifications, simplified, provisional MAs	1	1	1	11
Total	133	228	86	269

How to submit a MA application for a biocidal product

Who?

Applications for authorisation can be made by an individual or legal entity responsible for the placing on the market of the biocidal product. The applicant must have a permanent office in the European Union, and may be the future holder of the authorisation, or an individual/entity representing the applicant (third-party applicant).

How?

All applications for authorisation to place biocidal products on the market are to be submitted via the European R4BP (Register for Biocidal Products) platform managed by the European Chemicals Agency (ECHA). These applications all pass through the R4BP online platform. Thus, all the technical and administrative content of the dossier is digitised and placed on a secure platform.

This platform enables industrial companies and the authorities to exchange the information necessary for studying applications according to the assessment process defined by Regulation (EU) No 528/2012. ANSES, as the competent authority for France, accesses the applicant's dossier *via* this platform.

For more information on the submission of applications

Examination of MA application dossiers for biocidal products is conducted at national level. A helpdesk has been created to answer the questions of industrial companies wishing to submit such applications, when these questions relate to the application of national provisions. ANSES has set up this free service: http://www.helpdesk-biocides.fr/

At European level, the European Chemicals Agency's assistance service provides free advice to entities subject to the requirements of the regulations on biocidal products and responds to questions relating to European harmonisation. This service also offers support to users with ECHA's computer tools (such as R4BP).