

The Director General

Maisons-Alfort, 1 July 2015

Guidelines for issuing decisions on the marketing of fertilisers, growing media and fertiliser adjuvants

These guidelines have been established in the context of activities entrusted to ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, hereafter named “the Agency”, through application of Articles L.1313-1 to L.1313-6-1 of the French Public Health Code, last modified by the French Act on the future of agriculture, food and forestry adopted on 13 October 2014. This document presents the principles chosen by ANSES to guide the issuing of decisions on marketing authorisations (MA) for fertilisers, growing media and fertiliser adjuvants. It describes the criteria enabling the Agency to exercise its power of judgment on the basis of a scientific assessment of authorisation applications. The principles governing the marketing of fertilisers, growing media and fertiliser adjuvants are defined in Chapter V, Title V in Book II of the French Rural and Maritime Fishing Code (Articles L. 255-1 *et seq* and R.255-1 *et seq*).

These guidelines were submitted to public consultation in compliance with Articles L. 120-1 and L. 120-2 of the French Environmental Code.

They have been adopted by the Agency and shall be regularly revised after consultation of the committee to monitor marketing authorisations mentioned in Article L. 1313-6-1 of the Public Health Code. They are available on the Agency’s website at www.anses.fr.

1. General principles

Fertilisers, growing media and fertiliser adjuvants may be placed on the market without prior authorisation if they comply with the conditions of Article L. 255-5 of the Rural and Maritime Fishing Code and, more especially, with a standard having become mandatory or a European Union regulation that does not require prior marketing authorisation, or specifications approved by regulations guaranteeing their efficacy and safety.

For products requiring prior marketing authorisation, the assessment of MA applications submitted for fertilisers, growing media and fertiliser adjuvants takes into account Article L. 255-7 of the Rural and Maritime Fishing Code. It is summarised in a document giving the conclusions of the assessment.

Assessment conclusions indicate whether the product has harmful effects¹ on human health, animal health and the environment and whether it is effective with respect to the effects claimed under the recommended conditions of use. They shall therefore include:

- verification of the product’s constancy of composition (homogeneity, invariance, stability),

¹ In accordance with Article L. 255-7 of the Rural and Maritime Fishing Code

- an analysis of the physico-chemical, toxicological or environmental hazards able to be identified with respect to raw materials and the manufacturing process,
- an examination of the finished product's compliance with the safety criteria² defined for chemical and biological contaminants having reference values (concentrations and flux of ETM³, PAH⁴, PCB⁵ and microorganisms) for the requested use,
- an analysis of toxicology data (user, consumer), ecotoxicology and environmental data available for the finished product, taking into account insofar as possible likely exposure pathways leading, in certain cases, to classification under the regulations on dangerous preparations,
- an assessment of the product's efficacy and relevance of conditions of use, leading in particular to a suggested class and type, together with validation of claimed uses.

The conclusions also include any restrictions on use and/or risk management measures, together with requests for additional information (particularly monitoring of production processes), and specify, if relevant, the uncertainties arising from missing and/or contradictory data identified during the assessment procedure.

The application is assessed and validated within the Agency by the Regulated Products Assessment Department (DEPR), which acts independently from the Market Authorisations Department (DAMM), responsible for establishing draft decisions, according to the principle of functional separation between risk assessment and management. The Agency's quality management system, certified to ISO 9001 and regularly audited by an independent certifying body, guarantees traceability throughout the process.

The general principle to be applied to issuing of MAs is to only grant authorisation for a fertiliser, growing medium or fertiliser adjuvant if, for all or part of the claimed effects⁶, crops or crop categories and conditions of use, the assessment reveals the absence of any harmful effect on human health, animal health and the environment and its efficacy with respect to the effects claimed under the recommended conditions of use. In this context, the authorisation will be issued only for claims concerning effects, crops or crop categories and conditions of use that comply with these requirements, including in the decision restrictions on usage, appropriate risk management measures and any requests for additional information to be submitted for product authorisation.

The applicant will be notified of Agency decisions, which are also made public via the electronic register of decisions, rapidly accessible on the Agency's website. The assessment conclusions will also be posted on the website.

² As defined in Annex VII of CERFA document 50644#01 "Guide pour la constitution des dossiers de demande d'homologation Matières fertilisantes – Supports de culture" (Guide to application dossiers for the approval of Fertilisers – Growing Media)

³ MTE = Metal Trace Elements

⁴ PAH = Polycyclic Aromatic Hydrocarbons

⁵ PCB = PolyChlorinated Biphenyls

⁶ Direct and main effects on crops, growing media or *in situ* soil

2. Cases requiring further examination

In certain cases, the DAMM may need an additional examination of the application depending on its type and/or the result of the assessment in order to prepare the draft decision.

In these various cases, the MA monitoring committee covered by the French Act on the future of agriculture may be consulted by the Agency to shed light on decisions to be taken, particularly on the management measures relating to MAs but also on the agronomic benefits to be drawn from available products and their socio-economic impact.

Several situations warrant further examination before an authorisation decision is taken:

- when all or some of the risk management measures associated with the results of the assessment raise questions of feasibility in the field guaranteeing efficacy;
- in cases possibly justifying a change in or withdrawal of an MA currently in force:
 - o when new evidence reveals a harmful effect for human or animal health or the environment or when they demonstrate the product's inefficacy. In this case, the Agency re-examines the authorisation without waiting for expiry of the current MA in application of Article L. 255-15 of the Rural and Maritime Fishing Code on precautionary measures;
 - o when the duty to supply information needed for the approval decision is not fulfilled, the Agency may withdraw or change an MA in accordance with Article L. 255-11 of the French Rural and Maritime Fishing Code.

In the event of changes to or withdrawal of the MA currently in force, the Agency first informs the authorisation holder, who is allowed to make observations.

3. Specific case of MA requests by mutual recognition

In accordance with Article R. 255-17 of the Rural and Maritime Fishing Code, an MA by mutual recognition may be issued for fertilisers, growing media or fertiliser adjuvants if it is shown that the product has been legally placed on the market as a fertiliser, growing medium or fertiliser adjuvant in another European Union Member State.

4. Case of mixed products

In the case of a mixed product composed of a fertiliser or growing medium and a plant protection product, the principles behind the current guidelines and those behind guidelines for issuing decisions on plant protection products are applicable. MA applications for a mixed product are subject to a single decision by the Agency's Director General.

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KEYWORDS

Guidelines, decision, marketing authorisation, MA, fertilisers, growing media, adjuvants