

NOTE TO EDITORS

Update on the OSMOBIO case

Following the appearance in the media of several items on the status of a marketing application for a biocontrol herbicide from the company OSMOBIO, ANSES wishes to clarify the situation regarding this application and, in particular, to reiterate that the Agency is not currently in possession of the documents and data on the product necessary for assessing and processing the application for marketing authorisation, contrary to what OSMOBIO has stated in the media.

So-called "biocontrol" products are subject to the same requirements for the assessment of risks to users and the environment as chemical plant protection products, because the fact that substances are of natural origin does not guarantee the absence of risk. Products of natural origin may be highly toxic and present a risk to health and the environment.

OSMOBIO submitted an application to ANSES for marketing authorisation of a garden herbicide (for controlling weeds on paths) named *NETTOYANT ALLEES DALLAGES*, containing active substances of natural origin.

Upon receipt of the dossier, it became apparent that most of the necessary documents were missing, including the CERFA administrative application form, which in particular details the product's characteristics and its intended uses, as well as, for example:

- the entire composition (the active substances in the composition must previously have been approved at European level),
- the tests and studies for assessing the product's efficacy and its impact on health and the environment,
- the proposed product label.

The fee for processing the application (reduced to €2000 for biocontrol products, instead of €40,000) has also never been paid.

ANSES accordingly wrote to the company listing the items that had to be provided before the assessment phase could begin.

It should be noted that a document sent to ANSES in March 2017 brought some clarification concerning the composition and referred to tests carried out by INERIS and the DIRO (the authority responsible for roads in western France). However, these items did not correspond to those required by the regulations and requested since June 2014.

OSMOBIO has been contacted several times over the three years concerned, but to no effect. OSMOBIO sent a new email message on 31 August 2017 requesting information on the procedures for submitting a biocontrol application, without reference to the product named *NETTOYANT ALLEES DALLAGES*. ANSES sent a full answer on 4 September 2017.

Excluding these purely administrative exchanges, ANSES has not been contacted by OSMOBIO, nor has it received any request for an interview.

This case illustrates the broader issue of the ability of SMEs to submit applications that meet the regulatory requirements, which is a necessary condition for their assessment and approval, despite the fact that ANSES has set up a specific, fast-track procedure for processing biocontrol applications (shorter processing times and reduced fees) in order to facilitate their development.

For this reason, in line with other innovation support schemes (competitiveness clusters, structures helping start-ups achieve maturity and benefit from technology transfer, etc.), a support and guidance system for VSEs and SMEs should be set up to provide assistance in compiling applications for marketing authorisation, in order to facilitate their access to the biocontrol market. It would contribute substantially to the development of this pharmacopoeia based on substances of natural origin, and reduce the use of synthetic chemicals.

Find out more about [the marketing of biocontrol plant protection products](#).

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