

The mycoflora of bulk stored cocoa in the Port of Hamburg was investigated from winter 2013/2014 till late autumn 2014. The survey was conducted as part of a research project, which aimed at developing an integrated concept for protection of bulk stored commodities and was funded by the State Ministry of Economic Affairs, Transport and Innovation of the City of Hamburg. It was shown that growth of mycotoxin producing *Aspergilli* and other spoilage causing fungal species is not only a problem of storage in the producing countries. The specific characteristics of bulk stored commodities can form a variety of different microhabitats within a lot. Furthermore, frequently found species like *Aspergillus ruber* can act as a door opener for more fastidious fungi and insects.

Borderline Cases between Biocidal Products Regulation and Plant Protection Products Regulation

Carsten Dogs

Detia Freyberg GmbH Head of Regulatory Affairs, Dr.-Werner-Freyberg-Str. 11, D-69514 Laudendach, Germany,
E-Mail: carsten_dogs@detia-degesch.de
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Extended abstract

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Introduction - background

Legislation on the Single Market for goods aims to ensure that products placed on the EU market meet high health, safety and environmental requirements and that products allowed to be sold in the EU can circulate without barriers to trade, and with a minimum of administrative burden.

Plant protection products and biocidal products are used by professionals and non-professionals on harmful organisms, to destroy, deter or render them harmless. Before they can be placed on the market, the authorities are responsible among others for assessing the effectiveness of these products and the risks associated with their use.

Plant protection products are 'pesticides' that protect crops or desirable or useful plants. They will primarily be used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. Relevant function from a fumigation company point of view: protect plants or plant products against pests after harvest.

Regulation (EC) No 1107/2009 is the legislation concerning the placing of plant protection products (PPPs) on the market in the European Union.

Biocidal products used to control unwanted organisms that are harmful to human or animal health, or that cause damage to materials (e.g. dams and dikes). These harmful organisms include pests (e.g. insects, rats or mice) and microorganisms (e.g. moulds or bacteria).

Regulation (EC) No 528/2012 lays down the rules and procedures for authorization of biocidal products.

Both plant protection products and biocidal products contain at least one active substance. Before an active substance can be used within these kind of product in the European Union it must be officially approved.

Borderline cases

The determination of clear borderlines between the Plant Protection Products Regulation (EC) 1107/2009 and the Biocidal Products Regulation (EU) No 528/2012 is determined as a crucial issue for a proper implementation of both legislations. Sometimes difficulties may arise to decide which Directive applies to a given product and use.

The following criteria could be help to examine regarding the area of application:

- The intended purpose of the product.

- The target organism
 - If it is harmful to plant products, then the product will be considered as a plant protection product.
 - If it is harmful to humans or material (e.g. dams and dikes), then the product can be considered as a biocidal product.
- The place where the product will be applied to achieve the principal intended action.
 - Example: Products applied to the soil before sowing or planting of plants, are intended to destroy plant pests, and should be considered as plant protection products (e.g. soil fumigants).
 - In cases where products will be used for a general hygiene purpose (health protection), it is agreed, to consider these products as biocidal products (e.g. fumigants used in storage rooms for food).

Several documents to provide guidance to Member States on borderline cases are available. On the other hand, they are not legally binding since only the Court of Justice can give an authoritative interpretation of existing Community law. For instance, under the biocides legislation where the scope of the application is unclear, issues will be discussed at EU level.

In former times, when the EU Commission finalised decisions on scope issues, these were included in the Biocidal Manual of Decisions. Numerous borderline situations were settled in this document. Since 2015, this guidance provided in the Manual of Decision is obsolete. Now all information with regard to the submission process can be found on the European Chemicals Agency (ECHA) website (responsible for biocides).

Nevertheless, the Manual of Decision is still always a helpful tool for the industry to identify the correct regulatory scope. Again, this guidance is not law: it is not binding.

Practical example

Recently we had a question regarding the regulatory differentiation of the treatment of tobacco (storage protection, fumigation with phosphine-based products).

Status

In the beforehand mentioned biocidal Manual of Decision it was mentioned under 2.1.1.2.:

“According to the Guidance Document 2 on the borderline between biocides and plant protection products, products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves are plant products in the meaning of the Plant Protection Products Directive.

If the target organism is detrimental to plant or plant products then the product used is considered as a plant protection product either if applied directly on plants or plant products or applied indirectly on empty structures to control pests of plant or plant products exclusively.”

Reversal conclusion would mean that in case further processing steps are required it falls under the scope of the Biocides Regulation (EC) No 528/2012.

Tobacco

All tobacco are different, especially when it comes to curing the leaves. At first harvesting tobacco must be dried and cured. For instance, Virginia tobacco will be dried by ‘flue-curing’ where the leaves are hung for four to seven days in a drying barn and cured with warm air from a system of pipes. This drying process fixes the characteristic orange-yellow colour.

After tobacco is cured, it will be moved from the curing barn into a storage area for processing (e.g. involving several weeks of fermentation). The curing and fermentation processes establish the quality differences between tobaccos. While ‘drying’ may seem like a basic process, the end result is open to infinite variety, reflecting the weather and nutrients in the soil during growing, individual skill and expertise, as well as the type of drying process used.

Conclusions

Due to the fact there are definitely several steps within this treatment needed, it should fall into the above-mentioned Biocide Regulation. For fumigation purposes, only biocide products for product type 18 should be used, which have an approval.

Official feedback given by the German Authority BAuA (Federal Institute for Occupational Safety and Health):

"The storage protection of processed tobacco and tobacco products falls into the regulatory scope of the Regulation (EC) No 528/2012 and it needs a biocide approval. "Processed tobacco" correlates to tobacco after the pass of fermentation, which is in our opinion no simple pass."

ECHA confirmed this opinion too:

"The German competent authority has the possibility to consult with the other national competent authorities and/or to raise formally the issue to the European Commission by requesting a decision according to Article 3 (3) of the Biocidal Products Regulation. The fact that the German competent authority has not made a request for an Article 3 (3) decision indicate that they are confident in the validity of the answer they have provided you with."

Future prospects

However, a same product can be used in several situations and fall under both legislations. Dual authorizations would mean two dossiers, two contacts with different rapporteur Member States respectively evaluating Competent Authorities and two fees. Objective should be a better coordination at EU level and experience sharing between the Member States within the European Union.

A distinct answer by the legislator is required, under which regulatory scope the registration process should be started.

We need a pragmatic solution for the fumigation industry to reduce regulatory workload and costs. To avoid any confusion the industry would welcome a solution again, consisting of a document or database compiling all the answers relating to possible borderline cases. We need clear regulatory guidance.

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Customer complaints about insect contaminated ready meals

Lidia Limonta*, Sara Savoldelli, Daria P. Locatelli

DeFENS, Department of Food, Environmental and Nutritional Sciences, Università degli Studi di Milano, Via Celoria 2, 20133 Milan, Italy,

*Corresponding author: lidia.limonta@unimi.it

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Abstract

More than one-hundred food complaints about ready meals, coming from mass catering, were analyzed from 2003 to 2017. Even if insects in meals have an enormous negative impact on customers, the percentage relevance, considering the long period and the number of meals served, is negligible. Coleoptera (34%) was the most represented order, followed by Lepidoptera (27%), and Diptera (23%). Coleoptera insects were mainly field