Legislative Mapping Mycotoxins

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Summary Document

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1 Introduction

This document provides a summary of the legislative status of the mycotoxins within the HBM4EU Priority Substance Group. The mapping considers the relevant pieces of legislation under the European Chemicals legislative framework and International Conventions on chemical risk in order to provide an overview of relevant requirements for placing on the market, use and handling.

This document provides a tabulated summary of relevant legislation grouped by legislative area. It is to be used as an indication of those pieces of legislation which are applicable to the substances within this group. In order to provide more detailed information in an easier to read format, this document is supported by an excel database.

1.1 How to use the excel database

The Excel database provides detailed information, with links where appropriate, on the specific Article, Annex or Appendix which is applicable to the substance concerned. Substance identification information is provided for all substances including name, CAS number, EC number, HBM4EU category, and whether the substance is considered of high or medium priority by the HBM4EU Chemical Group Leads. All pieces of legislation are linked to the legal text on Eur-Lex. The database contains fourteen tabs which relate to groups of legislation or processes. The tabs are as follows:

- Table 1 – Links to information pages for each substance. This provides links to the Substance Information Pages, Brief Profiles (where applicable), and the CLI inventory on the ECHA website.
- Public consultations – summary of the status on public consultations for relevant regulatory processes. Includes Restriction intentions and SVHC intentions under REACH, CLH intentions, OELs.
- Table 2 – Legislative map. An overview of the applicable individual pieces of legislation. Where a piece of legislation is applicable to an individual substance it is marked by a Y (indicating yes). At the top of each section there is a link, which when clicked on will take you to the more detailed table found in subsequent tabs.
- Table 3 – POPs Regulation and PIC Regulation. Status and explicit provision.
- Table 4 – REACH Restriction process. Outlines specific entry within Annex XVII and the status of a Restriction intention.
- Table 5 – REACH SVHC/ Authorisation process. Outlines the specific entry in Annex XIV, whether a substance appears on the Candidate List and the status of an SVHC intention.
- Table 6 – REACH Evaluation process. Outlines the status on the PACT List and the CoRAP.
- Table 7 – CLP Harmonised Classification process. Current harmonised classification and the status of submitted CLH intentions.
- Table 8 – REACH Registration and Biocides. Outlines the Registered uses under REACH and the current status under the Biocidal Products Regulation.
- Table 9 – OELs on CAD/CMD. Status of OEL activity list status.
- Table 10 – other limit values. This provides the DNEL list of the DGUV, limit values under the Drinking Water Directive, Environmental Quality Standards, Groundwater limit values.
- Table 11 – Professional and Consumer legislation. Identifies the specific Article or Annex which is applicable to certain substances.
- Table 12 – OSH and Waste legislation. Specific Articles or Annexes applicable to certain substances.
- Table 13 – Environmental legislation. Specific Articles or Annexes applicable to certain substances.

1.2 Outline of this Summary Document

The summary information on legislative status presented in the Summary Document has been split by legislative group.

- Section 2 – International Conventions and Implementing EU Legislation.
- Section 3 – Cross Regulation Activities
- Section 4 – REACH Regulation
- Section 5 – CLP Regulation
- Section 6 – OSH Legislation
- Section 7 – Professional and Consumer Legislation
- Section 8 – Waste Legislation
- Section 9 – Environmental Legislation

As mentioned in the introduction, the information is tabulated and presents a tick-box style matrix, where a "Y" indicates the legislation is of relevance to the substance. Brief summaries are provided of the purpose of the relevant legislation. The tables indicate the substance identification information (name, CAS number) and indicates the HBM4EU category. Substances deemed of high importance to the HBM4EU Chemical Group Leads are highlighted in green and those of medium importance are highlighted in yellow. The categorisation of substances under HBM4EU is:

- Category A – substances for which HBM4EU data are sufficient to provide an overall picture of exposure levels across Europe, and interpretation of biomonitoring results in terms of health risks is possible. Improvement of knowledge for these substances will therefore focus on policy-related research questions and evaluation of the effectiveness of existing regulatory measures.
- Category B – substances for which HBM data exists, but not sufficiently to have a clear picture across Europe. Also, knowledge on the extend of exposure, levels and impact on the human health should be improved, in order to give policy makers relevant and strategic data to establish appropriate regulations and improve chemical risk management. Analytical method and capacities to monitor the substances across Europe might have to be improved.
- Category C – substances are substances for which HBM data scarcely or doesn't exists. Efforts to develop an analytical method to obtain relevant HBM results need to be done Hazardous properties of the substances are identified, yet greater knowledge on toxicological characteristics and effects on the human health is needed. Interpretation of HBM data is not possible, due to the lack of HBM guidance values.
- Category D – substances are substances for which a toxicological concern exists but HBM data are not available. HBM4EU research may be focused on the development of suspect screening approaches permitting to generate a first level of data enabling to document the reality of human exposure and better justify further investment in a full quantitative and validated method development.
- Category E – substances are substances not yet identified as of toxicological concern and for which no HBM data are available. A bottom-up strategy will be applied, consisting to non-targeted screening approaches coupled to identification of unknowns capabilities for revealing, and further identifying, new (i.e. not yet known) markers of exposure related to chemicals of concern for HBM (parent compound or metabolite).[1]

[1] HBM4EU (no date) Categorisation of Substances. Available at: https://www.hbm4eu.eu/categorisation-of-substances/ [Accessed 28/10/2019]

2 Summary of Mycotoxins legislation

The below table summarises what legislation affects mycotoxins.

Table 2-1: Simplified Summary Mycotoxins

Substance Name	CAS No.	CMD	CAD	Maximum levels of food contaminants Regulation	Tobacco Directive	Waste Framework Directive
Deoxynivalenol (DON)	51481-10-8		Y	Y	Y	Y
Fumonisin B1 (FB1)	116355-83-0	Y	Y			Y

3 International Conventions and Implementing EU Legislation

Mycotoxins are not subject to International Conventions and Implementing EU Legislation.

4 Cross Regulation Activities

Mycotoxins are not subject to PACT or CoRAP.

5 REACH Regulation

Mycotoxins are not REACH registered.

6 CLP Regulation

Mycotoxins do not have harmonised classifications or a registry of submitted CLH.

7 OSH Legislation

7.1 Carcinogens and mutagens Directive (CMD)

Legislative Act: Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

This Directive is an individual Directive within the meaning of Article 16 of the OSH Framework Directive. It aims to protect workers against risks to their health and safety, including the prevention of such risks, which may arise from exposure to carcinogens or mutagens at work. The definition of carcinogen and mutagen originally came from the Dangerous Substances Directive (67/548/EEC) or the Dangerous Preparations Directive (88/379/EEC). These classifications have been translated into CLP. Employers must abode by a hierarchy of measures, beginning with the obligation to reduce and replace carcinogens or mutagens where possible, prevent and reduce exposure where it is not possible to remove the substance, provide information and training to workers and carry out health surveillance in line with Member States.

7.2 Chemical Agents Directive (CAD)

Legislative Act: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

This Directive is the fourteenth individual Directive within the meaning of Article 16 of the OSH Framework Directive. It outlines the minimum requirements for the protection of workers health and safety arising, or likely to arise, from the effects of chemical agents in the workplace or the use of chemical agents at work. It applies where hazardous chemical agents are present or may be present at the workplace. Indicative occupational exposure limit values (IOELVs) are set at Community level. Member States are required to introduce a national occupational exposure limit value that takes into account the IOELV. Binding biological limit values (BBLVs) may be drawn up at Community level. Member States must establish a corresponding national binding biological limit value. There are a number of obligations for employers, including carrying out an assessment of the risk to health and safety arising from the presence of chemical agents and specific protection and prevention measures. The definition of a hazardous chemical agent is where it meets the criteria for classification under the Dangerous Substances Directive (67/548/EEC) or the Dangerous Preparations Directive (88/379/EEC). These classifications have been translated into CLP.

Table 7-1 below indicates how mycotoxins are regulated under OSH legislation.

Table 7-1: Applicable OSH Legislation

Cat.	Substance Name	CAS No.	CMD	CAD
C	Deoxynivalenol (DON)	51481-10-8		**Y**
C	Fumonisin B1 (FB1)	116355-83-0	**Y**	**Y**

8 Professional and Consumer Legislation

8.1 Maximum level food contaminants

Legislative Acts: Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

This regulation sets maximum levels for certain contaminants in foodstuffs, with a view to protecting public health. It sets forth maximum levels for certain contaminants in foodstuffs to keep them at levels which are toxicologically acceptable.

8.2 Tobacco Products

Legislative Acts: Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products

This Directive lays down the laws, regulations and administrative provisions of Member States with regard to:

- the ingredients and emissions of tobacco products, including reporting obligations for tar, nicotine and carbon monoxide;
- certain aspects regarding labelling and packaging of tobacco products, including health warnings, traceability and security features;
- prohibition of the placing on the market of tobacco for oral use;
- cross-border distance sales;
- notification of novel tobacco products;

the placing on the market and labelling of certain products, which are related to tobacco products, such as electronic cigarettes and refill containers and herbal products for smoking.

Table 8-1 below indicates how mycotoxins are regulated under professional and consumer legislation.

Table 8-1: Applicable Professional and Consumer Legislation

Cat.	Substance Name	CAS No.	Maximum levels food contaminants	Tobacco
C	Deoxynivalenol (DON)	51481-10-8	Y	Y
C	Fumonisin B1 (FB1)	116355-83-0	Y	

9 Waste Legislation

9.1 Waste Framework Directive

Legislative Acts:

- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives
- Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

This framework Directive lays down the measures to prevent or reduce the adverse impacts of the generation and management of waste by reducing resource use and improving efficiency of use. There are certain wastes excluded from the requirements of this Directive, such as radioactive waste. These are outlined in Article 2. The Waste Framework Directive presents a waste hierarchy which applies as a priority order in waste prevention and management legislation and policy. Requirements of this Directive are outlined for prevention of waste, recovery, reuse and recycling, and disposal. The properties of waste which render it hazardous are outlined in Annex III.

Table 9-1 below indicates how mycotoxins are regulated under waste legislation.

Table 9-1: Applicable Waste Legislation

Cat.	Substance Name	CAS No.	Waste Framework Directive
C	Deoxynivalenol (DON)	51481-10-8	**Y**
C	Fumonisin B1 (FB1)	116355-83-0	**Y**

10 Environmental Legislation

Mycotoxins are not subject to environmental legislation.

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