Annex to:

EFSA Panel on Contaminants in the Food Chain (CONTAM), Dieter Schrenk, Margherita Bignami, Laurent Bodin, James Kevin Chipman, Jesús del Mazo, Bettina Grasl-Kraupp, Christer Hogstrand, Jean-Charles Leblanc, Elsa Nielsen, Evangelia Ntzani, Annette Petersen, Salomon Sand, Tanja Schwerdtle, Christiane Vleminckx, Heather Wallace, Sven Daenicke, Carlo Stefano Nebbia, Isabelle P Oswald, Elena Rovesti, Hans Steinkellner and Laurentius (Ron) Hoogenboom, 2022 Scientific Opinion on the assessment of information as regards the toxicity of xxxxxxxxxxxxxxxxx. *EFSA Journal 2022*; xxxxxx, xxxxxx pp. doi: 10.2903/j.efsa.2022.xxxxxx

ANNEX A - Protocol for the information assessment for animal health related to the presence of Mycotoxins in feed - deoxynivalenol

The current protocol, or strategy, reports on the problem formulation and approach selected by the Panel on Contaminants in the Food Chain (CONTAM Panel) to perform an assessment of information as regards the toxicity of deoxynivalenol for horses and poultry other than laying hens and, if necessary, to update the scientific opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed.

The protocol is in accordance with the draft framework for protocol development for EFSA's scientific assessments (EFSA, 2020). This framework foresees that the extent of planning in the protocol (i.e. the degree of detail provided in the protocol for the methods that will be applied in the assessment) can be tailored to accommodate the characteristics of the mandate. Considering the timelines and the available resources, the CONTAM Panel applied a low level of planning (EFSA, 2020).

Should the need to amend the protocol emerge as the assessment proceeds, such amendments will be documented and justified.

A.1. Problem formulation

Objectives of the assessments

The CONTAM Panel published an Opinion on the risk assessment of deoxynivalenol (DON) in food and feed in 2017 (EFSA CONTAM Panel, 2017).

The objectives of the current assessment are to consider the additional information and comments submitted to the European Commission to assess the risk for toxicity in horses and poultry other than laying hens and, if necessary, update EFSA's previous scientific opinion on the risks to human and animal health related to the presence of DON in food and feed.

In case the CONTAM Panel decided to modify the reference points for DON in horses and poultry other than laying hens, the risks will be assessed against the animal dietary exposure assessment included in the previous EFSA opinion (EFSA CONTAM Panel, 2017).

Target populations

The target populations of the animal risk assessment for DON, are horses and poultry other than laying hens.

Adverse effects and endpoints

The animal risk assessment will address the adverse health effects associated with the exposure to DON in feed, as identified in the hazard identification step performed in the 2017 opinion.

Further considerations will be made by the WG during the assessment to re-evaluate existing and new evidence and take other adverse effects into account for the animal species under consideration.

Identification of the assessment sub-questions

A series of sub-questions to be taken into account will be answered and combined for performing the risk assessment. The sub-questions identified are reported in **Table A.1.2**.

For the **assessment**, studies in the target species will be used for the hazard identification and characterisation.

The specific studies which have been provided by the Commission as potentially generating a lower point of departure will be considered in the assessment. The studies are summarized in **Table A.2.1**.

The potential association between the target compound(s) and the endpoints of interest will be evaluated for each animal species of interest.

Table A.1.2. Sub-questions to be answered for the risk assessment

Risk assessment step	No	Sub-questions
Hazard identification	1	What adverse outcomes are caused by exposure to DON in horses/poultry other than laying hens
Hazard characterisation	2	What are the dose-response relationships between DON and relevant endpoints in the respective farm animals?

A.2. Method for answering the sub-questions

The sub-questions formulated in Table A.1.2 will be answered by a narrative approach. The research studies taken into account will be limited to those referred to by the Commission to inform an assessment to potentially derived a lower reference point for adverse effect on animal health, compared to the previous EFSA opinion (EFSA CONTAM Panel, 2017), but not be limited to these should other studies previously considered (or not) by the CONTAM Panel be deemed relevant.

The Working Group decided to perform a literature search to obtain further evidence to answer the formulated sub-questions, covering the period from 01/01/2017 until 01/02/2022 for the three animal species.

Table A.2.1 Selection of research studies to be (re)assessed

DON and its acetylated and modified forms	Poultry Antonissen et al. 2014. Yunus et al., 2012a Yunus et al., 2012b Horses Johnson et al., 1997 Khol-Parisini et al. 2012 Raymond et al., 2003 Raymond et al., 2005

The research studies on farm animals submitted for the assessment and those identified in the additional literature search will be considered for the hazard identification and characterisation. If possible, on the basis of the available evidence, a Reference Point (RP) will be derived for each animal

species of interest, together with an evaluation of possible uncertainties, which will be assessed in line with the guidance on communication of uncertainty in scientific assessments (EFSA, 2019).

A.3. Plans for updating the literature searches and dealing with newly available evidence

Given the limited nature of the opinion, aimed to assess submitted information rather than performing a comprehensive risk assessment, the WG does not foresee the need to perform repeated literature searches.

A.4. Public consultation

n/a

A.5. History of the amendments to the protocol

n/a

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