

Annex to:

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Leblanc J-C, Nielsen E, Ntzani E, Petersen A, Sand S, Schwerdtle T, Hoogenboom LR, Wallace H, Daenicke S, Nebbia CS, Oswald IP, Rovesti E, Steinkellner H and Hoogenboom LR, 2022. Scientific Opinion on the assessment of information as regards the toxicity of T-2 and HT-2 toxin for ruminants. EFSA Journal 2022;20(9):7564, 16 pp. <https://doi.org/10.2903/j.efsa.2022.7564>

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## **ANNEX A - Protocol for the development of the opinion**

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 T-2 and HT-2 toxins for ruminants, and, if necessary, to update the scientific opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxins 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 T2 and HT2 in food and feed in 2011 (EFSA CONTAM Panel, 2011).

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 ruminants and, if necessary, update EFSA's previous the scientific opinion on the risks to animal health related to the presence of T2 and TH2 in feed.

In case the CONTAM Panel decided to modify the reference points for the above mycotoxins and farm animals, the risks will be assessed against the animal dietary exposure assessment included in the most recent previous EFSA opinion (EFSA CONTAM Panel, 2011).

#### **Target populations**

The target populations of the risk assessment for T2 and HT2 in feed is ruminants.

#### **Adverse effects and endpoints**

The animal risk assessment will address the adverse health effects associated with the exposure to T2 and HT2 in feed, as identified in the hazard identification performed in the 2011 opinion.

Further considerations will be made by the Working Group (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 to perform the assessment. The sub-questions identified are reported in **Table A.1.1**.

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.1.1.** Sub-questions to be answered for the assessment

Risk assessment step	No	Sub-questions
Hazard identification	1	What adverse outcomes are caused by exposure to T2 and HT2 in ruminants
Hazard characterisation	2	What are the dose-response relationships between T2 and HT2 and relevant endpoints in ruminants?

## A.2. Method for answering the sub-questions

The sub-questions formulated in Table A.1.1 will be answered by a narrative approach. The research studies taken into account will be first of all 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, 2011), 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 01/01/2010 until 30/03/2022 for ruminants only.

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

T2 / HT2	<u>Ruminants</u> Hsu et al., 1972 Huszenicza et al., 2000 Kegl and Vanyi, 1991 Pier et al., 1976
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The research studies on ruminants 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, 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.4. 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.5. Public consultation

n/a

## A.6. History of the amendments to the protocol

n/a

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