Previous assessments

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This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

European Food Safety Authority (EFSA) 2012 opinion

7. In 2012, the European Food Safety Authority (EFSA) assessed the risks to public and animal health related to the presence of CIT in food and feed. Based on the available evidence, EFSA concluded that the establishment of a health-based guidance value (HBGV) would not be appropriate. While a concern for genotoxicity and carcinogenicity could not be excluded, EFSA did not consider the database sufficient to apply a margin of exposure (MOE) approach. Instead, the risk of CIT was characterised and a level of no concern set for nephrotoxicity in humans of 0.2 ug/kg bw per day. Based on the available exposure data EFSA was unable to reach a firm conclusion regarding the likelihood of consumers exceeding the level of no concern for nephrotoxicity on a daily basis over a prolonged period. A concern for genotoxicity and carcinogenicity could not be

excluded at the level of no concern for nephrotoxicity. This approach is discussed in more detail from paragraph 38.

Netherlands Food and Consumer Product Safety Authority (NVWA) 2015 risk assessment

8. The Netherlands Food and Consumer Product Safety Authority (NVWA) monitors the occurrence of mycotoxins in the Netherlands and advises the Dutch government on the food safety risks related to mycotoxins. In 2015, NVWA commissioned the National Institute for Public Health and Environment (RIVM) to produce a report in which a new literature search was performed to find out whether any new toxicity studies had been published since the EFSA opinion (2011 to 2015) that could be used to derive a benchmark dose (BMD) or a HBGV. The lowest BMD (lower confidence limit) (BMDL) derived from the studies was 48 µg/kg bw/day based on a reproductive toxicology study in rats. In their assessment, RIVM agreed with EFSA's concern regarding the genotoxicity and/or carcinogenicity of citrinin due to the lack of new evidence published since the EFSA opinion. The approach and outcomes are discussed further from paragraph 42.