SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 12 July 2022

doi: 10.2903/j.efsa.2022.7524

Decontamination process for dioxins and dioxin-like PCBs from fish oil and vegetable oils and fats by a physical process with activated carbon

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Abstract

Following a request from the European Commission, the EFSA Panel on Contaminants in the Food Chain (CONTAM) assessed a decontamination process of fish oils and vegetable oils and fats to reduce the concentrations of dioxins (polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans, abbreviated together as PCDD/Fs) and dioxin-like polychlorinated biphenyls (DL-PCBs) by adsorption to activated carbon. All feed decontamination processes must comply with the acceptability criteria specified in the Commission Regulation (EU) 2015/786. Data provided by the feed food business operator (FBO) were assessed for the efficacy of the process and to demonstrate that the process did not adversely affect the characteristics and properties of the product. The limited information provided, in particular on the analysis of the samples before and after decontamination, did not allow the CONTAM Panel to conclude whether or not the proposed decontamination process is effective in reducing PCDD/Fs and DL-PCBs in the fish- and vegetable oils and fats. Although there is no evidence from the data provided that the decontamination process leads to detrimental changes in the nutritional composition of the fish- and vegetable oils, it is possible that the process could deplete some beneficial constituents (e.g. vitamins). Taken together, it was not possible for the CONTAM Panel to conclude that the decontamination process as proposed by the FBO is compliant with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

Keywords: decontamination process, PCDD/Fs, PCBs, fish oil, vegetable oil and fat, physical filtration

Requestor: European Commission

Question number: EFSA-Q-2021-00629

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank Federico Cruciani for his support in the preparation of this opinion.

Suggested citation: 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, Hoogenboom L, Leblanc J-C, Nebbia CS, Nielsen E, Ntzani E, Petersen A, Sand S, Schwerdtle T, Vleminckx C, Wallace H, Rose M, Cottrill B, Lundebye AK, Metzler M, Christodoulidou A and Hogstrand C, 2022. Scientific Opinion on the decontamination process for dioxins and dioxin-like PCBs from fish oil and vegetable oils and fats by a physical process with activated carbon. EFSA Journal 2022;20(9):7524, 11 pp. https://doi.org/10.2903/j.efsa.2022.7524

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Directive 2002/32/EC[1] of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[1] provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive is prohibited.

Directive 2002/32/EC provides also that Member States are to ensure that measures are taken to guarantee the correct application of any acceptable detoxification process on products intended for animal feed and the conformity of those detoxified products with the provisions of Annex I of that Directive.

In order to ensure a uniform assessment across the European Union of the acceptability of detoxification processes, acceptability criteria for detoxification processes have been established at Union level by Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council.

The acceptability criteria for detoxification processes established by the Regulation shall ensure that the detoxified feed does not endanger animal and public health and the environment and that the characteristics of the feed are not adversely altered by the detoxification process. The Regulation furthermore provides that the compliance of a detoxification process with those criteria shall be scientifically assessed by the European Food Safety Authority (EFSA) on a request from the Commission.

The Commission has received the application of a detoxification process of fish oil and vegetable oils and fats for dioxins and dioxin-like PCBs by a physical process with activated carbon for assessment by EFSA of compliance with the acceptability criteria.

Terms of Reference

In accordance with Art. 29 (1) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority for an assessment of an application of a detoxification process of fish oil and vegetable oils and fats for dioxins and dioxin-like PCBs by a physical process with activated carbon for compliance with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

1.2. Interpretation of the Terms of Reference

EFSA received from the European Commission requests for scientific opinions on the assessment of applications referring to feed 'detoxification processes' to be compliant with acceptability criteria specified in the Commission Regulation (EU) 2015/786 of 19 May 2015.[2] In this context the term 'detoxification' is interpreted as either decontamination by removing the contaminants or by chemical or biological processes able to reduce the toxicity of the contaminants present.

This scientific opinion assesses the physical decontamination process of fish oils and vegetable oils and fats contaminated with organic lipophilic components (i.e. dioxins and dioxin-like PCBs) by means of treatment with activated carbon. With this approach, levels of dioxins (i.e. polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans, abbreviated together as PCDD/Fs) and dioxin-like polychlorinated biphenyls (DL-PCBs) are reduced in the processed oils and fats.

The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that the Terms of Reference provided by the European Commission were clear and that the opinion for the assessment of this physical decontamination process should mainly focus on data in order to:

- enable the assessment of the efficacy of the process to remove the contaminants from the feed batches to ensure compliance with the requirements of Directive 2002/32/EC, and
- demonstrate that the decontamination process does not adversely affect the characteristics and the nature of the feed.

Information concerning the safe disposal of the removed part of the feed was also considered.

[1] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10–21.

[2] Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification process applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council. OJ L 125, 21.5.2015, p. 10–14.

1.3. Additional information

The feed food business operator has provided the European Commission with information referring to the proposed decontamination process and its effectiveness as laid down in Directive 2002/32/EC.

1.4. Legislation

According to Directive 2002/32/EC as amended by Commission Regulation (EU) 2019/1869[3], for feed materials, a maximum content of 0.75 ng/kg for the sum of PCDD/Fs and of 1.5 ng/kg for the sum of PCDD/Fs and DL-PCBs in WHO-PCDD/F-PCB-TEQ[4] applies for vegetable oils. For fish oil a maximum content of 5.0 ng WHO-PCDD/F-TEQ/kg for the sum of PCDD/Fs and of 20.0 ng WHO-PCDD/F-PCB-TEQ/kg for the sum of PCDD/Fs and DL-PCBs applies. In addition, within the European Union action thresholds for feed products are laid down in Directive 2002/32/EC, last amended as regards dioxins and PCBs by Commission Regulation (EU) No 744/2012[5]. For vegetable oils the action threshold is of 0.5 ng WHO-PCDD/F-TEQ/kg for the sum of PCDD/Fs and 0.5 ng WHO-PCB-TEQ for the sum of DL-PCBs. For fish oil the action threshold is 4.0 ng WHO-PCDD/F-TEQ/kg for the sum of PCDD/Fs and 11.0 ng WHO-PCB-TEQ/kg for the sum of DL-PCBs.

Specific requirements concerning the methods of sampling and analysis for the official control of feed are laid down in Commission Regulation (EC) No 152/2009[6], as regards dioxins/PCBs last amended by Commission Regulation (EU) No 2017/771[7].

2. Data and methodologies

2.1. Data

The feed food business operator has submitted information in support of its claim regarding the efficacy of the decontamination process of fish oils and vegetable oils and fats from PCDD/Fs and DL-PCBs by adsorption to activated carbon followed by physical filtration. The documents provided included information on the decontamination process, on control steps and on analytical data (certificates of analysis).

The CONTAM Panel based its assessment on the information provided (see section 'Documentation provided to EFSA') to address the Terms of Reference.

2.2. Methodologies

The CONTAM Panel evaluated the acceptability of the proposed decontamination process as requested by the relevant regulations, specifically Directive 2002/32/EC and Commission Regulation (EU) 2015/786 and their Annexes. The assessment is conducted in line with the principles described in the EFSA guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and following the relevant existing guidance from the EFSA Scientific Committee, as appropriate and as depicted in the protocol of the Annex.

3. Assessment

3.1. Identity of the contaminants

Dioxins and polychlorinated biphenyls (PCBs) are toxic chemicals that persist in the environment and accumulate in the food chain. Dioxins, which are tricyclic planar compounds, can be divided into two groups: Polychlorinated dibenzo-*p*-dioxins (PCDDs) and dibenzofurans (PCDFs). Dependent on the number of chlorine atoms and their positions at the rings, 75 PCDDs and 135 PCDFs can occur. Only the 17 PCDD/Fs containing at least 4 chlorine atoms and substituted at positions 2, 3, 7 and 8 are of

[3] Commission Regulation (EU) 2019/1869 of 7 November 2019. OJ L 289, 8.11.2019, p. 32–36.
[4] Expressed in World Health Organization (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) as upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.
[5] Commission Regulation (EU) No 744/2012 of 16 August 2012. OJ L 219, 17.8.2012, p. 5–12.
[6] Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. OJ L 54, 26.2.2009, p. 1–130.
[7] Commission Regulation (EU) 2017/771 of 3 May 2017 amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls. OJ L 115, 4.5.2017, p. 22–42.

toxicological concern. PCBs are a group of organochlorine compounds that are synthesised by catalysed chlorination of biphenyl. Depending on the number of chlorine atoms (1–10) and their position on the two rings, 209 different compounds, also termed 'congeners', are possible. Some PCBs referred to as dioxin-like PCBs (due to their similar toxicological properties) are considered together within the context of public health. These DL-PCBs consist of 12 congeners that are non-*ortho* or mono-*ortho* chlorine substituted. Congeners in this group contain at least four chlorine substituents, can easily adopt a coplanar structure and show toxicological properties similar to PCDD/Fs. PCDD/Fs and DL-PCBs have different potencies as reflected in so-called Toxic equivalency factors (TEFs). After correction for these TEFs, the total content is summed and expressed in Toxic Equivalents (TEQs).

3.2. Method of analysis

The analysis of the samples took place prior to the entry into force of Commission Regulation (EU) No 709/2014[8] of 20 June 2014 amending Regulation (EC) No 152/2009[9] as regards the determination of the levels of PCDD/Fs and DL-PCBs, in line with the US EPA Method 1613,[10] with the exception of one sample analysed in line with Commission Regulation (EU) No 2017/771. The analytical reports provide the upper bound concentrations, but the lower bound values were missing. Furthermore, WHO_{98}-TEFs were applied. The CONTAM Panel used the data provided to calculate LB and UB levels based on WHO_{05}-TEFs.

3.3. Decontamination process

3.3.1. Description of the process

The feed food business operator (FBO) proposes a three-step process to lower the concentrations of PCDD/Fs and DL-PCBs in contaminated fish oils and vegetable oils and fats, which consists of adsorption of these contaminants to activated carbon followed by removal of the carbon by filtration (Figure 1). Information on two batches of vegetable oil and three batches of fish oil has been submitted to assess the process, which according to the FBO is effective for reducing PCDD/Fs and DL-PCBs from fish oils and vegetable oils and fats both before and after hydrogenation. The process is not suitable for removal of non-dioxin-like PCBs.

The process of adsorption from liquid media to activated carbon is well known for PCDD/Fs and DL-PCBs, and evidence of its efficacy is available in the scientific literature (Eppe et al., 2005; Maes et al., 2005; Oterhals et al., 2007). The effectiveness of the procedure may vary depending on different factors such as the medium to be decontaminated, the level of impurity and its composition in terms of congener profile, and the use of specific activated carbon.

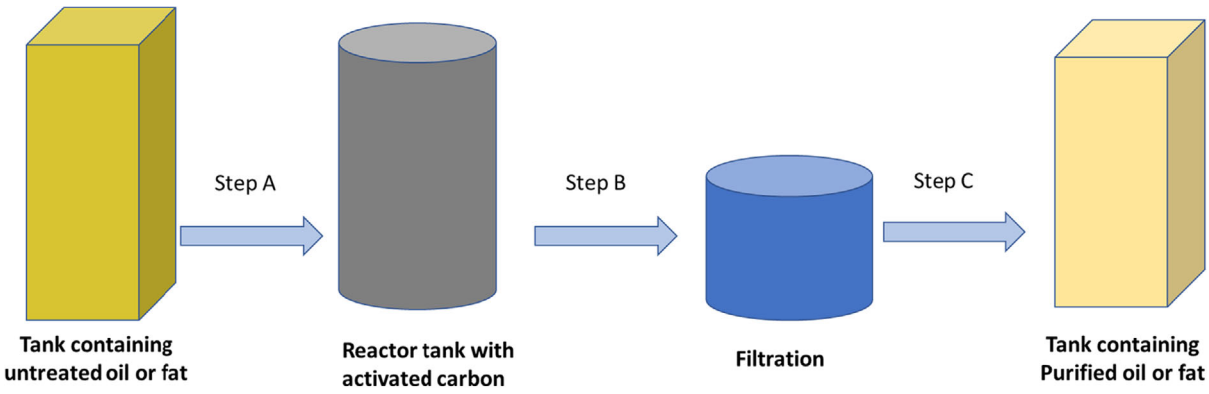

Figure 1: Schematic diagram of the process used by the feed food business operator

[8] Commission Regulation (EU) No 152/2009 of 20 June 2014 od 27 January 2009 laying mending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls. OJ L 54, 26.2.2009, p. 1–169.
[9] Commission Regulation (EU) No 709/2014 of 20 June 2014 down the methods of sampling and analysis for the official control of feed. OJ L 188, 27.6.2014, p. 1–18.
[10] Method 1613: Tetra-Through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS, September 1994. United States. Environmental Protection Agency. Office of Science and Technology. Engineering and Analysis Division. https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20002GR6.txt

The contaminated oil or fat is first transferred to the reactor tank (step A), which is heated to at a certain temperature with agitation. After application of a temporary vacuum the activated carbon is added. The activated carbon is removed by filtration (step B) and collected in a storage tank (step C). Three samples taken from the storage tank are combined to obtain a representative sample, which is analysed for the level of PCDD/Fs and DL-PCBs by an accredited laboratory.

The filters are changed when the efficacy of the procedure for removing PCDD/Fs and DL-PCBs decreases. The used filters containing the activated carbon are disposed by a specialised waste company.

3.3.2. Efficacy of the process

The FBO provided data on three fish oil and two vegetable oil samples that were treated using the proposed process. For two fish oil samples, they provided data on the original material, the material after treatment with bentonite earth for decolourisation and after additional treatment with activated carbon. However, both fish oils had PCDD/F and DL-PCB levels below the regulatory limits for feed materials already before they were processed. Levels of most PCDD/Fs in the original material were below the LOQs and as such are not suitable to demonstrate the efficacy of the process. When focusing on the lower bound levels, there is a reduction of 70% and 78% for the PCDD/F-TEQ and 81% and 90% for the DL-PCB-TEQ (based on WHO05 TEFs). Results seem to be derived from an experimental setting and it is unclear to what extent it applies to large-scale production. Two additional analytical reports were provided for fish oil samples, the first one with much higher PCDD/F-TEQ and DL-PCB-TEQ levels, being 3.7 and 29.3 ng TEQ/kg oil (88% DM), the sum-TEQ exceeding the ML of 20 ng TEQ/kg (88% DM). The second report by another laboratory, which might be presumed to refer to the treated oil, shows concentrations of 0.2 and 10.2 ng TEQ/kg (88% DM) for PCDD/Fs and DL-PCBs, implying a reduction of, respectively, 95% and 65%, and 69% for the sum-TEQ, reducing it to half of the regulatory levels. NDL-PCBs were also determined in these samples with levels of 322 and 310 μg/kg (88% DM), both exceeding the regulatory level of 175 μg/kg. The CONTAM Panel noted that the description of the latter two samples is rather sparse but that based on the replies of the applicant, this confirms that the procedure has the potential to reduce the concentrations of PCDD/Fs and DL-PCBs but not those of the NDL-PCBs.

Considering vegetable oils, the applicant provided data on a crude oil and on two hydrogenated palm fatty acid distillates (HPFAD) treated with the activated carbon process and after addition of extra activated carbon. It is unclear if the vegetable fat used as starting material was sampled before or after hydrogenation, which can be relevant when the sample contains higher concentrations of higher chlorinated PCDD/Fs. The PCDD/F-TEQ levels in this material was 2.2 ng TEQ/kg, which exceeding the regulatory limit. These were reduced to 1.5 and 0.6 ng TEQ/kg by the treatment with the two different amounts of activated carbon. Only the latter one was below the maximum level of 0.75 ng TEQ/kg, but above the action threshold of 0.5 ng TEQ/kg. The DL-PCB concentrations were too low to judge the efficacy of the process (< 0.01 ng TEQ/kg). Results for a second batch of oils, at least the treated one being an HPFAD again, showed PCDD/F levels of 1.4 and 0.4 ng TEQ/kg (UB, but similar to LB). This implies a reduction of 73% of the PCDD/F concentration.

3.4. Characteristics and nature of the processed oils and fat

3.4.1. Fish oil

Characterisation of the fish oil used in this report was restricted to the fatty acid composition determined by gas chromatography. Three samples of oil were taken before treatment and again after treatment with activated carbon. These were combined to provide a representative sample and analysed for their fatty acid composition. No differences between samples before and after treatment were observed that might not be explained by normal between-sample variation.

3.4.2. Vegetable oil

The report provides details of the fatty acid composition (determined by gas chromatography) of the palm oil before and after treatment with activated carbon. No further information regarding the composition of the oil was provided. As for the fish oils (above), three samples of oil were taken pre- and post-treatment and combined to provide two representative samples. Although published data for the composition of palm fatty acids vary, due principally to differences in processing, the composition

of the oil pre-treatment are broadly in line with published data. The small differences in the fatty acid composition of the oils following treatment might be explained by normal between-sample variation.

3.5. Disposal of the removed materials

The FBO submitted information about the removal and disposal of the used adsorbent. Following separation of the oil by filtration, the residue is stored in a metal drum, labelled as waste, and collected by an authorised company specialising in disposal of hazardous waste. The same process applies to both the fish and vegetable oils.

3.6. Discussion

The CONTAM Panel assessed the information made available in the documents submitted by the FBO and was of the view that insufficient information was available to conclude on the efficacy of the proposed decontamination process for PCDD/Fs and DL-PCBs from fish oil and vegetable oil and fat. To make such conclusions, the Panel would require analytical results before and after decontamination from at least three recent batches of each type of material generated from the process as proposed. The initial material should contain PCDD/Fs and DL-PCBs exceeding regulatory limits.

A description of the decontamination process was provided together with a process chart. The Panel also considered that a good general and practical knowledge for decontamination of vegetable and fish oil exists. However, the FBO gave insufficient evidence to conclude on the specific process as proposed.

The samples used were not adequately described and therefore the CONTAM Panel was not able to conclude on the efficacy of the decontamination process. The proposed process appears to be effective in reducing PCDD/Fs and DL-PCBs from the fish and vegetable oil products; however, more information would be required to support these findings.

It was stated by the FBO that each final product batch is released only after analytical control to verify regulatory compliance for PCDD/Fs and DL-PCBs. Batches that contain high concentrations of PCDD/Fs and DL-PCBs are likely also to contain high concentrations of NDL-PCBs and regulatory compliance for the latter needs to be met.

Experimental evidence was available for the fatty acid composition of the treated materials, and the CONTAM Panel was of the view that in principle the use of activated carbon should not result in any detrimental changes in the fatty acid composition of the decontaminated oils and fats. It is possible though that the process of decontamination could deplete levels of some beneficial constituents (e.g. lipid soluble vitamins (Maes et al., 2005)). There is little chance that hazardous substances are introduced into the final product.

The FBO reported that as soon as the efficacy of the decontamination procedure starts to decline, the activated carbon is replaced and it is properly disposed by a specialised waste company. The CONTAM Panel noted that it is the responsibility of Member States to ensure that measures are taken to guarantee the correct application of any acceptable decontamination process on products intended for animal feed, and the conformity of those decontaminated products with the provisions included in the Commission Regulation (EU) 2015/786 and its Annexes.

3.7. Uncertainty analysis

According to the interpretation of the Terms of Reference the assessment of a physical decontamination process should mainly focus on the evaluation of the efficacy of the process to remove the contaminants and on the evidence that the characteristics and the nature of the final product are not adversely affected.

Efficacy of the process: Due to the lack of the data requested an uncertainty analysis cannot be performed.

Characteristics of the product: The CONTAM Panel considered it very likely that the use of activated carbon will not result in any detrimental changes in the fatty acid composition of the decontaminated oils and fats. Characteristics and nature of the fish- and vegetable oil from decontaminated batches were only partially described, and therefore some uncertainty on the impact of the process on other than fatty acid composition characteristics of the final product remains.

4. Conclusions

- On the basis of the information submitted by the feed food business operator, the CONTAM Panel could not conclude whether or not the proposed decontamination process is effective in reducing PCDD/Fs and DL-PCBs in the fish oil and vegetable oils and fats;
- There is no evidence from the data provided that the decontamination process leads to detrimental changes in the nutritional composition of the fish- and vegetable oils; however, it is possible that the process could deplete some beneficial constituents (e.g. vitamins).
- Overall, it was not possible for the Panel to conclude that the decontamination process is compliant with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

5. Documentation as provided to EFSA (if appropriate)

Report on detoxification procedure (Dioxins and PCBs) for fish oil under Regulation (EU) 2015/786. September 2021. Submitted by AFAMSA.

Report on detoxification procedure (Dioxins and PCBs) for vegetable oil and fats under Regulation (EU) 2015/786. September 2021. Submitted by AFAMSA.

Report on detoxification procedure (Dioxins and PCBs) for fish oil under Regulation (EU) 2015/786. March 2022. Submitted by AFAMSA.

Report on detoxification procedure (Dioxins and PCBs) for vegetable oil and fats under Regulation (EU) 2015/786. March 2022. Submitted by AFAMSA.

Answer to EFSA questions. March 2022. Submitted by AFAMSA.

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Maes J, De Meulenaer B, Van Heerswynghelsa P, De Greyta W, Eppec G, De Pauwc E and Huyghebaertb A, 2005. Removal of dioxins and PCB from fish oil by activated carbon and its influence on the nutritional quality of the oil. Journal of the American Oil Chemists' Society, 82, 593–597.

Oterhals Å, Solvang M, Nortvedt R and Berntssen MHG, 2007. Optimization of activated carbon-based decontamination of fish oil by response surface methodology. European Journal of Lipid Science and Technology, 109, 691–705.

Abbreviations

Activated carbon	Charcoal that has been treated to increase its adsorptive power
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
DL-PCBs	dioxin-like polychlorinated biphenyls
FBO	food business operator
NDL-PCBs	non-dioxin-like polychlorinated biphenyls
PCBs	polychlorinated biphenyls
PCDD/Fs	polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans
PCDDs	polychlorinated dibenzo-*p*-dioxins
PCDFs	polychlorinated dibenzofurans
TEQ	Toxic equivalents
WHO	World Health Organization

Annex A – Protocol for the risk assessment the compliance of a detoxification process with the criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015

Introduction and scope of the protocol

The current protocol reports on the problem formulation and approach selected by the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel), for the risk assessment the compliance of a decontamination process with the criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015. This framework foresees that the extent of planning in the protocol (i.e., the degree of detail provided for the methods that will be applied in the assessment) can be tailored to accommodate the characteristics of the mandate. This draft protocol has been developed with the aim of setting out as far as possible beforehand, the strategy to be applied for appraising the relevant evidence, and analysing and integrating the evidence to draw conclusions that will form the basis for the scientific opinions.

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

Supporting information

Information on the detoxification/decontamination process and analytical methods to demonstrate compliance with the criteria of Commission Regulation (EU) 2015/786 of 19 May 2015 are provided by the Food Business Operator (FBO). EU legislation and additional literature, if needed, will be collected from the literature via official websites, review papers, peer-reviewed publications and legal text. The information will be summarized in a narrative way based on expert knowledge and judgment.

A.1. Problem formulation

Overall aim of the risk assessment

The overall aim is to assess the compliance of the decontamination process with the criteria set in Commission Regulation (EU) 2015/786 of 19 May 2015.

Identification of risk assessment sub-questions

A series of sub-questions will be answered and the answers combined to address the compliance of the decontamination process with the criteria set in Commission Regulation (EU) 2015/786 of 19 May 2015. The sub-questions identified are reported in Table A.1.

Table A.1: Sub-questions to be answered for the risk assessment

No	Sub-question
Physical and Chemical decontamination	
1.	Are the feed and the contaminant(s) that should be removed or detoxified clearly identified?
2.	Is the detoxification/decontamination process described adequately?
3.	Are the levels of identified contaminant(s) to be removed provided in an adequate number of feed batches?
4.	Are the levels of identified contaminant(s) after the detoxification/decontamination process of the feed batches complying with 2002/32/EC provisions in Annex I?
5.	Are the characteristics of the feed before and after the detoxification/decontamination process unchanged?
6.	Are details of the fate/disposal of the removed part of the feed provided, and are they appropriate?
Chemical decontamination	
7.	Is detailed information provided on the chemical process and its mode of action of the chemical substance
8.	Is there evidence that the detoxification/decontamination process does not result in harmful residues or reaction products after the detoxification in the feed?
9.	Is the process irreversible?

A.2. Method for answering the sub-questions

The sub-questions formulated in Table A.1 will be answered by a comprehensive narrative approach.

A.3. Method to address uncertainties in risk assessment

Uncertainties will be assessed qualitatively and if possible quantitatively as appropriate.

Recommendations will be included in the Scientific Opinion for the generation of additional data that could decrease the impact of the identified uncertainties on the conclusions of the risk assessment.

A.4. Approach for reaching risks characterisation conclusions

Conclusions will be drawn based on the answers to the risk assessment based on expert knowledge and judgment.