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SCIENTIFIC OPINION

Evaluation of alternative methods of tunnel composting (submitted by the European Composting Network) II

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Abstract

Two alternative methods for producing compost in a tunnel, from certain category (Cat.) 3 animal by-products (ABP) and other non-ABP material, were assessed. The first method proposed a minimum temperature of 55°C for 72 h and the second 60°C for 48 h, both with a maximum particle size of 200 mm. The assessment of the Panel on Biological Hazards (BIOHAZ) exclusively focused on Cat. 3 ABP materials (catering waste and processed foodstuffs of animal origin no longer intended for human consumption). The proposed composting processes were evaluated for their efficacy to achieve a reduction of at least 5 $\log_{10}$ of *Enterococcus faecalis* and *Salmonella* Senftenberg (775W, H_2S negative) and at least 3 $\log_{10}$ of relevant thermoresistant viruses. The applicant provided a list of biological hazards that may enter the composting process and selected parvoviruses as the indicator of the thermoresistant viruses. The evidence provided by the applicant included: (a) literature data on thermal inactivation of biological hazards; (b) results from validation studies on the reduction of *E. faecalis*, *Salmonella* Senftenberg 775W H_2S negative and canine parvovirus carried out in composting plants across Europe; (c) and experimental data from direct measurements of reduction of infectivity of murine parvovirus in compost material applying the time/temperature conditions of the two alternative methods. The evidence provided showed the capacity of the proposed alternative methods to reduce *E. faecalis* and *Salmonella* Senftenberg 775W H_2S negative by at least 5 $\log_{10}$, and parvoviruses by at least 3 $\log_{10}$. The BIOHAZ Panel concluded that the two alternative methods under assessment can be considered to be equivalent to the processing method currently approved in the Commission Regulation (EU) No 142/2011.

KEYWORDS

ABP, alternative method, category 3, compost, tunnel

CONTENTS

Summary

On 11 May 2023, the European Food Safety Authority (EFSA) received from the Belgian Competent Authority (Federal Agency for the Safety of the Food Chain) the application (mandate and technical dossier) (EFSA-Q-2023-00448) under Regulation (EU) No 1069/2009 referring to the evaluation of two alternative methods for tunnel composting of category (Cat.) 3 animal by-products (ABP) submitted by the European Compost Network (ECN) (hereinafter referred to as the applicant).

According to Section 1, Chapter III, Annex V of Regulation (EU) No 142/2011, the composting of Cat. 3 ABP shall be carried out according to the following processing method: particle size: 12 mm, ≥ 70°C, ≥ 60 min. As alternative methods, the applicant proposed Standard 1 (particle size 200 mm, ≥ 55°C, ≥ 72 h) and Standard 2 (particle size 200 mm, ≥ 60°C, ≥ 48 h).

In 2020, the EFSA Panel on Biological Hazards (BIOHAZ) published a scientific opinion, assessing a previous version of the dossier presented by the same applicant in 2019 and with the same two alternative methods. The BIOHAZ Panel considered that the evidence provided by the applicant did not demonstrate that the requirements of Annex V, Chapter 3, Section 2 of Commission Regulation (EU) No 142/2011 were achieved by the two alternative methods under evaluation because *'the applicant did not consider thermoresistant viruses as a relevant hazard and therefore did not provide any data from direct measurements of the reduction of infectivity of spiked thermoresistant viruses, nor provide data from validation studies undertaken at national level or data from literature supporting the efficacy of the proposed composting standards on thermoresistant viruses. However, thermoresistant viruses should be considered to be a relevant hazard in this context and validation data should have been provided accordingly.'*.

In this scientific opinion, the sections with no differences compared with the dossier evaluated in 2020 have not been re-evaluated, as they were already assessed in the 2020 scientific opinion (EFSA BIOHAZ Panel, 2020). Such sections appear verbatim for completeness in the corresponding sections of the current opinion.

The material to be treated is Cat. 3 ABP: in particular, as detailed in Regulation (EU) No 1069/2009, catering waste (except waste from means of transport operating internationally) and processed foodstuffs of animal origin that are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004.

In relation to hazard identification, the approach taken by the applicant was to provide a list of pathogens that may enter the composting process (*Toxoplasma, Campylobacter, Escherichia coli, Salmonella, Listeria, Clostridium perfringens, Clostridioides difficile, Staphylococcus aureus, Enterococcus faecalis*, porcine parvovirus, circovirus and chicken anaemia virus) and a list of biological hazards that are unlikely to enter the composting process, as follows: scrapie agents, BSE agents, foot and mouth disease virus, classical swine fever virus, African swine fever virus (ASFV), swine vesicular disease virus, Newcastle disease virus, *Clostridium botulinum* and *Trichinella spiralis*.

The BIOHAZ Panel agrees with the list of pathogens that may be present/enter the composting process, with the inclusion of ASFV, due to the current epidemiological situation of the disease in Europe.

The proposed composting processes were evaluated by the BIOHAZ Panel for their efficacy to achieve a reduction of at least 5 $\log_{10}$ of *E. faecalis* and *Salmonella* Senftenberg (775W, H_2S negative) and at least 3 $\log_{10}$ of the infectivity titre of relevant thermoresistant viruses.

The applicant selected parvoviruses as the indicator of relevant thermoresistant viruses among those included in the list of hazards that may enter the composting process, and the BIOHAZ Panel considered appropriate the approach followed by the applicant.

The evidence provided by the applicant to show the capacity of the proposed alternative methods to reduce *E. faecalis* or *Salmonella* Senftenberg 775W H_2S negative by at least 5 $\log_{10}$, and parvoviruses by at least 3 $\log_{10}$ – were: (a) literature data on thermal inactivation of biological hazards; (b) results from validation studies on the reduction of *E. faecalis*, *Salmonella* Senftenberg 775W H_2S negative and canine parvovirus carried out in composting plants across Europe; (c) and experimental data from direct measurements of reduction of infectivity of spiked murine parvovirus (minute virus of mice) in compost material applying the same time/temperature conditions as the two alternative methods.

The evidence showed the capacity of the two proposed alternative methods to reduce *E. faecalis* and *Salmonella* Senftenberg 775W H_2S negative by at least 5 $\log_{10}$, and parvoviruses by at least 3 $\log_{10}$ during composting.

The BIOHAZ Panel considers that the generic hazard analysis and critical control point (HACCP) plan provided, and the information about the risks of the interdependent processes and those associated with the intended end use, are generally appropriate and can be the basis for the validation and verification of the process once implemented at industrial level. The applicant provided procedures for the prevention of cross-contamination and reintroduction of pathogens during the transport of the end product, which are considered adequate by the BIOHAZ Panel. The end product of the process is compost, which, according to the applicant, may be used as a fertiliser and/or soil improver. Additional food safety risks associated with the intended end use of the product are not foreseen.

In conclusion, the BIOHAZ Panel considers that the two alternative methods under assessment can be considered to be equivalent to the processing methods currently approved in the Commission Regulation (EU) No 142/201.

1 | INTRODUCTION

1.1 | Background

On 11 May 2023, the European Food Safety Authority (EFSA) received from the Belgian Competent Authority (Federal Agency for the Safety of the Food Chain of Belgium), after evaluation of the dossier by the regional authorities of Belgium competent for composting, the application (mandate and technical dossier) (EFSA-Q-2023-00448) under Regulation (EU) No 1069/2009,[1] referring to the evaluation of alternative methods for tunnel composting of category 3 animal by-products (ABP) submitted by the European Compost Network (ECN) (hereinafter referred to as the applicant).

The applicant submitted an application following the procedure for authorisation of an alternative method of use or disposal of animal by-products or derived products, laid down in Article 20 of the Regulation (EU) No 1069/2009. On 25 June 2023, EFSA received the application through the EFSA portal for submission of ABP applications (Portalino) (CR-2023-000098), in line with the new provisions implemented by the Transparency Regulation (UE) 2019/1381.[2]

During the completeness check, performed according to Regulation (EU) No 1069/2009, it was noticed that some information was missing or incomplete, thus the dossier could not be considered complete. On 1 August 2023, EFSA sent a letter to the applicant with a request for information, including four requests: (a) submit a non-confidential and a confidential version of the dossier with all information claimed to be confidential (including personal data as well as technical or scientific parts of the dossier); (b) submit the relevant bibliography reference/citations in a separate document for the public (non-confidential version of the dossier); (c) confirm if the study 'Final report on the inactivation studies of murine parvovirus in composting' included in Annex 06 of the dossier was commissioned before 27 March 2021, i.e., before the entry into force of the study notification obligation; (d) improve the readability of a few sentences in one of the Annexes.

On 16 August 2023, EFSA received the missing information requested. After checking the content of the full dossier, EFSA considered that the application was valid on 11 September 2023. According to Regulation (EU) No 1069/2009, EFSA shall conduct the assessment within 6 months following receipt of a complete application.

In 2020, the EFSA BIOHAZ Panel published a scientific opinion assessing a previous version of the dossier, presented by the applicant in 2019 following a request from the Belgian Competent Authority (Federal Agency for the Safety of the Food Chain of Belgium), on behalf of the European Compost Network (ECN), to evaluate alternative methods to produce compost from category 3 animal by-products (ABP) in a tunnel. Based on the information provided in the current application, there are no differences concerning the parameters of the alternative methods evaluated in the previous scientific opinion (EFSA BIOHAZ Panel, 2020) and the two alternative methods under evaluation in this scientific opinion:

- Standard 1 (particle size 200 mm, ≥ 55°C, ≥ 72 h)
- Standard 2 (particle size 200 mm, ≥ 60°C, ≥ 48 h).

In 2020, the BIOHAZ Panel considered that the evidence provided by the applicant did not demonstrate that the requirements of Annex V, Chapter 3, Section 2 of Commission Regulation (EU) No 142/2011 were achieved by the two alternative methods under evaluation. In particular, it was stated that: "*the applicant did not consider thermoresistant viruses as a relevant hazard and therefore did not provide any data from direct measurements of the reduction of infectivity of spiked thermoresistant viruses, nor provide data from validation studies undertaken at national level or data from literature supporting the efficacy of the proposed composting standards on thermoresistant viruses. However, thermoresistant viruses should be considered to be a relevant hazard in this context and validation data should have been provided accordingly.*"

The standard transformation parameters for the composting of Category 3 ABP are detailed in Section 1, Chapter III, Annex V of Regulation (EU) No 142/2011. The composting of Cat 3 ABP shall be carried out according to the following processing standards:

a. '*maximum particle size before entering the composting reactor: 12 mm*;
b. *minimum temperature in all material in the reactor: 70°C; and*,
c. *minimum time without interruption: 60 min*.'

1.2 | Additional information

During the assessment process, it was deemed necessary to obtain additional information on the alternative methods. On the 3 November 2023, EFSA requested additional information from the applicant. In this case, EFSA decided not to apply any additional period as allowed by point 6 of Article 20 of Regulation (EU) No 1069/2009. The applicant provided the information on 17 November 2023.

[1]Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). OJ L 300, 14.11.2009, p. 1–33.

[2]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. GU L 231 del 6.9.2019, pag. 1–28.

With regards to Annex 06, 'Final report on the inactivation studies of murine parvovirus in composting' EFSA asked the applicant for the following:

a. the rationale for the use of compost in the experiment (rather than the start material – feedstock – entering the process) and its physicochemical characteristics (i.e. raw material, pH).
b. comprehensive information on the titration methodology used (number of replicates, dilutions tested, number of runs, readout methodology, internal controls), the access to the raw titration data and a description of the statistical methodology applied.
c. data about interference tests between matrix and detection system to evaluate the impact of the matrix on the viral detection performance.
d. the rationale for not performing the experiment with compost at 60°C.

The applicant presented industry testing data on composting plants in the UK regarding parvovirus inactivation, stating that only a few plants were able to provide details and confirming that they achieved a 3 $\log_{10}$ reduction of canine parvovirus. One of these plants showed up to 30 results with less than 3 $\log_{10}$ reduction of parvovirus. EFSA asked for clarification on this data (< 3 log reduction) since there is no mention about this data in the application dossier. The new information submitted by the applicant was considered as part of the application and reviewed during the assessment.

EFSA published a non-confidential version of the dossier on the OpenEFSA portal at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00448 and carried out a public consultation on the non-confidential version of the application from 21 September to 12 October 2023, for which no comments were received.

2 | DATA AND METHODOLOGIES

2.1 | Data

The data used in the assessment were provided by the Applicant as requested in Annex VII of Commission Regulation (EU) No 142/2011[3] and its amendment by Commission Regulation (EU) No 749/2011.[4] The dossier included: a process flow diagram, with a description of the proposed alternative process; a hazard analysis and critical control point (HACCP) plan; a description of validation exercises conducted in commercial scale composting plants across Europe, where validation was carried out in accordance with the procedure provided for in Annex V, Chapter 3, Section 2 of Regulation (EU) No 142/2011; as well as a description of a hazard reduction study carried out on behalf of the applicant. Additional data were also submitted by the applicant in response to a request for additional information as described above. The report submitted by the Competent Authority (CA) related to the application was also considered. Relevant scientific papers suggested by experts of the Working Group (WG) were also considered during the assessment.

2.2 | Methodologies

The EFSA Panel on Biological Hazards (BIOHAZ) evaluated the application for the two alternative methods for tunnel compost production, by individually assessing the following steps as set out in the 'Statement on technical assistance on the format for applications for new alternative methods for animal by-products' (EFSA BIOHAZ Panel, 2010). These steps are:

(i) full description of the process;
(ii) full description of the material to be treated;
(iii) hazard identification;
(iv) level of risk reduction;
(v) HACCP plan;
(vi) risk associated with interdependent processes;
(vii) risk associated with the intended end use of the product.

The applicant is required to document, as fully as possible, the different aspects of each of these steps. According to the assessment of the CA, the application meets the requirements as laid down in the EFSA Statement (EFSA BIOHAZ Panel, 2010).

[3]Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive. OJ L 54, 26.2.2011, p. 1–254.

[4]Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 implementing regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive. OJ L 198, 30.7.2011, p. 3–22.

As set out in Article 20 of European Union Regulation (EU) No 1069/2009, EFSA is required to assess whether the methods submitted ensure that the risks to public or animal health are

a. *'controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof'; or*
b. *'reduced to a degree which is at least equivalent, for the relevant categories of animal by- products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1)'*.

This requirement for applications is described in Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009 and amended by Commission Regulation (EU) No 749/2011. According to point 2 d, Chapter II, Annex VII of Commission Regulation (EU) No 142/2011, any application for the evaluation of alternative methods shall *'show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the wastewater, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products (ABP). The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable'*.

According to the EFSA Statement (EFSA BIOHAZ Panel, 2010) and to point 3, Chapter II, Annex VII of Commission Regulation (EU) No 142/2011, validated direct measurements as referred to above shall mean:

a. 'measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:

   – consistently present in the raw material in high numbers,
   – not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant, than the pathogens for which it is being used to monitor,
   – relatively easy to quantify and relatively easy to identify and to confirm; or

b. using a well-characterised test organism or virus introduced in a suitable test body into the starting material.'

The EFSA Statement (EFSA BIOHAZ Panel, 2010) asserts that '*results should be accompanied by evidence*'. Evidence '*includes, for measurements, information on the methodology used, nature of samples that have been analysed and evidence that samples are representative (e.g., number of samples, number of tests performed and selection of measuring points). If several treatment steps are involved, an assessment should be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps. In any case it is necessary to provide the sensitivity and specificity of the detection methods applied. Data on the repeatability and statistical variability of the measures obtained during the experiments should also be presented.*'

It also states that '*Generally, the level of risk reduction for human and animal health that can be achieved by the process should be evaluated on the basis of direct measurements (validation). In case no direct measurement of the risk reduction is available* (i.e. *no validation as defined above is feasible), modelling or comparison with other processes may be acceptable if*:

(i) *the factors leading to the risk reduction are well known;*
(ii) *the model of risk reduction is well established; and*
(iii) *continuous direct measurements of the factors leading to the risk reduction are provided for the full-scale process, which demonstrate that these factors are homogeneously applied throughout the treated batch'*.

In point 2 d, 'Level of risk reduction' of Section 2.1.2.1 'Content of applications' of the EFSA Statement (EFSA BIOHAZ Panel, 2010), it is stated that '*in principle, the new proposed process should be able to reduce the amount of the most resistant biological hazards associated with the category of the material to be processed for a defined final use to an acceptable level*'. Although Chapter II of Annex VII of Commission Regulation (EU) No 142/2011 adopted the proposal of the EFSA opinion to use 'the level of risk reduction' and 'the level of reduction of the most resistant biological hazards' interchangeably, it is acknowledged that these are different terms and that the purpose of the evaluation of alternative methods is not the estimation of the level of any risk, but the level of hazard reduction.

Annex V, Chapter 3, Section 2 of Commission Regulation (EU) No 142/2011, on the transformation parameters of ABP and derived products into biogas or composting, highlights that '*the CA* (in a Member State) *may authorise the use of parameters other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements*:

a. *Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters*

b. *A risk assessment, which evaluates how the specific transformation conditions referred to in point (a) are achieved in practice under normal and atypical situations*
c. *Validation of the intended process by measuring the reduction of viability/infectivity of*

(i) *endogenous indicator organisms during the process, where the indicator is*:

- *consistently present in the raw material in high numbers,*
- *not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,*
- *relatively easy to quantify and to identify and to confirm; or*

(ii) *a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.*

d. *The validation of the intended process referred to in point (c) must demonstrate that the process achieves the following overall risk reduction*:
(i) *For thermal and chemical processes by*:

- *a reduction of 5 $\log_{10}$ of Enterococcus faecalis or Salmonella Senftenberg (775W, H_2S negative), and*
- *a reduction of the infectivity titre of thermoresistant viruses such as parvovirus by at least 3 $\log_{10}$, whenever they are identified as a relevant hazard.*

(ii) *As regards chemical processes, also by*:

- a reduction of resistant parasites such as the eggs of Ascaris sp. by at least 99.9% (3 $\log_{10}$) of viable stages;

e. *Designing a complete control programme, including procedures for monitoring the functioning of the process referred to in point (c).*
f. *Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.*'

The BIOHAZ Panel has previously used the standards mentioned in point (d) (EFSA, 2015, 2020), in the assessment of the previous version of the dossier presented by the applicant in 2019. In relation to viruses, the approach to be followed is to assess whether the proposed alternative methods achieve a reduction of infectivity of at least 3 $\log_{10}$ for the most thermoresistant virus that could be present in the material to be treated. The hazards considered for the assessment are exclusively those that may pose a risk to human or animal health and that may be present in the material to be treated.

This is in line with a recent EFSA BIOHAZ Panel opinion (2022), where it was considered that '*the alternative methods for Category 3 ABP should be capable of reducing the concentration of the relevant pathogenic bacteria by at least 5 $\log_{10}$ and the infectious titre of the relevant viruses by at least 3 $\log_{10}$* (EFSA BIOHAZ Panel, 2005). *The determination of the relevant pathogenic bacteria and viruses should be defined by the hazard identification, specific for the material to be treated. If the hazard identification considers spore-forming pathogenic bacteria to be relevant, the required level of inactivation will also be a 5 $\log_{10}$ reduction of spores from these bacteria, with the exception of spores of* C. botulinum *for which a 12 $\log_{10}$ reduction would be required, as for processing canned petfood…. If needed/appropriate, for both spore-forming and non-spore-forming bacteria and viruses, adequately justified alternative non-pathogenic indicator or surrogate organisms with at least the same level of resistance may be used, demonstrating an equivalent level of reduction in the substrate of interest. These reductions should be achieved by the process independently from the reduction provided by the standard processing methods [methods 1–5 or 7 of Commission Regulation (EU) 2011/141], should these be required*'.

The proposed composting processes were evaluated for their efficacy to achieve a reduction of at least 5 $\log_{10}$ of *E. faecalis* and *Salmonella* Senftenberg (775W, H_2S negative) and at least 3 $\log_{10}$ of relevant thermoresistant viruses.

The sections with no differences compared with the dossier evaluated in 2020 have not been re-evaluated, as they were already assessed in the 2020 assessment (EFSA BIOHAZ Panel, 2020). Such sections appear verbatim for completeness in the corresponding sections of the current opinion.

3 | ASSESSMENT

In the current chapter, the sections defined as **'provided by the applicant'** present the description extracted from the application, edited for clarity and abridged in places for brevity.

3.1 | Description of the alternative methods

3.1.1 | Description of the process as provided by the applicant[5]

The ECN is proposing that the Cat. 3 materials listed in 'Section 3.2.1 Material to be treated' of this report are the only ABP feedstock used in a compost plant equipped with a composting tunnel (see Figure 1).

The proposed alternative methods for composting of Cat. 3 ABP consist of the following parameters:

Standard 1:

a. maximum particle size of ABP before entering the tunnel: 200 mm;
b. minimum temperature in all material in the tunnel: 55°C; and
c. minimum exposure time in the tunnel without interruption: 72 h

Standard 2:

a. maximum particle size of ABP before entering the tunnel: 200 mm;
b. minimum temperature in all material in the tunnel: 60°C; and
c. minimum exposure time in the tunnel without interruption: 48 h.

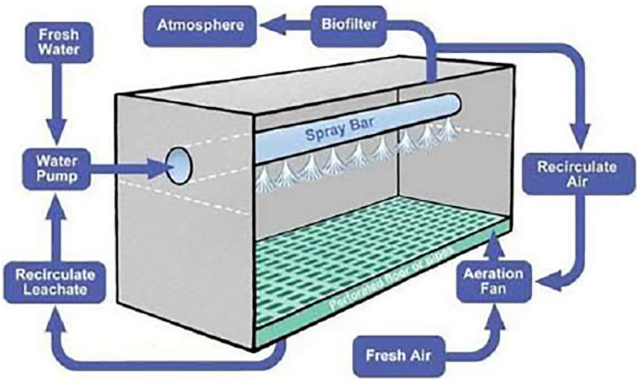

FIGURE 1 Typical schematic of a composting tunnel (provided by the applicant).

The material must meet the minimum requirements in compliance with the two proposed ECN standards for tunnel composting of catering waste and food of animal origin.The material flow in the composting process (Figure 2) is as follows:

1. **Feedstock intake:** Catering waste and products of animal origin will be accepted once it is from an approved feedstock supplier.
2. **Storage:** The feedstock will be stored for a maximum of 24 h in a manner that prevents access by vermin.
3. **Mixing/blending:** The feedstock will be prepared by blending with other non-ABP feedstock types to ensure the ABP material is less than 200 mm in size.
4. **Composting/hygienisation:** The blended feedstock will be placed in the tunnel for composting and hygienisation. If the moisture needs to be adjusted, liquids from the plant might be used at this stage before hygienisation. Any wastewater/leachate generated from the composting process can only be reused at the start of the composting process before hygienisation. After hygienisation, only clean water can be used.
5. **Post sanitisation treatment & screening:** After the thermophilic or high-temperature composting phase, which shall include either the 48-h (temperature > 60°C) or 72-h (temperature > 55°C) standard, the compost is moved with a clean loader to avoid cross-contamination for further processing or screening. Screening is done to remove impurities. This is done in a separate area from the raw feedstock to prevent cross-contamination of pathogens. It is important to note that the thermal process conditions providing a temperature range of > 55°C in most composting systems are kept for at least 10 days and, depending on the material mix, humidity and air supply, may last up to several weeks. This contributes to further security with respect to pathogen eradication.
6. **Storage of compost:** The compost is stored in a separated area to prevent recontamination with untreated ABP.
7. **Passed *Salmonella*, dispatched to end user:** If all the hygienisation requirements have been fulfilled, and a bacteriological analysis shows conformity with the limit value for *Salmonella* in the final product, it will be dispatched to end users.

[5]The content of the Section 'Description of the alternative method as provided by the applicant' is extracted verbatim from the application, edited for clarity and abridged in places for brevity.

The by-products generated in the process are:

- Water vapour and carbon dioxide, which are emitted to the air during composting;
- Leachate, which is generated from the composting tunnels and from wash water used to clean trucks/floor/machines in the reception hall and is typically used in the composting process prior to hygienisation; and
- Sanitised rejects (e.g. plastic/glass, screening overs), which are removed at the end of the process.

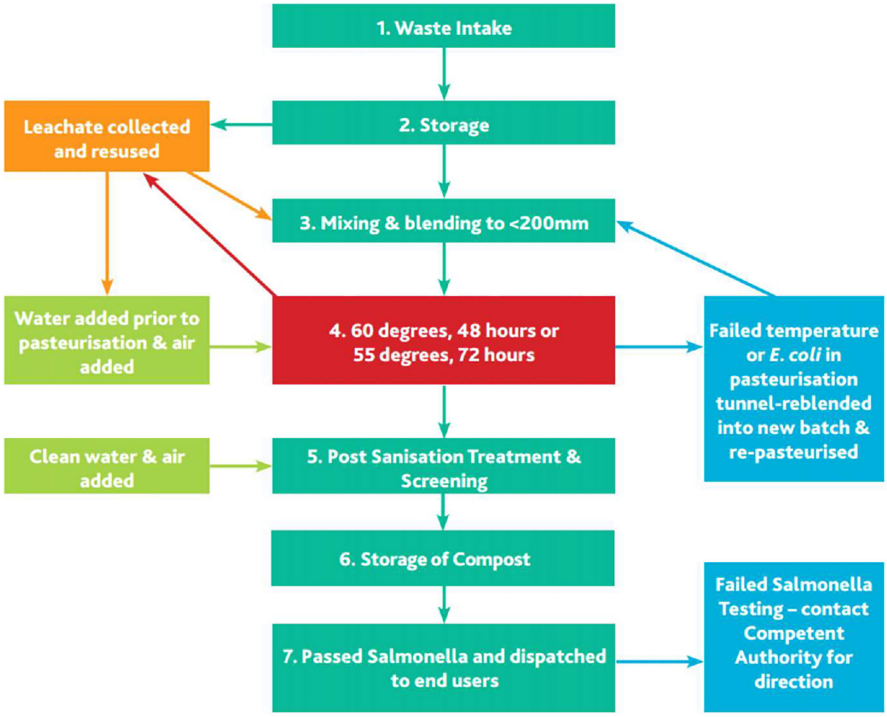

FIGURE 2 Process flow and by-products (as provided by the applicant).

The parameters that are critical for the inactivation of the pathogens in relation to the process are the combination of:

- **Time–Temperature.** Temperature and duration are important factors for pathogen inactivation. It is claimed by the applicant that the proposed time–temperature regimes of the two ECN standards are sufficient to inactivate pathogens that might possibly be present in the allowed feedstock. Temperature profiles during composting can be affected by:
  - Feedstock preparation;
  - Moisture content; and
  - Aeration/particle size/porosity.

- **Feedstock preparation**

  Special attention should be focused on the preprocessing stage. Getting the right mix of feedstock materials is perhaps the most important step in the composting process. It is vital that the composition of the feedstock is adjusted so that optimum conditions for composting are created. Optimum composting conditions will result in more efficient microbial degradation of organic matter and, hence, more heat generation. In addition, it is essential that feedstocks are blended sufficiently so that a uniform feedstock is created. A uniform feedstock helps to minimise temperature fluctuations and variability within the composting mass.
  The addition of green waste/woodchips/oversize material to catering waste serves several functions, including:

  - Improving the structure of the compost pile by providing air spaces within the pile. This facilitates aeration through piles during composting.
  - Absorbing moisture, especially for wet or high-moisture feedstocks. This is important so that wetter feedstock materials can be dried out to a point where they can be composted aerobically. If the material is too wet, the air spaces fill up with water, promoting anaerobic conditions, reducing heat production and promoting the generation of foul odours.

- **Moisture**

  If the material is too dry, biological decomposition will be slow or may even stop. If the material is too wet, aerobic composting will be turned into anaerobic conditions, and fermentation may be reduced or stopped. In both cases, the temperature will not reach the targeted minimum value.

The ABP to be processed will be mainly catering waste from households, which are typically drier than catering waste from restaurants, which are usually wet and sloppy. Attention to the moisture content of waste from restaurants will be required by operators.
For all feedstock materials, the moisture level should be adjusted prior to composting, as the microorganisms need some water to thrive**.**

- **Aeration/Particle Size/Porosity**

Optimal aeration is provided by a fan in the hygienisation tunnel (see **Figure** 1). The tunnel composting system is a static system aerated evenly from beneath. Aeration is provided by a fan that extracts the warm air from the roof. This air is then piped down into an aeration floor.
If the compost is not sufficiently aerated, the process is slowed, and the insufficient air supply leads to anaerobic conditions. The target temperature in the proposed standards will not be reached.
If the material has a too large particle size, microorganisms will develop more slowly, and the temperature will not rise fast enough. If the material is too small, air distribution will be reduced in the compost mass, leading to locally anaerobic conditions and lower temperatures.
The particle size affects the time to compost and, indirectly, aeration. A general rule of thumb is that the smaller the particle, the faster it will decay. This has to do with surface area and the ability of microorganisms to access nutrients in the feedstock materials. Conversely, large woody materials decay very slowly and would need to be shredded into smaller pieces to increase the surface area for them to decay efficiently. Furthermore, if the particle size is too small, then there will not be sufficient air space in the piles to promote passive aeration; this can only partly be overcome in tunnel systems with powerful aeration fans.
Porosity is the amount of air space in a blended feedstock mixture or compost pile. Piles with high porosity encourage airflow, while piles with low porosity limit or restrict airflow. So, porosity is crucial to maintain aerobic conditions, which in turn reduces the generation of foul odours caused by anaerobic conditions. Structural bulking materials, such as wood chips, are used to create porosity. These larger woody materials typically do not break down as fast as other non-woody materials and can persist until the end of the composting process. They are typically removed from the finished compost at the end of the process with the use of a screen. These screening overs (rejects) can then be reused in the composting process and introduced into new batches of compost as a structural bulking material and as an inoculant.

The technical data of the equipment used in the relevant process steps are presented in Table A1 of Appendix A.

3.2 | Material to be treated

3.2.1 | Material to be treated as provided by the applicant[6]

The feedstock materials to be composted are wastes, which are typically found in household food waste collection and commercial premises with the same characteristics. In Directive (EU) 851/2018,[7] the Waste Framework Directive, the definition for this type of waste is:

'biowaste' means *'biodegradable garden and park waste, food and kitchen waste from households, offices, restaurants, wholesale, canteens, caterers and retail premises and comparable waste from food processing plants*'.

Under the ABP regulations,[8] this waste would be defined as:

- ABP referred to in Article 10 (p) of Regulation (EU) No 1069/2009, that is catering waste other than as referred to in Article 8(f) of Regulation (EU) No 1069/2009. Catering waste '*means all waste food including used cooking oil originating in restaurants, catering facilities and kitchens, including commercial kitchens and household kitchens'*.
- ABP referred to in Article 10(f) of Regulation (EU) No 1069/2009 (i.e. '*products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise'*), which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004.[9]

This application presents two alternative methods of tunnel composting of Cat. 3 ABP. The Cat. 3 ABP in question are defined in Article 10(f) of Regulation (EU) No 1069/2009, as above, and Article 10 (p): *'catering waste other than as referred to in Article 8 (f)*[10]*'*.

[6]The content of the section 'Material to be treated as provided to the applicant' has been extracted from the application, edited for clarity and abridged in places for brevity.
[7]Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste OJ L 150, 14.6.2018, p. 109–140.
[8]Commission Regulation (EC) 1069/2009 and Commission Regulation (EU) 142/2011.
[9]Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs OJ L 139, 30.4.2004, p. 1–54.
[10]Article 8 (f) *'catering waste from means of transport operating internationally'*.

Additional feedstocks intended for use and that are not subject to Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011 include organic bulking materials. Cat. 3 material to which the proposed alternative methods would apply comprises the ABP listed above.

Non-ABP Material

Some household catering waste collection schemes will also include grass clippings/small branches. In addition, structural bulking materials, such as wood chips, straw and wood shavings, are used to create porosity. These larger woody materials typically do not break down as fast as other non-woody materials and can persist through to the end of the composting process. They are typically removed from the finished compost at the end of the process with the use of a screen. These screening overs (rejects) can then be reused in the composting process and introduced into new batches of compost as a structural bulking material and as an (microbial) inoculant.

3.2.2 | Assessment of the BIOHAZ Panel on the material to be treated

Extract *verbatim* from the EFSA BIOHAZ Panel 'Scientific opinion on the evaluation of alternative methods of tunnel composting (submitted by the European Composting Network) (EFSA BIOHAZ Panel, 2020).

'The raw materials to be processed by the two proposed transformation standards for composting in a tunnel include catering waste and processed foodstuffs of animal origin no longer intended for human consumption. The assessment exclusively focuses on ABP Cat. 3 materials as described in Article 10 of Regulation (EU) No 1069 of 2009. Article 10 (p) describes Cat. 3 catering waste as food waste other than catering waste (originating) from means of transport operating internationally. Derogation from point 1 Section 2, Chapter III, Annex V of Commission Regulation (EU) No 142/2011 describes products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise, which have been further processed as per Article 2(1)(m) of Regulation (EU) No 852/2004.

It is important to highlight that the assessment does not address biodegradable garden and park waste included in the definition of biowaste reported in the Directive (EU) 2018/851 amending Directive 2008/98/EC on waste.

A risk assessment (Gale, 2002) *on the use of composting and biogas production treatments to dispose of catering waste containing meat, conducted by the UK Department for Environment, Food and Rural Affairs (Defra), used data on the composition of household waste, showing that uncooked meat accounted for around 1% of the total weight of average household waste. A risk assessment conducted by the UK Waste and Resources Action Programme* (WRAP, 2017) *used estimates of percentages of uncooked meat discarded to waste and going to compost of 2.8% (poultry), 1.39% (pig meat), 0.8% (beef) and 1.09% (lamb). Therefore, it is considered that the material to be treated can contain uncooked or undercooked meat and bones*'.

3.3 | Hazard identification

3.3.1 | Hazard identification as provided by the applicant[11]

The hazards to be addressed are 'biological – animal/human pathogens'. The pathogens to consider are viruses, bacteria and parasites. The feedstocks envisaged to be used in composting plants affected by the ECN proposal will be mainly catering waste collected from households and commercial premises (e.g. restaurants, caterers, retailers etc.), with some possible processed foodstuffs.

This application is for catering waste and foodstuffs of animal origin that were intended for human consumption. There are many controls in place with this material because it was intended for human consumption.

The UK Defra conducted a comprehensive analysis more than 20 years ago of the microbial risks from composting catering waste (Gale, 2002). More recent research by Kohler (2017) was conducted by the German Quality Assurance Organisation for Compost of six different household food waste collection services, in which the waste was screened to determine what pathogens were present in the raw, untreated food waste from households. Based on these reports and a review of the recent occurrence of these pathogens, pathogens were subdivided into two groups:

- Pathogens that may enter the composting process, and
- Pathogens that are unlikely to enter the composting process.

The 12 pathogens identified by the applicant as a risk and that may enter the composting process are: *Toxoplasma*, *Campylobacter*, *Escherichia coli*, *Salmonella*, *Listeria, Clostridium perfringens, Clostridioides difficile, Staphylococcus aureus, E. faecalis*, porcine parvovirus, circovirus and chicken anaemia virus. Table A2 of Appendix A gives an overview of the properties of these pathogens that may enter the composting process.

[11]The content of the section 'Hazard identification as provided by the applicant' has been extracted from the application, edited for clarity and abridged in places for brevity.

The pathogens, which are unlikely to enter the composting process, according to the applicant, are: scrapie agents, BSE agents, foot and mouth disease virus, classical swine fever virus, African swine fever virus (ASFV), swine vesicular disease virus, Newcastle disease virus, *Clostridium botulinum* and *Trichinella spiralis*.

3.3.2 | Assessment of the BIOHAZ Panel on the hazard identification

The applicant provided a list of biological hazards that may enter the composting process. The first six hazards identified by the applicant were already included in the dossier presented in 2020. The applicant also provided a list of biological hazards that are considered unlikely to enter the composting process.

The assessment of the hazard identification performed in 2020 (EFSA BIOHAZ Panel, 2020) included an exhaustive evaluation of the biological hazards that could be introduced into the composting process by catering waste and foodstuffs. The pathogens considered are viruses, bacteria and parasites. It is important to note that the materials intended for treatment have already been approved to be introduced into the food chain; thus, the biological controls performed should diminish the introduction of part of these biological hazards, as stated in the previous evaluation (EFSA BIOHAZ Panel, 2020).

The BIOHAZ Panel agrees with the conclusions of Gale (2002) that the level of bacterial spores predicted in compost are no higher than those reported for some soils. Moreover, as stated in the previous EFSA opinion (2020), bacterial spores from *C. perfringens* and *C. difficile* present a much higher heat resistance and, therefore, they would not be sufficiently reduced either by the conditions proposed or by the approved method (Bhunia, 2018). The same rationale applies also for bacterial spores from *C. botulinum*, that can be present on the surfaces of fruit and vegetables, therefore possibly present in the raw material to be composted (Beuchat, 2002; Nguyen-the & Carlin, 1994; Peck, 1997).

The epidemiological situation of some of the viruses considered by the applicant as unlikely to enter the composting process, for example ASFV, has changed over time and may further change in the future. Gale (2002) and Kohler (2017) did not consider the risk of the ASFV within the EU. However, the situation has worsened in the last few years, and ASFV is an emerging risk in European countries (EFSA, 2022, 2023). Since 2014, the virus has been reported in different European countries, mostly linked to wild boars, but also to pigs, both in commercial farms and backyard pigs. Foodstuffs prepared with contaminated meat are a potential vehicle of disease transmission and are considered a major risk factor for ASFV spreading among EU countries.[12] Although meat from infected pigs is declared unfit for human consumption, ASFV could be present in catering waste and foodstuffs of animal origin, if not detected in the origin. Thus, the ASFV is one of the hazards that may be present in the raw material entering the compositing process due to the current epidemiological situation of the disease in Europe. The BIOHAZ Panel agrees with the list of pathogens that may be present/enter the process, with the inclusion of ASFV.

According to WOAH, the inactivation of ASFV is achieved by applying a mild temperature of 56°C for 70 min.[13] Also, applying lower temperatures for shorter times (48°C 10 min) reduces 6 $\log_{10}$ the viral titre. Therefore, the temperature and time of the composting process in the tunnel that the applicant includes in this document should be sufficient to inactivate ASFV. Other studies evaluating the composting of contaminated carcasses also demonstrate the ASFV inactivation by composting (Gabbert et al., 2023). Based on the inclusion of porcine parvovirus, circovirus and chicken anaemia virus (i.e. viruses with higher thermal resistance) in the hazards to be considered when evaluating the alternative method proposed by the applicant, it is assumed that a demonstration of the effectiveness of the alternative methods on these viruses would provide an appropriate demonstration of the reduction of other, less resistant viruses such as ASFV.

Among the hazards identified by the applicant, the most heat-resistant non-sporulating bacteria is considered to be *S*. Senftenberg 775W H_2S negative, the strain of *Salmonella enterica* with the highest thermal resistance reported. In addition, *Enterococcus* (mainly some *E. faecium* strains) is commonly also considered to be an appropriate surrogate for non-sporulating bacteria to validate thermal treatments, given its high intrinsic heat resistance (Brar & Daryluk, 2018; Hu & Gurtler, 2017; Liu et al., 2018; Ma et al., 2007; Smelt & Brul, 2014).

Regarding viruses, the applicant selected parvoviruses as the indicator of thermoresistant viruses among those included in the list. The BIOHAZ Panel acknowledges that all other viruses that may enter the composting process, including ASFV, are less thermoresistant than parvovirus and considers appropriate the approach followed by the applicant.

3.4 | Level of risk reduction

3.4.1 | Level of risk reduction as provided by the applicant[14]

The pathogens susceptible to enter in the compost system were examined using data available in the literature. The temperature and time conditions required for their inactivation, or their D-values, are presented in Table A3 of Appendix A.

[12] https://www.efsa.europa.eu/en/topics/topic/african-swine-fever.

[13] https://www.woah.org/app/uploads/2021/03/a-african-swine-fever-v2-0.pdf.

[14] The content of the section 'Level of risk reduction as provided by the applicant' has been extracted from the application, edited for clarity and abridged in places for brevity.

In the previous EFSA opinion (EFSA BIOHAZ Panel, 2020) dealing with the previous ECN application, the BIOHAZ Panel concluded that '*the proposed treatment standards, if maintained at or above the target temperature during the whole composting process and applied homogeneously in the composting tunnel, would be able to inactivate more than 5 log_{10} of E. faecalis or Salmonella Senftenberg 775W in the material to be tested*'.

In this application, the applicant has provided inactivation data available in the published literature for the following microorganisms and viruses: *Toxoplasma*, *Campylobacter jejuni*, *E. coli*, *Listeria monocytogenes*, *C. perfringens*, *Salmonella*, *C. difficile*, *S. aureus*, *E. faecalis*, parvovirus (porcine parvovirus and bovine parvovirus), circovirus and chicken anaemia virus (Table A3 of Appendix A).

3.4.1.1 | *Data provided from literature*

According to the applicant, the data available in the literature demonstrate that, in principle, the ECN proposed alternative methods of 55°C for 72 h and 60°C for 48 h are sufficient to inactivate the bacterial pathogens likely to enter the composting process. There is a lack of data on the fate of chicken anaemia and circovirus at 55°C and of porcine parvovirus and circovirus at 60°C. If present, *C. perfringens* and *C. difficile* can sporulate and survive as spores, but this is also true for the standard transformation parameters.

According to the applicant, the ECN proposal of 55°C for 72h is supported by other researchers. Droffner and Brinton (1995) suggested that at least 3 days at 55°C are needed for sufficient pathogen inactivation, and Burge et al. (1987) stated that a minimum temperature of 55°C for 2.5 days is required.

Although the application deals with Cat. 3 ABP material (catering waste and processed foodstuffs of animal origin), there is some work conducted by Elving (2009) that supports the ECN proposal of 55°C on higher-risk Cat. 2 material manure. It was found that the thermal treatment of fresh manure at 55°C over 16.9 h was sufficient to achieve a 5 log_{10} reduction of *Salmonella* Senftenberg 775W H_2S negative and *Enterococcus* spp. For bacterial pathogen inactivation at a lower temperature, an increased time is needed to reach the statutory requirements. Elving (2009) indicated that a time of 17.2 h at 52°C or 16.9 h at 55°C can be sufficient to reach the reduction targets set by European Communities (EC) legislation based on the inactivation of *Enterococcus* spp. in fresh cattle manure. This interval would also be sufficient for a 5 log_{10} reduction in *Salmonella* Senftenberg 775W H_2S negative.

Table A3 of Appendix A shows a summary of the data available in the literature on the inactivation of biological hazards. The table provides inactivation information for different microorganisms and viruses classified at genus and species taxonomic ranks. The information is provided either by the estimated D-value or the conditions for at least 3 log_{10} reduction of the pathogen (temperature and time in both values) (Table A4).

3.4.1.2 | *Summary of the inactivation studies of murine parvovirus in composting provided by the applicant*

An experimental study to investigate the reduction of the viruses was carried out on behalf of the applicant.

In that study, the minute virus of mice (MVM), a member of the family *Parvoviridae*, was used as a test organism. MVM is widely used in disinfectant testing. An advantage over bovine parvovirus is that MVM can be propagated and cultivated on permanent cell lines, whereas bovine parvovirus needs primary bovine embryonic cells. Primary bovine embryonic cells cannot be obtained anymore, as the slaughter of pregnant animals is no longer allowed. MVM can be propagated on murine lymphoblasts (cell line A9) and shows a cytopathic effect.

The study was conducted under laboratory conditions in a water bath. The biowaste compost used in the study originated from one of the clients' composting plants. For all experiments, control samples were kept at 4°C for the whole time and were examined together with the actual samples using the same method. Temperature was measured using data loggers introduced in the water bath.

To show the influence of the compost material on the inactivation, the first experiments were conducted in a water bath, using virus in growth medium, without composting material. These experiments were performed at two different temperatures with four different retention times. The temperatures chosen were 55 and 60°C, and the retention times were 24, 48, 72 and 96 h respectively. For each retention time, a triplet of reaction tubes with 1 mL of virus suspension was introduced into the water bath and removed after the respective retention time. After removing the tubes from the water bath, they were cooled down on ice, and a virus titration was performed. Readout of the results was performed after 7, 8 and 9 days. The virus titre was determined according to Spearman (1908) and Kärber (1931). The virus titre is shown in KID_{50} (tissue culture infectious dose, $TCID_{50}$).

To determine the influence of composting material and composting process on virus inactivation as well as the possible influence of the preheating step during the composting process, the following experiments were performed using 9 gram of fresh composting material mixed with 1 mL of virus suspension. Samples were put in 50-mL glass bottles and immersed in the water bath. The preheating was simulated by increasing the temperature by 10°C every 24 h, starting at 30°C for the first 24 h. So, temperatures for preheating were 30°C on the first day, 40°C on the second day and 50°C on the third day. On the fourth day, the temperature was increased by 5°C to reach the final temperature of 55°C. After reaching 55°C, the samples for testing without the influence of preheating were introduced into the water bath as well. A triplet of samples was removed after the retention time and cooled down on ice to stop any reaction.

Re-isolation of the virus was performed according to Katzenelson et al. (1976) and Glass et al. (1978). Each sample was mixed with 40 mL of 1% skimmed milk and mixed for 30 min at 150 rpm at room temperature. After that, the samples were

centrifuged at 23.000 *g*, and the supernatant was removed. The pH value of this supernatant was adjusted to 4.5 using 2N HCl, and afterwards again centrifuged at 23,000 *g* for 20 min The supernatant was discarded, and the pellet was resuspended using 5 mL of 0.15M Na_2HPO_4. Afterwards, another centrifugation step followed, using 3000 rpm for 15 min. The supernatant was removed and filtered using a syringe filter with a pore size of 0.2 µm. This filtrate was used for titration and virus quantification. A serial dilution in decadic steps was performed and plated into a 96-well plate with A9 cells. Incubation was performed at 37°C using 5% CO_2. Readout was performed on Days 7, 8 and 9. The virus titre was determined according to Spearman (1908) and Kärber (1931).

Following a request for clarification on the material used in the experiments, the titration methodology and the potential interference between the matrix and the detection system, the applicant provided these additional points:

a. In the lab trial, raw (unprocessed) material from the separate collection of biowaste (green waste and kitchen/catering waste as defined in the report in section B) was used. This was the same material used at the start of the industrial composting process.[15]
b. The titration method used is the one used by the German veterinary association for disinfection testing. Each test (temperature, time) was performed in triplicate, and two repetitions of each test were performed. The dilution was performed in $\log_{10}$ steps. Samples were diluted up to 10^{-6}. So, six different dilutions were tested. For the initial titre of the virus, the dilution was done up to 10^{-8}. On each 96-well plate, a positive control with the original virus suspension was used. The standard deviation was calculated using Microsoft Excel. No other statistical analysis was done.
c. Toxicity testing towards the cell culture detection system was performed using the same composting material as for the tests but without virus. The same extraction/re-isolation method was performed, and the same titration method was used. Readout was done as above. Results showed that the compost is toxic up to the first dilution step (10^{-1}).

The experiments show that both temperature and composting material have an influence on the inactivation of MVM. In the absence of compost, the temperature of 55°C for up to 72 h does not necessarily achieve a reduction of MVM infectivity of at least 3 $\log_{10}$ (Figures 3 and 4), while in the same conditions (absence of compost), a 3 $\log_{10}$ reduction is achieved with a 48-h treatment at a temperature of 60°C (Figures 5 and 6). In the presence of composting material, a reduction of MVM infectivity of at least 3 $\log_{10}$ is obtained within 24 h of treatment at 55°C (Figures 7 and 8).

The applicant concluded that these results indicate that a treatment time of 72 h under the influence of both a temperature of 55°C and the composting material should be more than sufficient to reach a 3 $\log_{10}$ reduction of parvoviruses. In the case of a treatment at 60°C, the temperature alone achieves a 3 $\log_{10}$ reduction of parvoviruses within 48 h. The results also show that there is no difference between the inactivation potential with or without preheating.

Following a request for clarification on the rationale for not performing the experiment with compost at 60°C, the applicant clarified that, as the results of the water bath experiments without composting material have shown that a > 3 $\log_{10}$ reduction of MVM was achieved after 48 h, there was no further need to facilitate the test with composting material as well. The required reduction was already achieved without the additional microbial inactivation by the rotting material or by the microbial activity prevailing in the rotting material.

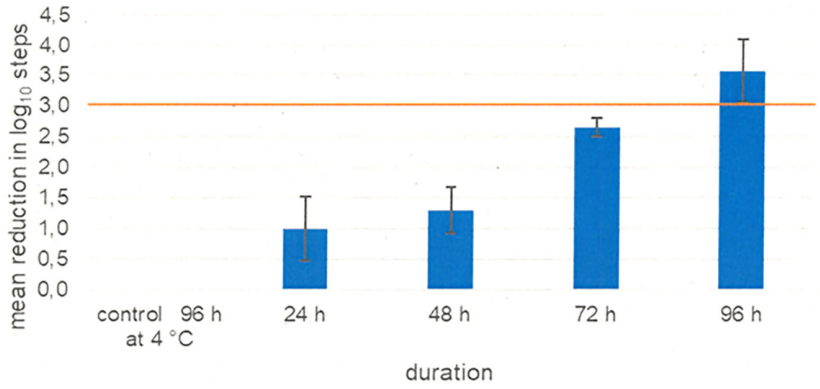

FIGURE 3 Results of minute virus of mice in water bath at 55°C first attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 5.6×10^6 $TCID_{50}$. All experiments were performed with three replicates.

[15]The material for the laboratory tests showed the following characteristics: Stability test: Rotting degree I (according to self-heating test EN 16087-2), pH (CaCl2) 6.9, dry matter 40%–50%.

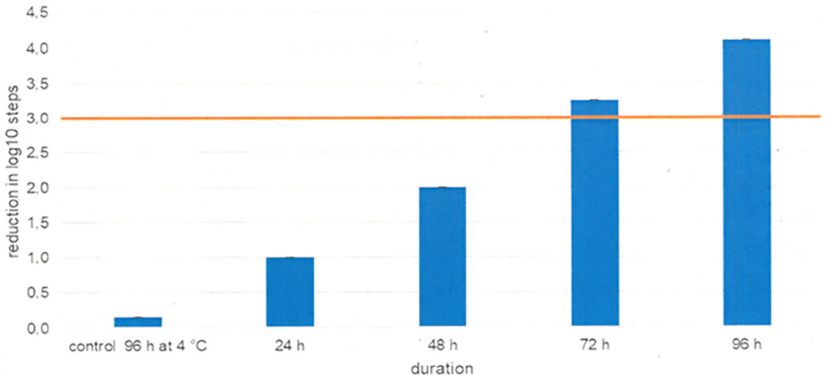

FIGURE 4 Results of minute virus of mice in water bath at 55°C second attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 1×10^5 $TCID_{50}$. All experiments were performed with three replicates.

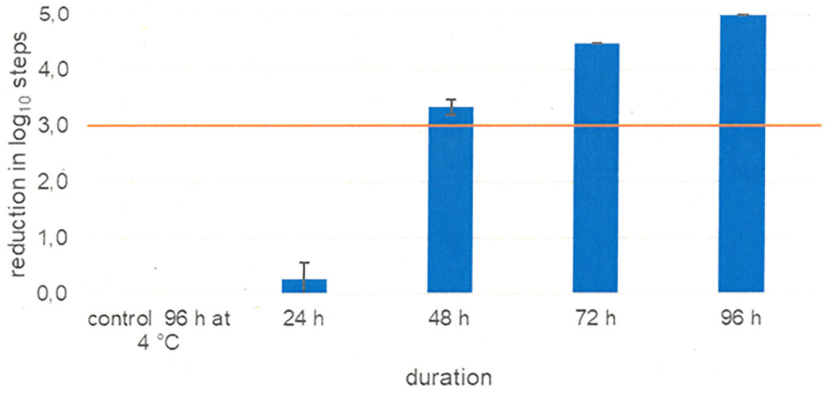

FIGURE 5 Results of minute virus of mice in water bath at 60°C first attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 1×10^5 $TCID_{50}$. All experiments were performed with three replicates.

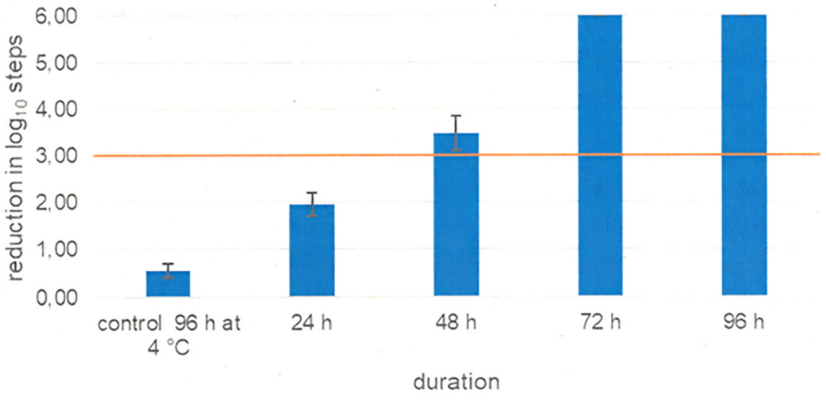

FIGURE 6 Results of minute virus of mice in water bath at 60°C second attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 1×10^6 $TCID_{50}$. All experiments were performed with three replicates.

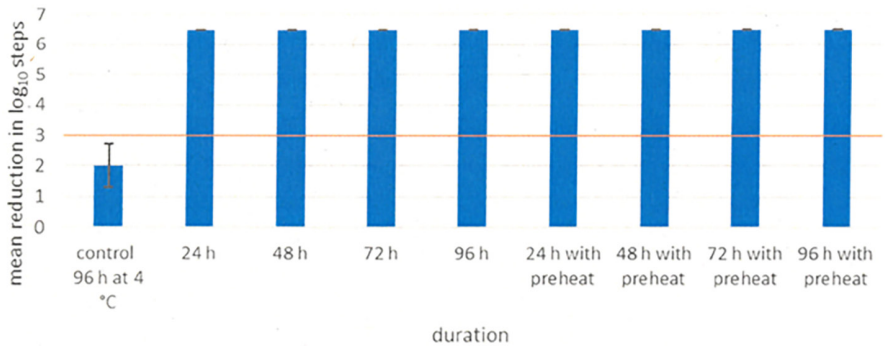

FIGURE 7 Results of minute virus of mice in water bath at 55°C using composting materials with and without preheating first attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 1×10^7 $TCID_{50}$. All experiments were performed with three replicates.

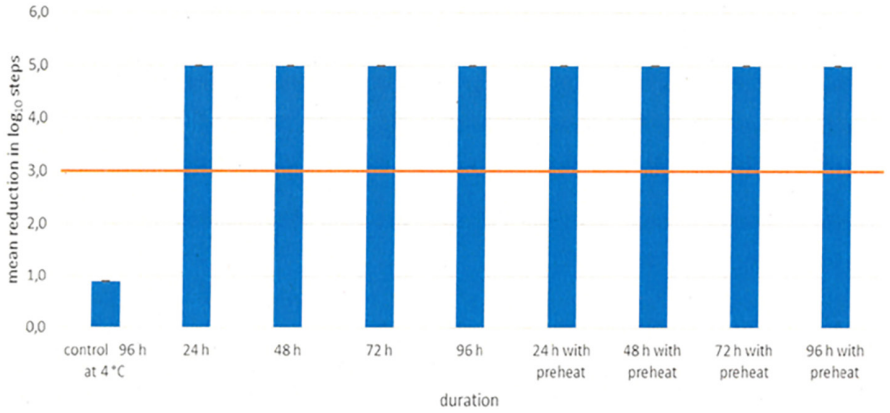

FIGURE 8 Results of minute virus of mice in water bath at 55°C using composting material with and without preheating second attempt; orange line indicating the objective of more than 3 $\log_{10}$ units' reduction. The original virus suspension had a titre of 3.13×10^6 $TCID_{50}$. All experiments were performed with three replicates.

3.4.1.3 | *Data on the validation reports of some composting plants in different EU countries*

Table 1 outlines the findings of some validation studies carried out at commercial scale composting plants in Portugal, the United Kingdom, Belgium and the Netherlands, where validation was carried out as part of an authorisation process carried out by the relevant CA in each member state, in accordance with the validation procedure provided for in Annex V, Chapter 3, Section 2 of Regulation (EU) No 142/2011.

The plants listed in Table 2 demonstrated the overall reduction of bacterial hazards requested in Annex V, Chapter 3, Section 2 of Regulation (EU) No 142/2011 and were approved to operate.

In 2015, Intermunicipal Waste Management of Greater Porto (LIPOR) (Portugal) developed a study to demonstrate that their composting plant was operating in accordance with the requirements of the EU ABP regulations. The plant processes up to 60,000 tonnes per year of catering waste (mostly restaurants) and market waste (fruit and products or foodstuffs, which may contain products of animal origin, which are no longer intended for human consumption or commercial purposes). The first stage of pre-composting lasts 14 days, in which the hygienisation period of 60°C for 48 h is achieved. The compost is cooled to around 50°C. At post-composting stage, the compost is moved into another tunnel, and the same process happens again, in which a second hygienisation period of 60°C for 48 h is achieved.

During the experiment, a spiked culture containing a high concentration (approximately 10^8 CFU ml^{-1}) of a surrogate organism, *E. faecalis* strain ATCC 29212, was used. The validation of alternative transformation parameters was done in three tunnels of the first phase and in a tunnel of second composting phase, all of which had continuous monitoring of temperature.

The analysis of experimental results concluded that, for a multi-tunnel system such as LIPOR's composting plant and the same mixing input, a period of exposure of 24 h and a temperature of 60°C ensured the sanitation conditions required under the guidelines applicable to ABP. The experimental results showed a reduction of more than 7 $\log_{10}$ cycles for *E. faecalis*.

Similarly, the LIPOR plant tunnel No 12 (Table 1) demonstrated that a standard with the same time – temperature regime as the ECN proposed standard number 2 (60°C for 48 h at 200 mm particle size), albeit at 150 mm particle size, does demonstrate the required log reduction of pathogens to be an approved plant.

OVAM (Public Waste Agency of Flanders) did a study in 2018 where three different composting plants with different systems were validated according to the procedure in Annex V, Chapter 3, Section 2 of Regulation (EU) No 142/2011. For tunnel composting, the tunnels were validated for working at 60°C for 24 h and 55°C for 48 h, and this showed that a decrease of >7 log10 of *E. faecalis* was achieved. This demonstrated that the alternative standard numbers 1 and 2 being proposed by the ECN do meet the requirement for approval of a tunnel composting system.

The Dutch Waste Management Association commissioned a national study in 2006 aimed at determining the microbiological status of the sector in light of the ABP Regulation (EU) No 1774/2002. During the 2006 study, 21 Dutch composting plants were assessed to determine if they could meet the EU ABP requirements. Overall, the 21 plants demonstrated a 4.7 $\log_{10}$ unit reduction for *Enterococcus* (7.1 down to 2.4 $\log_{10}$). Fifteen of the 21 plants showed a reduction of almost 5 $\log_{10}$ units or more and met the ABP requirements. The trials on the 21 plants were conducted as follows:

- Untreated biowaste was tested for *Enterococcus*.
- After the sanitation phase, the compost was sampled to show a $\log_{10}$ reduction.

The untreated biowaste samples of all 21 plants had almost the same level of *Enterococcus*.

TABLE 1 Summary of validation of compost plants according to Regulation (EU) No 142/2011.

Description of composting system and tunnel ID	Temperature (°C)	Time (hours)	Particle size limit (mm)	Log_{10} reduction for *Enterococcus faecalis*	Log_{10} reduction for *Salmonella* Senftenberg
Lipor Tunnel (No 15) pre-composting stage	63.5	48	150	> 7.46	
Lipor Tunnel (No 8) pre-composting stage	61	48	150	> 7.60	
Lipor Tunnel (No 12) pre-composting stage	60	48	150	> 7.66	
Lipor Tunnel (No 3) post composting stage	60	24	60	> 7.15	
Lipor Tunnel (No 3) post composting stage	60	48	60	> 7.15	
Lipor Tunnel (No 3) post composting stage	60	36	60	> 7.90	
Plant A, Belgium	55	48	Not provided	7	
Plant B, Belgium	55	48	Not provided	7	
Plant C, Belgium	60	24	< 120	7	
Attero Deurne, NL	60	24	Not provided	5.65	
Attero Maastricht, NL	60	24	Not provided	5.5	
Attero Venlo, NL	60	72	Not provided	7.3	
ARN, NL	57.5	24	60	7.18	
Valor, St. Oedenrode, NL	56	24	250	6.51	
Valor, Bladel, NL	59	24	250	6.54	
Twence, NL	51.2	24	60	6.38	
Meerlanden, NL	58	24	60	6.04	
van Vliet, NL	58	20	Not provided	7.18	
Envar, UK	60	48	400	6	
Envar, UK	60	24	400		> 7

In the United Kingdom, the Envar plants process 105,000 tonnes of catering waste per year. In 2009, the company got approval for a new alternative transformation standard (60°C for 48 h [<400 mm] in a tunnel) for composting catering waste from its national CA, the Animal & Plant Health Agency. The standard approved has the same time/temperature limits as the second standard of this alternative method but has a larger particle size of 400 mm. The ECN standard is stricter as it has a smaller particle size of 200 mm.

Since the implementation of the ABP Regulations in the United Kingdom, 14 composting plants achieved approval under Annex V, Chapter 3, Section 2 of Regulation (EC) No 142 of 2011. There is no general report on this data, and the applicant contacted each plant individually, and only a few were able to provide details as the work was done a long time ago (15 years+). These plants provided data on the temperature, time duration and particle size, and confirmed they achieved the required 3 log_{10} reduction of thermoresistant viruses using canine parvovirus and a 5 log_{10} reduction of *Salmonella*. Only two plants were able to provide information on the log_{10} reduction values obtained (see Table 2).

TABLE 2 Processing standards of UK Tunnel compost plants approved under alternative processing*

Plant	Temp (°C)	Time (hours)	Particle size (mm)	Parvovirus log_{10} reduction	*Salmonella* log_{10} reduction
Envar	60	48	400	5.75, 5.75, 5.75, 5.75, 5.75	> 7.23, > 7.23, > 7.23
Biowise Ltd Crewe	61	48	< 150	> 4.5 in 18 different trials**	Not able to share test results

*Data from two other UK plants were not available.

**Upon request for clarification, the applicant specified that the Biowise Ltd Crewe data on parvovirus log_{10} reduction shown in the dossier do not correspond to titre log_{10} reduction but to viral titres after processing, so the actual overall log_{10} reductions have been included here.

ECN Standards Particle Size Justification

The ECN is proposing for both standards a maximum particle size of ABP feedstock of 200 mm before entering the tunnel. The reported maximum particle size of collected biowaste/municipal solid waste from households is in the region of 100 mm (Lakshmikanthan et al., 2014; Nakamura et al., 2006).

It should be noted that in some Member States (France, Germany, Slovenia and Austria), National Standards for processing catering waste have no limits on the particle size.

In determining different time–temperature profiles for ABP materials information was gathered on:

- The time of inactivation of different types of animal pathogens at different temperatures (presented above).
- Information on heat conduction in compost particles, for example how long will it take for temperature to reach the core of the compost aggregates as a function of aggregate size and temperature. This information is obtained from data on

heat transfer coefficients and heat capacity, which is used for theoretical calculations.

Two mechanisms play a role during the inactivation of pathogens in tunnel composting:

1. Time to inactivate pathogens/viruses
2. Pathogens do not directly 'feel' the exposed temperature; it takes time for temperature to distribute evenly among the composting mass. This is because:

   a. particles are not infinitely small, but they have a certain size. Therefore, it takes time for the temperature to reach the centre of the particle;
   b. as a composting pile contains aggregates of individual particles (organics, inerts and water) where air cannot enter (unaerated zones), these larger aggregates can only reach higher temperatures by heat conduction.

The temperature distribution in a tunnel is homogenous due to the circulation of air. This guarantees that all the mass has been at the required inactivation temperature. Figure 1 shows the typical operation of a tunnel.

Heat Penetration in a Compost Particle/Aggregate

Compost consists of individual solid particles and aggregates (conglomeration of individual particles and water) of a certain size. As no air enters these aggregates, no aerobic degradation and self-heating takes place inside this particle/aggregate. The temperature within the core of these particles/aggregates can only increase by heat conduction from the surrounding warmer air and material. In other words, it takes time for the core of the particle/aggregate to reach the same temperature as the temperature at which the composting process is controlled.

The heat conduction of the material depends on its properties (thermal conductivity, heat capacity and density), and moreover, the time for the temperature to reach the core of the particle/aggregate depends on the size of the particle. The properties of the material measured for different types of composting materials were reviewed from the following publications:

- Study of thermal conductivity in organic solid wastes before composting (Huet, Druilhe, & Debenest, 2012).
- The impact of compaction, moisture content, particle size and type of bulking agent on the initial physical properties of sludge-bulking agent mixtures before composting (Huet, Druilhe, Tremier, et al., 2012).
- Determination of thermal properties of composting bulking materials (Ahn et al., 2009).
- Testing of the thermal properties of compost from municipal waste with a view to using it as a renewable, low-temperature heat source (Klejment & Rosiński, 2008).

Models are available in the food processing industry to calculate heat penetration in food and determine the required time to pasteurise and sterilise food in cans. A model (Rouweler, 2014) was used to calculate the core temperature of a particle/aggregate in warm air as a function of the material properties and the size. The model can be used for different geometries (sphere, oval, brick, cylinder, cube, etc.).

Figure A1 in Appendix A shows the temperature development in the core of a sphere-shaped particle/aggregate in time as a function of the particle diameter, as predicted through modelling. The initial particle temperature is 20°C, and the temperature of composting is 60°C.

The time to reach the target temperature increases significantly when the particles get larger. If a time–temperature profile of 2 days at 60°C for pathogen eradication is required, the particles should be smaller than 200 mm. Otherwise, it takes too long to reach a temperature of 60°C in the core of the particles (Figure A2).

3.4.2 | Assessment of the BIOHAZ Panel on the level of risk reduction

The applicant provided as supporting information: (i) data from the literature on thermal inactivation and D-values of the listed biological hazards which, according to the applicant, may contaminate the raw materials to be composted, with ranges (shortest and longest) of inactivation times for pathogens and viruses at 55°C and 60°C; (ii) the findings of some validation studies carried out at composting plants across Europe, where validation of similar alternative composting methods was carried out in accordance with the validation procedure provided for in Annex V, Chapter 3, Section 2 of Regulation (EU) No 142/2011; and (iii) experimental data from direct measurements of reduction of infectivity in compost material of spiked murine parvovirus (MVM), used as surrogate of those viral hazards identified as relevant (porcine parvovirus and circovirus or chicken anaemia virus), applying the same time/temperature conditions of the two alternative methods.

The data gathered by the applicant on thermal inactivation and D-values of *Toxoplasma, Campylobacter, E. coli, L. monocytogenes, C. perfringens, Salmonella, C. difficile, S. aureus, E. faecalis*, and viruses, including thermoresistant viruses such as porcine parvovirus, bovine parvovirus, circovirus or chicken anaemia virus, come from experimental studies carried out in a range of different matrices. The data presented in the tables on the inactivation times at different temperatures of the main hazards include studies reporting results on very different scales that, in most cases, can be translated into hazard

reductions higher than 3 $\log_{10}$ (Table A3 in Appendix A). The data provided can differ from thermal inactivation in the system under assessment due to differences in the physicochemical characteristics of the medium, bacterial physiological status and the scale of the system employed in the study (e.g. laboratory scale vs. industrial plant), among others (EFSA BIOHAZ Panel, 2020).

Regarding bacterial hazards, in the previous assessment of the same alternative processes (EFSA BIOHAZ Panel, 2020), considering the data the applicant presented on D-values and thermal inactivation of *Salmonella* Senftenberg 775W, H_2S negative and *E. faecalis* and the results of validation studies carried out at commercial scale composting plants across Europe, it was concluded that the proposed alternative processing methods, if the target temperature/time combinations are maintained during the whole composting process and applied homogeneously in the composting tunnel, would be able to inactivate more than 5 $\log_{10}$ of *E. faecalis* or *S.* Senftenberg 775W H_2S negative in the material to be treated, as required in Section 2, Chapter III, Annex V, of Regulation (EU) No 142/2011. The revision of the evidence provided in the new application dossier, which also includes thermal inactivation data for more bacterial hazards with relatively high heat resistance, such as *S. aureus*, does not change this conclusion.

In relation to thermoresistant viruses, the validation studies carried out at commercial UK Tunnel compost plants showed a reduction of 5.75 $\log_{10}$ for canine parvovirus in the data provided by Envar, and the data from Biowise Ltd Crewe showed reductions of > 4.5 log10 for canine parvovirus in 18 different trials at 60°C for 48 h. The 200 mm particle size proposed by the applicant are included in the range of particle size (mm) presented for those validation studies (< 150–400 mm). Data from the other two plants for which the standards are approved in the UK were not available for this assessment, but it was claimed by the applicant that they reached the required level of reduction (> 3 $\log_{10}$) for canine parvovirus.

Furthermore, an experimental study was provided to demonstrate the reduction of thermoresistant viruses. The MVM, a member of the family *Parvoviridae*, was used as an indicator, because it is thermostable, can be propagated and cultivated in permanent cell lines and displays a cytopathic effect on cells. Whereas, contrary to what was stated in the experimental study, cell culture systems are also established for bovine parvovirus (Torgeman et al., 2017) and other parvoviruses relevant for the application, such as porcine parvovirus (Lukula et al., 2017), the BIOHAZ Panel considers MVM as a suitable indicator. In fact, the choice of the MVM virus is supported by a systematic literature review on viral heat inactivation performed by Nims and Plavsic (2013, 2014), in which they support the routine use of parvoviruses such as MVM or PPV as worst-case virus models for evaluating heat inactivation. By providing new experimental data, the applicant demonstrated the capacity of the proposed alternative processing methods to inactivate MVM by 3 $\log_{10}$ at 60°C for 48 h in growth medium. Moreover, the experimental data on feedstock material showed a reduction of MVM of at least 4.1 $\log_{10}$ in samples treated at 55°C for 24 h as compared to untreated (control) samples. Although the degree to which the viral recovery from the feedstock material, the method detection limit and the variability of the composition of the feedstock material might affect the appraisal of the exact level of MVM reduction in the treated samples were not specifically addressed in the study, it is considered that the experimental data demonstrate the capacity of the processes to reduce MVM by at least 3 $\log_{10}$.

The experiments described in the study report simulated the treatment conditions in laboratory settings since the composting conditions in plants cannot be fully reproduced. Nevertheless, considering the evidence provided by the applicant on the validation activities in composting plants together with the results of the experimental trial conducted, it can be concluded that the two proposed alternative methods are able to achieve a reduction of parvoviruses by at least 3 $\log_{10}$ during composting.

3.5 | HACCP PLAN

3.5.1 | HACCP Plan as provided by the applicant[16]

A generic HACCP plan was designed to assess the risks in a composting plant scenario that had the proposed two ABP alternative processing methods (Tables 3, 4 and 5). The HACCP plan was drawn up based on the HACCP principles and includes the seven HACCP steps.

Prerequisite programmes

The plant must have in place a number of prerequisite programmes including:

- Feedstock acceptance procedures;
- Procedures in relation to transformation parameters achievement;
- Hygienisation procedures;
- Material sampling procedures;
- Microbial failure procedures;
- Cleaning and hygiene procedures;
- Procedures to prevent recontamination of post-hygienisation material and compost, respectively;

[16]The content of the section 'HACCP plan as provided by the applicant' has been extracted from the application, edited for clarity and abridged in places for brevity.

- Vermin and pest control procedures;
- Maintenance and calibration procedures;
- Dispatch procedures;
- Procedures required in order to implement the HACCP plan effectively – HACCP Audit;
- Training.

Relevant Regulations

The HACCP plan was developed in compliance with:

- Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011.

Code of Practice

The following codes of practice/guidelines were followed:

- The document 'Guidance Document Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses',
- The BRI Campden HACCP intermediate training course manual.

Hazard Analysis

A multidisciplinary team was established to develop the HACCP plan. The scope of the HACCP plan should follow the HACCP principles and cover the entire composting process. It covers the entire process from raw material intake from suppliers to the dispatch of the finished compost to the end user. The hazards to be addressed are 'biological–animal/human pathogens'. The pathogens to consider are viruses, bacteria and parasites. Based on the feedstocks going to be used in the compost plant, the relevant pathogen hazards are listed in Section 3.3.1.

TABLE 3 Description of the compost product.

Composition	Category 3 ABP materials
Structure and physical–chemical properties	The material is a semi-solid material with a water content of less than 40%
Processing	Standard 1: a. maximum particle size of ABP before entering the tunnel: 200 mm; b. minimum temperature in all material in the tunnel unit: 55°C; and c. minimum exposure time in the tunnel unit without interruption: 72 h. Standard 2: a. maximum particle size of ABP before entering the tunnel: 200 mm; b. minimum temperature in all material in the tunnel unit: 60°C; and c. minimum exposure time in the tunnel unit without interruption: 48 h
Packaging	Some sold in bulk trailer loads and some in bags
Storage conditions	It will be stored in a clean area separate from the dirty area
Shelf-life	Not applicable
Instructions for use	It will be used on agricultural land, landscaping, growing media and horticulture
Microbiological criteria	Samples of compost are taken after hygienisation for *E. coli* and samples of compost are taken from the plant (during storage) prior to dispatch for *Salmonella* *Escherichia coli*: $n=5$, $c=1$, $m=1000$ cfu/g, $M=5000$ cfu/g; *Salmonella*: absence in 25 g; $n=5$; $c=0$ n = number of samples to be tested; m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m; M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less

Identification of intended use

The compost will be used on agricultural land, landscaping projects and in horticultural uses (Figure 2, flow diagram).

TABLE 4 List of hazards, controls and corrective actions.

Process step	Hazard	Control	Corrective action
1. Waste intake	The presence of pathogens (other than those mentioned in Table A2) from wrong type of ABP waste allowed into the plant	Prerequisite programme 1: 'feedstock acceptance form Supplier approval in advance by the Feedstock Approval Contract Supplier commercial document (if applicable) Visual inspection of solid waste by operator	Review acceptability of load Non-conforming material is rejected Review suitability of suppliers
2. Storage	Proliferation of pathogens if stored for a long time	The feedstock will be stored for a maximum of 48 h in a manner which prevents access by vermin	Re-training of staff
3. Mixing & blending of ABP materials to less than 200 mm particle size	Survival of pathogens after hygienisation due to incorrect size of ABP feedstock Keeping the mixture at optimal moisture range for composting	Training of staff Visual check by operators and taking of random samples to pass ABP feedstock through 200 mm mesh screen If required, moisture may be added using a hose or sprinkler system Moisture is controlled by visual assessment by operators	Failed material is re-blended Re-training of staff
4. Hygienisation of feedstock	Survival of *E. coli*/pathogens due to incorrect hygienisation (under-processed)	Consistent application of the scheduled process (temperature and time) Temperature recording device would be used to record temperature continuously during the pasteurisation period. Twice a year a handhold probe would be used to check for cold spots in the composting mass. The competent authorities for checking the approval conditions should have a checklist when controlling the plant for this requirement Checking and calibrating the thermograph Prerequisite programmes of planned maintenance and calibration of temperature probes Trained staff Check mixes Mixing system Procedure for failure of hygienisation	If the compost fails to reach the required heat treatment, the material is reprocessed again The cause of the problem is investigated and appropriate action taken to ensure an effective process
5. Post sanitisation treatment and screening	Microbial pathogens could re-contaminate the compost	Separate areas. Trained staff Cleaning and disinfection of material when used in both the clean and dirty area No use of leachate water (percolate) after required time/ temp has been reached	Re-training of staff If compost is re-contaminated, it will be reprocessed
6. Storage of compost	Microbial pathogens could re-contaminate the compost	Separate areas Trained staff Cleaning and disinfecting of material when used in both clean and dirty areas No use of leachate water (percolate) after required temp/time has been reached The compost material at this stage is still hot and starting the stage of cooling down. The additional period at hot temperatures will aid further pathogen inactivation	Re-training of the staff. If compost is re-contaminated, it will be reprocessed
7. Passed *E. coli*, *Salmonella* and dispatched to end users	Microbial pathogens could re-contaminate the compost. Biosecurity: dissemination of hazards to local farm and environment	Laboratory analysis of compost for *Salmonella*	If the compost has *Salmonella* present the veterinary officer is contacted for instructions on what to do. The cause of the problem is investigated, and appropriate action taken to ensure an effective process

Determining CCPs

The decision tree is based on a generic HACCP CCP decision tree and was used to assess if a hazard was a CCP (Figure A3 in Appendix A).

TABLE 5 List of hazards, controls and determination of CCP.

			Campden tree						
Process step	**Hazard**	**Control**	**Q1**	**Q2**	**Q2a**	**Q3**	**Q4**	**Q5**	**CCP?**
1. Waste intake	The presence of pathogens from wrong type of ABP waste allowed into the compost plant	Prerequisite programme (PRP): 'feedstock acceptance form' Supplier approval in advance by the Feedstock Approval Contract Supplier commercial document – if applicable Visual inspection of solid waste by operator	Yes						Not a CCP Operational PRP as it is an important PRP 1
2. Storage	Proliferation of pathogens if stored for a long time	The feedstock will be stored for a maximum of 48 h in a manner which prevents access by vermin	Yes						Not a CCP, managed by PRP 2
3. Mixing/ shredding all feedstocks to less than 200 mm particle size	Survival of pathogens at hygienisation due to incorrect size of feedstock	Visual inspection to ensure less than 200 mm of ABP feedstock	Yes						Not a CCP, managed by PRP 2
4. Hygienisation of feedstock	Survival of *E. coli* due to incorrect hygienisation (under-processed)	PRP – Consistent application of the scheduled process (temperature and time) Prerequisite programmes of planned maintenance and calibration of temperature probes Trained staff	No	Yes		Yes			Yes, CCP1
5. Post sanitisation treatment and screening	Microbial pathogens could re-contaminate the compost	PRP Use of clean loader	Yes						Not a CCP
6. Storage of compost	Microbial pathogens could re-contaminate the compost	PRP Use of Clean loader Stored in separate area from untreated ABP	Yes						Not a CCP
7. Passed *E. coli*, *Salmonella* and dispatched to end users	Microbial pathogens could re-contaminate the compost	PRP Use of Clean loader *Salmonella* testing	Yes						Not a CCP

3.5.2 | Assessment of the BIOHAZ Panel on the HACCP plan

The biological hazards identified by the applicant as a risk for the composting process are listed in Section C of the dossier.

Figure 2 summarises the process flow diagram and by-products, and Table 4 lists the process steps as in Figure 2. However, in Figure 2, step 4 is named '60 degrees, 48 h or 55 degrees, 72 h', while in Tables 4 and 5, it is called 'Hygienisation of feedstock'. The CCPs were identified following a generic HACCP CCP decision tree.

- Step 1 – waste intake was not identified as a CCP in relation to the presence in the feedstock of additional pathogens in

comparison to those listed in Section C, and this is considered to be correct. Feedstock suppliers sign a contract describing the waste material that can be provided.

- Step 2 – storage was not identified as a CCP, and this is considered to be correct. An indicative storage time has been included to avoid the proliferation of the pathogens identified in section C. The storage time indicated by the applicant in Table 5 is 24 h, while in the description of the process (Section 3.1.1), it is 48 h.
- Step 3 – mixing and blending of ABP materials to less than 200 mm particle size was not identified as a CCP, and this is considered to be correct. As specified by the applicant, if the expected particle size is not achieved, pathogens listed in section C might survive after hygienisation. However, this feedstock preparation phase should enable the achievement of the expected particle size as well as the water content (50%–65%) specified in the technical data. The process efficacy is verified by taking random samples tested through a 200-mm mesh screen. It is important to highlight that (1) the thermal properties of compost bulking materials change according to particle size but also according to water content and bulk density (Ahn et al., 2009); (2) at present, in some member states (i.e. France, Germany, Slovenia and Austria), national standards for processing catering waste have no limits on the particle size. According to the applicant, water is added when needed to maintain an adequate water content, based on a visual assessment by the operators. A more objective measurement of the moisture content should be preferred, indicating also when this is controlled.
- Step 4 – Hygienisation of feedstock is identified as a CCP, and this is considered to be correct because, as stated by the applicant, if the process is not performed at the appropriate temperature and water content for the appropriate time, the pathogens listed in section C might survive. The applicant specified that the temperature was recorded continuously during the pasteurisation period and that, twice a year, a check for cold spots in the control mass will be conducted as a means of verification and recording systems. This control measure also involves the competent authorities, who should have a checklist for this requirement. However, the HACCP plan should be implemented by the composting plant itself, without the need for any external checking by competent authorities.
- Step 5 – The post sanitisation treatment and screening step is not identified as a CCP, and this is considered to be correct. Indeed, the only identified hazard is cross-contamination of the processed compost, but this can be avoided by keeping the treated compost in a dedicated area that must be different from that used for the storage of untreated ABP waste and using separated instruments for transport. This step contributes to pathogen eradication because the thermophilic process conditions, which provide a temperature range > 55°C, are kept between 10 days and several weeks. The applicant did not clarify if this was always the case regardless of the season or weather conditions, and they did not identify this step as a key and relevant barrier for pathogen inactivation. The applicant refers to the cleaning and disinfection of material when used in both clean and dirty areas, while separate equipment should be used.
- Step 6 – Storage of compost is not identified as a CCP, and this is considered to be correct. This step is considered to contribute to pathogen inactivation, since the compost is still hot. Again, separate equipment should be used for clean and dirty areas.
- Step 7 – Dispatch of compost is not identified as a CCP, and this is considered to be correct. As above, the only identified hazard is cross-contamination of the processed compost, which can be avoided by keeping the treated compost in a dedicated area well separated from the dirty area. The laboratory analysis of *Salmonella* cannot be considered as a validation of the control measure, but a means of verification.

As the only reference to the approved method by the ABP Regulation (EU) No 1069/2009 was a hygienisation provision for compost by direct methods of *E. coli* or *Enterococcaceae* for process verification (< 1000 CFU/g in four of five samples; 1000–5000 CFU/g in one of five samples) and for *Salmonella* in the final compost, which should not be detected (in 25 g) in five of five samples, it is considered that an alternative process should comply with those requirements from a hygienic point of view.

Overall, the generic HACCP plan provided is generally appropriate and can be the basis for the validation and verification of the process once implemented at industrial level.

3.6 | Risk associated with interdependent processes

3.6.1 | Risk associated with interdependent processes as provided by the applicant[17]

Leachate from the Process

Leachate collected from the composting tunnels and wash water used to clean trucks/floor/machines in the reception hall is typically used in the composting process prior to hygienisation. This leachate should be stored separately from clean water. Procedures should be in place to ensure that no unpasteurised/dirty water is used in the process after the minimum hygienisation temperature of 60°C is maintained for at least 48 h or 55°C for 72 h, as it carries a risk of reintroducing pathogens if used.

[17]The content of the section 'Risk Associated with interdependent processes as provided by the applicant' has been extracted from the application, edited for clarity and abridged in places for brevity.

Storage

The end product, compost (organic fertiliser and/or soil improver), should be stored in an area of the compost plant where there is no possibility of cross-contamination with raw, unprocessed ABP. This will ensure there is no reintroduction of pathogens.

Transportation

Compost should only be loaded onto the trailer with a 'clean loader/equipment' (i.e. not used in moving untreated ABP). This prevents any cross-contamination. Trailers used to deliver the end product compost to final users should be ideally dedicated to transporting finished compost only and not be used for transporting untreated ABP material. In the case the trailer is not dedicated, it should be cleaned and disinfected between use and this activity is recorded. This prevents any potential risk of cross-contamination and the reintroduction of pathogens.

3.6.2 | Assessment of BIOHAZ Panel on the risk associated with interdependent processes

The applicant provided a description of the risks associated with leachate from the process and storage of raw materials and the end product, as well as the procedures that would be implemented for dealing with these risks.

The transport of the end product was also considered by the applicant, as suggested in the assessment of the risk associated with interdependent processes performed in 2020. The applicant provided procedures for the prevention of cross-contamination and reintroduction of pathogens during the transport of the end product, which are considered adequate.

3.7 | Risk associated with the intended end use of the product

3.7.1 | Risk associated with the intended end use of the product as provided by the applicant[18]

The end point in the manufacturing chain for compost is currently not defined in the ABP Regulation. Once the compost end product meets all the proposed transformation standard requirements, and meets the required pathogen thresholds, there will be no risks associated with the end use of the product.

3.7.2 | Assessment of BIOHAZ Panel on the risk associated with intended end use of the product

The following extract was taken verbatim from the EFSA BIOHAZ Panel 'Scientific opinion on the evaluation of alternative methods of tunnel composting (submitted by the European Composting Network) (EFSA BIOHAZ Panel, 2020).

The end product of the process is compost, which, according to the applicant, may be used as a fertiliser and/or soil improver (it will be used on agricultural land, for landscaping projects and for horticultural uses). The applicant envisages the establishment of the end point of the process at the composting plant when the end product complies with microbial testing standards. Provided that the alternative method is capable of achieving a risk reduction level equivalent to that of the method in the Regulation and that these microbial standards are met, no additional risks associated with the intended end use of the product are foreseen.

4 | CONCLUSIONS

- Two alternative methods for the production of compost were assessed. The first proposed a minimum temperature of 55°C for 72 h; the second 60°C for 48 h, each with a maximum particle size of 200 mm.
- The materials to be composted by the two alternative methods for tunnel composting include ABP catering waste and processed foodstuffs of animal origin, which are no longer intended for human consumption, and other non-ABP material (i.e. garden and park waste). The assessment of the BIOHAZ Panel exclusively focuses on Cat. 3 ABP raw materials: catering waste and processed foodstuffs of animal origin, which are no longer intended for human consumption.
- All hazards included in the list of biological hazards that may enter the composting process provided by the applicant (*Toxoplasma, Campylobacter, E. coli*, *Salmonella*, *L. monocytogenes*, *C. perfringens, C. difficile, S. aureus, E. faecalis*, porcine parvovirus, circovirus and chicken anaemia virus) are considered relevant. Although the applicant considers ASFV unlikely to enter the composting process, the BIOHAZ Panel considers that it should be included in the list because ASFV could be present in catering waste and foodstuffs of animal origin, due to the current epidemiological situation of the disease in Europe.

[18]The content of the Section 'Risk associated with intended end use as provided by the applicant' is extracted *verbatim* from the application, edited for clarity and abridged in places for brevity.

- The EFSA BIOHAZ Panel considered that a reduction of at least 5 $\log_{10}$ of *E. faecalis* and *Salmonella* Senftenberg 775W H_2S negative, and at least 3 $\log_{10}$ of relevant thermoresistant viruses should be demonstrated to consider the alternative methods at least equivalent to the processing method currently approved in the Commission Regulation (EU) No 142/2011.
- The applicant selected parvoviruses as the indicator of thermoresistant viruses among those included in the list of hazards that may enter the composting process. The BIOHAZ Panel acknowledges that all other viruses that may enter the composting process, including ASFV, are less thermoresistant than parvovirus and considers the approach followed by the applicant to be appropriate.
- The efficacy of the alternative methods was asserted by the applicant by providing: (a) literature data on thermal inactivation of bacterial hazards; (b) results on the reduction of *E. faecalis*, *Salmonella* Senftenberg 775W H_2S negative and canine parvovirus from validation studies carried out in composting plants across Europe; (c) and experimental data from direct measurements of reduction of infectivity of spiked murine parvovirus (MVM) in compost material applying the same time/temperature conditions of the two alternative methods. The evidence showed the capacity of the two proposed alternative methods to reduce *E. faecalis* and *Salmonella* Senftenberg 775W H_2S negative by at least 5 $\log_{10}$, and parvoviruses by at least 3 $\log_{10}$.
- The generic HACCP plan provided, together with the information about the risks of the interdependent processes and those associated with the intended end use, are appropriate. They can be the basis for the validation and verification of the process once implemented at industrial level.
- The BIOHAZ panel concludes that the two alternative methods under assessment can be considered to be equivalent to the processing method currently approved in the Commission Regulation (EU) No 142/2011.

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Application for the evaluation of alternative methods for tunnel composting of category 3 animal by-products (ABP) submitted by the European Compost Network (ECN) to the Belgian Competent Authority (Federal Agency for the Safety of the Food Chain of Belgium) and then submitted to EFSA on 11 May 2023

5.1 | List of annexes provided by the applicant

A01: ECN_application dossier.
A02: Report Validation.
A03: Methodological approach process validation.
A04: Report Validation PLANT A (and PLANT B).
A05: Report Validation PLANT C.
A06: Final report on the inactivation studies of murine parvovirus in composting.
A07: Validation Plan.
A08: Study carried out by DWMA (2006).
A09: List of References.
A10: Evidence on study University Hohenheim

- Resubmission of the amended dossier on 16 August 2023 with the same annexes.
- Additional information submitted by the European Compost Network (ECN) to EFSA on 17 November 2023.

ABBREVIATIONS

ABP	animal by-products
ASFV	African swine fever virus
BIOHAZ	EFSA Panel on Biological Hazards
CA	competent authority
Cat.	category
CCP	critical control point
Defra	Department for Environment, Food and Rural Affairs (United Kingdom)
ECN	European Compost Network
HACCP	hazard analysis and critical control point
MVM	minute virus of mice
PRP	prerequisite programme
WOAH	World Organisation for Animal Health

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APPENDIX A

Information provided by the applicant in support of the evaluation

The tables and figures in the appendix were extracted verbatim from the application.

TABLE A1 Technical data of the equipment used.

Factors	Tunnel composting
Tunnel	The tunnel will be of concrete or other non-corrosive construction as an enclosed vessel
Water content at start-up in the feedstock mixture	50%–65%
Watering	As required during the process. During the post-hygienisation phase, only clean water can be added
Ventilation	Forced aeration is provided by an aeration floor beneath the mass in the tunnel. The warm air is recirculated
Turning Equipment	Front end loader in order to load and unload the tunnels. Automatic filling system
Temperature during hygienisation	Standard 1: 55°C; Standard 2: 60°C
Temperature monitoring	Temperature should be monitored to ensure that it is representative of the temperatures within the composting mass

TABLE A2 Pathogens that may enter the composting process.

Organism	Where does it come from	Potential consequence (disease description)	Where does it occur	What is the relationship with compost	References
Toxoplasma	A parasite that infects vertebrates including birds. Domestic and feral cats are the definitive hosts, but other mammals, including humans, can be infected	Toxoplasmosis in pregnant women, infection which can lead to mental retardation and loss of vision in their congenitally infected children	Through the ingestion of undercooked meat, or by ingestion of the oocysts from soil contaminated with cat faeces	Cat faeces might be disposed of in the household food waste bin	Nichols (2000)
Campylobacter	It may occur in the guts of animals	Campylobacteriosis, Guillain–Barre syndrome, reactive arthritis and post infectious irritable bowel syndrome	Unwashed and uncooked root crops	Chicken is discarded uncooked in the catering waste bin This organism does not grow outside a mammalian or avian host and this may reduce the risk of disease transmission via compost	Macklin et al. (2008), Berry et al. (2013), Jones and Martin (2003), Hakkinen et al. (2007)
Escherichia coli (E. coli)	Lives in the intestines of humans, chickens and other animals	Depends on the toxins they produce. Symptoms of *E. coli* infection include diarrhoea, stomach cramps and vomiting	Associated with contaminated manure or with manure-contaminated irrigation water	*E. coli* can enter the composting process via contaminated material	Singh et al. (2010, 2011), Singh (2011), Jiang et al. (2003), Berry et al. (2013)
Salmonella	Lives in the intestines of the chicken but can occur also in other animals	Causes diarrhoea, abdominal cramps and fever, usually within 12–72 h after infection	Lives in the intestinal tracts of humans and other animals	Can enter the composting process via contaminated material. Also, there is a possibility of re-contaminating the compost after the heat phase	Macklin et al. (2008), Singh et al. (2010)
Listeria	Humans presumably acquire *listeriosis* from direct contact with infected animals, but several recent outbreaks have confirmed an indirect transmission from animals to humans through consumption of contaminated food products	Listeriosis, flu-like symptoms, vomiting, diarrhoea, meningitis, septicaemia, spontaneous abortions	Contaminated food products, including raw milk, pasteurised milk, chocolate milk, butter, soft cheeses and processed meat and poultry products, have been implicated as sources of human listeriosis cases	Inadequately pasteurised compost could be spread on land used in vegetable growing Contaminated food products sent for composting	Nightingale et al. (2004), Vivant et al. (2013)
Clostridium perfringens	Illness appears 8–24 h following ingestion of large numbers of vegetative cells in temperature-abused protein foods, typically meat and poultry	Cause of food-borne illness, though cases are widely under-reported because of the mild nature of the gastrointestinal illness, which consists of diarrhoea and abdominal cramps	Cells sporulate in the small intestine, producing an enterotoxin	Meat products will be found in catering waste which is sent for composting.	Labbé and Juneja (2013)
Clostridioides difficile	Infects pigs, calves and humans.	Causes diarrhoea and colitis.	Prevalent in soil, faeces of domestic animals and humans, sewage, the human intestinal tract and retail meat.	*C. difficile* may be present in manure and foods	Lorine et al. (2021)*

TABLE A2 (Continued)

Organism	Where does it come from	Potential consequence (disease description)	Where does it occur	What is the relationship with compost	References
Staphylococcus aureus	Usual member of the microbiota of the body, frequently found in the upper respiratory tract and on the skin	Common cause of skin infections including abscesses, respiratory infections, such as sinusitis, and food poisoning	*Staphylococcus* spp are also a small component of the soil microbiome. *S. aureus* has been found in chicken flocks	*S. aureus* may be present in manure	Kirby et al. (2019)*
Enterococcus faecalis	Lives in gastrointestinal tract of humans	Can cause urinary tract, wound and soft tissue infections	Also associated with foods, especially those of animal origin	*E. faecalis* may be present in foods	Bertolatti et al. (2001)*
Porcine parvovirus	Ubiquitous among swine	Not known to infect humans. Causes reproductive failure of swine	Contaminated premises likely to be major reservoirs	P. parvovirus may be present in manure	Welch et al. (2006)
Porcine circovirus	Infects pigs	Associated with multiple disease conditions in pigs	Widespread in most pig populations throughout the world	P. circovirus may be present in manure	Pitino et al. (2021)*
Chicken anaemia virus	Infects chickens	Clinical disease is rare today because of the widespread practice of vaccinating breeders	Ubiquitous throughout the world in poultry operations	May be present in manure	Welch et al. (2006)

*Reference not provided in the application.

TABLE A3 D-values and inactivation conditions for pathogens and viruses that may enter the composting system.

	D-value		Conditions for inactivation or at least 3 log_{10} reduction[a]		
Organism	**Temp°C**	**Time**	**Temp°C**	**Time**	**References**
Toxoplasma					
Toxoplasma gondii oocysts in water under laboratory conditions			55	2 min	Dubey (1998)
T. gondii oocysts in water under laboratory conditions			60	1 min	Dubey (1998)
T. gondii tissue cysts in meat under laboratory conditions			60	4 min	Dubey et al. (1990)
T. gondii tissue cysts in experimentally infected sheep muscles			60	10 min	El-Nawawi et al. (2008)
Campylobacter					
Campylobacter jejuni in agri wastes in laboratory scale digester			55	0.99 min	Ugwuanyl et al. (1999)
C. jejuni in agri wastes in laboratory scale digester			60	0.71 min	Ugwuanyl et al. (1999)
C. jejuni heated in meat			60	20 sec	Doyle and Schoeni (1986)
Escherichia coli					
Escherichia coli O157:H7 in cow manure composting			45	48 h	Lung et al. (2001)
E. coli O157: H7 in fresh dairy compost with 50% moisture content			50	72 h	Singh et al. (2011)
E. coli O157: H7 in fresh dairy compost with 50% moisture content			55	48 h	Singh et al. (2011)
E. coli O157: H7 in unautoclaved manure compost	55	35.4 min			Jiang et al. (2003)
E. coli O157: H7 in autoclaved manure compost	55	50.3 min			Jiang et al. (2003)
E. coli O157: H7 in autoclaved manure compost			55	3 h	Jiang et al. (2003)
E. coli NCTC 9001 in sludge			55	2.13 min	Lang and Smith (2008)
E. coli O157: H7 in manure-based mushroom compost substrate			54.4	8 h	Weil et al. (2013)
E. coli O157: H7 in unautoclaved manure compost	60	3.9 min			Jiang et al. (2003)
E. coli O157: H7 in autoclaved manure compost	60	4.1 min			Jiang et al. (2003)
E. coli O157: H7 in autoclaved manure compost – inactivated			55	15 min	Jiang et al. (2003)
E. coli O157: H7 in manure compost			65	3.9 min	Jiang et al. (2003)
E. coli O157: H7 in fresh dairy compost with 50% moisture content			60	24 h	Singh et al. (2011)
Listeria					
Listeria monocytogenes in ground beef roast			54.4	22.4 min	Schoeni et al. (1991)
L. monocytogenes in ground beef roast			57.2	15.7 min	
L. monocytogenes in ground beef roast			60	4.47 min	
L. monocytogenes in ground beef roast			62.8	2.56 min	

TABLE A3 (Continued)

Organism	D-value		Conditions for inactivation or at least 3 log_{10} reduction[a]		References
	Temp°C	Time	Temp°C	Time	
L. monocytogenes in mushroom growth compost substrate			54.5	8 h	Weil et al. (2013)
L. monocytogenes in mushroom growth compost substrate			60	30 min	Weil et al. (2013)
L. monocytogenes in ready-to-eat chicken-fried beef patties	55	81.37 min			Osaili et al. (2006)
L. monocytogenes in ready-to-eat chicken-fried beef patties	60	22.98 min			Osaili et al. (2006)
L. monocytogenes in compost			55	6 h	Singh et al. (2010)
L. monocytogenes in compost			60	70 min	Singh et al. (2010)
Clostridium perfringens					
Clostridium perfringens enterotoxin			60	5 min	Naik and Duncan (1977)
Clostridium perfringens vegetative cells in pork luncheon roll			55	16.3 min	Byrne et al. (2006)
Rapid death of vegetative cells at 51.6°C, no recovery 24 h later 'Complete inhibition of growth occurring at 49–52°C'			51.6	24 h	Hall and Angelotti (1965)
Clostridium perfringens vegetative cells in beef	55	21.6 min			Juneja and Marmer (1998)
Clostridium perfringens vegetative cells in beef	60	5.3 min			
Clostridium perfringens vegetative cells in turkey	55	17.5 min			
Clostridium perfringens vegetative cells in turkey	62.5	1.3 min			
Six Strains of *Clostridium perfringens* – little or no growth at 55°C			55		Rey et al. (1975)
Salmonella					
Salmonella Senftenberg 775W in liquid manure			50	56.7 min	Soldierer and Strauch (1991)
Salmonella in cattle manure			50	18 h	Singh et al. (2010)
Salmonella spp. in poultry compost with 50% moisture content			50	96 h	Singh (2011)
Salmonella Senftenberg 775W			50.5	11.7 h	Elving (2012)
Salmonella Senftenberg 775W in saline solution			49	26 h	Elving (2009)
Salmonella Senftenberg in fresh manure			49	107.9*	
Salmonella Senftenberg 775W in saline solution			52	8.3 h	
Salmonella Senftenberg in fresh manure			52	17.2 h**	
Salmonella Senftenberg 775W in saline solution			55	4.5 h	
Salmonella Senftenberg in fresh manure			55	16.9 h**	
Salmonella Senftenberg 775W in meat, 100% moisture			55	36 min	Ceustermans et al. (2006)
Salmonella Senftenberg 775W in meat, 60% moisture			55	104 min	Ceustermans et al. (2006)
Salmonella Senftenberg 775W in liquid manure			55	11.5 min	Soldierer and Strauch (1991)

(Continues)

TABLE A3 (Continued)

Organism	D-value		Conditions for inactivation or at least 3 log_{10} reduction[a]		References
	Temp°C	Time	Temp°C	Time	
Salmonella Senftenberg 775W in sludge			55	3.2 min	Lang and Smith (2008)
Salmonella in cattle manure			55	4 h	Singh et al. (2010)
Salmonella Senftenberg 775W			55	89 min	Burge et al. (1987)
Salmonella Senftenberg 775W in meat under lab scale composting trials			60	10 h	Ceustermans et al. (2006)
Salmonella – composting trial of biowaste			60	10 h	Ceustermans et al. (2006)
Salmonella-composting of biowastes in tunnels at the DDSVerko composting plant in Belgium			60	10 h	Ceustermans et al. (2006)
Salmonella spp. in poultry compost with 50% moisture content			60	24 h	Singh (2011)
Salmonella Senftenberg 775W in liquid manure			60	2.3 min	Soldierer and Strauch (1991)
Salmonella in manure-based mushroom compost substrate			60	30 min	Weil et al. (2013)
Salmonella Senftenberg 775W			60	7.5 min	Burge et al. (1987)
Salmonella in cattle manure			60	10 min	Singh et al. (2010)
Salmonella Senftenberg 775W in saline solution			70	15 min	Elving (2009)
Salmonella Senftenberg 775W			70	5 min	Elving (2012)
Clostridioides difficile					
Ground beef – spores			63	30 min for 1 log_{10}	Rodriguez-Palacios and Lejeune (2011)
Gracy (0%) fat – spores	63	~55 min			Rodriguez-Palacios and Lejeune (2011)
Ground Beef (30% fat) – spores	63	~45 min			Rodriguez-Palacios and Lejeune (2011)
Ground Beef (3% fat) – spores	63	~100 min			Rodriguez-Palacios and Lejeune (2011)
Beef			63	30 min for 7 log_{10}	Juneja (2003)
C. difficile in manure, including spores	55	3.0–4.1 days			Mößnang et al. (2019)
Staphylococcus aureus					
Baird Parker Agar (BPA)	50	94.3 min			Kennedy et al. (2005)
Tryptone Soya Agar (TSA) and BPA	50	104.2 min			Kennedy et al. (2005)
Tryptone Soya Agar (TSA) and BPA	55	20.4 min			Kennedy et al. (2005)
Baird Parker Agar (BPA)	55	13 min			Kennedy et al. (2005)
McIlvaine citrate phosphate buffer of pH 7	58	0.93 to 0.17 min			Rodriguez-Calleja et al. (2006)
Baird Parker Agar (BPA)	60	4.8 min			Kennedy et al. (2005)
Tryptone Soya Agar (TSA) and BPA	60	5.9 min			Kennedy et al. (2005)

TABLE A3 (Continued)

Organism	D-value		Conditions for inactivation or at least 3 $\log_{10}$ reduction[a]		References
	Temp°C	Time	Temp°C	Time	
Enterococcus faecalis					
Saline solution			55	4.7 h for 5 $\log_{10}$	Elving (2009)
Fresh manure			55	16.9 h for 5 $\log_{10}$	Elving (2009)
Digestion waste			55	8.3 min	Ugwuanyl et al. (1999)
Digestion waste			55	4.72 min	Ugwuanyl et al. (1999)
Cattle faeces			55	3.3 h for 5 $\log_{10}$	Elving (2012)
Digestion waste			60	6.61 min	Ugwuanyl et al. (1999)
Digestion waste			60	5.24 min	Ugwuanyl et al. (1999)
Porcine Parvovirus					
Cattle faeces			55	42 h for 3 $\log_{10}$	Elving (2012)
Fresh Manure			55	87.3 h for 3 $\log_{10}$	Elving (2009)
Dried manure			55	22.7 h for 3 $\log_{10}$	Elving (2009)
Biogas substrate – manure with 20% household waste	55	14 h			Lund et al. (1996)
Fresh manure with household waste	55	11 h			Elving et al. (2014)
Biowaste digestate			55	1 h for 1.4 $\log_{10}$	Emmoth (2010)
Bovine Parvovirus					
Bovine parvovirus in liquid manure	55	6 h			Srivastava and Lund (1980)
Liquid cattle manure thermophilic AD process			55	Not detected after 30 min	Monteith et al. (1986)
Co-digestion (catering waste and cattle slurry) Dt ′ values			55	4.67 h	Hoferer (2002) cited by Böhm (2007)
Co-digestion (catering waste and pig slurry) Dt ′ values			55	5.47 h	Hoferer (2002) cited by Böhm (2007)
Sewage sludge – aerobic thermophilic fermentation			56.4	8.5 h for 3 $\log_{10}$	Spillmann et al. (1987)
Sewage sludge – anerobic thermphilic digestion			60.6	14.1 h for 3 $\log_{10}$	Spillmann et al. (1987)
Circovirus					
Human plasma			60	10 h for 1.6 $\log_{10}$	Welch et al. (2006)
Porcine circovirus 2-human albumin			65	30 min for 0.25 $\log_{10}$	Welch et al. (2006)
Chicken anaemia virus					
Human factor VIII concentrate			65	30 min for 0.91 $\log_{10}$	Welch et al. (2006)
Human factor VIII concentrate			60	30 min for 0.16 $\log_{10}$	Welch et al. (2006)

*While performing the review, this value was corrected.

**While performing the review, it was noticed that these data refer to *E. faecium* and not *S.* Senftenberg 775W.

[a]The level of reduction could be different if clearly stated in the table.

TABLE A4 Range (shortest & longest) of inactivation times for pathogens and viruses at 55°C and 60°C.

	Inactivation temperatures			
	55°C		60°C	
Pathogen name	**Shortest time**	**Longest time**	**Shortest time**	**Longest time**
Toxoplasma	2 min	2 min	1 min	10 min
Campylobacter	0.99 min	0.99 min	20 s	0.71 min
Escherichia coli O157: H7	2.13 min	48 h	3.9 min D-value	24 h
Salmonella	3.2 min	16.9 h	10 h	10 h
Listeria	22.4 min	8 h	4.47 min	70 min
Clostridium perfringens	21.6 min D-value	16.3 min	5.3 min D-value	5 min
Clostridioides difficile	3 days	4.1 days	63°C – 30 min	63°C – 100 min
Staphylococcus aureus	13 min	20.4 min	4.8 min	5.9 min
Enterococcus faecalis	4.72 min	16.9 h	5.24 min	6.61 min
Porcine parvovirus	6 h	87.3 h	No data available	No data available
Circovirus	No data available	No data available	10 h – 1.6 $\log_{10}$ reduction	No data available
Chicken anaemia virus	No data available	No data available	30 min – 0.16 $\log_{10}$ reduction	10 h 1.4 $\log_{10}$

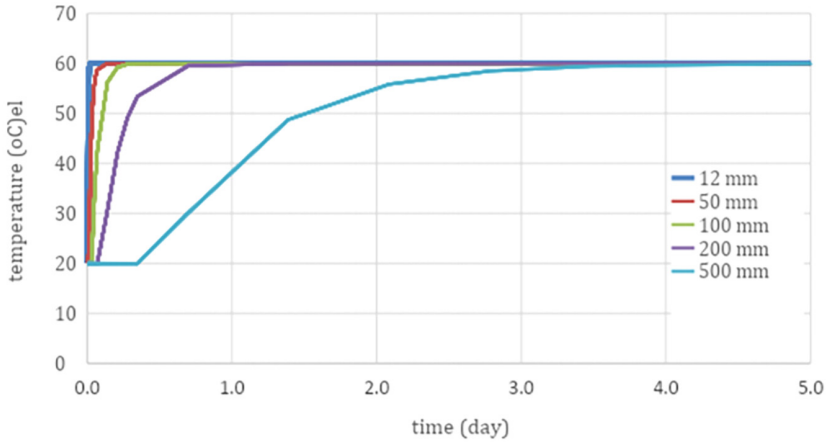

FIGURE A1 Development of core temperature as function of time for different compost particles.

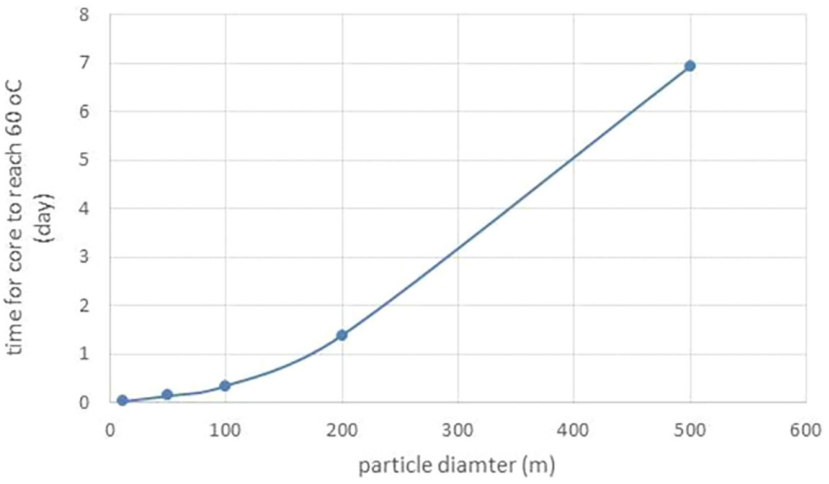

FIGURE A2 Time for particles of different diameter sizes to reach 60°C.

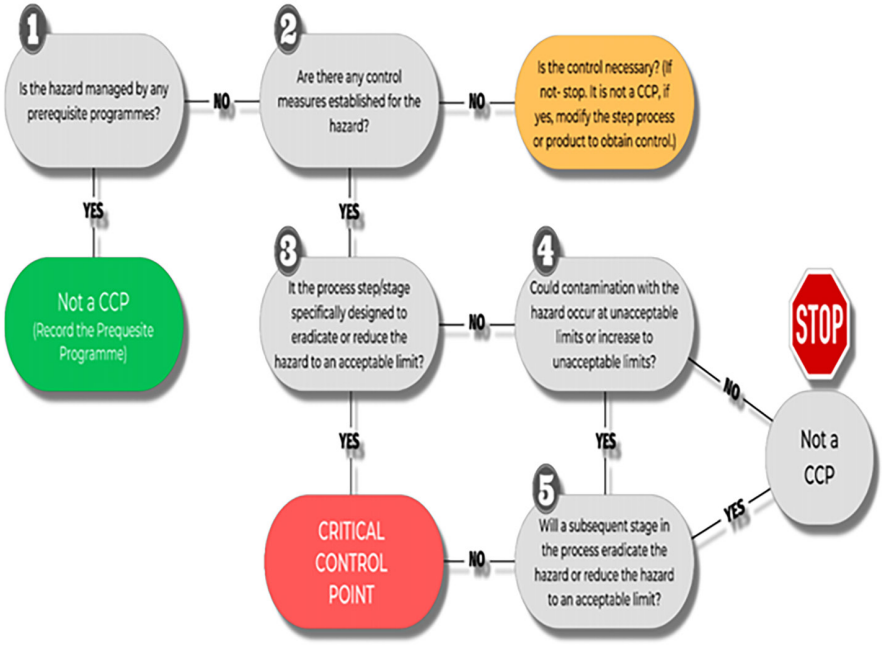

FIGURE A3 Hazard analysis and critical control point decision tree.