

Scientific opinion on the inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers

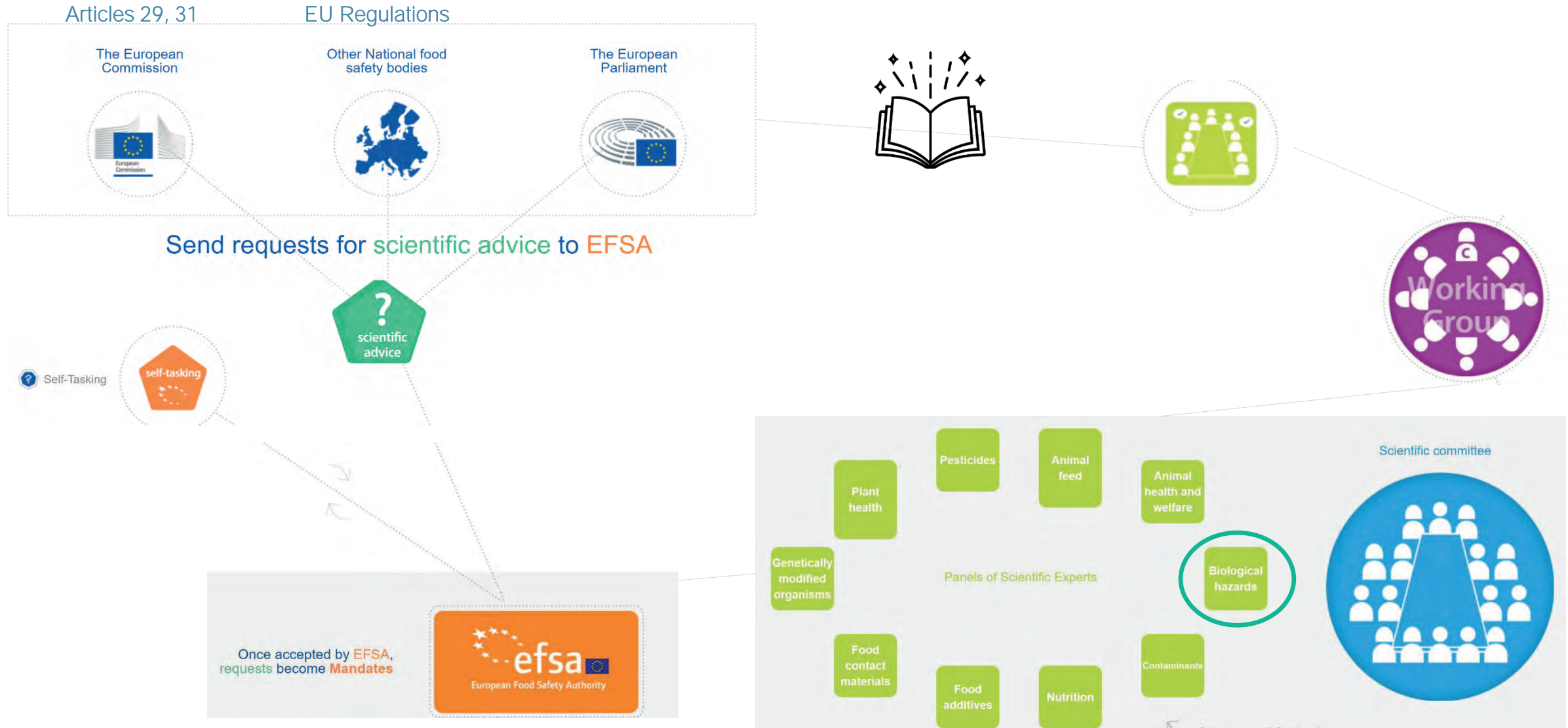
PAFF committee

Web-conference

10 February 2022

- Background, EFSA remit
- Mandate and Terms of reference
- Approach and Methodology
- Results
- Conclusions and considerations

EFSA remit: legal mandate



Regulation (EC) 1069/2009 Article 20 (ABP Regulation)

- EFSA shall assess, within six months following receipt of a complete application, whether the method submitted ensures that 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 category of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

EFSA shall issue an opinion on the application submitted

Regulation (EU) 2019/1009 (EU fertilising products)

(4) Within six months after 15 July 2019, the Commission shall initiate a first assessment of derived products referred to in Article 32 that are already widely used in the Union as organic fertilisers and soil improvers. This assessment shall cover at least the following products:

meat meal, bone meal, meat-and-bone meal, hydrolysed proteins of Category 3 materials, processed manure, compost, biogas digestion residues, feather meal, glycerine and other products of Category 2 or 3 materials derived from the production of biodiesel and renewable fuels, as well as petfood, feed and dog chews that have been refused for commercial reasons or technical failures, and derived products from blood of animals, hides and skins, hoofs and horns, guano of bats and birds, wool and hair, feather and downs, and pig bristles.

Regulation (EU) 2019/1009 (EU fertilising products)

- (4) Where the assessment concludes that... no longer pose any **significant risk** to public or animal health, the Commission shall determine an end point **in the manufacturing chain...**;
- (5) The Commission shall assess such derived products with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain in accordance with Regulation (EC) No 1069/2009
- (53) EU fertilising products should be placed on the market only if they are sufficiently effective and **do not present a risk** to human, animal or plant health, to safety or to the environment when properly stored and used for their intended purpose...

Regulation (EU) 2019/1009 Annex II Part II

- Component Material Categories (CMC)

CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009

An EU fertilising product may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined

Deadline for implementation: 16 July 2022

Regulation (EC) 1069/2009 (ABP Regulation)

- Article 5 End point in the manufacturing chain

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation

- Declaration of end point: risk management decision
- No definition of end point in terms of level of safety (any, significant risk of public or animal health, biological/chemical/environmental, etc).
- Previously, the EC has used EFSA evaluations of ABP **alternative methods to declare end points. Never as such...**
- Mandate: under Article 29 **Regulation (EC) 178/2002**
Not under Article 20 **Regulation (EC) 1069/2009**

Timeline: EFSA-Q-2020-00401



EFSA is asked

To provide a scientific opinion concerning the capacity of certain specific processing or transformation methods used in the production of organic fertilisers and soil improvers (OF/SI) in view of determining the endpoints in the manufacturing chain of CE-marked EU fertilising products.

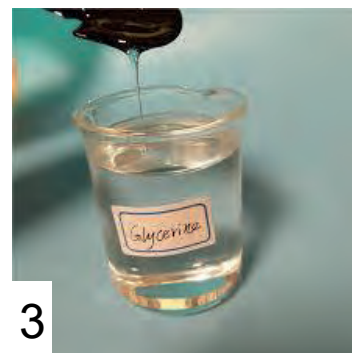
ToR1

In particular, the scientific opinion should comprise an assessment of the biological risks to animal and public health deriving from the use as OF/SI of the following Category 2 and 3 materials and derived products processed in accordance with Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011:

Mandate: Term of Reference (1)

ToR1

- (1) biogas digestion residues and compost;
- (2) ash derived from incineration, co-incineration and combustion;
- (3) glycerine and other products of materials derived from the production of biodiesel and renewable fuels;
- (4) pet food;
- (5) feed and dog chews;
- (6) hides and skins;
- (7) wool and hair;
- (8) feather and downs;
- (9) and pig bristles.



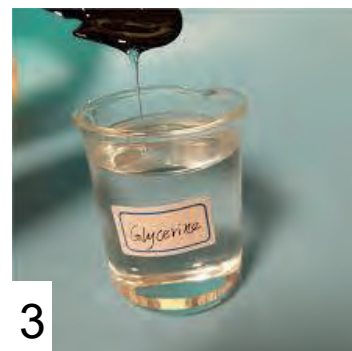
...EFSA is asked

to assess the requirements for alternative transformation parameters for biogas and composting plant in terms of the validation of the intended process, referred to in Section 2 of Chapter III of Annex V to Regulation (EC) No 142/2011, when **applied to other derived products as listed below...**

Mandate: Term of Reference (1)

ToR

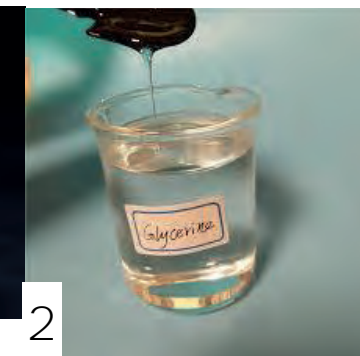
- (1) biogas digestion residues and compost;
- (2) ash derived from incineration, co-incineration and combustion;
- (3) glycerine and other products of materials derived from the production of biodiesel and renewable fuels;
- (4) pet food;
- (5) feed and dog chews;
- (6) hides and skins;
- (7) wool and hair;
- (8) feather and downs;
- (9) and pig bristles.



Mandate: Term of Reference (2)

ToR: new list of materials

- (1) ash derived from incineration, co-incineration and combustion;
- (2) glycerine
- (3) other materials derived from the production of biodiesel and renewable fuels;
- (4) hides and skins;
- (5) wool and hair;
- (6) feather and downs;
- (7) pig bristles;
- (8) horns, horn products and hoof products



Section 2 Chapter III of Annex V to Regulation (EC) No 142/2011

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, H₂S negative),
 - reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 \log_{10} , **whenever they are identified as a relevant hazard**; and
- ii. as regards chemical processes also by:
 - a reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 \log_{10}) of viable stages



Cat.2/3 ABP and derived products in compliance with (EC) 1069/2009 and (EC) 142/2011	(EC) 142/2011 Processing standards	Annex V, Chapter III, Section 2, Point 1 Validation requirements for alternative transformation parameters for biogas and compost
(1) ash derived from incineration, co-incineration and combustion;	(1) 850°C >2" or 1100°C >0.2"	I. For thermal and chemical processes - Senftenberg (775W, H2S negative) A reduction of 5 log ₁₀ of Enterococcus faecalis or Salmonella
(2) glycerine derived from the production of biodiesel and renewable fuels;	(2) <i>Biodiesel production</i> : pre-treated with a standard processing method ¹ for Cat. 2 materials and methods 1-7 for Cat.3 materials; esterification (pH <1, 72°C, >2h) and transesterification (pH 14, 35-50°C, >15min)	- Reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log ₁₀ , whenever they are identified as a relevant hazard
(3) other materials derived from the production of biodiesel and renewable fuels;	(3) <i>Catalytic production for renewable fuels and catalytic hydrotreatment for renewable fuels</i> : pre-treated with a standard processing method ¹ for Cat. 2 materials and methods 1-7 for Cat.3 materials	II. As regards chemical processes also by: i. A reduction of resistant parasites such as eggs of Ascaris sp. by at least 99.9% (3 log ₁₀) of viable stages
(4) hides and skins;	(4) <i>Treated hides and skins</i> after the complete process of tanning, 'wet blue', pickled pelts, limed hides (pH 12-13, 8h)	
(5) wool and hair;	(5) factory-washed in in series of baths of water, soap and sodium hydroxide or potassium hydroxide	
(6) feathers and down;	(6) Factory-washed and hot steam (100°C) for 30min	
(7) pig bristles;	(7) Boiled, dyed or bleached or undergone some other form of treatment which is certain to kill pathogenic agents	
(8) horns, horn products, hoofs and hoof products	(8) 80°C for 1h	



Cat.2/3 ABP and derived products in compliance with (EC) 1069/2009 and (EC) 142/2011	(EC) 142/2011 Processing standards	Annex V, Chapter III, Section 2, Point 1 Validation requirements for alternative transformation parameters for biogas and compost
(1) ash derived from incineration, co-incineration and combustion;	(1) 850°C >2" or 1100°C >0.2"	I. For thermal and chemical processes <ul style="list-style-type: none"> - Senftenberg (775W, H2S negative) A reduction of 5 log₁₀ of <i>Enterococcus faecalis</i> or <i>Salmonella</i> - Reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log₁₀, whenever they are identified as a relevant hazard II. As regards chemical processes also by: <ul style="list-style-type: none"> i. A reduction of resistant parasites such as eggs of <i>Ascaris</i> sp. by at least 99.9% (3 log₁₀) of viable stages
(2) glycerine derived from the production of biodiesel and renewable fuels;	(2) <i>Biodiesel production</i> : pre-treated with a standard processing method ¹ for Cat. 2 materials and methods 1-7 for Cat.3 materials; esterification (pH <1, 72°C, >2h) and transesterification (pH 14, 35-50°C, >15min)	
(3) other materials derived from the production of biodiesel and renewable fuels;	(3) <i>Catalytic production for renewable fuels and catalytic hydrotreatment for renewable fuels</i> : pre-treated with a standard processing method ¹ for Cat. 2 materials and methods 1-7 for Cat.3 materials	
(4) hides and skins;	(4) <i>Treated hides and skins</i> after the complete process of tanning, 'wet blue', pickled pelts, limed hides (pH 12-13, 8h)	
(5) wool and hair;	(5) factory-washed in in series of baths of water, soap and sodium hydroxide or potassium hydroxide	
(6) feathers and down;	(6) Factory-washed and hot steam (100°C) for 30min	
(7) pig bristles;	(7) Boiled, dyed or bleached or undergone some other form of treatment which is certain to kill pathogenic agents	
(8) horns, horn products, hoofs and hoof products	(8) 80°C for 1h	

- Materials ✓
- Standard ✓
- Processing methods ?
- Inactivation ?

AQ1: What are the technical parameters of the transformation processes for the declaration of the end points in the manufacturing chain, and the standard or alternative methods approved to produce... the Category 2 and 3 materials and derived products as defined in the mandate?

AQ3: Which viral hazards can be intrinsically found in ... as defined in the clarification of the mandate?



AQ4: Is the 3 log₁₀ reduction of the selected thermoresistant viruses identified in AQ3 achieved for ..., by the technical parameters identified in AQ1?

AQ2: Is the 5 log₁₀ reduction of the indicator microorganisms *Enterococcus faecalis* (EF) or *Salmonella Senftenberg* (SS) achieved for... by the technical parameters identified in AQ1?

AQ5: Is the 3 log₁₀ reduction of eggs of *Ascaris* sp. achieved for ... by the technical parameters identified in AQ1 for the chemical processes (group 4 – 5)?

- **Hazard identification (virus):**
Multiple literature searches
Final list of viruses to be assessed

- **Processing methods**
Clearly defined in the legislation (1-6-8)
Adapted from the legislation (2-3-4)
Insufficient information: scenarios (5-7)

- **Inactivation:**
Multiple literature searches
Data extraction (time, temperature, pH)

1. Ash derived from incineration	1.1. 850 °C >2 s 1.2. 1100 °C >0.2 s
2. Glycerine derived from the production of biodiesel and renewable fuels If Category 2 materials are used: Method 1 + esterification + transesterification If Category 3 materials are used: Method 1-7 + transesterification	2.1. 133 °C, 20min 3 bar (Method 1) + pH <1/72°C/>2 h (esterification) + pH~14/35°C to 50 °C/>1min (transesterification) 2.2. 100°C 60min (Method 5(b)) + pH~14/35°C to 50°C/>15min (transesterification)
3. Other products of materials derived from the production of biodiesel and renewable fuels If Category 2 materials are used: Method 1 If Category 3 materials are used: method 1-7	3.1 Method 1: 133°C, 20 min 3 bar 3.2 Method 5(b): 100°C, 60 min
4. Hides and skins Lime hides Pickled pelts, wet blue, complete tanned hides	4.1. pH 12-13, 8 h 4.2. pH ~12 > 8 h + pH <3, 16 h
5. Wool and hair Factory-washing: immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide	5.1. pH >12-13, 5 min 5.2. pH >12-13, 60 min
6. Feathers and down Factory-washed and treated with hot steam	6. 100°C for at least 30 min
7. Pig bristles Boiling (from ASF countries)	7.1. 100°C in water, 5 min 7.2. 100°C in water, 60 min
8. Horns, horn products, hooves and hoof products Heat treatment	8. 80°C 1 h

Expert knowledge elicitation (EKE)

- What is the probability that a 5 \log_{10} reduction of *E. faecalis* is achieved, in more than 99% of cases, by application of the relevant process/es, assuming that the process/es is/are performed as prescribed and that the indicated process conditions are achieved?
- What is the probability that a 5 \log_{10} reduction of *Salmonella* Senftenberg (775 W, H₂S negative) is achieved, in more than 99% of cases, by application of the relevant process/es, assuming that the process/es is/are performed as prescribed and that the indicated process conditions are achieved?
- What is the probability that a 3 \log_{10} reduction of **parvovirus or the identified most resistant viruses** is achieved, in more than 99% of cases, by application of the relevant process/es, assuming that the process/es is/are performed as prescribed and that the indicated process conditions are achieved?
- What is the probability that a 3 \log_{10} reduction of eggs of *Ascaris* sp. is achieved, in more than 99% of cases, by application of the relevant chemical process/es, assuming that the process/es is/are performed as prescribed and that the indicated process conditions are achieved?

Results

Material	Type	Salmonella S. log ₁₀)	(5 Enterococcus f (5 log ₁₀)	Ascaris eggs log ₁₀)	(3 Parvovirus (or other virus/es) (3 log ₁₀)
1. Ash derived from incineration					
1.1. 850 °C >2 s	T	99-100%	99-100%		99-100%
1.2. 1100 °C >0.2 s	T	99-100%	99-100%		99-100%
2. Glycerine derived from the production of biodiesel and renewable fuels					
If Category 2 materials are used: 2.1. 133 °C, 20' 3 bar (Method 1) + pH <1/72°C/>2 h (esterification) + pH~14/35°C to 50 °C/>15' (transesterification)	T/C	98-100%	98-100%		98-100%
If Category 3 materials are used: 2.2. 100°C, 60 min (Method 5) + pH~14/35°C to 50°C/>15' (transesterification)	T/C	90-99%	90-99%		90-95%
3. Other products of materials derived from the production of biodiesel and renewable fuels					
If Category 2 materials are used: 3.1 Method 1: 133°C, 20 min 3 bar	T	90-99%	90-99%		90-99%
If Category 3 materials are used: Method 5: 100°C, 60 min	T	66-90%	66-95%		66-90%
4. Hides and skins					
Lime hides: pH 12-13, 8 h	C	66-90%	66-90%	10-66%	33-66%
Pickled pelts, Wet blue, Complete tanned hides pH~12 >8h + pH <3, 16h	C	66-95%	66-95%	33-66%	50-90%
5. Wool and hair					
pH >12-13, 5 min	C	10-50%	10-50%	1-33%	10-50%
pH> 12-13, 60 min	C	33-80%	33-80%	10-50%	33-66%
6. Feathers and down					
100°C for at least 30 min	T	90-99%	90-99%		66-90%
7. Pig bristles					
100°C in water, 5 min	T	80-95%	80-95%		33-66%
100°C in water, 60 min	T	95-99%	95-99%		50-95%
8. Horns, horn products, hooves and hoof products					
80°C 1 h	T	66-95%	66-95%		66-99%

Parvoviridae

Parvoviridae

Parvoviridae

Papillomaviridae, Picornaviridae, Reoviridae

Picornaviridae, Parvoviridae

Anelloviridae, Circoviridae

Picornaviridae

8. Horns, horn products, hooves and hoof products:





*"It was judged 66-95% certain that the transformation process, as defined in the legislation (80°C for 60 min), is able to reduce, to the required extent, the indicator bacteria (*E. faecalis* and *S. Senftenberg*), the most resistant of the three indicator microorganisms and biological hazards (*E. faecalis*, *S. Senftenberg* and *Picornaviridae*)"*

- Very low variability in the certainty of the inactivation between indicators (1-2-3-6-8). High variability in 4-5-7
- Thermal or thermo-chemical: higher certainty of inactivation. Virus most resistant
- Chemical: Eggs of *Ascaris* sp. limiting factor (4-5)
- Uncertainty on processes (scenarios). The longer, the higher inactivation (5-7)

- NOT a full risk assessment: no relationship between presence of hazards and risks to human or animal health of the use OF/SI
- Materials: derived products (1-2-3), materials with end points (4-5-6), materials with conditions for placing in the market (7-8)
- Only biological hazards have been considered
- Theoretical exercise: no confirmation of intrinsic presence of the indicator microorganisms in the matrices. Cross-contamination
- No actual inactivation data of these indicators in these matrices. Extrapolation. Worst case scenarios

- No consideration of industrial processes before used as OF/SI
- No conclusion/recommendation on the end point

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Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers

EFSA Panel on Biological Hazards (BIOHAZ) ✉ Konstantinos Koutsourmanis, Ana Allende, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Robert Davies, Alessandra De Cesare ... [See all authors](#) ▾

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
Question number: EFSA-Q-2020-00401




Panel members: Ana Allende, Avelino Alvarez-Ordóñez, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Robert Davies, Alessandra De Cesare, Lieve Herman, Friederike Hilbert, Konstantinos Koutsourmanis, Roland Lindqvist, Maarten Nauta, Luisa Peixe, Giuseppe Ru, Marion Simmons, Panagiotis Skandamis and Elisabetta Suffredini.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

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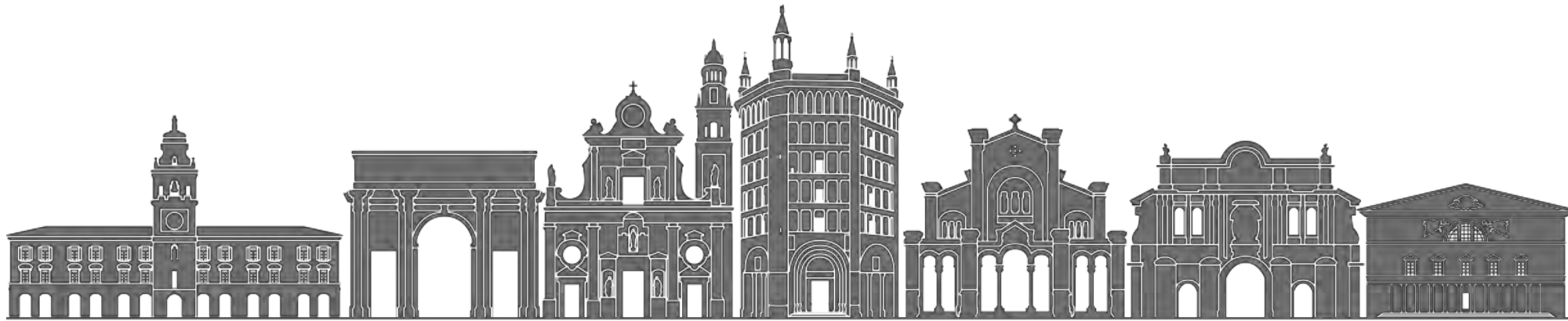
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Thank you
Questions?

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