

Assessment of prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials for Cat A diseases

Andrea Gervelmeyer

Terms of Reference

ToR 4.1 Assess the effectiveness to control the spread of disease of prohibitions set out in Annex VI of the Delegated Regulation with respect to the risk associated for each Category A disease, to the listed activities and commodities.

ToR 4.2 Review the available scientific information on risk-mitigating treatments that are effective to control the presence of Category A disease agents in products of animal origin and other relevant materials. Based on this:

a) provide an opinion on the effectiveness of the risk-mitigating treatments for products of animal origin and other materials produced or processed in the restricted zone set out in Annex VII and VIII, and

b) if relevant, suggest new treatments or procedures that can be effective to mitigate or eliminate such risk.



Annex VI



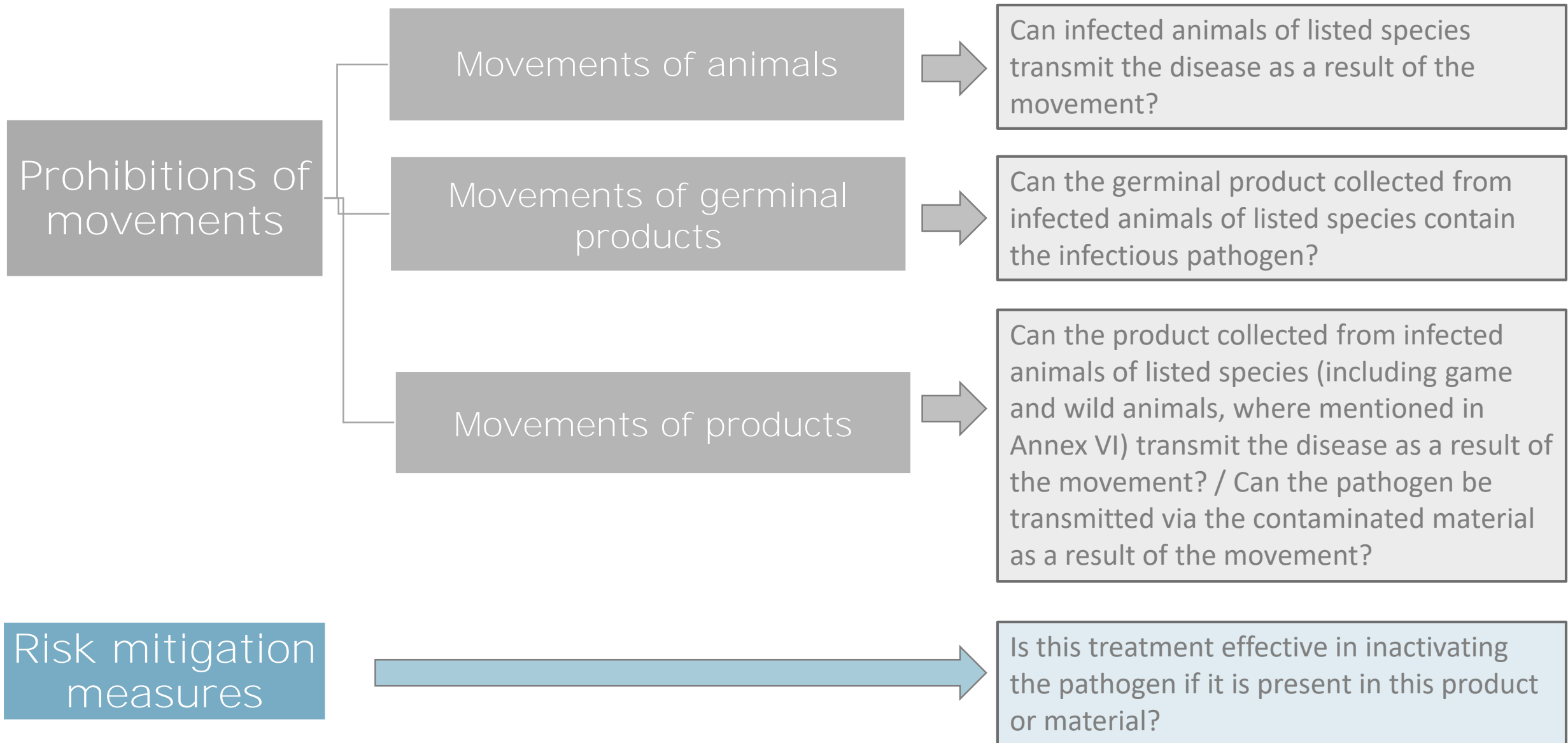
Annex VII

Annex VIII

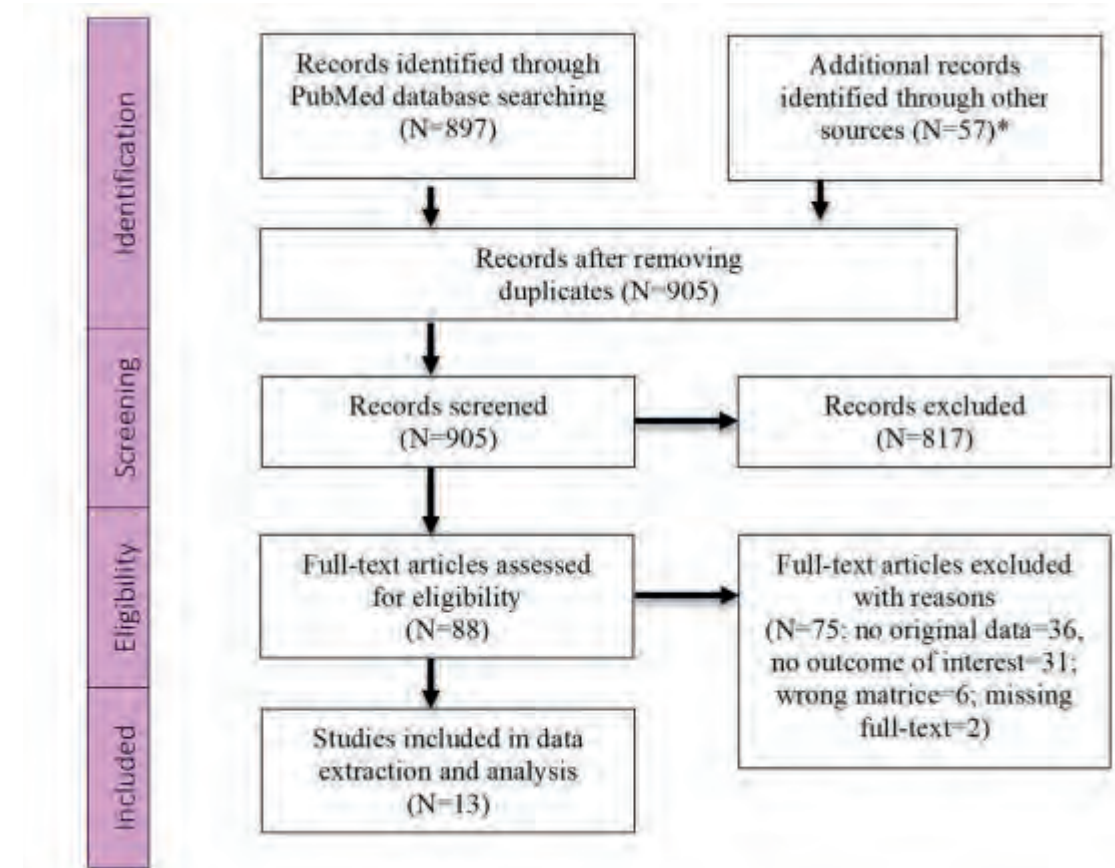
PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS RELATED TO CATEGORY A DISEASES ¹	FMD	RP	RYFV	LSD	CBPP	SPGP	PRR	CCTP	CSF	ASF	AHS	GLAND	HPAI	NCD
Movements of kept animals of listed species from establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of kept animals of listed species to establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Restocking of game animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Fairs, markets, shows and other gatherings of kept animals of listed species including collection and dispersion of those species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of semen, oocytes and embryos obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X ²	X	X	X	X	X	X	X	NA	NA	NA
Collection of semen, oocytes and embryo from kept animals of listed species	X	X	X	X	X	X	X	X	X	X	NP	NA	NA	NA
Itinerant artificial insemination of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Itinerant natural service of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Movements of hatching eggs from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X
Movements of fresh meat excluding offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	NP	NP	X	X	NP	X	X	NP	NA	X	X
Movements of offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	NP	NA	X	X
Movements of meat products obtained from fresh meat of listed species from establishments in the restricted zone	X	X	X	NP	NP	NP	X	NP	X	X	NP	NA	X	X
Movements of raw milk and colostrum obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movements of dairy products and colostrum based products from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movements of eggs for human consumption from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X
Movements of animal by-products from kept animals of listed species from establishments in the restricted zone, except entire bodies or parts of dead animals	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X

Treatment	Treatment	
	FMD ³	RP
Heat treatment, minimum temperature of 80°C and for a minimum of 10 minutes, steam in a closed chamber	X	X
Storage in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak and releasing from the premises do not take place before at least three months have elapsed following the completion of cleaning and disinfection according to Article 15	X	X

Treatment	Treatment													
	FMD ³	RP	RYFV	LSD	CBPP	SPGP	PRR	CCTP	CSF	ASF	AHS	HPAI	NCD	
MEAT														
Heat treatment in an hermetically sealed container, to achieve a minimum F_0^{4} value of 3	X						X		X	X		X	X	
Heat treatment to achieve a core temperature of 80°C	X						X		X	X		X	X	
Heat treatment to achieve a core temperature of 70°C	X						X		X			X	X	
Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70°C for a minimum of 30 minutes	X						X		X					
In an hermetically sealed container, applying 60°C for a minimum of 4 hours	X						X		X	X				
Core temperature of 73,9 °C for a minimum of 0,51 seconds ⁵	X												X	
Core temperature of 70,0 °C for a minimum of 3,5 seconds ⁵													X	
Core temperature of 65,0 °C for a minimum of 42 seconds ⁵													X	
Core temperature of 60 °C for a minimum of 507 seconds ⁵													X	
Heat treatment to achieve desiccation to maximum values of Aw of 0, 93 and pH of 6									X					
Heat treatment to achieve a core temperature of 65°C for a period of time to achieve a minimum pasteurisation value of 40									X					



- Spread through animal movements
 - Extensive literature search (ELS) on Category A diseases
- Presence of the disease agents in different organ systems of infected animals
 - ELS on experimental infections of listed animal species
- Survival of the disease agents in different products of animal origin and other products
 - ELS on pathogen survival in the products
- Presence of the disease agents in different germinal products
 - ELS on the presence and survival of the disease agents in semen, oocytes and embryos
- Effectiveness of risk mitigation treatments
 - ELS on treatments to mitigate the risk of the different disease agents in different matrices



Assessment step 1

Annex VI of the DR

Question 1 - Can the product collected from infected animals of listed species (including game and wild animals, where mentioned in Annex VI) transmit RVF as a result of the movement?

- Movements of semen obtained from fresh meat excluding offal from slaughterhouses or game handling establishments in the restricted zone.

Annex VII & VIII of the DR

Question - Is this treatment effective in inactivating FMD if it is present in this product or material?

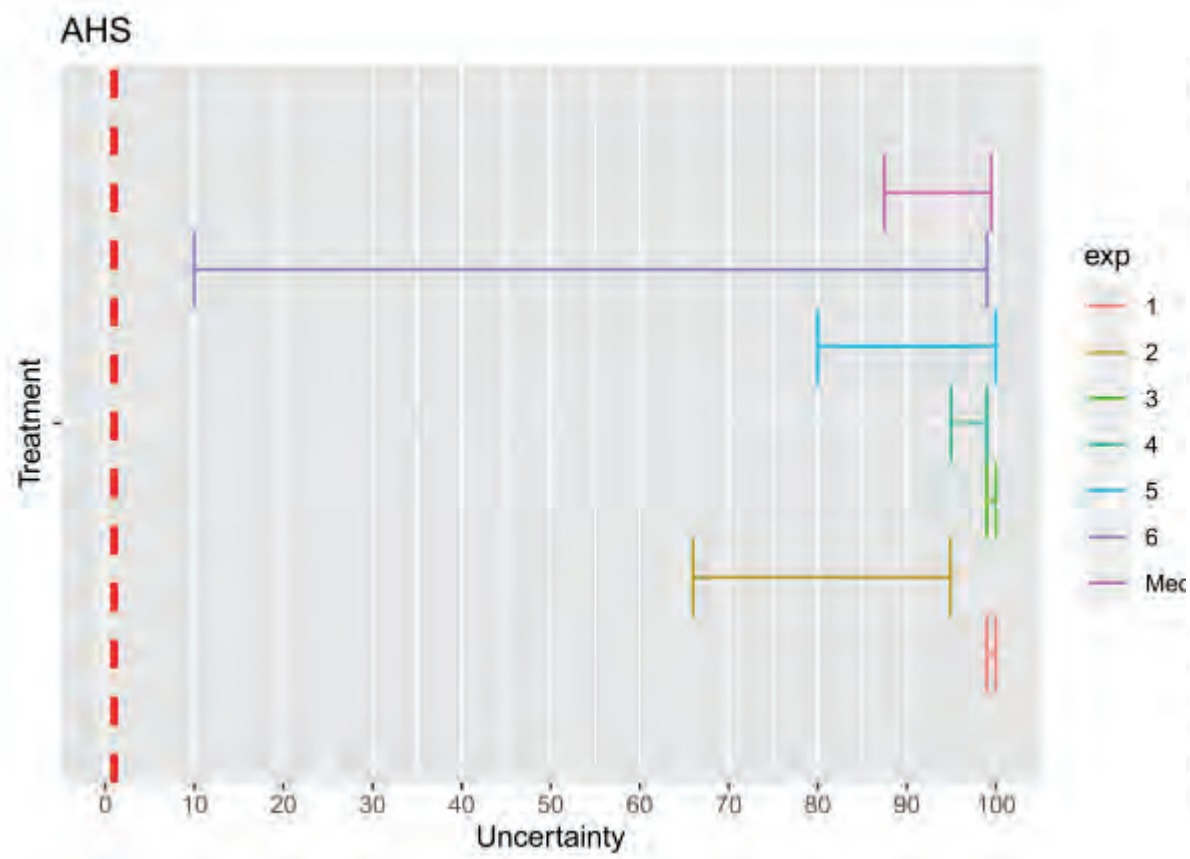
Almost impossible 0-1	Extremely unlikely 1-5	Very unlikely 5-10	Unlikely 10-33	About as likely as not 33-66	Likely 66-90	Very likely 90-95	Extremely likely 95-99	Almost certain 99-100	%
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Find the evidence here: https://efsa815.sharepoint.com/:w:/r/sites/AHLdiseasecontrolmeasurecat.A/Shared%20Documents/ToR%204/Outsourcing/Treatments/ToR4.2_Report_V1_reviewed.docx?d=w99e9f4b7fb3243cea2b10f09

Find the references here: https://efsa815.sharepoint.com/:f:/r/sites/AHLdiseasecontrolmeasurecat.A/Shared%20Documents/ToR%204/Outsourcing/References%20for%20report_ToR4.2?csf=1&web=1&e=noq

Matrix	Risk-mitigating treatments for products of animal origin from the Restricted Zone (Annex VII)	Lower Bound	Upper bound	Reasoning
Meat	Heat treatment in a hermetically sealed container, to achieve a minimum F0 value of 3			
Meat	Heat treatment to achieve a core temperature of 80°C			
Meat	Heat treatment to achieve a core temperature of 70°C			
fresh meat				
offal				

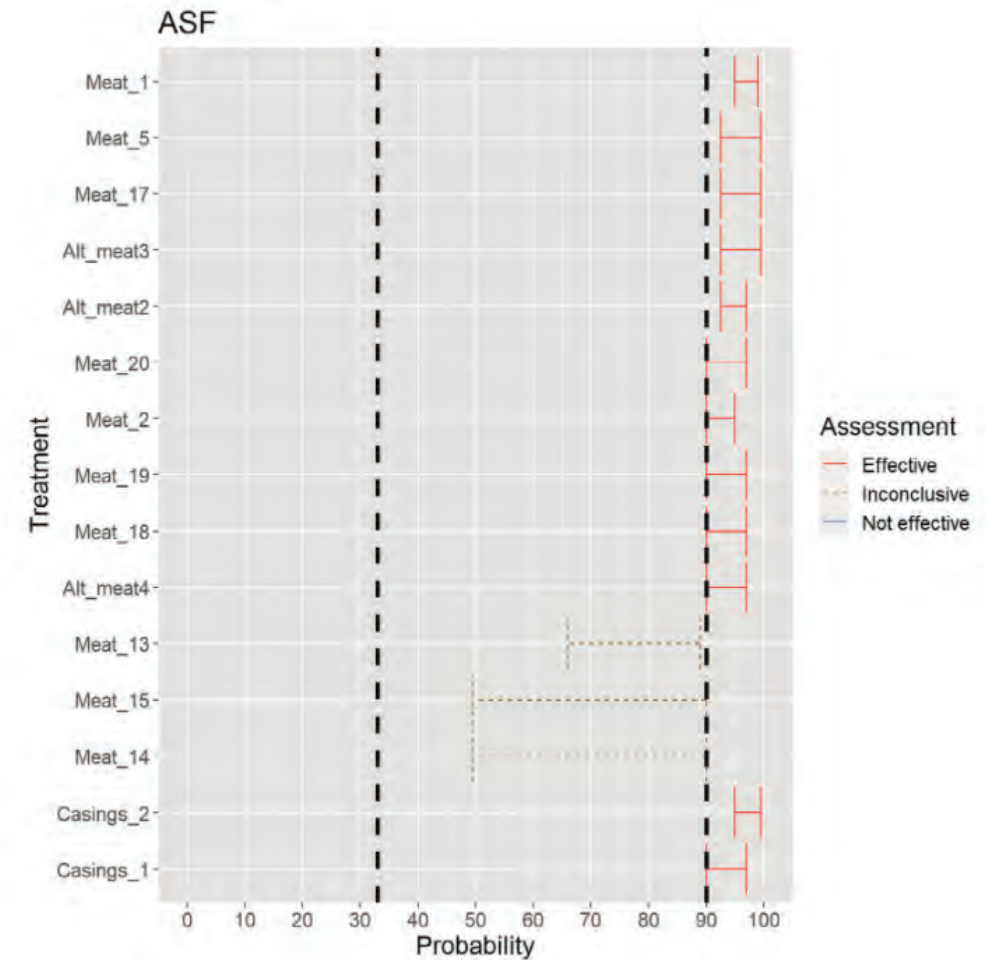
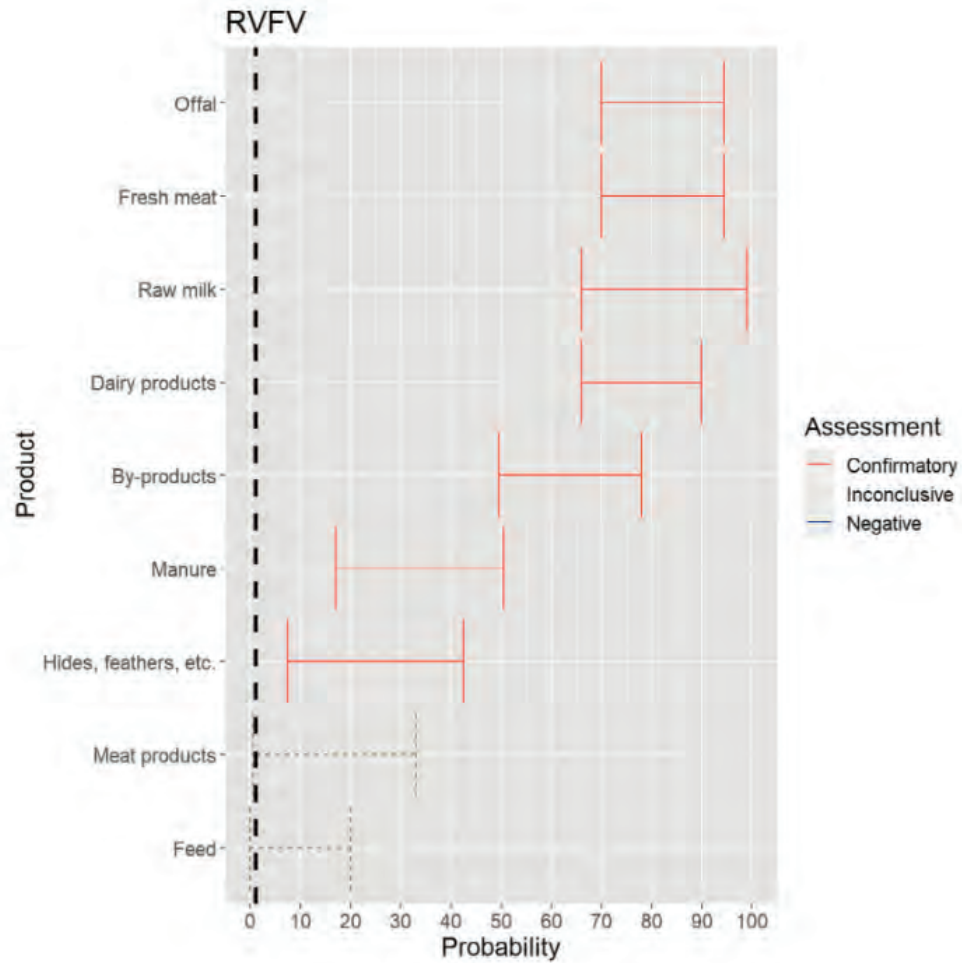
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 fresh_meat
 offal



- ## [1] "Expert 1 - Vector borne disease. Transmission via infected midges from the culicoides genus. Outbreaks in previously free areas associated with animal movements"
- ## [2] "Expert 2 - All about vector transmission so provided there are competent vectors and the environmental conditions allow for transmission, these activities could lead to onward indirect transmission. But vector control could be applied, or the temperature for extrinsic incubation period could be incompatible with transmission. Infected animals may provide a new virus source for competent vectors."
- ## [3] "Expert 3 - AHS is transmitted by infected midges (Diptera; Ceratopogonidae) from the Culicoides genus; in particular Culicoides imicola (present in the EU) is considered the major field vector, while there are evidences that other species such as C. obsoletus, C. pulicaris (both present in the EU) and Culicoides bolitinos (not present in the EU) can act also as vectors. AHS outbreaks occur in previously AHS-free countries, probably due to a combination of climate change affecting the vector's habitat and increasing international movement of animals, including illegal or not well controlled equid movement."
- ## [4] "Expert 4 - Conditional on vector season. Bluetongue and Schmallenberg are reference for AHS. My judgment is based on the assumption of vector presence"
- ## [5] "Expert 5 - AHS is transmitted by infected midges (Diptera; Ceratopogonidae) from the Culicoides genus; in particular Culicoides imicola (present in the EU) is considered the major field vector. No

Movement prohibitions

Risk mitigation treatments



Prohibitions of movements of animals - Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

	FMD	RP	RVF*	LSD*	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS*	HPAI	ND
Movements of kept animals from establishments in the restricted zone	99-100	99-100	95-100	95-100	99-100	99-100	99-100	99-100	99-100	99-100	95-100	99-100	99-100
Movements of kept animals to establishments in the restricted zone	99-100	99-100	95-100	95-100	99-100	99-100	99-100	99-100	99-100	99-100	95-100	99-100	99-100
Restocking of game animals	99-100	99-100	95-100	95-100	99-100	99-100	99-100	99-100	99-100	99-100	95-100	99-100	99-100
Fairs, markets, shows and other gatherings of kept animals including collection and dispersion of those species	99-100	99-100	95-100	95-100	99-100	99-100	99-100	99-100	99-100	99-100	95-100	99-100	99-100
Itinerant natural service of kept animals	99-100	99-100	95-100	95-100	99-100	99-100	99-100	99-100	99-100	99-100	95-100		

*: In the case of vector-borne diseases, transmission is intended to include vector-borne transmission of the disease agent.

green = confirmatory, blue = inconclusive, yellow = negative, grey = not applicable

Prohibitions of movements of germinal products - Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

Can the germinal product collected or derived from infected animals of listed species contain the infectious disease agent?	FMD	RP	RVF	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	ND
Semen	90-100	85-100	90-100	95-100	70-100	10-99	33-100	33-95	95-100	80-100	66-100	90-100	90-100
Oocytes	0-66	1-66	10-90	33-100	50-100	5-99	10-95	33-99	33-99	10-95	10-90		
<i>In vivo</i> derived embryos	1-50	0-50	10-90	33-100	66-100	5-99	10-95	33-95	10-75	66-100	0-90		
<i>In vitro</i> produced embryos	33-95	1-50	10-89.9	33-100	66-100	5-99	10-95	50-95	10-95	66-100	0-99		
Hatching eggs												70-100	70-100

green = confirmatory, blue = inconclusive, yellow = negative, grey = not applicable

Prohibitions of movements of products - Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

Prohibitions of activities concerning movements of animal products, animal by-products and feed of plant origin and straw related to Category A diseases	FMD	RP	RVF*	LSD*	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS*	HPAI	ND
Movements of fresh meat excluding offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	93-100	66-95	70-95	22-50	0-10	1-33	66-95	3-15	97-100	97-100	0-5	95-99	97-100
Movements of offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	95-100	78-99	70-95	33-66	38-90	17-50	66-95	50-90	97-100	97-100	0-5	95-99	97-100
Movements of meat products obtained from fresh meat of listed species from establishments in the restricted zone	85-100	33-90	1-33	1-23	0-10	1-15	50-95	0-10	95-100	97-100	0-5	95-100	97-100
Movements of raw milk and colostrum obtained from kept animals of listed species from establishments in the restricted zone	95-100	66-92	66-99	70-88	0-10	42-73	66-99	0-10			0-5		
Movements of dairy products and colostrum-based products from establishments in the restricted zone	85-100	66-90	66-90	58-85	0-8	42-73	58-90	0-5			0-5		
Movements of eggs for human consumption from establishments in the restricted zone												81-95	85-98
Movements of animal by-products from kept animals of listed species from establishments in the restricted zone, except entire bodies or parts of dead animals: manure, including litter and used bedding	93-100	58-95	17-51	22-54	3-10	50-83	55-90	0-8	90-100	90-100	0-1	93-100	93-99
Movements of animal by-products from kept animals of listed species from establishments in the restricted zone, except entire bodies or parts of dead animals: hides, skins, wool, bristles and feathers	93-100	33-66	8-43	80-95	3-10	80-95	33-90	0-10	78-99	88-95	0-1	95-100	90-100
Movements of animal by-products from kept animals of listed species from establishments in the restricted zone, except entire bodies or parts of dead animals: animal by-products other than manure, including litter and used bedding, and other than hides, skins, wool, bristles and feathers	78-100	58-93	50-78	22-58	5-33	22-58	66-95	3-33	95-100	97-100	0-5	95-100	95-100
Movements of feed material of plant origin and straw obtained in the protection zone	75-97	45-73	0-20	3-27	0-10	66-90	29-66	0-10	50-90	61-90	0-1	90-100	90-99

green = confirmatory, blue = inconclusive, yellow = negative, grey = not applicable

Risk mitigation measures- Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

Product	Assessed risk-mitigating treatments for products of animal origin listed in Annex VII (ToR 4.2a)	Short name	FMD	RP	RVF	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	ND
Meat	Heat treatment in a hermetically sealed container, to achieve a minimum F0 value of 3	Meat_1	97-100						95-100		95-100	95-99		95-99	95-100
	Heat treatment to achieve a core temperature of 80°C	Meat_2	66-90						90-99		85-97	90-97		95-99	80-95
	Heat treatment to achieve a core temperature of 70°C	Meat_3	50-90						70-99	90-99	66-95			90-99	66-95
	Heat treatment (to meat previously deboned and defatted) to achieve a core temperature of 70°C for a minimum of 30 min	Meat_4	97-100						95-100		95-99				
	In a hermetically sealed container, applying 60°C for a minimum of 4 h	Meat_5	33-78						93-100		80-97	93-100			
	Core temperature of 73.9 °C for a minimum of 0.51 s	Meat_6	33-66											95-99	10-32
	Core temperature of 70.0°C for a minimum of 3.5 s	Meat_7												93-100	10-32
	Core temperature of 65.0°C for a minimum of 42 s	Meat_8												93-97	10-32
	Core temperature of 60.0°C for a minimum of 507 s	Meat_9												93-98	10-66
	Heat treatment to achieve a core temperature of 65°C for a period of time to achieve a minimum pasteurisation value of 40	Meat_11								95-99					
	Natural fermentation and maturation for bone-in meat: minimum 9 months, to achieve maximum values of A _w of 0.93 and pH of 6	Meat_12		71-95								50-89			

green = effective, blue = inconclusive, yellow = not effective, empty cells = no assessment requested)

Risk mitigation measures- Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

Product	Assessed risk-mitigating treatments for products of animal origin listed in Annex VII (ToR 4.2a)	Short name	FMD	RP	RVF	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	ND
Milk	Heat treatment (sterilisation process) to achieve a minimum F0 value of 3	Milk_1	95-99												
	Heat treatment UHT (Ultra-high temperature): Minimum 132°C for a minimum of 1 s	Milk_2	42-90						66-95						
	Heat treatment UHT (Ultra-high temperature): Minimum 135°C for a suitable holding time	Milk_3	42-85												
	Heat treatment HTST (High-temperature short-time) pasteurisation if milk pH is lower than 7, minimum 72°C for a minimum of 15 s	Milk_4	10-32						33-80						
	Heat treatment HTST (High-temperature short-time) pasteurisation if milk pH is 7 or higher, minimum 72°C for a minimum of 15 s, applied twice	Milk_5	42-78						90-99						
	Heat treatment HTST (High-temperature short-time) pasteurisation combined with a physical treatment to achieve pH value below 6 for a minimum of 1 h or Heat treatment HTST to achieve a minimum of 72°C, combined with desiccation	Milk_6	50-89												
	Pasteurisation consisting in a single heat treatment with an effect at least equivalent to that achieved by applying 72°C for 15 s	Milk_7	10-32			33-66	33-66								
Eggs	Whole egg: 60°C - 188 s	Egg_1												90-95	
	Whole egg: completely cooked	Egg_2												95-100	
	Whole egg blends: 60°C - 188 s	Egg_3												90-97	
	Whole egg blends: 61.1°C - 94 s	Egg_4												90-97	
	Whole egg blends: completely cooked	Egg_5												93-100	
	Liquid egg white: 55.6°C - 870 s	Egg_6												93-100	
	Liquid egg white: 56.7°C - 232 s	Egg_7												93-99	

green = effective, blue = inconclusive, yellow = not effective, empty cells = no assessment requested)

Additional risk mitigation measures- Conclusions

Median of the lower and upper bounds of the subjective probability ranges (in %)

Product	Assessed risk-mitigating treatments for products of animal origin identified by the ELS (ToR 4.2b)	Short name used in figures and text	FMD	RP	RVF	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	ND
Casings	Salting with citrate-supplemented salt 89.2% NaCl, 8.9% trisodium citrate dehydrate and 1.9% citric acid monohydrate (wt/wt/wt), with pH 4.5 for a continuous period of 30 days or longer at an ambient temperature of 20°C or above	Alt_casings1									93-100				
Eggs	Dried egg white: 54.4°C - 21.38 days	Alt_egg1												93-97	
	Liquid whole egg: 64.4°C - 200 s	Alt_egg2													38-73
	Fortified egg: 61.1°C - 6.2 min	Alt_egg3													90-95
	Fortified egg: 62.2°C - 3.5 min	Alt_egg4													90-95
	sugared/salted egg: 62.2°C - 6.2 min	Alt_egg5													90-97
	sugared/salted egg: 63.3°C - 3.5 min	Alt_egg6													90-97
	plain yolk: 60°C - 6.2 min	Alt_egg7													90-95
	plain yolk: 61.1°C - 3.5 min	Alt_egg8													90-95
Meat	Drying after salting Serrano hams: minimum 182 day	Alt_meat1	97-100												
	Heat treatment to achieve a core temperature of 70°C for at least 30 min	Alt_meat2										93-97			
	Drying after salting Italian style bone-in hams: minimum 400 days	Alt_meat3										93-100			
	Drying after salting (Italian style) loins: minimum 137 days	Alt_meat4										90-97			

green = effective, blue = inconclusive, yellow = not effective, empty cells = no assessment requested)


Concluding main recommendations




Heat treatment to achieve a core temperature of 80°C	?
Heat treatment to achieve a core temperature of 70°C	
Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70°C for a minimum of 30 minutes	
In an hermetically sealed container, applying 60°C for a minimum of 4 hours	✓
Core temperature of 73,9 °C for a minimum of 0,51 seconds ⁵	
Core temperature of 70,0 °C for a minimum of 3.5 seconds ⁵	

Product	Assessed risk-mitigating treatments for products of animal origin listed in Annex VII (ToR 4.2a)	Short name	FMD	RP	RVF	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	ND
Meat	Heat treatment in a hermetically sealed container, to achieve a minimum F0 value of 3	Meat_1	97-100						95-100		95-100	95-99		95-99	95-100
	Heat treatment to achieve a core temperature of 80°C	Meat_2	66-90						90-99		85-97	90-97		95-99	80-95
	Heat treatment to achieve a core temperature of 70°C	Meat_3	50-90						70-99	90-99	66-95			90-99	66-95
	Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70°C for a minimum of 30 min	Meat_4	97-100						95-100		95-99				
	In a hermetically sealed container, applying 60°C for a minimum of 4 h	Meat_5	33-78						93-100		80-97	93-100			
	Core temperature of 73.9 °C for a minimum of 0.51 s	Meat_6	33-66											95-99	10-32
	Core temperature of 70.0°C for a minimum of 3.5 s	Meat_7												93-100	10-32
	Core temperature of 65.0°C for a minimum of 42 s	Meat_8												93-97	10-32
	Core temperature of 60.0°C for a minimum of 507 s	Meat_9												93-98	10-66
	Heat treatment to achieve a core temperature of 65°C for a period of time to achieve a minimum pasteurisation value of 40	Meat_11							95-99						
	Natural fermentation and maturation for bone-in meat: minimum 9 months, to achieve maximum values of A _w of 0.93 and pH of 6	Meat_12		71-95								50-89			

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Assessment of the control measures of the Category A diseases of the Animal Health Law: prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials

EFSA Panel on Animal Health and Welfare (EFSA AHAW Panel)  Søren Saxmose Nielsen, Julio Alvarez, Dominique Joseph Bicout, Paolo Calistri, Elisabetta Canali, Julian Ashley Drewe, Bruno Garin-Bastuji, José Luis Gonzales Rojas, Christian Gortázar Schmidt, Mette Herskin, Virginie Michel, Miguel Ángel Miranda Chueca, Barbara Padalino, Paolo Pasquali, Karl Stahl, Antonio Velarde Calvo, Arvo Viltrop, Christoph Winckler, Kris De Clercq, Ylva Sjunnesson, Andrea Gervelmeyer, Helen Clare Roberts ... [See fewer authors](#) ^

Supporting information:

Annex A – Extensive literature search on the presence of selected Category A disease pathogens in germinal products

Estelle Meroc, Wendy Hartig-Merkel
P95 Epidemiology and Pharmacovigilance, Leuven, Belgium

Annex B – Extensive literature search on the presence of selected Category A disease pathogens in animal products, animal by-products and feed of plant origin and straw

CoVetLab consortium (Swedish National Veterinary Institute (SVA), Sweden; Wageningen Bioveterinary Research (WBVR), The Netherlands; Animal and Plant Health Agency (APHA), UK)
University of Surrey, UK)

Annex C – Extensive literature search on the effectiveness of risk mitigation treatments for products of animal origin and products of non-animal origin

Estelle Méroc, Wendy Hartig-Merkel
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