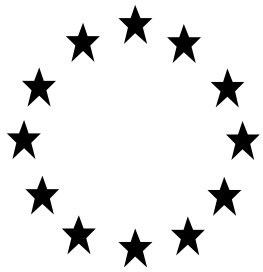
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



GERM-IOD

Product type 03

Iodine (including PVP iodine) as included in the Union list of approved active substances

Case Number in R4BP: BC-SF019364-41

Evaluating Competent Authority: SPAIN

April 2023

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

GERM-IOD is SL (Soluble concentrate) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an SL formulation. The stability data indicate a shelf life of at least 2 years at ambient temperature.

The biocidal product is not considered to be explosive, oxidising or pyrophoric. This product has a flash point of 53ºC, so according to CLP Regulation, it is categorized as flammable level 3 (H226). Moreover, it is categorized as corrosive to metals.

Concerning analytical methods, potentiometric titration can be considered to be acceptable for the identification and quantification of the active substance in the biocidal product "Iodo 2.5% concentrado soluble"

Efficacy

The biocidal product GERM-IOD is considered to be sufficiently effective as disinfectant on professional use against target organisms by spraying /sprinkling application on non-porous surfaces in low dirty conditions at the dilution rate of 1.5% (w/v) with a contact time of 30 minutes. (See point 2.2.5 Efficacy against target organisms for details)
The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

Risk assessment for human health

After evaluating the exposure and characterizing the risk to human health of the product GERM-IOD according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Mixing and loading	A **safe** situation has been identified for pouring formulation from a container into a portable receiving vessel (e.g. knapsack sprayer) when PPEs and RMMs are used.	Professional / Trained Professional users
2.	Indoor application	A **safe** situation has been identified for spraying the biocide product on the animal housings surface/area when PPEs are worn.	Professional / Trained Professional users
3.	Post application	A **safe** situation has been identified for cleaning of the spray equipment when PPEs are worn.	Professional / Trained Professional users
Combined scenarios 1 + 2 + 3	M&L + Indoor application + Post application	A **safe** situation has been identified during the disinfection process when PPEs and RMMs are used.	Professional / Trained Professional users

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
4.	Inhalation of volatilised residues	A **safe** situation has been identified for adults inhaling volatilized residues during and after treatment when RMMs are used.	General public
5.	Adults contact with treated surfaces	A **safe** situation has been identified for adults touching treated surfaces when RMMs are used.	General public
6.	Laundering	A **safe** situation has been identified for adults washing contaminated work clothes when PPEs and RMMs are used.	General public
Combined scenarios 1 + 2 + 3 + 4 + 5 + 6	M&L + Indoor application + Post application + Inhalation + Laundering	A **safe** situation has been identified during the disinfection process and possible subsequent secondary exposure when PPEs and RMMs are used.	General public

All scenarios resulted in acceptable risk. In addition, risk assessment for consumers via residues in food and animal health is not foreseen when RMMs are set on the product label.

The assessment of the endocrine disrupting (ED) properties of the co-formulants used in the biocidal product GERM-IOD has been performed according to CA-March18-Doc.7.3.b-final document on "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation".
After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants.
According to the document agreed at the CG-49 meeting on Criteria – significant indications of ED properties for non-active substances at present, non-active substances contained in the biocidal product GERM-IOD should not be considered as having significant indication of ED properties.

Environmental risk

Based on this risk assessment and available data, no unacceptable risk to the environment has been identified for the product "GERM-IOD", when is applied for the intended uses according to the instructions of use.

Overall conclusion

According to the assessment performed for the biocidal product GERM-IOD, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the table below:

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
Use # 1 – Spraying / Sprinkling application on surfaces - Professional / Trained Professional use	Bacteria and yeasts	Professionals / Trained Professionals	Application rate: 125-500 $mL_{solution}/m^2$ (equivalent to max. application rate of 7.5 $mL_{product}/m^2$). The Frequency: It depends on the species of animals: - Meat poultry species: minimum 40 days - Laying poultry species: annually - Rabbits: monthly - Porcine species: minimum every six months - Meat bovine species: minimum once a year	It is recommended to use a dosing pump to fill the application equipment with the product. Keep out of reach of children and pets. Keep uninvolved persons, children and pets away from treated surfaces/areas. Do not enter treated area until dry. Only use in empty animal housing. Cover all surfaces and facilities likely to be in contact with feed and drinking water. Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines. Cover all water storage tanks and ponds before application of the product. Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock. Avoid the presence of further professionals who are not targeted to disinfect the premises during the application. To protect groundwater and soil organisms, application of this product is restricted to areas with a hard standing. Spills and residues containing the product need to be discharged to the sewer with connection to a sewage treatment plant. The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures). Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
				product information). Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1] Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory (the material must be specified by the authorization holder in the product information). The use of eye protection during handling of the product is mandatory (chemical googles).

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
GERM-IOD	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	CENAVISA S.L.
	Address	Camí Pedra Estela, s/n 43205 – Reus – Tarragona (Spain)
Authorisation number	ES/APP(NA)-2023-03-00860	
Date of the authorisation	19/04/2023	
Expiry date of the authorisation	19/04/2028	

2.1.1.3 Manufacturer of the product

Name of manufacturer	CENAVISA S.L.
Address of manufacturer	Camí Pedra Estela, s/n 43205 – Reus – Tarragona (Spain)
Location of manufacturing sites	Camí Pedra Estela, s/n 43205 – Reus – Tarragona (Spain)

2.1.1.4 Manufacturer of the active substance

Active substance	Iodine
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Via Trajana 53-59 08020 Barcelona - SPAIN
Location of manufacturing sites	SQM Europe N.V. St Pietersvliet 7, bus 8, 2000 Antwerpen, Belgium Plant location: Chile, Sociedad Química y Minera S.A.

2.1.2 Product (family) composition and formulation

NB: the full composition of the product has been provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Iodine
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	-
Minimum purity / content	min. 995 g/kg
Structural formula	

2.1.2.2 Candidate for substitution

Currently, the active substance iodine is not a candidate for substitution in accordance with Article 10 of the BPR (EU) Regulation 528/2012. Therefore this product has not been subject to a comparative assessment. However, according to the note *CA-September18.Doc.7.5.a-final* on "Implementation of scientific criteria to determine the endocrine-disrupting properties of already approved active substances", it is proposed for iodine to trigger an early review as this active substance may have endocrine disrupting properties.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine	Iodine	Active substance	7553-56-2	231-442-4	2.5
Alcohols C12-14, ethoxylated	Alcohols C12-14,ethoxylated	Non-active substance	68439-50-9	500-213-3	9
Isopropyl alcohol	2-propanol	Solvent	67-63-0	200-661-7	6.57

Full composition is included as confidential information in Confidential annex.

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family

Not applicable.

2.1.2.5 Information on technical equivalence

The source of iodine is the same as evaluated for inclusion in the Union list of approved substances. Hence, no assessment of technical equivalence is needed.

2.1.2.6 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), GERM-IOD contains one substance of concern (Alcohols, c12-14, ethoxylated).
One substance of the biocidal product, i.e. Propan-2-ol, have been considered as substance of concern (SoC) according the rules laid down in BPR Art 3(f) in the environmental section. However, it does not contribute to the environmental classification of the product.

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

SL-Soluble concentrate

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Flammable liquid cat.3 Corrosive to metals cat. 1 Eye Damage 1 STOT RE 2 Aquatic chronic 2
Hazard statement	H226: Flammable liquid and vapour H290: Corrosive to metals H318: Causes serious eye damage. H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure. H411: Toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Pictograms	

	GHS02 GHS05 GHS08 GHS09
Hazard statements	H226: Flammable liquid H290: Corrosive to metals H318: Causes serious eye damage. H373: May cause damage to organs through prolonged or repeated exposure (thyroid gland). H411: Toxic to aquatic life with long lasting effects
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P234: Keep only in original packaging. P233: Keep container tightly closed. P260: Do not breathe dust/fume/gas/mist/vapours/ spray. P273: Avoid release to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/… P314: Get medical advice/attention if you feel unwell. P390: Absorb spillage to prevent material damage P391: Collect spillage P403 + P235: Store in a well-ventillated place. Keep cool. P406: Store in a corrosion- resistant/… container with a resistant inner liner. P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations

ES CA will apply article 37 according to BPR in the authorisation of this product including in this section the P statements that are recommended and highly recommended according to the result of the risk assessment of the product and considering the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 March 2021).

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Spraying / Sprinkling application on surfaces - Professional / Trained Professional use

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Veterinary hygiene biocidal product used as disinfectant on areas in which animals are housed or kept. It is applied on surfaces such as floors, walls and ceilings.
Target organism (including development stage)	Bacteria and yeasts
Field of use	Indoor Cover all water storage tanks and ponds before application of the product.
Application method(s)	Spraying / sprinkling: The product is diluted with water (15 $mL_{product}$/1L_{water}) in a tank or container before the application.

Application rate(s) and frequency	Application rate: 125-500 $mL_{solution}/m^2$ (equivalent to max. application rate of 7.5 $mL_{product}/m^2$). The Frequency: It depends on the species of animals: - Meat poultry species: minimum 40 days - Laying poultry species: annually - Rabbits: monthly - Porcine species: minimum every six months - Meat bovine species: minimum once a year
Category(ies) of users	Professional and Trained Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use

See section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See section 2.1.5.2.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The use of eye protection during handling of the product is mandatory.

Apply only on non porous surfaces.

Cleaning prior to disinfection is required.

Spray and leave wet for 30 minutes.

Ventilate treated areas thoroughly until spray has dried before re-entry.

Do not enter treated area until dry.

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

Only use in empty animal housing.

Cover all surfaces and facilities likely to be in contact with feed and drinking water.

Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines.

Cover all water storage tanks and ponds before application of the product.

Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

The established safety period to introduce the animals in the previously treated area is 24 hours.

The frequency of application will depend on the animal species:

- Meat poultry minimum 40 days
- Laying poultry annual frequency
- Cuniculture monthly frequency
- Porcine species minimum period of 6 months
- Beef bovine minimum periodicity per year.

2.1.5.2 Risk mitigation measures

It is recommended to use a dosing pump to fill the application equipment with the product.

Keep out of reach of children and pets.

Keep uninvolved persons, children and pets away from treated surfaces/areas.

Do not enter treated area until dry.

Only use in empty animal housing.

Cover all surfaces and facilities likely to be in contact with feed and drinking water.

Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines.

Cover all water storage tanks and ponds before application of the product.

Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

Avoid the presence of further professionals who are not targeted to disinfect the premises during the application.

To protect groundwater and soil organisms, application of this product is restricted to areas with a hard standing. Spills and residues containing the product need to be discharged to the sewer with connection to a sewage treatment plant.

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1]

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory (the material must be specified by the authorization holder in the product information).

The use of eye protection during handling of the product is mandatory.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

IF EXPOSED: Call a POISON CENTRE or a doctor.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Keep the product only in original container.

Keep the containers closed in a well ventilated area, protected from direct sunlight.

Keep the product in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition.

Keep containers away from any incompatible materials.

Shelf life of product: 24 months from the date of manufacture.

2.1.6 Other information

According to national legislation, in Spain there are these user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P or NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional users the maximum size that can be authorized is 5 L, except in the livestock field, where there are no container size restrictions for professional users.

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can/Tin	1, 5, 25 and 200 L	HDPE	-	Trained Professional / Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data have been submitted

2.1.8.2 Access to documentation

CENAVISA S.L as applicant of the NA-APP of the biocidal product GERM-IOD has submitted a LoA granted by Alcoholes Montplet, S.A. (Laboratorios Montplet S.L.U. currently) to the Access to the active substance data.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Use # 1 – Bactericide, fungicide and yeasticide product - Professional use

Product Type	PT03 – Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use	Iodo 2.5% concentrado soluble (GERM-IOD, Yodo S.P.) is a veterinary hygiene biocidal product intended to be used as a disinfectant product against fungi, yeast and bacteria. It is only to be used by professional users.
Target organism (including development stage)	*Pseudomonas aeruginosa* *Enterococcus hirae* *Proteus vulagris* *Candida albicans* *Staphylococcus aureus* *Aspergillis brasiliensis*
Field of use	Indoor. The product is applied in areas in which animals are housed, kept or transported. It is applied in surfaces such as floors, walls and ceilings by sprinkling and spraying methods. The product is also applied by immersion when the product is intended to be used as footbath.
Application method(s)	Spraying: The product is diluted with water in a tank or container before the application. The spaying method can be applied using hand pressure equipment (backpacks manual spraying), small electrical enclosures /electric backpacks) or equipment of hydraulic pressure hoses (tractor tanks) for large holdings. In most of the treatments the professional operator is present during the application. Sprinkling: The product is dilute with water in atank or container before application. The sprinkling method can be applied using hand pressure equipment (backpacks manual sprinkling), small electrical enclosures (electric backpacks) or equipment of hydraulic pressure hoses (tractor tanks) for large holdings. In most of the treatments the professional operator is present during the application. Inmersion: The product is diluted and spilled in the recipent intended to be used as footbath.
Application rate(s) and frequency	Spraying: Application rate: 125-500 mL/m^2 Frequency: It depends on the species of animals: - Meat poultry species: minimum 40 days - Laying poultry species: annually - Rabbits: monthly - Porcine species: minimum every six months - Meat bovine species: minimum once a year Sprinkling: Application rate: 125-500 mL/m^2 Frequency: It depends on the species of animals: - Meat poultry species: minimum 40 days - Laying poultry species: annually - Rabbits: monthly - Porcine species: minimum every six months - Meat bovine species: minimum once a year Inmersion: Application rate: The application dose depends of the volume of recipent to be used as footbath Frequency: The diluted product contained in the recipent should be replaced each 48 hours

Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	2.5% Iodine	Viscous liquid	Report nº ES/IODO2.5/0115 (2015)
Colour at 20 °C and 101.3 kPa	Visual method	2.5% Iodine	Dark brown	Report nº ES/IODO2.5/0115 (2015)
Odour at 20 °C and 101.3 kPa	Visual method	2.5% Iodine	Characteristic	Report nº ES/IODO2.5/0115 (2015)
Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	2.5% Iodine	2.39 at 25ºC Acidity: 2.217% m/m H_2SO_4	Report nº ES/IODO2.5/0115 (2015) and Peña, M. (2020)
Relative density / bulk density	CIPAC MT 3.2 (pycnometer)	2.5% Iodine	1.023 g/mL at 25ºC	Report nº ES/IODO2.5/0115 (2015) and Peña, M. (2020)
Storage stability test – **accelerated storage**	CIPAC MT 46.3	2.5% Iodine	Temperature: 54°C (14 days) $[C]_0$ = 2.62% $[C]_f$ = 2.61% $\Delta[C]$ = -0.38 < 10% The appearance of the proposed commercial packaging and the weight of the test item in the commercial packaging did not change significantly.	Report nº ES/IODO2.5/0115 (2015)
Storage stability test – **long term storage at ambient temperature**	Iodine monograph of the European Pharmacopoeia	2.5% Iodine	Temperature 25°C (2 years) <u>3 months</u> $[C]_0$ = 2.62% $[C]_f$ = 2.57% $\Delta[C]$ = -1.91 < 10% <u>6 months</u> $[C]_0$ = 2.62%	Report nº ES/IODO2.5/0115 (2017)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			$[C]_f$ = 2.56% $\Delta[C]$ = -2.29 < 10% <u>9 months</u> $[C]_0$ = 2.62% $[C]_f$ = 2.52% $\Delta[C]$ = -3.82 < 10% <u>12 months</u> $[C]_0$ = 2.62% $[C]_f$ = 2.49% $\Delta[C]$ = -4.96 < 10% <u>18 months</u> $[C]_0$ = 2.62% $[C]_f$ = 2.44% $\Delta[C]$ = -6.87 < 10% <u>24 months</u> $[C]_0$ = 2.62% $[C]_f$ = 2.39% $\Delta[C]$ = -8.78 < 10% The results of physico-chemical tests (pH, density, kinematic viscosity, foaming and dilution stability) remain stable. No changes were observed in the appearance of the solution or signs of damage in the proposed marketing package. Results show that the product is stable after 24 months at ambient temperature.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	Not performed.			
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	The product package is opaque, so no effect of light is expected. Keep the containers protected from direct sunlight.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Stability at elevated and decreased temperatures confirmed by the respective storage stability test. Humidity does not affect the properties of the product as t he product is water based.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	The product is stable in its container. Please refer to the Storage stability test			
Wettability	Not applicable			
Suspensibility, spontaneity and dispersion stability	Not applicable			
Wet sieve analysis and dry sieve test	Not applicable			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable			
Disintegration time	Not applicable			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming	CIPAC MT 47.2	2.5% Iodine	The result of persistent foaming test was a volume of foam lower than 60 mL. (14 mL of foam after 1 min)	Report nº ES/IODO2.5/0115 (2015)
Flowability/Pourability/Dustability	Not applicable			
Burning rate — smoke generators	Not applicable			
Burning completeness — smoke generators	Not applicable			
Composition of smoke — smoke generators	Not applicable			
Spraying pattern — aerosols	Not applicable			
Physical compatibility	Not applicable. The product is not intended to be used in combination with other products.			
Chemical compatibility	Not applicable. The product is not intended to be used in combination with other products.			
Degree of dissolution and dilution stability	CIPAC MT 41	2.5% Iodine	The formulation is an opalescent solution without visible particles or any visible sediment or particles passing through the sieve of 45µm.	Report nº ES/IODO2.5/0115 (2015)
Surface tension	EU Method A.5	2.5% Iodine	27.2 mN/m at 20 ºC	Report nº VA-15/02328 (2015)
Viscosity	CIPAC MT 22 CIPAC MT 192	2.5% Iodine	Dynamic viscosity: 9.5 mPa·s at 20°C 10.4 mPa·s at 40°C Kinematic viscosity: 22.21 mm^2/s at 25ºC	Report nº ES/IODO2.5/0115 (2015) and Peña, M. (2020)

Conclusion on the physical, chemical and technical properties of the product
The product "GERM-IOD" is a SL (Soluble Concentrate) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a dark-brown soluble concentrate liquid. The pH value for the product at 25ºC is 2.39. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54 ºC, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for an SL formulation.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	According to the guide EC method A.14, the study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosives properties and hence, the classification procedure does need to be applied			
Flammable gases	Not applicable			
Flammable aerosols	Not applicable			
Oxidising gases	Not applicable			
Gases under pressure	Not applicable			
Flammable liquids	EU Method A.9	2.5% Iodine	The flash point of the test item was 53ºC under the conditions of the test. The product need to be classified as 'flammable liquid', concretely "Flam.Liq Cat 3 (H226)"	Report nº VA-15/02328 (2015)
Flammable solids	Not applicable			
Self-reactive substances and mixtures	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.			
Pyrophoric liquids	It is not a pyrophoric liquid since no spontaneous ignition is observed when it is manufactured and handled into contact with air at normal temperatures. In addition, the auto-ignition temperature of this product is higher than ambient temperature, another evidence to confirm that it is not a pyrophoric liquid			Peña, M. (2020)
Pyrophoric solids	Not applicable			
Self-heating substances and mixtures	Not applicable			
Substances and mixtures which in contact with water emit flammable gases	Not applicable			
Oxidising liquids	EU method A.21	2.5% Iodine	Non-oxidising	Report nº VA-15/02328 (2015)
Oxidising solids	Not applicable			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Organic peroxides	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of test and criteria.			
Corrosive to metals	MT 37.4, Manual of test and Criteria of the Transport of Dangerous Goods of United nations	2.5% Iodine	The product resulted corrosive for both metals, aluminium and steel, since the maximum weight loss registered was above the threshold weight loss after 7 days.	Report nº 22171-01 C (2022)
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15	2.5% Iodine	Auto-ignition Temperature: >500 ºC	Report nº VA-15/02328 (2015)
Relative self-ignition temperature for solids	Not applicable.			
Dust explosion hazard	Not applicable.			

Conclusion on the physical hazards and respective characteristics of the product
GERM-IOD (SL) has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was 53º·C. The product require classification under Regulation (EC) No 1272/2008 for physical hazards, it is categorized as flammable level 3 (H226) and as corrosive to metals. (H290).

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Iodine	Potentiometric titration	2.00%, 2.50%, 3.00 % (in triplicate)	R^2>0.99	The applied method to quantify Iodine in the test item is specific.	[99.60–100.50]	99.87	0.0071	0.400%	Report nº ES/IODO2.5/0115 (2015)

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the active substance data.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the active substance data.

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the active substance data.

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the active substance data.

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the active substance data.

Conclusion on the methods for detection and identificationof the product
According to Iodine monograph of the European Pharmacopoeia the analytical methods provided are fully validated for the determination of the active substances "Iodo 2,5% concentrado soluble".

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

GERM-IOD (Iodine 2.5% w/w) is a veterinary hygiene biocidal product intended to use as disinfectant product against yeast and bacteria to be applied in areas in which animals are housed or kept. The product is applied in surfaces such as floors, walls and ceiling by sprinkling and spraying methods. It is only to be used by professional users.

Field of use : MG 01: Disinfectants
PT3: Veterinary hygiene - Hard surfaces.
Indoor use.
The product is intended to be applied diluated with water 15 ml product/1 L water.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

GERM-IOD provides disinfection against bacteria and yeast.

2.2.5.3 Effects on target organisms, including unacceptable suffering

GERM-IOD provides disinfection against bacteria and yeast.

The controlled organisms on the tests have been bacteria *Enterococcus hirae* ATCC 10541, *Proteus hauseri (ehemals/* formerly *P. vulgaris)* ATCC 13315, *Pseudomonas aeruginosa* ATCC 15442 and *Staphylococcus aureus* ATCC 6538 and yeast *Candida albicans*.

The unacceptable suffering has not been possible to assess.

2.2.5.4 Mode of action, including time delay

The mode of action of iodine is non-selective and is based on the following mechanisms:

- Iodine rapidly penetrates into microorganisms showing a high affinity pattern of adsorption.
- Iodine combines with protein substances in the bacterial cell; these could be peptidoglycans in the cell walls or enzymes in the cytoplasm. This results in irreversible coagulation of the protein and consequent loss of function.
- Iodine is known to act on thiol groups in the cell, if a thiol enzyme is part of a metabolic chain then metabolic inhibition will result.
- Iodine reacts with key groups of proteins, in particular the free-sulphur amino acids cysteine and methionine, nucleotides and fatty acids.
- Iodine interferes at the level of the respiratory chain of the aerobic microorganisms by blocking the transport of electrons through electrophilic reactions with the enzymes of the respiratory chain.

The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Iodine is more effective at higher temperatures. The germicidal activity of iodine-containing solutions is characterised by their colour. Amber solutions are active whilst pale yellow or colourless solutions are less effective and must be replaced by new solutions.

The efficacy of iodine as a biocide has been demonstrated over 170 years of use and due to this long history of use there are numerous papers demonstrating the microbiocidal activity of iodophor products in laboratory and field tests. A time of 24 hours is established prior to the re-entrance to disinfected premises where the product is used.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Bacteria*:* *Pseudomonas aeruginosa CECT 116* *Proteus vulgaris CECT 484* *Staphylococcus aureus CECT 239* *Enterococcus hirae CECT 4081*	EN 1656: 2010	Phase 2 step 1 test (suspension test) Concentrations tested:1%, 0.4% and 0.2%. Temperature: 10°C Contact time: 30 minutes Soiling conditions: Clean 3g/l bovine albumin Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 0.4%: -0.4% against *Pseudomonas aeruginosa* -0.2% against *Proteus vulgaris* -0.4% against *Staphylococcus aureus* -0.4% against *Enterococcus hirae*	Report No: 200055922
Bactericide	Hard Surface (PT3) Indoor	GERM-IOD	Bacteria*:* *Enterococcus hirae* ATCC 10541 *Proteus hauseri (ehemals /* formerly *P. vulgaris)* ATCC 13315 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538	EN 14349: 2013	Phase 2 step 2 test (carrier test) Concentrations tested: 3.5%, 2.5%, 2%, 1.5%, 1%, 0.4%, 0.2% (v/v) Temperature: 10°C Contact time: 30 minutes Soiling conditions: Clean, 3g/l bovine serum albumin Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 1.5% (w/v) 30 min: -1.5% (w/v) against *Staphylococcus aureus* -1% (w/v) against *Enterococcus hirae* (20min) -1% (w/v) against *Pseudomonas aeruginosa* (16min) -0.4% (w/v) against *Proteus hauseri* (18min)	Report No: SN 2020-2037, 2020-3127
Yeasticide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Yeast*:* *C. albicans* DSM 1394	EN 1657: 2016	Phase 2 step 1 test (suspension test) Concentrations tested:1%, 0.4% and 0.2%. Temperature: 10°C Contact time: 30 minutes Soiling conditions: Clean 3g/l bovine albumin Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 0.4% against C. *albicans*	Report No: 200046818

Experimental data on the efficacy of the biocidal product against target organism(s)							
Yeasticide	Hard Surface (PT3) Indoor	GERM-IOD	Yeast: *Candida albicans* ATCC 10231	EN 16438: 2014	Phase 2 step 2 test (carrier test) Concentrations tested: 3%, 2.5%, 2%, 1.5%, 1%, 0.4%, 0.2% (v/v) Temperature: 10°C Contact time: 30 minutes Soiling conditions: Clean, 3g/l bovine serum albumin Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 1.5% against C. *albicans*	Report No: 2020-2038, 2020-3128
ADDITIONAL INFORMATION							
Bactericide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Bacteria: *Enterococcus hirae DSM 3320* *Proteus vulgaris DSM 30118* *Pseudomonas aeruginosa DSM 939* *Staphylococcus aureus DSM 799*	EN 1656: 2010	Phase 2 step 1 test (suspension test) Concentrations tested: -10% (w/v) against *E. hirae* DSM 3320 -2.5% (w/v) against *P. vulgaris* DSM 30118 -5% (w/v) against *P. aeruginosa* DSM 939 -10% (w/v) against *S. aureus* DSM 799 Temperature: 10°C Contact time: 30 minutes Soiling conditions: Dirty 10 g/L bovine albumin + 10 g/L yeast extract Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 5%: -5% (w/v) against *E. hirae* -1% (w/v) against *P. vulgaris* -2.5% (w/v) against *P. aeruginosa* -5% (w/v) against *S. aureus*	Report No. 241/0415-1
Bactericide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Bacteria: *Enterococcus hirae DSM 3320* *Proteus vulgaris DSM 30118* *Pseudomonas aeruginosa DSM 939* *Staphylococcus aureus DSM 799*	EN 14349: 2012	Phase 2 step 2 test (carrier test) Concentrations tested: -10% (w/v) against *E. hirae* DSM 3320 -5% (w/v) against *P. vulgaris* DSM 30118 -5% (w/v) against *P. aeruginosa* DSM 939 -10% (w/v) against *S. aureus* DSM 799 Temperature: 10°C Contact time: 30 minutes	Bactericidal activity demonstrated at 5%: -5% (w/v) against E. *hirae* -2.5% (w/v) against P. *vulgaris* -2.5% (w/v) against P. *aeruginosa* -5% (w/v) against S. *aureus*	Report No. 241/0415-3

Experimental data on the efficacy of the biocidal product against target organism(s)							
					Soiling conditions: Dirty 10 g/L bovine albumin + 10 g/L yeast extract Criteria: at least a 4 log reduction		
Yeasticide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Yeast*:* *C. albicans* DSM 1386 Fungal espores: *A. brasiliensis* DSM 1988	EN 1657: 2006	Phase 2 step 1 test (suspension test) Concentrations tested: - 10% (w/v) against *C. albicans* DSM 1386 - 80% (w/v) against *A.brasiliensis* DSM 1988 Temperature: 10°C Contact time: 30 minutes Soiling conditions: Dirty 10 g/L bovine albumin + 10 g/L yeast extract Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 5% (w/v) against C. *albicans* Fungicidal activity 40% (w/v) against A.*brasiliensis*	Report No. 241/0415-4
Yeasticide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Yeast*:* *C. albicans* DSM 1386 Fungal espores: *A. brasiliensis* DSM 1988	EN 16438: 2014	Phase 2 step 2 test (carrier test) Concentrations tested: - 10% (w/v) against C. albicans DSM 1386 - 100% (w/v) against A.brasiliensis DSM 1988 Temperature: 10°C Contact time: 60 minutes Soiling conditions: Dirty 10 g/L bovine albumin + 10 g/L yeast extract Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 5% (w/v) against C. *albicans* Fungicidal activity 50% (w/v) against *Aspergillus brasiliensis*	Report No. 241/0415-2
Bactericide	Hard Surface (PT3) Indoor	GERM-IOD Iodine 2.5% w/w	Bacteria*:* *Staphylococcus aureus CECT 239*	EN 1656: 2010	Preliminary trial - Phase 2 step 1 test (suspension test) Concentrations tested:1%, 0.4% and 0.2%. Temperature: 10°C Contact time: 30 minutes Soiling conditions: Clean 3g/l bovine albumin Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 0.4% against *Staphylococcus aureus*	Report No: 200046819

Conclusion on the efficacy of the product

According yo the Guidance on the Biocidal Products Regulation – Volume II Efficacy – Assessment and Evaluation (Parts B+C)), veterinary biocidal products to disinfect hard surfaces should be at least sufficiently effective against bacteria and yeasts. Efficacy tests with these organisms should always be provided.

To substantiate the claims for bactericidal and yeasticidal activity of the product, efficacy studies have been performed according to European Standards (EN). As the products within the BPF are intended to be applied for hard surfaces, the formulation was tested in a tiered approach with a phase 2, step 1 test (quantitative suspension test) followed by a phase 2, step 2 test (quantitative carrier test). All studies were performed with obligatory test conditions (contact time: 30 minutes; temperature: 10°C) and under clean soiling conditions (3 g/l bovine albumin).

Study results on the efficacy of the biocidal product against target organisms

European Standard	Contact time	Dilution	Meet the requirements	Activity
EN 1656	30 minutes	0.2%	no	bactericidal
		0.4%	**yes**	
		1%	**yes**	
EN 14349	30 minutes	0.2%	no	
		0.4%	no	
		1%	yes	
		1.5%	**yes**	
		2%	**yes**	
		2.5%	**yes**	
		3%	**yes**	
EN 1657	30 minutes	0.2%	no	yeasticidal
		0.4%	**yes**	
		1%	**yes**	
EN 16438	30 minutes	0.2%	no	
		0.4%	no	
		1%	no	
		1.5%	**yes**	
		2%	**yes**	
		2.5%	**yes**	
		3%	**yes**	

The assessment of the biocidal activity of the product GERM-IOD has demonstrated that, according to submitted tests, the product showed a good level of efficacy in clean conditions (3g/l bovine albumin) at dilution rate of 1.5 % (w/v), with a contact time of 30 minutes, as bactericide against *Enteroccoccus hirae*, *Proteus vulgaris*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* and as yeasticide against *Candida albicans.*

Spray the disinfectant making sure surfaces are thoroughly wetted and leave to dry. The contact time should be at least 30 minutes.

As regards phase 2 step 2 test (EN 14349), Report No: SN 2020-2037, 2020-3127, it can be considered that the longer the contact time, the more effective the disinfectant is.

According to the Efficacy Guidance on the BPR, "in the veterinary area very often rough, porous surfaces have to be disinfected (i.e. wood, concrete, rough plastic materials). When tests for porous surfaces are available it is recommended to use these tests for

Conclusion on the efficacy of the product
general surface disinfection in veterinary areas". The carrier test submitted has demonstrated efficacy on non-porous surface conditions whereas there was a test available on porous surface conditions (EN 16437). No test has been submitted for the demonstration of efficacy on porous surfaces. EN 16437,a phase 2 step 2 porous surface test for bactericide has not been submitted. Thus, the efficacy on porous surfaces is not proven. Therefore, **only on non-porous surfaces** should be labelled. Since efficacy has been demonstrated in clean conditions (3g/l bovine albumin), the label instructions should state **that cleaning prior to disinfection is necessary.** Fungicidal activity against the strain *Aspergillus brasiliensis* DSM 1988 has been demonstrated at the dilution rate of 40% (w/v). As activity against fungi is required for products used in hatcheries, and the product will be used at the dilution rate of 1.5% (w/v), the product GERM-IOD **do not be used in hatcheries.** Suspension test, phase 2 step 2 test (EN 1656) Report No: 200046819, developed only against *Staphylococcus aureus,* is considered additional data. Four tests submitted with author Carre, A. (2015) and number of report 241/ 0415-1, 0415-2, 0415-3 and 0415-4 are also considered additional tests. In conclusion, the required laboratory and simulated-use tests have been performed (using the required test organisms and test conditions), and the pass criteria for the tests have been met. Therefore, the biocidal product GERM-IOD is considered to be sufficiently effective as disinfectant for hard surfaces in low dirty conditions at the dilution rate of 1.5% (w/v).

2.2.5.6 Occurrence of resistance and resistance management

Taking into account the mode of action of iodine which is non-selective, development of resistance against iodine is unlikely.

On the other hand, Iodine and iodophors have been used for over 170 years as disinfectants for a variety of applications. Such applications include disinfection of skin in the human hygiene and medical area but also skin of animals using teat dips as well as surfaces such as milk tanks. No reduction in efficacy was reported to the producers of iodine/iodophor-based products for such applications indicating that no development of resistant microorganisms or viruses has occurred.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

Not available.

2.2.5.8 Evaluation of the label claims

GERM-IOD is a soluble concentrate intended to be applied as disinfectant by spraying or sprinkling on technical equipment and/or floor, walls and ceiling of animal housing facilities.

The assessment of the disinfectant activity of the product demonstrated that it has a good level of efficacy at the dilution rate of 1.5% (w/v) as:

- bactericide against *Enteroccoccus hirae, Proteus vulgaris, Pseudomonas aeruginosa and Staphylococcus aureus*
- yeasticide against *Candida albicans.*

(Please see efficacy tests summarized in point 6.7 of the IUCLID dossier).

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

GERM-IOD product is not intended to be use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritating to skin
Justification for the value/conclusion	Test for skin irritation with the biocidal product has not been performed. Data of the active substance iodine were evaluated by the Rapporteur Member State (RMS) Sweden and published as Chemical Assessment Report (RMS SE, 2013). According to the CAR, iodine is classified as Skin Irrit. 2, H315. In addition, one co-formulant has harmonized classification and labelling as skin corrosion 1B; H314 with specific concentration limits. Nevertheless, according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation), considering the generic and specific concentration limits, GERM-IOD is not classified with regards to skin irritation properties.
Classification of the product according to CLP	GERM-IOD does not need to be classified for corrosive/irritant to skin.

Data waiving	
Information requirement	Skin irritation/corrosion
Justification	Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in CLP REgulation, and synergistic effects between any of the components are not expected. According to the CAR, a classification as Skin irrit.2; H315 has been assigned for iodine. In addition, the biocidal product contains less than 10% of co-formulants classified as skin irritation category 2; H315. Therefore, the biocidal product GERM-IOD is classified as no irritant or corrosive to skin and no further studies are needed with the formulated product.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	Test for eye irritation with the biocidal product has not been performed. Data of the active substance iodine were evaluated by the Rapporteur Member State (RMS) Sweden and published as Chemical Assessment Report (RMS SE, 2013). According to the CAR, iodine is classified as Eye Irrit. 2, H319. In addition, the product contains more than 3% of one coformulant classified as serious eye damage category 1; H318 Therefore, according to the CLP Regulation GERM-IOD should be classified as Eye damage 1; H318.
Classification of the product according to CLP	GERM-IOD should be classified as Eye Damage 1; H318

Data waiving	
Information requirement	Eye irritation
Justification	Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. According to the CAR, a classification as Eye irrit.2; H319 has been assigned for iodine. In addition, the product contains more than 3% of one co-formulant classified as serious eye damage category 1; H318. Therefore, the biocidal product GERM-IOD is classified as causing of serious eye damage (Eye Dam.1; H318) and no further studies are needed with the formulated product.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	According to the CAR, the active substance iodine is classified as irritant to respiratory tract. No co-formulants are classified for respiratory tract irritation.
Classification of the product according to CLP	GERM-IOD is not classified as specific target organ toxicity - single exposure -, Category 3 (STOT SE 3); H335

Data waiving	
Information requirement	Respiratory tract irritation

Justification	No data on respiratory tract irritation is available. According to the CAR, the active substance iodine is classified as STOT SE 3; H335. The concentration of iodine is far below the generic concentration limit of 20%. Regulation (EC) Nº 1272/2008 (CLP Regulation) establishes the following: "Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value" On the other hand, the Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 4.1; June 2015 stablishes the following: "Classification in STOT-SE Category 3 for respiratory tract irritation and narcotic effects does not take potency into account and consequently does not have any guidance values. A pragmatic default generic concentration limit of 20% is suggested, although a lower or higher specific concentration limit may be used where it can be justified". Therefore, as iodine is present at a concentration below the concentration limit of 20%, and no coformulants are classified as irritant to respiratory tract, the product GERM-IOD is not classified as respiratory tract irrittant.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer.
Justification for the value/conclusion	Based on the classification of the active substance iodine and the different coformulants and, their respective content in the final formulation
Classification of the product according to CLP	GERM-IOD is not classified as skin sensitizer.

Data waiving	
Information requirement	Skin sensitisation
Justification	Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Active substance iodine is not classified as skin sensitizer. In addition, data are also available for the other coformulants and none is considered as skin sensitizer too.

	Therefore, the product GERM-IOD is not classified as skin sensitizer and no further studies are needed with the formulated product.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	Neither active substance iodine nor coformulants are classified for respiratory sensitisation.
Classification of the product according to CLP	GERM-IOD is not classified as respiratory sensitizer.

Data waiving	
Information requirement	Respiratory sensitization
Justification	No animal or human data have been provided to assess the potential for respiratory sensitization. Active substance iodine is not classified as respiratory sensitizer. In addition, data is also available for the coformulants and none is considered as respiratory sensitizer too . Therefore, the product GERM-IOD is not classified as respiratory sensitizer.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL_{50}>2000mg/kg bw
Justification for the selected value	No acute oral toxicity studies have been conducted with the biocidal product. Iodine is subject to harmonised classification and labelling. According to annex VI of CLP Regulation, iodine is not classified for acute oral toxicity. According to the CAR, Iodine is not classified for acute oral toxicity. However, according to database of registered substances under REACH in ECHA website, iodine is classified as acute tox 4; H302. In addition, one coformulant is classified as acute tox 4; H302 in accordance with its SDS. Taking into account this, the calculation of ATE_{mix} for oral toxicity is >2000 mg/Kgbw and no classification is triggered. Based on these data, a classification of GERM-IOD for this endpoint is not necessary.
Classification of the product according to CLP	GERM-IOD is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute oral toxicity are available.

Data waiving	
Information requirement	Acute oral toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL_{50}:>5mg/l
Justification for the selected value	No acute inhalation toxicity studies have been conducted with the biocidal product. Iodine is subject to harmonised classification and labelling. According to annex VI of CLP Regulation, iodine is classified for acute inhalation toxicity as Acute tox 4*; H332. No coformulant is classified for acute inhalation toxicity. The concentration of iodine in the biocidal product is 2.5% w/w, using the criteria for classifying mixtures under CLP Regulation, the calculation of ATE_{mix} for inhalatory toxicity is >5mg/l and no classification is triggered.
Classification of the product according to CLP	GERM-IOD is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute inhalation toxicity are available.

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	DL_{50}: >2000mg/kg bw

Justification for the selected value	No acute dermal toxicity studies have been conducted with the biocidal product. Iodine is subject to harmonised classification and labelling. According to annex VI of CLP Regulation, iodine is classified for acute dermal toxicity as Acute tox 4*; H312. No coformulant is classified for acute dermal toxicity. The concentration of iodine in the biocidal product is 2.5% w/w, using the criteria for classifying mixtures under CLP Regulation, the calculation of ATE_{mix} for dermal toxicity is >2000mg/kgbw and no classification is triggered.
Classification of the product according to CLP	GERM-IOD is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute dermal toxicity are available.

Data waiving	
Information requirement	Acute dermal toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substances	Iodine
Value(s)	12%
Justification for the selected value(s)	According to the Swedish CAR for the active substance Iodine (including PVP-I), using the data obtained in the dermal absoption studies, the dermal absoption was estimated to 12%.

Data waiving	
Information requirement	Dermal absorption study
Justification	No study on dermal absorption has been provided for GERM-IOD. The active substance dossier on iodine (incl. PVP-iodine) (Sweden 2013), includes a human skin *in-vitro* dermal absorption study (De Ligt, 2009), in which two iodine-based biocidal products have been investigated. Both products are different from the compositional point of view and contain a different iodine concentration. The results of the two dermal absorption studies demonstrated that regardless of iodophor type (i.e. alcohol ethoxylate-complexed iodine or PVP-iodine) and type and

	concentration of co-formulants, the dermal absorption of total iodine was ca. 12%. On the other hand, although the formulation contains one co-formulant that is irritating or corrosive to the skin, it is below its specific classification limit, so GERM-IOD is not classified with regards to skin irritation properties. Therefore, no impact on the skin integrity and on the dermal absorption of iodine from the biocidal product is expected. In addition, only alcohol etoxylate is classified for eye damaging effect which causes the classification of GERM-IOD as H318, however, it is present at lower level compared to the tested formulation in the CAR. For these reasons, a dermal absorption of 12% will be used for the calculation of human health exposure.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), GERM-IOD contains one substance of concern.
Alcohols C12-14, ethoxylated is classified as eye damage 1; H318 and acute tox 4 (oral); H302. This SoC contained in the product are included in Band B. Associated evaluation and risk management requirements according to the SoC banding approach for Band B are limited to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.
For more information see confidential annex.

Available toxicological data relating to a mixture

No further studies on the toxicity of the product are required as there are valid data available on the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) 1272/2008 (CLP).

Other

Specific target organ toxicity, repeated exposure (STOT RE)

Value used in the Risk Assessment – STOT RE	
Justification	For Iodine a concern for specific target organ toxicity was identified. According to database of registered substances under REACH in ECHA website, the Iodine REACH consortium has proposed a classification for Iodine with STOT RE (thyroid gland), category 1; H372. In line with other biocides dossier evaluations, this classification and the generic concentration limit for mixture classification (if the concentration is ≥1% →STOT RE 2; H373) is taken into account for GERM-IOD
Classification of the products according to CLP	GERM-IOD is classified as STOT RE 2, H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains only one active substance. Assessment report (Sweden, December 2013) of Iodine indicates "*Iodine is an essential element and has a physiological function in thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both iodine deficiency as well as excess iodine can impair thyroid homeostasis/thyroid hormone levels. This is to be considered as an endocrine effect. However, it would not be justified to conclude from this that iodine should be considered to be an endocrine disruptor. In contrast to typical xenobiotic substances, which are not needed at all for the functioning of the human body, and which normally only have negative effects on man, Iodine is a physiologically essential element.*
Consequently, the concept of endocrine disruption is not meaningful for essential elements such as iodine since it neglects that they are needed for maintaining hormone homeostasis. Furthermore, neither iodine nor iodide are included in the lists of the EU on substances suspected of interfering with the hormone systems of humans and wild-life.".

Currently, the active substance Iodine was identified with 4 more substances as possible endocrine disruptors in the screening study performed "Impact Assessment Report on Criteria to identify EDs, European Commission, 2016". In this document, only the substances included in option 2 and option 3 category I match with the established ED criteria in Commission Delegated Regulation (EU) 2017/2100. Iodine was established within these options.
So, according to Doc CA-September18.Doc.7.5.a-final, the Commission considers that there are significant indications that Iodine and PVP-Iodine no longer fulfils the conditions laid down in Article 4(1) or Article 5(2) of BPR, so that they are subject to the process for the early review of biocidal substances in relation to ED, since renewal is not provided according to BPR before of the end of 2020.
This process, described in Doc CA-September18.Doc.7.5.a-final, will have a specific duration and the Commission decision will depend on the conclusions on the ED properties of these substances in ECHA's opinion. Then, the conditions for granting the biocidal product authorization will be revised"

Assessment of the ED properties of non-active substances (co-formulants):

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants.
According to the document agreed at the CG-49 meeting on Criteria – significant indications of ED properties for non-active substances at present, non-active substances contained in the biocidal product GERM-IOD should not be considered as having significant indication of ED properties.

Overall conclusion on the biocidal product regarding ED properties:

If iodine and one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

2.2.6.2 Exposure assessment

General Remarks
The assessment of occupational exposure towards *GERM-IOD* as disinfectant in veterinary hygiene is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to *GERM-IOD* is based on the selected models and default values from the Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations and the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.
The proposed tiered approach for human exposure assessment is applied as follows. In several cases it is considered not to be appropriate to calculate a "reasonable worst case" exposure (Tier 1) according to the Guidelines. The dermal absorption of iodine in humans is well established as outlined above. Assuming no protection by the human skin (as proposed for Tier 1 estimates) is considered not to be reasonable. For all of the following calculations the established dermal absorption figure for humans is applied. Despite the fact that protective measures could be supposed to be carefully observed in a professional environment, a Tier 1 is proposed as a worst case. Then, personal protective equipment will be assumed to be worn as second scenario (Tier 2).
Unless otherwise specified, a default penetration value of 10% for gloves and clothing was assumed, which is in accordance with HEEG Opinion on "Default protection factors for protective clothing and gloves" (when potential hand exposure data are available, a factor of 10 -90 % reduction of exposure by gloves manufactured from appropriate material- can be used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves: MOTA v6, 4.2.9.9 HEEG Opinion 9). On the other hand, if data on exposure inside protective gloves is available, these will be used for exposure assessment (MOTA v6, 4.2.9.2 HEEG Opinion 2).
If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.
Where exposure is calculated based on empirical data (Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations), these data are applied in agreement with the recommendations given by the guidelines as follows: In case of continuous (chronic) exposure scenarios the typical exposure is calculated based on the 75%-ile of the data. The 95%-ile is considered to represent the typical case when recommended by applicable guidelines. Where 95%-iles are not given, the maximum values are used instead.

Local dermal risk assessment
According to the criteria of the Regulation 1272/2008, the biocidal product *GERM-IOD* is proposed to be classified as severe eye irritant (H318 - Eye Dam 1). Therefore, a qualitative assessment of local effects will be performed in Section 2.2.6.3 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Dermal Absorption
See section 2.2.6.1.

Identification of main paths of human exposure towards active substance and substances of concern from its use in biocidal product

GERM-IOD is a soluble concentrate intended to be applied as disinfectant by spraying or sprinkling on technical equipment and/or floor, walls and ceiling of animal housing facilities.

GERM-IOD (2.5% Iodine) is considered to be sufficiently effective as disinfectant for hard surfaces in low dirty conditions at the dilution rate of 1.5% (0.0375% Iodine).

The product formulation is intended to be applied only by professional operators wearing personal protective equipment (PPE) and respiratory protective equipment (RPE).

In addition, considering that the product can cause eye damage, direct contact with the eyes should be avoided by using proper eye protection.

The relevant routes of primary exposure to biocidal iodine are dermal contact and inhalation. Oral exposure is not relevant because the users of biocidal iodine are considered professionals.

On the other hand, secondary exposure is differentiated among oral and dermal exposures. In general terms, secondary oral exposure may be due to the consumption of milk which contains iodine residues and due to the consumption of meat from exposed food producing animals. Regarding this route of exposure, it should be taken into account that the product is applied in absence of animals so this route of exposure should be negligible. Furthermore, secondary dermal exposure via contact with freshly treated surfaces may be relevant for children on farms, especially toddlers living on farms as family members could be in contact with freshly treated surface or they could fall into a footbath while exploring their environment. The possible routes of exposure for these children are dermal contact and possibly the hand-mouth contact (non-dietary ingestion).

According to Iodine's CAR, secondary exposure by inhalation is considered to be negligible.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	No	Yes	No	No	Yes	Yes	n.a.
Dermal	No	Yes	No	No	Yes	Yes	n.a.
Oral	No	No	No	No	Yes	Yes	Yes

n.a.: not applicable

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing & loading	Primary exposure. professional operator pours formulation from a container into a portable receiving vessel (e.g. knapsack sprayer). Dermal and inhalation routes are expected.	Professionals

2.	Application	Primary exposure. Disinfection of the surfaces by spraying Dermal and inhalation routes are expected.	Professionals
3.	Post-application	Primary exposure Cleaning of the spraying equipment. Dermal and inhalation routes are expected.	Professionals
4.	Post-application	Secondary exposure Inhalation of volatilised residues after applications. Inhalation exposure is expected.	Profesionals and Non-professionals (general public)
5.	Post-application	Secondary exposure Contact with treated surfaces Dermal and oral exposure are expected.	Profesionals and Non-professionals (general public)
6.	Post-application	Secondary exposure: Adult launders contaminated work clothing at home. Dermal route is expected.	Profesionals and Non-professionals (general public)

Industrial exposure

Not considered, the product is intended to be applied by professional users.

Professional exposure

Scenario [1] – Mixing & loading

Description of Scenario [1]			
This task can be performed before the product application is made or as a routine task without product application. The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 6. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day. Inhalation exposure during automated transfer is considered negligible, because of low vapour pressure. In Tier 2 PPE (gloves) are considered.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	2.5%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 6, 2020
	Dermal exposure		
	Indicative value without gloves	101 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	12%	Section 2.2.6.1.
	Inhalation exposure		

	Indicative value	0.94 mg/min	Recommendation no. 6, 2020
	inhalation Absorption	100%	Default value
Tier 2a	Indicative value with gloves	1.01 mg/min	Recommendation no. 6, 2020
Tier 2b	RPE	APF = 10	TNsG

Calculations for Scenario [1]

Systemic effects

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg/day)**	**Estimated dermal uptake (mg/kg/day)**	**Estimated oral uptake (mg/kg/day)**	**Estimated total uptake (mg/kg/day)**
Scenario [1]	Tier 1 / no PPE	5.05E-02	8.16E-05	--	5.06E-02
	Tier 2a / PPE	5.05E-04	8.16E-05	--	5.87E-04
	Tier 2b / PPE, RPE	5.05E-04	8.16E-06	--	5.13E-04

Further details about calculations can be found at Annex section 3.2.

Further information and considerations on scenario [1]
As the product is classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed in Section 2.2.6.3.

Scenario [2] – Spray application

Description of Scenario [2]			
The product is only intended to be applied on animal housing by professional users. This treatment is considered to be applied by the operator *in situ* with handbag equipment. According to the recommendation 6 of the Ad hoc WG on human exposure, exposure during animal house disinfection by spraying should be assessed with Spraying model 2 (medium pressure spray application) considering a duration of 120 minutes. The following parameters have been considered in this scenario assessment.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.0375%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	120 minutes	Recommendation no. 6, 2020
	Dermal exposure		

Description of Scenario [2]			
	Body indicative value	222 mg/min	Recommendation no. 6, 2020
	Hand indicative value without gloves	273 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	12%	Section 2.2.6.1.
	Inhalation exposure		
	Indicative value	76 mg/min	Recommendation no. 6, 2020
	Inhalation Absorption	100%	Default value
Tier 2a	Hand exposure with gloves	7.8 mg/min	Recommendation no. 6, 2020
Tier 2b	RPE	APF = 10	TNsG
	Coated coverall	10%	HEEG opinion no. 9

Calculations for Scenario [2]

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d]**	**Estimated total uptake [mg/kg bw d]**
Scenario [2]	Tier 1 / no PPE	1.19E-03	4.46E-02	-	4.57E-02
	Tier 2a / PPE	1.19E-03	2.07E-02	-	2.19E-02
	Tier 2b / PPE, RPE	1.19E-04	2.70E-03	-	2.82E-03

Further details about calculations can be found at Annex section 3.2.

Further information and considerations on scenario [2]
As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in Section 2.2.6.3.

Scenario [3] – Cleaning of spray equipment

Description of Scenario [3]
Exposure to the ready-to-use solution may occur in the post-application phase during cleaning the spraying equipment. This scenario considers the human exposure during the cleaning the spray equipment. The assessment is performed following the Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure with the BEAT scenario "Cleaning of the Spray equipment" from TNsG second version of 2007. As

Description of Scenario [3]			
no inhalation data are presented in BEAT's study, the same data as for application phase are used (expert judgement). The following parameters have been considered in the scenario assessment.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.0375%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Density	1.023 g/mL	Section 2.2.2.
	Cleaning process duration	20 min	Recommendation no. 4, 2014.
	Dermal exposure		
	Body indicative value	19.28 µL/min	Recommendation no. 4, 2014.
	Hand indicative value	35.87 µL/min	Recommendation no. 4, 2014.
	Dermal Absorption	12%	Section 2.2.6.1.
	Inhalation exposure		
	Indicative value	76 mg/min	Recommendation no. 2, 2020. Scenario 2.
	Inhalation uptake	100%	Default value.
Tier 2a	Chemical gloves	10%	HEEG opinion no. 9
Tier 2b	Coated coverall	10%	HEEG opinion no. 9
	RPE	APF = 10	TNsG

Calculations for Scenario [3]

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d]**	**Estimated total uptake [mg/kg bw d]**
Scenario [3]	Tier 1 / no PPE	1.98E-04	8.46E-04	-	1.04E-03
	Tier 2a / PPE	1.98E-04	3.51E-04	-	5.49E-04
	Tier 2b / PPE, RPE	1.98E-05	8.46E-05	-	1.04E-04

Combined scenarios

The professional would be exposed to the product by mixing and loading, spraying and cleaning the spray device.

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw d]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d]**	**Estimated total uptake [mg/kg bw d]**
Scenario [1, 2, 3]	Tier 1 / no PPE	1.47E-03	9.59E-02	--	9.74E-02
	Tier 2a / PPE	1.47E-03	2.15E-02	--	2.30E-02
	Tier 2b / PPE, RPE	1.47E-04	3.29E-03	--	3.44E-03

Non-professional exposure

All applications of biocides within PT-3 area are assumed to be only for "professional" use, therefore general public exposure is not foreseeable.

Exposure of the general public by secondary exposure

The product is only intended to be applied on animal housing by professional users, therefore, adults (general public) and children are not expected to be in contact with treated areas specially since a 24 hours waiting period is set. Children are not expected to be present on animal housings, transportation, etc.

On the other hand, adults (e.g.: farm-staff…) might be present in the treated facilities (or nearby) and might be exposed to product GERM-IOD via:

a) Inhalation route (inhalation of volatilised residues).
b) Dermal and oral routes by contact with treated surface.

Scenario [4] – Inhalation of volatilised residues

Description of Scenario [4]
Professional and general public may be exposed to volatilised residues from treated surfaces. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues: - For Iodine: $0.328*(Mw*Vp)/AEL_{long\text{-}term} = (0.328*253.81*40.7)/0.01 = 339000 > 1$ Remark: the mw (molecular weight), vp (vapour pressure) and $AEL_{long\text{-}term}$ come from the CAR/AR (Sweden CA, 2013). The result of this equation is higher than 1 for Iodine. The **exposure to volatilised residues indoor cannot** be considered **negligible** for workers and general public for the active substance. Exposure is assessed with a dilution of product at 1.5% (0.0375% of iodine).

Description of Scenario [4]

Inhalation of volatilised residues is assessed with RIVM ConsExpo Web, version 1.1.0 "Exposure to vapour" considering the exposure to vapor during 8 hrs as it is a professional exposure (worst case), a dilution at 0.0375% of iodine applied on a floor of 20 m^2 in a room of 25 m^3 with a ventilation rate of 0.5/h.

The day of treatment, the professional will not stay in the room for 8 hours. However, he could enter into the room for control task. Anayway inhalation exposure has been estimated for 8 hours as worst case.
To our case:

- The product largely consists of a single component (water) and therefore the mol weight matrix should be roughly equal to 18 g/mol for water.
- In a worst case basis, the solution (in use concentration) required to treat a floor of 20 m^2 with 500 $mL_{solution}/m^2$ is 10000 mL of product (10230 grams for a liquid with a density of 1.023 g/mL).

This scenario of control task after treatment will be combined with the exposure during application and exposure during touching a treated surface.

	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.0375%	Section 2.1.2.
	Application rate	500 mL/ m^2	Section 2.2.5
	Density	1.023 g/mL	Section 2.2.2.
	Body weigh	60 kg	Recommendation no. 14, 2017
	Frequency	365 days per year	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Exposure duration	8 h	Worst case
	Molecular weight matrix	18 g/mol	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Product amount	10230 g	Calculated value.
	Room volume	25 m^3	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Ventilation rate	0.5 / h	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Application temperature	20 ºC	CAR/AR
	Vapour pressure	40.7 Pa	CAR/AR
	Molecular weight	254 g/mol	CAR/AR
	Mass transfer coefficient	10 m/h	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Release area (Floor surface)	20 m^2	RIVM report 320005003/2006 Disinfectant Products Fact Sheet

Description of Scenario [4]			
	Emission duration	8 h	Worst case
	Inhalation absorption rate	100%	Default value.

Calculations for Scenario [4]

Summary table: systemic exposure from professional user by secondary exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [4]	Tier 1 / no PPE	2.26E-05	--	--	2.26E-05

See Annex 3.2 for further information

Further information and considerations on scenario [4]
As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in Section 2.2.6.3.

Scenario [5] – Exposure of an adult who touches a treated surface with his hands (wet and dry surface)

Description of Scenario [5]			
Exposure is assessed with a dilution of product at 1.5% (0.0375% of iodine). This scenario considers the exposure of an adult who touches a treated surface with his hands (wet and dry surface) is assessed. The dose of application is 500 mL of diluted product per m². In this assessment the dilution of 0.0375% is used. Scenario 5a: A source of potential indirect exposure to iodine in treated surface is post-application dermal contact of a freshly treated wet surface by an adult. According Recommendation no. 5, an adult may contact wet treated surface, and 50% of the BP on the coated surface may be dislodged and adhere to the skin. The reasonable worst-case acute exposure is for a 60 kg adult with 410 cm^2 of hand surface area touching the treated surface containing 375 ppm Iodine. Scenario 5b: Assuming the Iodine is concentrated by a factor of 2x as the surface dries (i.e., 750 ppm w/w in the dried surface).			
	Parameters	**Value / Units**	**Justification / Source**

Description of Scenario [5]			
Tier 1 (wet surface)	Weight fraction of a.s.	0.0375%	Section 2.1.2.
	Application rate	500 mL/ m^2	Section 2.2.5
	Density	1.023 g/mL	Section 2.2.2.
	Body weigh	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Application rate	51.2 mg/cm^2	Calculated value
	Total area of hands in contact with the removed wet surface – palms of both hands	410 cm^2	Recommendation 5, 2017
	Transfer coefficient of wet surface from treated surface to hand	50%	Recommendation 5, 2017
	Proportion of palms of hand in contact with the treated surface	100%	Recommendation 5, 2017
	Dermal Absorption	12 %	Section 2.2.6.1.
	Oral exposure		
	Transferable fraction of wet surface from hand to mouth (i.e. from two fingers only)	10 %	Recommendation 5, 2017
	Oral absorption	100 %	Default value.
Tier 1 (dried surface)	Weight fraction of a.s.	0.0750%	Assumption
	Application rate	500 mL/ m^2	Section 2.2.5
	Density	1.023 g/mL	Section 2.2.2.
	Body weigh	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Application rate	51.2 mg/cm^2	Calculated value
	Total area of hands in contact with the removed dried surface – palms of both hands	410 cm^2	Recommendation 5, 2017
	Transfer coefficient of wet surface from treated surface to hand	3%	Recommendation 5, 2017
	Proportion of palms of hand in contact with the treated surface	40%	Recommendation 5, 2017

Description of Scenario [5]			
	Dermal Absorption	12 %	Section 2.2.6.1.
	Oral exposure		
	Transferable fraction of dried surface from hand to mouth (i.e. from two fingers only)	50 %	Recommendation 5, 2017
	Oral absorption	100 %	Default value.

Calculations for Scenario [5]

Summary table: systemic exposure from professional user by secondary exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [5a]	Tier 1 / No PPE	--	7.08E-03	6.55E-03	1.36E-02
Scenario [5b]	Tier 1 / No PPE	--	1.89E-04	1.57E-03	1.76E-03

See Annex 3.2 for further information

Further information and considerations on scenario [5]
As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in Section 2.2.6.3.

Scenario [6]: Laundering work clothes

Description of Scenario [6]
Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five day work week, hence the total amount of product on work clothes is assumed to be five times the daily

Description of Scenario [6]			
contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a professional. The contamination of clothes is based on the professional spraying from which the tier that shows safe use is tier 2b. It is assumed that applicator wear regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Indicative value of body from model	24637 mg	Scenario 2.
	Regular clothes penetration	50%	HEEG Opinion 9
	Surface medium-sized coverall	22700 cm^2	Estimated parameter usually accepted
	Total area of hands in contact with the work clothes – Twice with palms of both hands and once with the total hands surface.	1640 cm^2	HEEG Opinion 1. CAR for Propiconazole in PT8 (FI CA, 2007)
	Transfer coefficient	30%	TNsG 2002, part 2, p 204
	Dermal Absorption	12 %	Section 2.2.6.1.

Calculations for Scenario [6]

Summary table: systemic exposure from professional user by secondary exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [6]	Tier 1 / no PPE	--	1.00E-03	--	1.00E-03

See Annex 3.2 for further information

Further information and considerations on scenario [6]
As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in Section 2.2.6.3.

Combined scenarios

The professional would be exposed to the product by mixing and loading, spraying, cleaning the spray device and contact treated surfaces.

Summary table: systemic exposure from professional uses				
Exposure scenario	**Estimated inhalation uptake [mg/kg bw d]**	**Estimated dermal uptake [mg/kg bw d]**	**Estimated oral uptake [mg/kg bw d]**	**Estimated total uptake [mg/kg bw d]**
Scenario [1, 2, 3, 4, 5b, 6]	1.69E-04	4.48E-03	--	4.65E-03

Monitoring data

No study has been developed with the product. The applicant considers that there is enough data to assess the derived human risk from the product's application.

Dietary exposure

The product is not intended to be applied over foodstuffs or drinking water nor animals. However, livestock can be exposed to the active substance iodine as product's residue. So residue of iodine can be found in food and products from animal origin. As a consequence, the human dietary assessment needs to be performed in this dossier.

The disinfection of animal housings takes place maximum 13 times per year according to the ESD for PT3 "veterinary hygiene biocidal products" so the exposure is very occasional (contrary to the 300 ays on 365 days of exposure for teat disinfection of cows). Furthermore, disinfection of animal housings takes generally place between batches, meaning that animals joining the slaughterhouses are not exposed to iodine of products used for animal housings disinfection.

Residue definitions

In water, iodide (I^-) and iodate ($IO3^-$) are the predominant species. In addition, a natural background level of methyl iodide might also be found in water. At pH values between 4 and 9, iodide is the predominant species. In alkaline and well oxidized waters iodate is the predominant specie.

The livestock is expected to be exposed to the active substance iodine (I_2), and iodide (I^-). When absorbed, iodine is quickly reduced to iodide by nonenzymatic reactions. Iodide is readily and (almost) completely absorbed. The bioavailability after oral administration is > 90%.
The residue of iodine expected in food and products from animal origin is iodide (I^-).

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Surface disinfection in animal housing			

1.	Use in animal husbandry	Indirect exposure of animals by rubbing and licking of treated surfaces. No direct exposure is taken into account, as treatment takes place when no animals are present	Meat from animals from treated animal housing
Additional notes: • Scenario 1 – dietary exposure will be addressed for humans by indirect exposure by eating livestock from animal treated housing. The livestock exposure is included in section: risk assessment for animal health.			

The active substance iodine is not considered as a cumulative substance:
- no log P_{ow} is defined,
- no data suggests a potential bioaccumulation of iodine/iodide in the body under normal circumstances,
- Iodide in excess of physiological requirement is excreted mainly via the urine, and in smaller quantities via faeces, saliva, milk, sweat, tears, bile, other secretions and exhaled air.

So no bioaccumulation of iodine is expected.

Information of non-biocidal use of the active substance

According to Regulation (EU) No. 2015/861, several iodine-containing compounds are authorized as feed additives, and also as antiseptics and sanitisers in veterinary medicine.

Residue definitions

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference values**
1.	Feed additive Iodine as - Potassium iodide, - Calcium iodate anhydrous, - Coated Granulated calcium iodate anhydrous	The recommended maximum content of total iodine in complete feed for: - equines is 3 mg/kg feed/d - dogs is 4 mg/kg feed/d - cats is 5 mg/kg feed/d - ruminants for milk production is 2 mg/kg (0.080 mg/kg bw/d) - laying hens is 3 mg/kg feed/d (0.205 mg/kg bw/d)	These values were recommended by the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) in 2013[1] to bring the exposure of adult consumers below the Upper Intake Level.

[1] EFSA Journal 2013 ; 11(2) :3099 : Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species : calcium iodate anhydrous and potassium iodide, based on a dossier submitted by Ajay Europe SARL

2.	Veterinary medicine Iodine and iodine inorganic compounds including: - Sodium/potassium-iodide - Sodium/potassium-iodate - Iodophors including polyvinylpyrrolidoneiodine (PVP-iodine) and iodoform	All food producing species: Various iodine-containing compounds are used in veterinary medicine as antiseptics and sanitisers. Iodine compounds are used in teat dips for the prevention and control of mastitis in cattle and in topical preparations for prevention of infections in wounds. Preparations for oral and parenteral administration are also available for the treatment of iodine-deficiency.	Regulation (EU) No.37/2010 The Committee for Veterinary Medicinal Products (CVMP) decided in 1996 that it would be **inappropriate to elaborate MRLs for iodine**. Therefore, iodine was included in Annex II of Council Regulation (EEC) No. 2377/90[2] and later, in Annex of Commission Regulation (EU) No.37/2010[3].

The Committee for Veterinary Medicinal Products (CVMP) has reviewed iodine for the use in veterinary medicine as antiseptic, sanitiser, teat dip for prevention and control of the mastitis, topical preparation for preventing wounds infections. CVMP reported that "only small increases in serum iodine concentration were found after teat dipping indicating that the procedure had a negligible effect on tissue iodine concentrations", and it was concluded that no MRL is required for any food-producing species (see Commission Regulation (EU) No 37/2010).

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Scenario [1]: Surface disinfection in animal housing

Description of Scenario [1]
A livestock exposure assessment must be performed whenever the intended use of a biocidal product is such that livestock animals are exposed indirectly to the product, which is the case of this product. The relevant exposure routes of animals in treated premises are summarised below. The product IODO 2.5% CONCENTRADO SOLUBLE (GERM-IOD, YODO S.P.) is a soluble concentrate (SC) containing Iodine (2.5% w/v) intended to be used for disinfection in empty farms by professional users.

2 Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Official Journal of the European Communities, No L 224/1.

3 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. Official Journal of the European Union, L 15/1.

Description of Scenario [1]

The product is applied on floors, walls, ceilings in animal houses by spraying. Before starting the product application, animals must be removed and all exits should be closed and a warning sign should be placed in all the entries in order to avoid any person entering the premise during the treatment. The treatment is performed for 1 to 2 hours. After the treatment, a minimum time of 24 hours must be considered before the re-entry of animals in the premises. This restriction is clearly mentioned in the label.

Livestock animals can be **exposed orally** by licking treated surfaces or objects and by consumption of contaminated feed (it is considered as a worse case that feed is present during the treatment and is not covered or protected). Regarding the consumption of contaminated feed, this route of exposure can be avoided if the feed is properly covered during the treatment or if the stables are equipped with computerised systems that provide the exact amount of feed which is consumed in a single sitting or when this feeding is controlled by the farmer following the same practice. This feeding practice is applicable to pigs and cattle. However, feeding practices for poultry feeding differs as they are usually held in battery cages (worse-case situation). In this case, the label of the biocidal product may stipulate that feed, water and troughs shall be properly covered during treatment.

Animals can be also exposed through the **dermal route** by rubbing against surfaces such as walls and pen enclosures that are treated with the biocide. Only large slaughter animal like cattle and pigs engage in this type of behaviour but not small animals such as poultry or rabbits. Therefore, as the biocide label requires that animals shall be removed from the premises to be treated and this practice will be effectively followed by farmers for large and small animals, we can consider the dermal exposure negligible for these animals.

Finally, livestock animals may be exposed via **inhalation** (e.g. for volatile substances). This exposure will depend on the potential for volatilization of the substance.

In framework of this dossier the applicant has performed livestock exposures estimation for PT03. When sufficiently relevant and in accordance with guidance documents, the calculations and arguments were considered and presented below.

Estimation of livestock exposure was performed using the ”livestock exposure calculator”. This document is a tool to facilitate the estimation of livestock exposure to biocidal active substances as described in the draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (ongoing guidance, ARTFood 2016).

For Tier 1 (screening step), the total exposure was estimated by the model with the following calculation:

Exposure=AR*Aw+f/Noanim/bw

where:

- AR: Application rate (mg/m^2)
- Aw+f: wall+floor area per stable (m^2)
- Noanim: No. of animals per stable
- bw: body weight (kg)

For Tier 2 (realistic worst case), the total exposure was estimated by the model considering the different routes of exposure (oral with licking, feed and feeding trough contamination, dead insect ingestion, dermal with rubbing behaviours, inhalative).

Description of Scenario [1]			
This Calculator applies assumptions and default values as detailed below.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1 Screening step	Concentration in the concentrated product (% a.s. w/w, considering total Iode; I_2 et NaI)	2.5%	Section 2.1.2.
	Concentration in a diluted solution (% a.s. v/v)	0.0375%	Section 2.2.5
	Application rate	500 mL BP / m^2	Section 2.2.5
	Density	1.023 g BP /mL BP	Section 2.2.2.
	Average content per unit area	192 mg a.s./m^2	Calculated value.
Tier 2 Realistic worst case	Vapour pressure iodine at 25°C (Pa)	40.7	CAR/AR (Sweden CA, 2013)
	Molecular weight iodine (g/mol)	253.81	CAR/AR (Sweden CA, 2013)
	Gas constant (J/K mol)	8.31451	values used to estimate inhalation exposure
	Temperature (°K)	298.15	values used to estimate inhalation exposure
	Emission factor (fraction emitted to floor during surface treatment by spraying)	0.11	oral exposure: default factor 0.11 used to refined feed contamination
	Consumption of biocidal product by fly	0.0035 mL/d	value used to estimate exposure from dead fly ingestion
	Emission factor (fraction emitted to the treated surface area during surface treatment by spraying)	0.85	default factor used to refined dermal exposure (direct exposure, rubbing) and oral exposure (licking, contaminated trough)
Tier 3 Refinements	Factor due to recommendation of 48 h re-entry delay	0	values used to estimate inhalation exposure
	Dermal Absorption	12 %	Section 2.2.6.1.
	Fraction excreted (%)	70	70% of iodine is expected to be excreted by urine (WHO, 2009), the internal dose can be estimated to be reduced
	Fraction of remained iodine in body (%) (non excreted)	30	

Description of Scenario [1]			
			to 30% (corresponding to the thyroid level)
	Fraction of remained iodine available for tissues (non located in thyroid) (%)	40	60 to 90% of total iodine in the body is located in thyroid the main storage organ, the internal dose can be estimated reduced with 40% factor (EFSA, 2013)

Calculations for estimating livestock exposure for Scenario [1]:

Initially the risk assessment is based on the assumption that no risk mitigation measures are taken in order to reduce the exposure (Tier I). In addition, real case simulations are then presented for these representative species based on the worst application conditions of 2.5% Iodine formulation (application rate: 25 mL product/m^2 (0.5 L dilution/m^2), application method: spraying) taking into account all possible mitigation measures (label restrictions) such as:

- Only use in empty animal housing [N-169: IFU & RMM])
- Cover feeding area with plastic sheets. Animals must not be present during spraying [N-122: IFU & RMM]
- Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines [N-124: IFU & RMM]
- Cover all water storage tanks and ponds before application of the product [N-125: IFU & RMM]
- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock [N-127: RMM]

According to *Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b)* the livestock assessment has been realized for the scenario: **Animal housing**, taking in account the livestock of: dairy cattle, beef cattle, fattening pigs, breeding pigs, broiler chicken and laying hens as representative cases.

The table below summarized results from estimation after Tier 1 and Tier 2:

Table with all outputs can be found in Annex section 3.2.

External dose received by the animal					
livestock exposure calculator: surface treatment of animal housing (floor and wall of stable without partition)					
	Animal livestock Group (worst case model)*	Tier 1: Screening step		Tier 2: Realistic worst case	
		Livestock Total exposure (mg/kg bw/d)	Exceedance of threshold value (0.004 mg/kg bw/d)	Livestock Total exposure (mg/kg bw/d)	Exceedance of threshold value (0.004 mg/kg bw/d)
Scenario 1	Beef cattle	3.07	Y	417	Y
	Dairy cattle	4.93	Y	398	Y
	Calf	3.96	Y	522	Y
	Fattening pig	4.66	Y	585	Y
	Breeding pig	--	--	481	Y
	Breeding pig (individual hounsing)	5.09	Y	0.69	Y
	Breeding pig (group housing)	6.49	Y	0.50	Y
	Sheep	--	--	667	Y
	Lamb	--	--	730	Y
	Slaughter goat (= goat kids)	--	--	965	Y
	Lactating goats	--	--	656	Y
	Broilers	--	--	490	Y
	Broilers (free range, litter floor)	9.04	Y	--	--
	Broilers [parent broilers, free range (grating floor)]	9.68	Y	--	--
	Broilers [parent broilers in rearing, free range (grating floor)]	9.41	Y	--	--
	Laying hen	--	--	439	Y
	Laying hen (battery)	5.29	Y	0.09	Y
	Laying hen [free range (litter floor)]	20.51	Y	--	--

	Laying hen [free range (grating floor)]	9.21	Y	--	--
	Turkey	--	--	357	Y
	Horse	--	--	449	Y
	Rabbit	12.90	Y	1500	Y

* the worst case model of each livestock category is selected

Further information and considerations on scenario [1]

All scenario Tiers (1 and 2) show an exceedance of the threshold value 0.004 mg/kg bw/d for all livestock animals, and the main route of exposure is the inhalative way. So refinement can be taken into account to adjust and limit the animal exposure.

Inhalation exposure:

The GERM-IOD is recommended to be used in empty housing. As a consequence, a re-entry delay can be set to reduce the animal exposure. Considering a re-entry delay of 24 h after housing treatment, the inhalation exposure will be negligible for all representative animal species (assumption confirmed by ConsExpo: calculations detailed in Annex 3.2).

Dermal exposure:

The exposure via dermal route was estimated and exceeds the threshold value of 0.004 mg/kg bw/d. No residue measures on surface treated are available.

However, according to the ADME endpoints, a value of 12% is set for the active substance based on in vitro skin penetration studies through human skin with a diluted product (diluted at 0.66% iodine) and a ready-to-use product (0.26% iodine). The low dermal penetration was confirmed by the French Institut National de Recherche et de Sécurité (INRS)[4] and the International Programme on Chemical Safety[5], and the value was supported by information provided by US Department of Health and Human Services (US HHS)[6] and the World Health Organization (WHO)[7].

Internal dose: Distribution and availability of iodine in body

The metabolism of Iode was largely studied and iodine metabolism in food-producing animals is well-known and has been summarised by EFSA (2005[8]).

The information available demonstrated that:

4 Fiche toxicologique Iode, FT 207, INRS (2006)

5 http://www.inchem.org/documents/pims/pharm/iodine.htm#SectionTitle:5.3

6 Toxicological profile for Iodine, US Department of Health and Human Services (2004)

7 World Health Organization (WHO) – Iodine and inorganic iodides : Human health aspects (Doc. 72)

8 EFSA Journal 2005 ; 168, 1-42 : opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of iodine in feedingstuffs

- the thyroid gland contained 60-90 % of the body pool of the element being the tissue with the highest iodine concentration relative to its physiological function (EFSA 2013[9])
- approximately 20 to 30% of the iodine was distributed to the thyroid whereas 30 to 60% was excreted in the urine, few hours after oral administration to human subjects (WHO 2009[10]). This confirms the endpoint defined in the Assessment Report: "About 30% of the bioavailable iodide is removed by the thyroid for hormonal synthesis". Therefore, 70% of the remaining substance is excreted by the kidney via urinary route.
- The content of iodine in animal tissues and products is related to the iodine intake and, thus, to the iodine concentration in the feed. In response to feed supplementation with iodine sources, the iodine level in edible tissues/products is generally found to be highest in milk and eggs, followed by kidney and liver, whereas in muscle tissue it is rather low (EFSA 2005 and 2013). This being in agreement with consumption surveys (Gireli et al., 2004; Bader et al., 2005; Hampel et al., 2009; Johner et al., 2011, 2012a,b; Soriguer et al., 2011).

As a consequence the following factors can be used to estimate the transfer to animal tissue and products, and consequently refine the consumer exposure:

- Excretion factor: 70%, as 70% of iodine is expected to be excreted by urine
- Body fraction factor: 30%, as 30% of iodine is expected to remain in the body (corresponding to the thyroid level)
- Available body fraction factor: 40%, as 40% of the remaining iodine can be considered as available for the body tissues (except thyroid) as a worst case, since thyroid is the main storage organ for iodine cumulating 60 to 90% of total iodine in the body of food-producing animals (EFSA, 2013).

As a result, it can reasonably be considered that:

- 30% * 40% of the internal exposure value is distributed into the edible tissues,
- And until 70% of the internal exposure value is excreted into the edible products

9 EFSA Journal 2013 ; 11(2) :3099 : Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species : calcium iodate anhydrous and potassium iodide, based on a dossier submitted by Ajay Europe SARL

10 Iodine and inorganic iodides: Human health aspects, Concise international chemical assessment document 72,WHO, 2009

Internal dose received by the animal							
Tier 3: Realistic worst case refined							
	Animal livestock Group (worst case model)*	**via Inhalation exposure**	**via Dermal exposure (dermal exposure*0.12)**	**via Oral exposure**	**Total internal exposure**	**Available internal dose in tissues (total exposure*0.3*0.4)**	**Available internal dose in product (total exposure*0.7)**
		mg/ kg bw of animal /d				***mg/ kg of tissues and products***	
Scenario 1	Beef cattle	0	0.1446	0.0564	0.2010	0.0241	--
	Dairy cattle	0	0.2825	0.0506	0.3331	0.0400	0.2332
	Calf	0	0.2897	0.0852	0.3749	0.0450	--
	Fattening pig	0	0.4178	0.0881	0.5059	0.0607	--
	Breeding pig	0	0.0502	0.0633	0.1135	0.0136	--
	Breeding pig (individual housing)	0	0.6941	0.0000	0.6941	0.0833	--
	Breeding pig (group housing)	0	0.5045	0.0000	0.5045	0.0605	--
	Sheep	0	0.1741	0.0000	0.1741	0.0209	--
	Lamb	0	0.3264	0.0000	0.3264	0.0392	--
	Slaughter goat (= goat kids)	0	1.0043	0.2260	1.2303	0.1476	--

Internal dose received by the animal							
Tier 3: Realistic worst case refined							
	Animal livestock Group (worst case model)*	**via Inhalation exposure**	**via Dermal exposure (dermal exposure*0.12)**	**via Oral exposure**	**Total internal exposure**	**Available internal dose in tissues (total exposure*0.3*0.4)**	**Available internal dose in product (total exposure*0.7)**
		mg/ kg bw of animal /d				***mg/ kg of tissues and products***	
	Lactating goat	0	0.1865	0.1259	0.3124	0.0375	--
	Broilers	0	0.2059	0.0000	0.2059	0.0247	--
	Laying hen	0	0.2787	0.0000	0.2787	0.0334	0.1951
	Laying hen (battery)	0	0.0945	0.0000	0.0945	0.0113	0.0661
	Turkey	0	0.0500	0.0000	0.0500	0.0060	--
	Horse	0	0.0000	0.0793	0.0793	0.0095	--

* the worst case model of each livestock category is selected

Conclusion

These results demonstrate that the exposure to iodine residues via food from animal origin is mainly expected to be related to milk and egg consumption rather than meat.

The calculations are performed considering the worst case situations, and cannot be better refined at this step without any measurements of iodine residue on surfaces, in animal tissues or in food from animal origin. As a consequence, although this assessment might overestimate the contamination of animal tissues and products, these estimations are used to estimate the human dietary exposure.

Exposure associated with production, formulation and disposal of the biocidal product

The active substance contained in the product GERM-IOD is manufactured in the EU by SQM Europe N.V. The whole reaction process of the active substance production (including loading of raw materials) is carried out in a closed device. All substances related with occupational limit concentrations are far below critical values defined by legal regulations (MAK1 / TRK2 values). Potential human exposure is only possible during loading and cleaning processes. Handling is always carried out using personal protection measures, which are related to the respective task (up to full personal protection for special cleaning and service tasks).

On the other hand, in modern formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). The workers (trained professionals) usually wear personal protective equipment (e.g. gloves) according to the Technical Notes for Guidance on Human Exposure to Biocidal Products (June 2007). Therefore, the human exposure during the formulation task should be negligible. In relation to this, processes including the manufacturing of the active substances and the biocide product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of the active substance and the formulation is not considered here.

Regarding the product formulation stage, GERM-IOD is produced in small batches in closed systems with appropriate control measures in place to exclude release of the active substance iodine to the environment during formulation of the product.

Aggregated exposure

No aggregated exposure is foreseen.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake mg/kg/d**
1	Professional / Trained Professional	Tier 1 / No PPE	5.06E-02
1	Professional / Trained Professional	Tier 2a / PPE (Gloves)	5.87E-04
1	Professional / Trained Professional	Tier 2b / PPE (Gloves and coated coverall) + RPE (APF=10)	5.13E-04
2	Professional / Trained Professional	Tier 1 / No PPE	4.57E-02

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake mg/kg/d**
2	Professional / Trained Professional	Tier 2a / PPE (Gloves)	2.19E-02
2	Professional / Trained Professional	Tier 2b / PPE (Gloves and coated coverall) + RPE (APF=10)	2.82E-03
3	Professional / Trained Professional	Tier 1 / No PPE	1.04E-03
3	Professional / Trained Professional	Tier 2a / PPE (Gloves)	5.49E-04
3	Professional / Trained Professional	Tier 2b / PPE (Gloves and coated coverall) + RPE (APF=10)	1.04E-04
[1, 2, 3]	Professional / Trained Professional	Tier 1 / No PPE	9.74E-02
[1, 2, 3]	Professional / Trained Professional	Tier 2a / PPE (Gloves)	2.30E-02
[1, 2, 3]	Professional / Trained Professional	Tier 2b / PPE (Gloves and coated coverall) + RPE (APF=10)	3.44E-03
4	General public	Tier 1 / No PPE	2.26E-05
5a	General public	Tier 1 / No PPE	1.36E-02
5b	General public	Tier 1 / No PPE	1.76E-03
6	General public	Tier 1 / No PPE	1.00E-03
[1, 2, 3, 4, 5b, 6]	General public		4.65E-03

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
AELshort-term AELmedium-term AELlong-term	-	600 µg/kg bw/day	1.5	no	0.01 mg/kgbw/d
$AEC_{inhalation}$					1 mg/m^3 (0.1 ppm)
ARfD	Not applicable. Substance is not acute toxic or harmful.				
ADI	Not available	-	-	-	-

Maximum residue limits or equivalent

Residue definitions:

MRLs or other relevant reference values	Reference	Relevant commodities	Value
AEL = UL (Upper Intake Level)	Iodine CAR	Food	Europe: 600 µg/day (0.01 mg/kg bw/d.) USA: 1200 µg/day, 0.02 mg/kg bw/d.
ARfD	Iodine CAR	-	Not applicable. Substance is not acute toxic or harmful.
Drinking water limit	Iodine CAR	water	No drinking water limit is established. 30 µg/L is a threshold proposed and calculated is based on 10% Upper Intake Level and a daily intake of 2 L drinking water

The Scientific Committee on Food (SCF) based the iodine tolerable upper intake (UL) on studies of short term duration and in a small number of subjects (n=10-32). For iodine intakes about 1700-1800 µg/day, the studies showed an increased serum thyroid-stimulating hormone (TSH) and thyrotropin-releasing hormone (TRH), but these changes were considered marginal and not associated with any clinical adverse effects. The results were supported by a five years study where, for approximately similar iodine intakes, no clinical thyroid pathology occurred. An uncertainty factor of 3 was selected to derive the UL for adults. The ULs for toddlers and children were derived by adjustment of the adult UL on the basis of metabolic weight, since there is no evidence of increased susceptibility in children. The SCF adopted the value of 600 µg/day as a UL for adults including pregnant and lactating women (2002)[11]. The UL for toddlers was set at 200 µg/day.
Nevertheless, in the iodine CAR, it is reported that a healthy adult can tolerate iodine intake of more than 1000 µg/day without any adverse effects.

As indicated by the SCF, the tolerable upper intake levels ULs are not a safety threshold. Indeed, the SCF indicated that the UL "may be exceeded for short periods without appreciable risk to the health of the individuals concerned".

Furthermore, besides the exposure due to the treatment the user is also exposed by dietary exposure. An assessment for dietary exposure is included. User is exposed to iodine through background in milk (due to natural sources and feed supplementation) and by other dietary sources. This exposure represents between 25% and 46% of the UL considering respectively

[11] SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine. 15 pp.

the recommended dietary intake of iodine (approach proposed in the CAR) or the dietary intake values discussed recently for iodine union authorisations at the European level.

As the background value has been recently discussed (between 25% or 46% of UL) in the framework of Union authorisations, both risk assessment have been performed in this report.

Risk for industrial users

The active substance contained in the product GERM-IOD is manufactured in the EU. Regarding the product formulation stage, GERM-IOD is produced in small batches in closed systems with appropriate control measures in place to exclude release of the active substance to the environment during formulation of the product. In addition to this, according to the Technical Notes for Guidance on Human Exposure to Biocidal Products (June 2007), processes including the manufacturing of the active substances and the biocide product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of the active substance and the disinfectant is not considered here.

Risk for professional users

Systemic effects

Task / Scenario	**Tier / PPE***	**$AEL_{long\text{-}term}$ mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Estimated uptake/ AEL due to biocidal use + dietary intake 46%**	**Estimated uptake/ AEL due to biocidal use + dietary intake 25%**
Scenario 1 Mixing & loading	1 / none	0.01	5.06E-02	**506**	**552**	**531**
	2a / PPE	0.01	5.87E-04	5.87	51.9	30.9
	2b / PPE, RPE	0.01	5.13E-04	5.13	51.1	30.1
Scenario 2 Spray application	1 / none	0.01	4.57E-02	**457**	**503**	**482**
	2a / PPE	0.01	2.19E-02	**219**	**265**	**244**
	2b / PPE, RPE	0.01	2.82E-03	28.2	74.2	53.2
Scenario 3 Cleaning of spray equipment	1 / none	0.01	1.04E-03	10.4	56.4	35.4
	2a / PPE	0.01	5.49E-04	5.49	51.5	30.5
	2b / PPE, RPE	0.01	1.04E-04	1.04	47.0	26.0
Combined scenarios [1, 2, 3]	1 / none	0.01	9.74E-02	**974**	**1020**	**999**
	2a / PPE	0.01	2.30E-02	**230**	**276**	**255**
	2b / PPE, RPE	0.01	3.44E-03	34.4	80.4	59.4
* (2a) gloves; (2b) gloves, coated coverall and RPE (APF=10)						

The estimated systemic exposure of worker is above the reference value for scenarios 1 (mixing and loading) and 2 (disinfection by spraying) when no PPE is used. The estimated

systemic exposure is acceptable when worker is wearing gloves, coated coverall and RPE (APF=10).

Assuming one person is performing all tasks, the combined exposure was estimated. The estimated systemic exposure of worker is below the reference value only when gloves, coated coverall and RPE (APF=10) are worn.

Due to irritant properties of biocidal product any dermal exposure to the biocidal product must be prevented using the technical and organizational RMM adequate for **high hazard** chemicals and appropriate PPE must be used (see next chapter for details).

Local effects

According to the criteria of the Regulation 1272/2008, GERM-IOD is proposed to be classified as severe eye irritant (H318 - Eye Dam 1). The most critical local effect is eye irritation. Therefore, as AEC is set, both quantitative and qualitative assessment of local effects is performed in this section for the biocidal product.
As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in this section. Therefore, as AEC is set, only quantitative assessment of local effects is performed in this section for the dilution product.

Quantitative assessment

Task / Scenario	Tier / PPE*	$AEC_{inhalation}$ mg/m³	Estimated uptake mg/m³	Exceedance of threshold value (1 mg/m³)
Scenario 1 Mixing & loading	1 / none	1	2.35E-02	No
	2a / PPE	1	2.35E-02	No
	2b / PPE, RPE	1	2.35E-03	No
Scenario 2 Spray application	1 / none	1	2.85E-02	No
	2a / PPE	1	2.85E-02	No
	2b / PPE, RPE	1	2.85E-03	No
Scenario 3 Cleaning of spray equipment	1 / none	1	2.85E-02	No
	2a / PPE	1	2.85E-02	No
	2b / PPE, RPE	1	2.85E-03	No
Combined scenarios [1, 2, 3]	1 / none	1	8.05E-02	No
	2a / PPE	1	8.05E-02	No
	2b / PPE, RPE	1	8.05E-03	No
* (2a) gloves; (2b) gloves, coated coverall and RPE (APF=10)				

When the inhalation exposures are compared to the AEC of 1 mg/m³, the risk is also considered acceptable for all scenarios.

Qualitative assessment

Primary Exposure / Professional use – Use of the concentrated product (Mixing and Loading phase)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion on risk**
High hazard	Eye Damage. 1 (H318)	Concetration of 2.5%	3	Professionals	Pouring and mixing pure product in receiving container (2.5% a.s.)	Splash in the eyes	Application at each sanitation period. Depends on the type of breeding every 3 to 7 weeks on average 1/day (disinfection professional)	Low	**RMM Technics**: - Containment as appropriate; - Segregation of the emitting process; - Effective contaminant extraction; - Good standard of general ventilation; - Minimisation of manual phases; - Regular cleaning of equipment and work area; - Avoidance of contact with contaminated tools and objects;	Exposure must be limited to brief contacts (Practically no exposure, no splashes, no hand to eye transfer, no aerosol formation). Technical RMM and PPE are required Considering that these recommendations can be followed during this task, the risk is acceptable.

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion on risk**
									RMM Organisation: - Minimise number of staff exposed; - Management / supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene **PPE** - Use appropriate gloves anr respirator	

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion on risk**
									- Optional face shield - Skin coverage with appropriate barrier material based on potential for contact with the chemicals - Use chemical goggles as eye protection	

The undiluted product concentrate (2.5% a.s.) has been allocated to the "High" hazard category according to the classification as severe eye irritant (H318 - Eye Dam 1) and the hazard categories proposed in the Guidance for Human Health Risk Assessment & evaluation (Volume III – Part B + C). The mixing & loading task involves simple dilution of the product concentrate. The task is of short duration, taking only a few minutes (i.e. opening/closing valve) and is expected to be performed once or twice per day by workers. The product may be used on a daily basis by these workers. The PPE which have to be used for protection from the eye irritant potential of the disifectant product are described as follows.

Exposure controls
Personal protective equipment:

- Substance/task appropriate gloves.
- Skin coverage with appropriate barrier material based on potential for contact with chemicals.
- Eye protection.

Respiratory protection is considered necessary when mixing and loading in adequately ventilated areas due to the high vapour pressure of iodine (the vapour pressure at ambient temperature is 40.7 Pa). Further, airborne particles are expected to be formed during mixing and loading operations. Therefore, where ventilation is inadequate a suitable substance/task appropriate respirator is considered necessary.

Organisation:

- General safety and hygiene measures:

Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).

Conclusion
The estimated systemic exposure to iodine linked to biocidal use is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) when workers are wearing protective gloves, coated coverall and RPE (APF=10) in order to prevent any contact with iodine.
The risk of local dermal and respiratory effects during M&L into the final product is also considered to be acceptable when RMM for high hazard class chemicals are implemented and workers are wearing protective gloves, coated coverall, face mask (optional), RPE (APF=10) and chemical googles in order to prevent any contact with iodine.
Considering a background value of 25% and 46% of UL even if PPE/RPE are worn during M&L, disinfection by spraying and cleaning of the equipment, the exposure to iodine is lower to upper limit intake proposed by SCF.
Therefore, RMMs are needed to avoid exposure to iodine linked to biocidal use:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1].
- Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory (the material must be specified by the authorization holder in the product information).
- The use of eye protection during handling of the product is mandatory (chemical googles).

Risk for non-professional users

The product is not intended to be applied by non-professional users.

Risk for the general public

Systemic effects

Task / Scenario	Tier / PPE*	$AEL_{long-term}$ mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Estimated uptake/ AEL due to biocidal use + dietary intake 46%	Estimated uptake/ AEL due to biocidal use + dietary intake 25%
Scenario 4 Inhalation of volatilised residues	1 / none	0.01	2.26E-05	0.23	46.2	25
Scenario 5a Contact with wet surface	1 / none	0.01	1.36E-02	**136**	**182**	**161**
Scenario 5b Contact with dried surface	1 / none	0.01	1.76E-03	18	64	43
Scenario 6 Laundering contaminated work cloths	1 / none	0.01	1.04E-03	10	56	35
Combined scenarios [1, 2, 3, 4, 5b, 6]		0.01	9.74E-02	47	93	72

No unacceptable risk has been identified for different tasks considered, with the exception of the scenario "wet surface", where considering a maximal concentration of 375 ppm of pure iodine, the risk is considered unacceptable

Local effects

As the dilution product is not classified as severe eye irritant (H318 - Eye Dam 1), qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is not performed in this section. Therefore, as AEC is set, only quantitative assessment of local effects is performed in this section for the dilution product.

Quantitative assessment

Task / Scenario	Tier / PPE*	$AEC_{inhalation}$ mg/m³	Estimated uptake mg/m³	Exceedance of threshold value (1 mg/m³)
Scenario 4 Inhalation of volatilised residues	1 / none	1	4.52E-05	No
Scenario 5a Contact with wet surface	1 / none	1	Negligible	No
Scenario 5b	1 / none	1	Negligible	No

Task / Scenario	Tier / PPE*	$AEC_{inhalation}$ mg/m³	Estimated uptake mg/m³	Exceedance of threshold value (1 mg/m³)
Contact with dried surface				
Scenario 6 Laundering contaminated work cloths	1 / none	1	Negligible	No
Combined scenarios [1, 2, 3, 4, 5b, 6]		1	8.10E-03	No

When the inhalation exposures are compared to the AEC of 1 mg/m^3, the risk is also considered acceptable for all scenarios.

Qualitative assessment

Not applicable.

Conclusion
The estimated systemic exposure to iodine is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) in all studied scenarios with the exception of the scenario 5b, where when even if considering a background value of 25% and 46% of UL the exposure to iodine is unacceptable.
Therefore, IFU and RMMs are needed to exclude contact with wet surfaces:

- Do not enter treated area until dry.
- Ventilate treated areas thoroughly until spray has dried before re-entry.

Risk for consumers via residues in food

Actually, EMA considers only adult chronic risk assessment. Therefore, only adult chronic exposure calculations were performed in the frame of this dossier. Maximal residues estimated in animal tissues, eggs and milk were used to calculate consumer exposure.

Consumer exposure was estimated using EU consumption values for food of animal origin (Consumer standard food basket). It is assumed that the average person consumes, on a daily basis, 500 g of meat (made up of 300 g of muscle, 100 g of liver, 50 g of kidney and 50 g of fat) together with 1.5 L of milk and 100 g of eggs for an adult of 60 kg bw.

The scenario 1 for disinfection of empty breeding is considered as the use involving the major animal exposure, and therefore inducing the highest contribution to residue level.

Internal dose received by the animal and WCCE*				
mg/ kg of tissues and products			mg / d	mg /kg bw/d
Animal food Group (worst case model)	**Total residue levels**	**Worst case residue level**	WCCE	Adult exposure
Tissues bovine (calf)	0.0450	**0.0833**	0.04165	**0.00685**
Tissues Pig (breeding in individual housing)	0.0833			
Tissues Poultry (laying hens in battery)	0.0334			

Milk (dairy cattle)	0.2332	**0.2332**	0.3498	
Eggs Poultry (laying hens)	0.1951	**0.1951**	0.01951	
*Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey)				

The worst case estimation of **iodine combined treatments** shows that the maximal daily intake could reach **0.00685 mg/kg bw/d**, with the residue level estimated in milk as the main contributor.

This estimation in milk is a worst case, and could be refined considering a homogeneous partition of iodine between the different excretion ways. A volume ratio between milk and urine might be estimated, milk representing only 30% of volume excreted (70% excretion via urine). So using a ratio of excretion between milk and urine to refine the expected residue level in milk, the residue level of iodine should be moderated and provided more reliable values.

Internal dose received by the animal and WCCE*				
mg/ kg of tissues and products			mg / d	mg /kg bw/d
Animal food Group (worst case model)	**Total residue levels**	**Worst case residue level**	WCCE	Adult exposure
Tissues bovine (calf)	0.0450	**0.0833**	0.04165	**0.0028**
Tissues Pig (breeding in individual housing)	0.0833			
Tissues Poultry (laying hens in battery)	0.0334			
Milk [1] (dairy cattle)	0.06996	**0.06996**	0.10494	
Eggs Poultry (laying hens)	0.1951	**0.1951**	0.01951	
*Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey [1] using volume ratio between milk and urine: milk represents only 30% of volume excreted (70% excretion via urine)				

The Upper Intake Level (UL) of 0.01 mg/kg/d is a reference value considered to compare the exposure via food estimated for the uses of GERM-IOD. The UL is an indicative upper value exposure, but does not represent a threshold directly linked to a toxicological risk. In the iodine CAR, it is reported that a healthy adult can tolerate iodine intake more than 1000 µg/day (0.0167 mg/kg/d for 60 kg bw) without any adverse effects.

The exposure from the intended uses of this biocide product can also be compared to other iodine uses in biocide and veterinary or feed additive areas. Considering the recommended maximum content of total iodine in complete feed, the maximum exposure estimated for this scenario is in the same ranges as the estimations above (feed additive for dairy cattle 0.080 mg/kg bw/d, for laying hens: 0.205 mg/kg bw/d). Indeed, these other uses should

be considered more critical as the treatment is directly administrated to animals, or can contaminate directly food from animal origin. So the intended uses assessed in framework of this dossier are considered to be minor contributor to the residue level expected in food from animal origin.

The worst case estimation of iodine combined treatments is lower than the UL of 0.01 mg/kg/d. Therefore, considering all the worst case assumptions taken into account, exposure via food from animal origin is expected to be below the theoretical estimation presented above.

General conclusion

Considering the intended use of GERM-IOD and based on overall available information, a risk via food can be excluded.
To limit livestock exposure the following risk mitigation measures are proposed when the product is used for disinfection of breeding rooms:

- Only use in empty animal housing.
- Cover all surfaces and facilities likely to be in contact with feed and drinking water.
- Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines.
- Cover all water storage tanks and ponds before application of the product.
- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- The established safety period to introduce the animals in the previously treated area is 24 hours.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant, the product only contains one active substance and does not contain SoCs.

2.2.7 Risk assessment for animal health

Risk assessment performed according with the Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b) resulted in acceptable values of animal exposure after treatment with IODO 2.5% CONCENTRADO SOLUBLE (GERM-IOD, YODO S.P.) taking in consideration the following mitigation measures:

- Only use in empty animal housing.
- Cover all surfaces and facilities likely to be in contact with feed and drinking water.
- Before use In dairy production facilities, cover carefully feed, drinking systems, tethers and milking parlours and machines.
- Cover all water storage tanks and ponds before application of the product.
- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- The established safety period to introduce the animals in the previously treated area is 24 hours.

2.2.8 Risk assessment for the environment

ES-CA:

Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The ES-CA position is presented in **green evaluation boxes**.

2.2.8.1 Effects assessment on the environment

The PNECs of Iodine as active substance were taken from the corresponding CAR, which values are based on acute or short-term studies using the standard assessment factor of 1000. Following CAR's criterion, this seems to be an over-conservative approach when taking into account the fact that the natural background concentrations are higher than the calculated PECs, which most probably do not cause any risk to terrestrial or aquatic species in environment.

$PNEC_{aquatic}$ was derived from the available short-term and long-term studies performed with aquatic organisms (fish, *Daphnia* and algae) with each active substance by applying an assessment factor of 1000 to the lowest relevant endpoint.

	Iodine (I^2)	**Iodate (IO_3^-)**	**Iodide (I^-)**
$PNEC_{surfacewater}$ (mg/L)	0.00059	0.0585	0.00083

$PNEC_{stp}$ was taken from the respective CAR and is based on the toxicity data concerning STP microorganisms.

	Iodine (I^2)
$PNEC_{STP}$ (mg/L)	2.9

Following ESD-PT3 guide, freshwater sediment compartment was not considered relevant in the risk assessment.

According to the TGD on Risk Assessment (ECB Part II, 2003), there is currently no appropriate guidance to calculate a $PNEC_{air}$, and following ESD-PT3 guide, atmosphere compartment was not considered relevant in the risk assessment.

The PNECs and other degradation data for iodine active substance were taken from the respective CAR and are based on the toxicity data concerning soil organisms. This information is summarised in the table below.

	Iodine (I^2)	**Iodate (IO_3^-)**	**Iodide (I^-)**
$PNEC_{soil}$ (mg/kg wwt)	0.0118	0.304	0.0043

The product GERM-IOD contains Propan-2-ol (CAS n. 67-63-0) which is approved as active substance for PT1, PT and PT4. Therefore, according to BPR (ver 2.0. October 2017), this substance must be considered as SoC in the environmental risk assessment.

According to Propona-2-ol's CAR as PT2 (January 2015), Propan-2-ol is practically non-toxic to aquatic organisms. The lowest acute effect value for fish is the 96 h LC_{50} of 8692 mg a.s./L (*Pimephales promelas*) and for invertebrates an 48 h EC_{50} value of 2285 mg a.s./L for

Daphnia magna was estimated. The toxicity to algae (*Pseudokirchneriella subspicata*) is also very low (E_rC_{50} = 10500 mg/L).

The estimation of long-term effects is limited to studies on invertebrates (Daphnia magna) and algae and the lowest chronic effect value is a 16 d NOEC of 141 mg/L determined for the endpoint growth. A PNECwater of 2.82 mg/L was derived from the available studies considering an assessment factor of 50.

By using equilibrium partitioning method a PNECsediment of 2.41 mg/kg ww could be estimated according to TGD on Risk Assessment (EC 2003), based on PNECwater.

Based on PNECwater and according to TGD on Risk Assessment (EC 2003) a PNECsoil of 0.496 mg/kg ww was derived by using equilibrium partitioning method.

The following PNEC values are deemed in the risk assessment.

Substance	**$PNEC_{STP}$ (mg/L)**	**$PNEC_{surfacewater}$ (mg/L)**	**$PNEC_{sediment}$ (mg/kg wwt)**	**$PNEC_{soil}$ (mg/kg wwt)**
Propan-2-ol	10	2.82	2.41	0.496

ES – CA:

The environmental exposure assessment of GERM-IOD, was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment, version 2.0, October 2017) and the technical agreements for biocides (TAB, July 2021). This assessment was likewise performed following the recommendations of the Emission Scenario Document for PT3.

All the PNEC values are correct and summarized as following:

PNECs on Iodine species as presented in the AR for Iodine (Sweden 2013)

Environmental compartment		**Iodine species**	**PNEC**
Aquatic. freshwater	Surface water	Iodine (I_2)	5.90E-04 mg/L
		Iodate(IO_3^-)	5.85E-02 mg/L
		Iodide(I^-)	8.30E-04 mg/L
	Freshwater sediment	-	not used in the risk assessment
Terrestrial		Iodine (I_2)	1.18E-02 mg/kg_{wwt}
		Iodate(IO_3^-)	3.04E-01 mg/kg
		Iodide(I^-)	4.30E-03 mg/kg
STP		Iodine (I_2)	2.9 mg/L

The environmental risk assessment was performed for the active substance Iodine (I_2) and its ionic species Iodide (I^-) and Iodate (IO_3^-).

The coformulant Propan-2-ol was authorized as active substance of other biocidal product types and is present in the product GERM-IOD at a concentration above 0.1%. Therefore, according the rules laid down in BPR Art 3(f) and further definition of the scope of the

concept of SoC given in Guidance on BPR Vol IV Part B+C (2017), this substance should be considered a SoC for the environment.

Summary of PNECs values: Propan-2-ol

PNEC	Unit	Value
$PNEC_{STP}$	mg/L	10
$PNEC_{WATER}$	mg/L	2.8
$PNEC_{SEDIMENT}$	mg/kg	2.4
$PNEC_{SOIL}$	mg/kg ww	0.5
$PNEC_{GROUDWATER}$	mg/L	0.0001

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Following Iodine's CAR there are a lot of data concerning that is regarding of relevance to the aquatic compartment for the active substance.

According to Propan-2-ol's CAR, propan-2-ol is neigther PBT nor VP/vB candidate and there is no indication for endocrine disrupting properties of the substance.

According to Regulation (EC) No 1272/2008 the product is classified as H400 - Very toxic to aquatic life (Aquatic Acute 1) and in absence of chronic endpoints as H410 - Very toxic to aquatic life with long lasting effects based on an LC50 of 0.59 mg/L (M=1). Therefore, the product should be classified as Aquatic Chronic 2 with the hazard statement H411 Toxic to aquatic life with long lasting effects.

Conclusion on the environmental classification and labelling of the product

Classification:
Aquatic Acute cat. 1 (H400)
Aquatic Chronic cat. 2 (H410)

Labelling:
Aquatic Chronic cat. 2 (H411)

Precautionary statements
P273 – Avoid release to the environment
P391 – Collect spillage
P501 - Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations

ES-CA:

Environmental classification of the product

Harmonised environmental classification of the active substances

The environmental classification of the active substances is the following:

Classification for the active substance			
Active substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**
Iodine	H400, H411	M = 1	2.5

According to Reg. (EC) No 1272/2008 (0.ATP) the harmonised classification of Iodine for its environmental effects is Aquatic Acute 1, H400 Very toxic to aquatic life (M=1). At the WG ENVII-2018 it was decided to classify Iodine as Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects. Based on the content of Iodine in the single members of the biocidal product family (0.1-3% (w/w)) products containing iodine concentrations ≤0.25% are not classified for the environment, ≥0.25% – <2.5% classified as Aquatic Chronic 3, H412, Harmful to aquatic life with long lasting effects and ≥2.5% as Aquatic Chronic 2 H411, Toxic to aquatic life with long lasting effects.

Environmental classification of the substance(s) of concern

The biocidal product does not contain substances that influence the environmental classification.

Classification for the Propan-2-ol
Classification: Not classified

Environmental classification of the biocidal product

Classification for the biocidal product
Classification: H411 Toxic to aquatic life with long lasting effects. ***Precautionary statements*** P273 – Avoid release to the environment. P391 – Collect the spill. <u>Professional</u>

P501: Dispose of content and/or its container as hazardous waste according to the regulations in force.

Trained professional
P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations

PBT-assessment:

According to the AR of Iodine (2013), the term persistence is not appropriate, since iodine is an element and not degradable. Estimation of bioaccumulation potential for iodine is not considered relevant. In the concerned environmental compartments iodine speciates into the ionic forms iodide and iodate. In line with what has been discussed for inorganic metals (e.g. Ni and Zn), bioaccumulation is not relevant because these substances (and iodine) are regulated in animals of several taxonomic groups. The acute toxicity to mammals is low, but iodine is very toxic to aquatic organisms. However, the screening T criterion (L(E)C50 to aquatic organisms less than 0.1 mg/L) is not fulfilled, and there is no chronic data available, which is needed to assess the T criterion. It is concluded that iodine is not a PBT or vPvB substance.

The active substance propan-2-ol is neither PBT - nor vP/vB substance.

ED-assesssment:

Iodine is an essential element and has a physiological function in thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both iodine deficiency, as well as excess iodine, can impair thyroid homeostasis/thyroid hormone levels. This is to be considered as an endocrine effect. However, it would not be justified to conclude from this that iodine should be considered to be an endocrine disruptor. In contrast to typical xenobiotic substances, which are not needed at all for the functioning of the human body, and which normally only have negative effects on man, Iodine is a physiologically essential element.
Consequently, the concept of endocrine disruption is not meaningful for essential elements such as iodine since it neglects that they are needed for maintaining hormone homeostasis. Furthermore, neither iodine nor iodide are included in the lists of the EU on substances suspected of interfering with the hormone systems of humans and wild-life.

There is no indication for endocrine disrupting properties of the Propan-2-ol.

Further Ecotoxicological studies

No further data is available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data is available

Supervised trials to assess risks to non-target organisms under field conditions

No data is available

7

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data is available

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No data is available

Foreseeable routes of entry into the environment on the basis of the use envisaged

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the substance as well as its formulation type, mode of application, use and disposal when considering releases after use in household and commercial/public areas. In addition, different types of animal housing and manure have also influence in the environmental behaviour of the active substances when used in breeding premises. Following the Emission Scenario Document for Product Type 3 (ESD - PT3), pigs, veal cattle, ducks and turkeys have been identified as the most relevant livestock animals and thus they have been considered in this assessment.

According to the mode of application of the product GERM-IOD and the ESD - PT3, the relevant exposure compartments are summarized in table below:

Scenario		**Relevant exposure compartment**				
		Air	**Soil**	**WWTP/STP**	**Surface Water**	**Ground Water**
Animal housing	*Connected to WWTP*	Primary exposure	Secondary exposure	Primary exposure	Secondary exposure	Secondary exposure
	Non-Connected to WWTP	Primary exposure	Primary exposure	-	-	Secondary exposure

The main environmental receiving compartments for PT3 disinfectants are agricultural soil and air (from spreading of manure/slurry) and waste water treatment plant or sewage treatment plant. Run-off as well as leaching processes after manure/slurry application to agricultural soil can also lead to exposure of biocides to surface water and groundwater, respectively. In general, across Europe, it is prohibited to discharge waste water containing slurry to the public (municipal) sewer, and hence liquid waste containing manure is either removed to a slurry or waste water collection tank and may be subsequently applied to agricultural soil or treated in a municipal on-farm sewage water treatment plant (WWTP). In contrast, PT 3 products applied for milking parlours outside the stable are mainly emitted to waste water treated in on-site STPs or in municipal STPs.

Further studies on fate and behaviour in the environment (ADS)

No further data is available.

Leaching behaviour (ADS)

Leaching tests are not considered necessary and no further data is available

Testing for distribution and dissipation in soil (ADS)

No data is available.

Testing for distribution and dissipation in water and sediment (ADS)

No data is available.

Testing for distribution and dissipation in air (ADS)

No data is available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

GERM-IOD is not intended to be applied near to surface waters, so no overspray study is deemed necessary.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 3
Assessed scenarios	Scenario 1: Disinfection of animal housings.
ESD(s) used	Following the ESD - PT3, the ESD for PT 18 (OECD, Series on Emission Scenario Documents No. 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems) was used as the basis for the application of disinfectants in stables (PT 3), because the application methods are very similar and the emission paths are almost identical
Approach	Scenario 1: Average consumption
Distribution in the environment	The main environmental receiving compartments for PT3 disinfectants are agricultural soil and air (from spreading of manure/slurry) and waste water treatment plant or sewage treatment plant. Run-off as well as leaching processes after manure/slurry application to agricultural soil can also lead to exposure of biocides to surface water and groundwater, respectively. In general, across Europe, it is prohibited to discharge waste water containing slurry to the public (municipal) sewer, and hence liquid waste containing manure is either removed to a slurry or waste water collection tank and may be subsequently applied to

	agricultural soil or treated in a municipal on-farm sewage water treatment plant (WWTP). In contrast, PT 3 products applied for the disinfection of milking parlours outside the stable are mainly emitted to waste water treated in on-site STPs or in municipal STPs.
Groundwater simulation	FOCUS PEARL was used as tier 2 for groundwater compartment
Confidential Annexes	YES: In the confidential Annex Section
Life cycle steps assessed	Scenario [1] Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

Scenario [1] – Disinfection in animal housing

Following the ESD for PT3, the ESD for PT 18 (OECD, Series on Emission Scenario Documents No. 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems; cited in the following as "ESD for PT 18 No. 14") was used as the basis for the ESD for PT 3 since the application of insecticides in stables (PT 18) and the application of disinfectants in stables (PT 3) are very similar and the emission paths are almost identical. The ESD for PT 18 already provides detailed scenarios and emission descriptions including respective calculation procedures and formula. Details of estimations can be found in Annex section 3.2.

GERM-IOD is intended to be used in rural hygiene applications indoors in animal houses/shelters by spraying. It is used by professionals.

GERM-IOD is a soluble concentrate containing 2.5% (w/w) iodine as active substance and 6.57% (w/w) Propanol-2-ol as SoC. The soluble concentrate can be diluted at 1.5 (15 $ml_{product}$/ 1 L_{water}) to get a solution-in-use which must be applied at maximum application rate of 500 $mL_{solution}/m^2$.

The releases of GERM-IOD to the environment are assessed by applying emission models to soil after manure applications on grassland and arable land followed by emission models to groundwater and then surface water.

It is intended to be used in the majority of animal categories (i1=18) according to the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (2006).

In the following table the concerned animal subcategories and manure storage types are presented. These different categories are referenced with the appropriate number.

Subcat. (*i1*)	**Number of animals**	**Floor area**	**Wall and Roof area**	**total area (incl. slats, other areas and manure area)**	**Housing volume**
	[-]	**[m²]**	**[m²]**	**m²**	**m³**
(1) Dairy cows	100	1170	1670	3230	9630

Subcat. (*i1*)	Number of animals	Floor area	Wall and Roof area	total area (incl. slats, other areas and manure area)	Housing volume
	[-]	[m²]	[m²]	m²	m³
(2) Beef cattle	125	370	1000	1750	3063
(3) Veal calves	80	160	330	650	590
(4) Sows, in individual pens	132	560	910	1930	1960
(5) Sows in groups	132	710	1160	2200	2480
(6) Fattening pigs	400	600	970	2020	2110
(7) Laying hens in battery cages without treatment	21000	750	1100	4410	2810
(8) Laying hens in battery cages with aeration (belt drying)	21000	750	1100	4410	2810
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	21000	750	1100	3810	2810
(10) Laying hens in compact battery cages	21000	750	1100	3510	2810
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	10000	1430	2030	4610	5360
(12) Broilers in free range with litter floor	20000	1110	1600	2730	4170
(13) Laying hens in free range with grating floor (aviary system)	20000	1270	1822	4992	4780
(14) Parent broilers in free range with grating floor	7000	390	600	1290	1458
(15) Parent broilers in rearing with grating floor	9000	500	750	1640	1880
(16) Turkeys in free range with litter floor	10000	3330	4650	8040	12500
(17) Geese in free range with litter floor	10000	2000	2820	4880	7500
(18) Ducks in free range with litter floor	10000	2500	3500	6060	9380

ES-CA:

There was a mistake in the last two lines of above table, because the subcategory 17 correponds to Ducks and the subcategory 18 to Geese. Therefore, the default values have been corrected.

Subcat. (*i1*)	Number of animals	Floor area	Wall and Roof area	total area (incl. slats, other areas and manure area)	Housing volume
	[-]	[m²]	[m²]	m²	m³
(1) Dairy cows	100	1170	1670	3230	9630

(2) Beef cattle	125	370	1000	1750	3063
(3) Veal calves	80	160	330	650	590
(4) Sows, in individual pens	132	560	910	1930	1960
(5) Sows in groups	132	710	1160	2200	2480
(6) Fattening pigs	400	600	970	2020	2110
(7) Laying hens in battery cages without treatment	21000	750	1100	4410	2810
(8) Laying hens in battery cages with aeration (belt drying)	21000	750	1100	4410	2810
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	21000	750	1100	3810	2810
(10) Laying hens in compact battery cages	21000	750	1100	3510	2810
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	10000	1430	2030	4610	5360
(12) Broilers in free range with litter floor	20000	1110	1600	2730	4170
(13) Laying hens in free range with grating floor (aviary system)	20000	1270	1822	4992	4780
(14) Parent broilers in free range with grating floor	7000	390	600	1290	1458
(15) Parent broilers in rearing with grating floor	9000	500	750	1640	1880
(16) Turkeys in free range with litter floor	10000	3330	4650	8040	12500
(17) Ducks in free range with litter floor	10000	2000	2820	4880	7500
(18) Geese in free range with litter floor	10000	2500	3500	6060	9380

The input parameter used for the environmental exposure assessment for professional use in rural hygiene (stables i.e. animal houses/shelters) is taken from the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (OECD ESD No.14) and the Technical Agreement for Biocides TAB (ENV2019). Additional calculations were performed according to the Guidance on the biocidal products Regulation. Volume IV Environment - Part B Risk Assessment (active substances) (BPR, ECHA, 2015b), as well as from output values given by EUSES and Simple Treat 4.0.

Default values regarding e.g. number of animals (see table below), the fractions of a.i. released to the relevant streams, number of disinfectant applications etc. were directly used in accordance with the ESD for PT18 (2006) and associated documents. There were no deviations from the defaults given in the ESD for PT 18. The treated area in the stables, which is used for calculations, is the total area of the housing (floor, walls and ceiling) plus the slatted areas and other areas, taken the worst case scenario.

ES-CA:

A mistake was done in the calculations. In the table from page 124 where outputs were summarized, the area used for calculations by the applicant was the area of the floor only and was not used the total area of the housing. The treated area in the stables which should have been used for the calculations should have been the total area of the housing (floor, slatted, walls and roof, manure and others). Therefore, ES—CA has corrected these results.

Calculations were done for all animal sub-categories (i1 = 1-18). The mode of application was spraying (i3 = 1) and the exposure streams considered were all (i4= 1 (manure), i4= 2 (waste water) and i4= 3 (slurry).

The following input parameters were used to calculate the local emissions to soil.

Input parameters for calculating the local emission – Scenario 1			
Scenario 1: Rural hygiene; professional use in animal houses/ shelters.			
Input	**Value**	**Unit**	**Remarks**
Fraction of substance in commercial product			
Iodine	2.5	[% w/w]	
Propan-2-ol	6.57	[% w/w]	
Amount of b.p. prescribed to be used for area specified for application	500	[ml/m^2]	
Product's dilution to get the solution in use	1.5	%	
Application rate of substance in use solution			
Iodine	187.5	[µl/m^2]	S
Propan-2-ol	492.75	[µl/m^2]	S
Maximum immission standards for nitrogen on grassland and arable land	170	*[Kg.ha^{-1}.yr^{-1}]*	D
Number of prescribed maximum repeated biocide treatments in a year			
- Meat poultry species (i1=12, 14-18)	9	*[-]*	
- Laying poultry species (i1=7-11, 13)	1	*[-]*	
- Rabbits (no ESD reference is available)	12	*[-]*	
- Porcine species (i1=4-6)	2	*[-]*	
- Meat bovine species (i1=1-3)	1	*[-]*	
Period between biocide treatments:			
- Meat poultry species (i1=12, 14-18)	40	*[d]*	
- Laying poultry species (i1=7-11, 13)	365	*[d]*	
- Rabbits (no ESD reference is available)	30	*[d]*	
- Porcine species (i1=4-6)	183	*[d]*	
- Meat bovine species (i1=1-3)	365	*[d]*	
Number of land application - on grassland - on arable land	 4 1	 *[Yr^{-1}]* *[Yr^{-1}]*	 default
Manure storage time - grassland - arable land	 53 212	 *[d]* *[d]*	 default

Input parameters for calculating the local emission – Scenario 1			
Scenario 1: Rural hygiene; professional use in animal houses/ shelters.			
Input	**Value**	**Unit**	**Remarks**
Number of biocide application during manure storage period of application for arable land [Napp_bio_manure_ar]			Estimation of number of applications during manure storage (reference: OECD ESD No.14 Sections 2.2-2.3 of the Addendum (2015))
- Meat poultry species (i1=12, 14-18)	5	*[-]*	
- Laying poultry species (i1=7-11, 13)	1	*[-]*	
- Rabbits (no ESD reference is available)	-	*[-]*	
- Porcine species (i1=4-6)	1	*[-]*	
- Meat bovine species (i1=1-3)	1	*[-]*	
maximum number of applications during manure storage period of manure to be spread on grassland [Napp_manure_gr]			Estimation of number of applications during manure storage (reference: OECD ESD No.14 Sections 2.2-2.3 of the Addendum (2015))
- Meat poultry species (i1=12, 14-18)	2		
- Laying poultry species (i1=7-11, 13)	1		
- Rabbits (no ESD reference is available)	-		
- Porcine species (i1=4-6)	1		
- Meat bovine species (i1=1-3)	1		
Half-life for biodegradation in soil (DT50bio_Soil)			Default values considered for readily biodegradables substances
Iodine	n.a.	*[d]*	
Propan-2-ol	30	*[d]*	

n.a.: not available

ES-CA:

Regards the calculation of the maximum number of applications during manure storage period of manure to be spread on grassland and arable, there are several discussions and interpretations. ES-CA has decided to use Napp-biomanure values rounded off at 1 decimal place in the calculations (ENV 212, TAB 2021) as a worst case.

Input parameters for calculating the local emission – Scenario 1			
Scenario 1: Rural hygiene; professional use in animal houses/ shelters.			
Input	**Value**	**Unit**	**Remarks**
Fraction of substance in commercial product			
Iodine	2.5	[% w/w]	
Propan-2-ol	6.57	[% w/w]	
Amount of b.p. prescribed to be used for area specified for application	500	[ml/m^2]	
Product's dilution to get the solution in use	1.5	%	
Application rate of substance in use solution			
Iodine	187.5	[µl/m^2]	S
Propan-2-ol	492.75	[µl/m^2]	S
Maximum immission standards for nitrogen on grassland and arable land	170	*[Kg.ha^{-1}.yr^{-1}]*	D
Number of prescribed maximum repeated biocide treatments in a year			
- Meat poultry species (i1=12, 14-18)	9	*[-]*	

- Laying poultry species (i1=7-11, 13)	1	*[-]*	
- Rabbits (no ESD reference is available)	12	*[-]*	
- Porcine species (i1=4-6)	2	*[-]*	
- Meat bovine species (i1=1-3)	1	*[-]*	
Period between biocide treatments:			
- Meat poultry species (i1=12, 14-18)	40	*[d]*	
- Laying poultry species (i1=7-11, 13)	365	*[d]*	
- Rabbits (no ESD reference is available)	30	*[d]*	
- Porcine species (i1=4-6)	183	*[d]*	
- Meat bovine species (i1=1-3)	365	*[d]*	
Number of land application - on grassland - on arable land	 4 1	 *[Yr^{-1}]* *[Yr^{-1}]*	default
Manure storage time - grassland - arable land	 53 212	 *[d]* *[d]*	default
Number of biocide application during manure storage period of application for arable land [Napp_bio_manure_ar]			ENV 212, TAB 2021
- Meat poultry species (i1=12, 14-18)	5.3	*[-]*	
- Laying poultry species (i1=7-11, 13)	1	*[-]*	
- Rabbits (no ESD reference is available)	-	*[-]*	
- Porcine species (i1=4-6)	1.2	*[-]*	
- Meat bovine species (i1=1-3)	1	*[-]*	
maximum number of applications during manure storage period of manure to be spread on grassland [Napp_manure_gr]			ENV 212, TAB 2021
- Meat poultry species (i1=12, 14-18)	1.3		
- Laying poultry species (i1=7-11, 13)	1		
- Rabbits (no ESD reference is available)	-		
- Porcine species (i1=4-6)	1		
- Meat bovine species (i1=1-3)	1		

Calculations for Scenario [1]

Phosphorous immission standards were not considered in the current assessment since they are unique in The Netherlands and therefore not applicable EU wide. At the technical meeting I/08 it was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1}.yr^{-1}$ for all soils (arable land and grassland).

In function of type of emission pathway via manure /slurry or via STP, different local predicted environmental concentrations (PECs) were obtained for the terrestrial compartment, including groundwater and for the aquatic compartment (incl. sediment) due to run-off from soil.

Further information related to PECs calculations can be found at Annex section 3.2.2 of the current dossier.

Fate and distribution in exposed environmental compartments.

In this assessment, Iodine and its relevant metabolites, iodide and iodate have been taken into account and PEC values have been derived.

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. According to EU Assessment Report of Iodine (December, 2013), environmental background values presented in the table below are likely to be encountered for soil, water and air.

Compartment	**Background level (as iodine)**
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/L Range: < 1-70 µg/L with extremes up to 400 µg/L
Freshwater (river and lake)	0.5 - 20 µg/L
Marine water	45 - 60 µg/L
Rainwater	0.1-15 µg/L
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3-400 mg/kg
Air	Atmosphere: 10-20 ng/m^3 Atmospheric concentration: over land 2-14 ng/m^3; over ocean 17-52 ng/m^3 Marine air contains: 100 µg/L (may refer to local inhalable air)

Following Iodine's CAR, the presence of different forms of iodine is largely dependent on redox potential and pH. Iodide and iodate are the dominant iodine species in soil. Iodate is the dominant chemical form of iodine in the soil solution under non-flooded conditions whilst under flooded conditions iodide is the dominant chemical form. In water, the prevalent iodine forms are iodide (I^-) and iodate ($IO3^-$). In surface waters, the proportion of iodide to iodate will vary depending on microbial activity and the release of iodine species from terrestrial sources. Microbial action converts iodide to organic forms of iodine, primarily methyl iodide (CH3I).

Considering the lack of information about the proportion of the different forms of iodine in the different compartments, 100% of Iodine degradation into Iodide and Iodate metabolites has been assumed as the worst case for all compartments for the PEC calculations.

The route of exposure of GERM-IOD to the environment from pest control in animal housings is mainly via direct application of manure/slurry to arable land and grassland. Exposed compartments are surface water, sediment, soil and groundwater as well as biota. In addition, there are six avian scenarios (i1= 8, 11, 12, 16-18) where waste water route for animal categories can take place when the stables/animal housings are connected to a sewage treatment plant.

In the following table, the compartments which are exposed from the use of GERM-IOD in rural hygiene (animal houses/shelters) by professionals are given:

Scenario [1] - Identification of relevant receiving compartments based on the exposure pathway							
	via	**STP**	**Surface water**	**Sediment**	**Soil**	**Ground-water**	**Air**
Scenario [1]	manure / Slurry*	No	Yes	Yes	Yes	Yes	n.r.
	STP**	Yes	Yes	Yes	Yes	Yes	n.r.

* Exposure can occur via the route usage in animal houses/shelters → application of slurry/manure to soil → runoff to surface water / leaching to groundwater.

** Exposure can occur via the route usage in animal houses/shelters → release by STP application → emission to surface water and/or sludge concentrate which is emitted to soil → leaching to groundwater.

ES-CA:

If calculated PEC/PNEC values are >1, the PEC values are compared to the natural background levels in the concerned compartments, which is acceptable according to the AR of Iodine (Sweden 2013) that was agreed in the BPC ENV WG-IV-17 (WGIV-2017 ENV 7-2a and 7-2b).

The route of exposure of iodine to the environment is either via application of manure/slurry to agricultural land or by release from the facility drain to an STP and subsequent compartments. Relevant receiving compartments are soil, groundwater and surface water. PEC values are reported as iodine, iodide and iodate. The reason is that it is assumed that iodine is transformed to iodide in the alkaline anaerobic conditions in the manure, whilst when it is spread and mixed into the top layer of agricultural soil it will predominantly be transformed into iodate. In the case of release via STP iodine will be transformed into iodide and iodate, depending on the redox conditions. PECsoil, PECgw and PECsw values were calculated for application to grassland and arable land, based on nitrogen standards.

For the PEC values following the application of manure onto grassland or arable land it is assumed that 100% iodine is transferred either to 2 iodide or iodate ions. The molecular weight of 2 iodide ions corresponds to the molecular weight of iodine, consequently, the PECs for iodide are the same as for iodine. The molecular weight of 2 iodate ions is a factor of 1.3782 higher than the molecular weight of iodine, therefore the PECs for iodate were calculated by multiplying the PEC's of iodine by this factor.

For spreading of sewage sludge on arable land it is assumed that 100% of iodine is transformed into iodate and 14% into iodide. For the calculation of PECsoil it is assumed that 100% of iodine is transformed into iodate and 14% into iodide.

Sewage treatment plants (STP) are an important emission pathway. The release of STP effluents containing potential iodine residues leads to emissions to surface water and sediment, both freshwater and marine. Emissions to soil could arise indirectly, via the application of STP sludge and via aerial deposition. Furthermore, soil pore water concentrations as an indicator for potential groundwater levels will be assessed.

The values of background level (as iodine) are correct.

Input parameters (only set values) for calculating the fate and distribution in the environment for iodine			
Input	***Value***	***Unit***	***Remarks***
Molecular weight	253.81	[g.mol-1]	
Melting point	113.5-113.7	°C	

Vapour pressure (at 25ºC)	40.7	Pa	
Water solubility (at 20°C)	0.29	g/L	
Log Octanol/water partition coefficient	1.89 – 2.49	Log 10	
Organic carbon/water partition coefficient (Koc)	165.8	L/kg	
Henry's Law Constant (at X C)*[if measured data available]*	34.43	$Pa/m^3/mol$	
Biodegradability	Not applicable because iodine is an element		

Input parameters (only set values) for calculating the fate and distribution in the environment for propan-2-ol			
Input	***Value***	***Unit***	***Remarks***
Molecular weight	60.09	g/mol	
Melting point	-89.5	°C	
Boiling point	82.5	°C	
Vapour pressure (at 25°C)	5780	Pa	
Water solubility	1×10^5	mg/L	
Partition coefficient n-octanol/water (log Kow or Pow)	0.05	log 10	
Partition coefficient organic carbon/water (Koc)	3.3	L/kg	
BCF earthworm	0.85	L/kg	
BCF fish	0.22	L/kg	
Henry's law constant (25°C)	0.8	Pa. m^3/mol	
Biodegradability	Readily biodegradable*	-	
Air: degradation	DT50 = 3.1 days	days	

* Following table 6 of Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017, a DT50 of 30 days can considered for readily biodegradable substances in soil. Therefore, 30 days has been used in the Risk assessment:

Calculated fate and distribution in the STP			
Compartment	**Percentage [%]**		**Remarks**
	Iodine*	**Propan-2-ol**	
Air	0	0.292	Calculated via Simple Treat 4.0
Water	80	7.951	
Sludge	20	0.03	
Degraded in STP	0	91.73	

* According to Iodine's AR, the Simple Treat model normally used, and that resulted in a sludge retention factor of 1.93%, was not appropriate. Molecular iodine is a chemically unstable element with oxidizing properties and it is assumed that when iodine reaches the wastewater stream it will speciate into iodate and iodide. Therefore, sludge retention factors are based on literature data and laboratory and field experiments, which range between 20 and 80% retention. Considering that iodide is not highly adsorbed to sludge under typical conditions and iodate can form complexes with calcium which easily adsorb to negatively charged particle surfaces, the majority of the iodine that passes an STP will most probably not be retained in sludge and a sludge retention factor of 20% is chosen for the risk assessment (i.e. 80% of the iodine discharged to the STP remains in the effluent). Exposure to air is not considered as iodide and iodate are assumed not to be volatile.

ES-CA:

Input parameters (only set values) for calculating the fate and distribution in the environment for Iodine			
Input	Value	Unit	Remarks
Molecular weight	253.81		Assessment report 2013
Melting point	113.5	°C	Assessment report 2013
Boiling point	184.24	°C	Assessment report 2013
Vapour pressure (at 25ºC)*	$1x10^{-6}$	Pa	Assessment report 2013
Water solubility (at 25°C)	$1x10^{5}$	mg/l	Assessment report 2013
Log Octanol/water partition coefficient	2.49	Log 10	Assessment report 2013
Organic carbon/water partition coefficient (Koc)	165.8	l/kg	Assessment report 2013
Henry's Law Constant (at 25 C)	34.43	Pa/m3/mol	Assessment report 2013
Biodegradability	Not biodegradable		Inorganic substance
Solids-water partition coefficient in soil ($K_{p, soil}$)	5.8	[L/kg]	Assessment report 2013
Solids-water partition coefficient in sediment ($K_{p, sed}$)	200	[L/kg]	Assessment report 2013
Solids-water partition coefficient in suspended matter ($K_{p, susp}$)	220	[L/kg]	Assessment report 2013
Solids-water partition coefficient in soil ($K_{p, soil}$)	5.8	[L/kg]	Assessment report 2013

* Although Iodide (I_2) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised Iodine species are volatile. Therefore, emission to air was not considered.

Input parameters (only set values) for calculating the fate and distribution in the environment [Propan-2-ol]			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	60.09	g/ mol	Assessment report 2015
Melting point	-89.5	°C	Assessment report 2015
Boiling point	82.5	°C	Assessment report 2015
Vapour pressure at 25°C (12 °C)	5780 (2302)	Pa	Assessment report 2015
Water solubility at 25 °C (12 °C)	1000000 (831846)	mg/ L	Assessment report 2015

Log Octanol/water partition coefficient	0.05	Log 10	Assessment report 2015
Organic carbon/water partition coefficient (K_{OC})	3.3	L/ kg	Assessment report 2015
Henry's Law Constant at 25 °C (12 °C)	0.80 (0.383)	Pa/ m^3/ mol	Assessment report 2015
DT_{50} for degradation in air	3.1	days	Assessment report 2015
Biodegradability	Readily biodegradable	N/A	Assessment report 2015

According to EU Assessment Report of Iodine (December, 2013), sludge retention factors are based on literature data Iodine Product types 1, 3, 4, 22 December 2013 Page 31 of 107 and laboratory and field experiments, which range between 20 and 80% retention. Considering that iodide is not highly adsorbed to sludge under typical conditions and iodate can form complexes with calcium which easily adsorb to negatively charged particle surfaces, the majority of the iodine that passes an STP will most probably not be retained in sludge and a sludge retention factor of 20% is chosen for the risk assessment (i.e. 80% of the iodine discharged to the STP remains in the effluent). Exposure to air is not considered, iodide and iodate are assumed not to be volatile.

Calculated fate and distribution in the STP			
Compartment	**Percentage [%]**		**Remarks**
	Iodine	**Propan-2-ol**	
Air	0	0.18	Simple Treat 4.0 (EUSES 2.2)
Water	80	7.98	
Primary settle	20	0.03	
Surplus sludge	0	0.001	
Degraded in STP	0	91.81	

Calculated PEC values

A **worse case application dose of 500 mL of product's solution diluted at 1.5% per m^2** has been considered for PEC calculations, in order to cover all possible intended application doses.
In accordance with TGD for Risk Assessment (2003) and the ESD-PT 3 (2011), a quantitative approach is used in the risk assessment for GERM-IOD. The different PEC values have been derived from model calculations, as outlined in these guidelines, and have been estimated for the three disinfection scenarios for the corresponding compartments.

PEC in aquatic compartments (incl. sewage treatment plant).

- ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the aquatic compartment includes PECs for surface water (PECsw) and sediment (PECsed). **PECsw** and **PECsed** were calculated for the route of exposure of Iodine and Propan-2-ol via slurry/manure to soil and subsequent run-off to surface water (incl. sediment). PECsw was derived by diluting the $PEC_{groundwater}$ by a factor of 10 (OECD ESD No. 14). PECsed was calculated according to equation (50) of the Guidance on BPR IV/B (2015):

- **Surfacewater**

Subcat (*i1*)	PEC sw (mg/L)			
	Iodine, Iodate, Iodide		Propan-2-ol	
	grass	arable	grass	arable
(1) Dairy cows	7.79E-05	1.81E-05	3.54E-03	8.23E-04
(2) Beef cattle	2.32E-05	5.38E-06	1.05E-03	2.45E-04
(3) Veal calves	1.90E-04	4.40E-05	8.62E-03	2.00E-03
(4) Sows, in individual pens	2.70E-04	3.13E-05	1.23E-02	1.42E-03
(5) Sows in groups	3.42E-04	3.97E-05	1.55E-02	1.80E-03
(6) Fattening pigs	2.23E-04	2.58E-05	1.01E-02	1.17E-03
(7) Laying hens in battery cages without treatment	3.99E-05	9.26E-06	1.82E-03	4.21E-04
(8) Laying hens in battery cages with aeration (belt drying)	4.45E-05	1.03E-05	2.03E-03	4.70E-04
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	7.13E-05	1.65E-05	3.24E-03	7.52E-04
(10) Laying hens in compact battery cages	4.45E-05	1.03E-05	2.03E-03	4.70E-04
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	1.13E-04	2.63E-05	5.15E-03	1.20E-03
(12) Broilers in free range with litter floor	4.34E-04	5.59E-05	1.97E-02	2.54E-03
(13) Laying hens in free range with grating floor (aviary system)	8.38E-05	1.95E-05	3.81E-03	8.85E-04
(14) Parent broilers in free range with grating floor	3.80E-04	4.90E-05	1.73E-02	2.23E-03
(15) Parent broilers in rearing with grating floor	8.24E-04	1.06E-04	3.75E-02	4.83E-03
(16) Turkeys in free range with litter floor	8.42E-04	1.09E-04	3.83E-02	4.94E-03
(17) Geese in free range with litter floor	6.32E-04	8.15E-05	2.88E-02	3.71E-03
(18) Ducks in free range with litter floor	8.90E-04	1.15E-04	4.05E-02	5.22E-03

ES-CA:

For the concentration in surface water (via runoff) the sorption onto suspended matter can be considered (ENV 11, TAB 2021):

$Clocal_{water} = PEC_{porewater}/(1+Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION$

Subcat (*i1*)	PEC sw (mg/L)					
	Iodine, Iodide		Iodate		Propan-2-ol	
	grass	arable	grass	arable	grass	arable
(1) Dairy cows	1.78E-03	2.69E-04	2.45E-03	3.70E-04	8.62E-04	2.13E-04
(2) Beef cattle	9.08E-04	1.37E-04	1.25E-03	1.89E-04	4.39E-04	1.09E-04

(3) Veal calves	6.37E-03	9.61E-04	8.79E-03	1.32E-03	3.08E-03	7.63E-04
(4) Sows, in individual pens	3.85E-03	6.96E-04	5.30E-03	9.59E-04	1.86E-03	5.52E-04
(5) Sows in groups	4.38E-03	7.93E-04	6.04E-03	1.09E-03	2.12E-03	6.30E-04
(6) Fattening pigs	3.10E-03	5.61E-04	4.27E-03	7.73E-04	1.50E-03	4.46E-03
(7) Laying hens in battery cages without treatment	2.17E-03	3.27E-04	2.99E-03	4.51E-04	1.05E-03	2.60E-04
(8) Laying hens in battery cages with aeration (belt drying)	3.04E-03	4.58E-04	4.18E-03	6.31E-04	2.10E-03	5.19E-04
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	1.87E-03	2.82E-04	2.58E-03	3.89E-04	9.06E-04	2.24E-04
(10) Laying hens in compact battery cages	1.55E-03	2.33E-04	2.13E-03	3.21E-04	7.48E-04	1.85E-04
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	5.04E-03	7.60E-04	6.94E-03	1.05E-03	4.88E-04	1.21E-03
(12) Broilers in free range with litter floor	2.13E-03	1.31E-03	2.93E-03	1.80E-03	2.06E-03	2.08E-03
(13) Laying hens in free range with grating floor (aviary system)	2.73E-03	4.11E-04	3.76E-03	5.67E-04	1.32E-03	3.27E-04
(14) Parent broilers in free range with grating floor	1.50E-03	9.24E-04	2.07E-03	1.27E-03	7.27E-04	7.33E-04
(15) Parent broilers in rearing with grating floor	3.23E-03	1.99E-03	4.45E-03	2.74E-03	1.56E-03	1.58E-03
(16) Turkeys in free range with litter floor	4.05E-03	2.49E-03	5.59E-03	3.43E-03	3.92E-03	3.96E-03
(17) Ducks in free range with litter floor	4.33E-03	2.66E-03	5.96E-03	3.67E-03	4.19E-03	4.22E-03
(18) Geese in free range with litter floor	3.05E-03	1.88E-03	4.21E-03	2.59E03	2.96E-03	2.98E-03

- **Sediment**

According to BPR Guidance of Risk Assessment Vol IV, Part B, active substances with a Koc lower than 500 cm^3/g are not probable to be adsorbed by the sediment. Therefore and following Iodine's CAR, PEC value for this compartment is not evaluated for Iodine.

Subcat (*i1*)	**PEC sed (mg/kg)**	
	Propan-2-ol	
	grass	**arable**
(1) Dairy cows	3.03E-03	7.03E-04
(2) Beef cattle	9.01E-04	2.09E-04
(3) Veal calves	7.36E-03	1.71E-03
(4) Sows, in individual pens	1.05E-02	1.22E-03
(5) Sows in groups	1.33E-02	1.54E-03
(6) Fattening pigs	8.65E-03	1.00E-03
(7) Laying hens in battery cages without treatment	1.55E-03	3.60E-04
(8) Laying hens in battery cages with aeration (belt drying)	1.73E-03	4.02E-04
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	2.77E-03	6.43E-04
(10) Laying hens in compact battery cages	1.73E-03	4.02E-04
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	4.40E-03	1.02E-03
(12) Broilers in free range with litter floor	1.69E-02	2.17E-03
(13) Laying hens in free range with grating floor (aviary system)	3.26E-03	7.56E-04
(14) Parent broilers in free range with grating floor	1.48E-02	1.90E-03
(15) Parent broilers in rearing with grating floor	3.20E-02	4.13E-03

Subcat (*i1*)	PEC sed (mg/kg)	
	Propan-2-ol	
	grass	arable
(16) Turkeys in free range with litter floor	3.27E-02	4.22E-03
(17) Geese in free range with litter floor	2.46E-02	3.17E-03
(18) Ducks in free range with litter floor	3.46E-02	4.46E-03

- ***Local PEC values for the emission pathway via STP***

In this case, the estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 39, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015)

In some animal housing systems, particularly for poultry (*i1*= 8, 11, 12, 16-18) a fraction of the applied biocidal product can be released to waste water that is later discharged to a STP. Release fractions to waste water for these animal categories were calculated according to OECD ESD No. 14 on which ESD PT 3 refers. Further calculation of influent and effluent concentration in STP, PEC_{STP}, $PEC_{surface\_water}$ were carried out by assuming that only one farm releases liquid wastes into the sewer at one day.

In function of physicochemical charcteristics of substance, different Fraction of emission directed to water and to sludge by STP were considering according to respective AR:

	Iodine	**Propan-2-ol**
Fraction of emission directed to water by STP	0.8	0.125
Fraction of emission directed to sludge by STP	0.2	0.0003*

* 91.73% of Propan-2-ol is deemed degraded at STP and no emission to sludge can be deemed.

Taking this assumption into account the following PECs are obtained:

Poultry systems	**Clocal_inf**	**Clocal_eff**	**PECstp**	**PECsw**	**PECsed**
	[mg.l^{-1}]	**[mg.l^{-1}]**	**[mg.l^{-1}]**	**[mg.l^{-1}]**	**[mg.kg^{-1}]**
Iodine, Iodide, Iodate					
(8) Laying hens in battery cages with aeration (belt drying)	1.41E-02	1.13E-02	1.41E-02	1.12E-03	4.93E-03
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	2.68E-02	2.15E-02	2.68E-02	2.14E-03	9.41E-03
(12) Broilers in free range with litter floor	2.08E-02	1.67E-02	2.08E-02	1.66E-03	7.30E-03
(16) Turkeys in free range with litter floor	6.24E-02	5.00E-02	6.24E-02	4.99E-03	2.19E-02
(17) Geese in free range with litter floor	4.69E-02	3.75E-02	4.69E-02	3.75E-03	1.64E-02

Poultry systems	Clocal_inf	Clocal_eff	PECstp	PECsw	PECsed
	[mg.l^{-1}]	[mg.l^{-1}]	[mg.l^{-1}]	[mg.l^{-1}]	[mg.kg^{-1}]
(18) Ducks in free range with litter floor	3.75E-02	3.00E-02	3.75E-02	3.00E-03	1.32E-02
Propan-2-ol					
(8) Laying hens in battery cages with aeration (belt drying)	3.70E-02	4.62E-03	3.70E-02	4.62E-04	3.95E-04
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	7.05E-02	8.81E-03	7.05E-02	8.81E-04	7.52E-04
(12) Broilers in free range with litter floor	5.47E-02	6.84E-03	5.47E-02	6.84E-04	5.84E-04
(16) Turkeys in free range with litter floor	1.64E-01	2.05E-02	1.64E-01	2.05E-03	1.75E-03
(17) Geese in free range with litter floor	1.23E-01	1.54E-02	1.23E-01	1.54E-03	1.32E-03
(18) Ducks in free range with litter floor	9.86E-02	1.23E-02	9.86E-02	1.23E-03	1.05E-03

ES-CA:

The values recalculated by the ES-CA taking into account Simple treat 4.0 (EUSES) are the following and for spreading of sewage sludge on arable land it is assumed that 100% of iodine is transformed into iodate and 14% into iodide (according to CAR)

Poultry systems	Elocal$_{wastewater}$	PECstp	PECsw	PECsed
	[kg·d^{-1}]	[mg.l^{-1}]	[mg.l^{-1}]	[mg.kg^{-1}]
IODINE/IODIDE				
(8) Laying hens in battery cages with aeration (belt drying)	1.65E-01	6.60E-02	6.58E-03	
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	1.73E-01	6.92E-02	6.90E-03	
(12) Broilers in free range with litter floor	1.02E-01	4.08E-02	4.07E-03	
(16) Turkeys in free range with litter floor	3.02E-01	1.21E-01	1.20E-02	
(17) Ducks in free range with litter floor	1.83E-01	7.32E-02	7.30E-03	
(18) Geese in free range with litter floor	2.27E-01	9.08E-02	9.05E-03	
IODATE				
(8) Laying hens in battery cages with aeration (belt drying)	2.27E-01	9.10E-02	9.07E-03	
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	2.38E-01	9.54E-02	9.51E-03	
(12) Broilers in free range with litter floor	1.41E-01	5.62E-02	5.61E-03	
(16) Turkeys in free range with litter floor	4.16E-01	1.67E-01	1.65E-02	
(17) Ducks in free range with litter floor	2.52E-01	1.01E-01	1.01E-02	

(18) Geese in free range with litter floor	3.13E-01	1.25E-01	1.25E-02	
PROPAN-2-OL				
(8) Laying hens in battery cages with aeration (belt drying)	2.17E-01	8.65E-03	8.65E-04	
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	2.27E-01	9.05E-03	9.05E-04	
(12) Broilers in free range with litter floor	1.35E-01	5.38E-03	5.38E-04	
(16) Turkeys in free range with litter floor	3.96E-01	1.58E-02	1.58E-03	
(17) Ducks in free range with litter floor	2.40E-01	9.56E-03	9.56E-04	
(18) Geese in free range with litter floor	2.99E-01	1.19E-02	1.19E-03	

According to BPR Guidance of Risk Assessment Vol IV, Part B, active substances with a Koc lower than 500 L/Kg are not probable to be adsorbed by the sediment. Therefore and following Iodine's CAR, PEC value for this compartment was not evaluated.

PEC in soil compartments

- ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the terrestrial compartment includes PEC_{soil} according to equation 24b and 25b of the Recommendation of the AHEE, Addendum to OECD ESD No. 14 considering recent decisions concerning the parameters $Tgr\text{-}_{intno\_manure}$ (365 d instead 206 d) and k_{leach} (according to eq. 58, Guidance on the BPR, Vol. IV, Part B (2015)). In addition, four manure application events per year are considered for grassland following endpoint 3.3 of the mentioned AHEE Addendum before.

The calculations of the releases of Iodine and Propan-2-ol during slurry/manure applications are accomplished for all animal categories and sub-categories according to PT 18, ESD No.14. For soil, the calculation of initial environmental concentrations **(PIECs)** assumes application of slurry/manure onto arable and grassland soils taking biodegradation of Iodine and Propan-2-ol into account in the first instance. The predicted soil concentration, after 10 years of consecutive manure/slurry applications, PIEC10_degr, is used as the PECsoil in risk assessment, considering the worst case scenario (according to the WG(V) November, 2015 for risk assessment, after the calculation corrections for PIECsoil_grassland after 10 years, agreed at the WG-I-2018, January 2018).

Predicted environmental concentrations due to the application of the biocide and after 10 years of successive manure application in stables have been estimated. Concentrations are based on the nitrogen immision standards. Degradation of the active substance and SoC in soils is included. DT_{50} values described above were used in the risk assessment for Iodine and Propan-2-ol.

PECsoil after one manure application on arable or four manure applications on grassland without degradation

Subcat (*i1*)	**PECsoil (mg/kgwwt)**			
	Iodine		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(1) Dairy cows	3.05E-03	7.63E-04	8.02E-03	2.01E-03
(2) Beef cattle	9.08E-04	2.27E-04	2.39E-03	5.97E-04

PECsoil after one manure application on arable or four manure applications on grassland without degradation				
Subcat (*i1*)	**PECsoil (mg/kgwwt)**			
	Iodine		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(3) Veal calves	7.43E-03	1.86E-03	1.95E-02	4.88E-03
(4) Sows, in individual pens	1.06E-02	1.32E-03	2.78E-02	3.47E-03
(5) Sows in groups	1.34E-02	1.67E-03	3.52E-02	4.40E-03
(6) Fattening pigs	8.72E-03	1.09E-03	2.29E-02	2.86E-03
(7) Laying hens in battery cages without treatment	1.56E-03	3.91E-04	4.11E-03	1.03E-03
(8) Laying hens in battery cages with aeration (belt drying)	1.75E-03	4.36E-04	4.59E-03	1.15E-03
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	2.79E-03	6.98E-04	7.34E-03	1.83E-03
(10) Laying hens in compact battery cages	1.75E-03	4.36E-04	4.59E-03	1.15E-03
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	4.44E-03	1.11E-03	1.17E-02	2.92E-03
(12) Broilers in free range with litter floor	1.70E-02	2.36E-03	4.47E-02	6.20E-03
(13) Laying hens in free range with grating floor (aviary system)	3.28E-03	8.21E-04	8.63E-03	2.16E-03
(14) Parent broilers in free range with grating floor	1.49E-02	2.07E-03	3.91E-02	5.43E-03
(15) Parent broilers in rearing with grating floor	3.23E-02	4.48E-03	8.48E-02	1.18E-02
(16) Turkeys in free range with litter floor	3.30E-02	4.58E-03	8.67E-02	1.20E-02
(17) Geese in free range with litter floor	2.48E-02	3.44E-03	6.51E-02	9.04E-03
(18) Ducks in free range with litter floor	3.49E-02	4.84E-03	9.16E-02	1.27E-02

PECsoil after one manure application on arable or four manure applications on grassland With degradation				
Subcat (*i1*)	**PECsoil (mg/kgwwt)**			
	Iodine		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(1) Dairy cows	2.20E-03	5.51E-04	5.79E-03	1.45E-03
(2) Beef cattle	6.55E-04	1.64E-04	1.72E-03	4.31E-04
(3) Veal calves	5.36E-03	1.34E-03	1.41E-02	3.52E-03
(4) Sows, in individual pens	7.62E-03	9.52E-04	2.00E-02	2.50E-03
(5) Sows in groups	9.66E-03	1.21E-03	2.54E-02	3.17E-03
(6) Fattening pigs	6.29E-03	7.86E-04	1.65E-02	2.07E-03
(7) Laying hens in battery cages without treatment	1.13E-03	2.82E-04	2.96E-03	7.41E-04
(8) Laying hens in battery cages with aeration (belt drying)	1.26E-03	3.15E-04	3.31E-03	8.27E-04
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	2.01E-03	5.04E-04	5.29E-03	1.32E-03
(10) Laying hens in compact battery cages	1.26E-03	3.15E-04	3.31E-03	8.27E-04
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	3.20E-03	8.00E-04	8.41E-03	2.10E-03

PECsoil after one manure application on arable or four manure applications on grassland With degradation				
Subcat (*i1*)	**PECsoil (mg/kgwwt)**			
	Iodine		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(12) Broilers in free range with litter floor	1.23E-02	1.70E-03	3.22E-02	4.47E-03
(13) Laying hens in free range with grating floor (aviary system)	2.37E-03	5.92E-04	6.23E-03	1.56E-03
(14) Parent broilers in free range with grating floor	1.07E-02	1.49E-03	2.82E-02	3.92E-03
(15) Parent broilers in rearing with grating floor	2.33E-02	3.23E-03	6.12E-02	8.50E-03
(16) Turkeys in free range with litter floor	2.38E-02	3.31E-03	6.25E-02	8.69E-03
(17) Geese in free range with litter floor	1.79E-02	2.48E-03	4.70E-02	6.52E-03
(18) Ducks in free range with litter floor	2.51E-02	3.49E-03	6.61E-02	9.18E-03

PECsoil after 10 year consecutive application, degradation in soil included				
Subcat (*i1*)	**PECsoil_10 years (mg/kgwwt)**			
	Iodine		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(1) Dairy cows	2.37E-03	7.64E-04	6.23E-03	2.01E-03
(2) Beef cattle	7.06E-04	2.27E-04	1.85E-03	5.97E-04
(3) Veal calves	5.77E-03	1.86E-03	1.52E-02	4.88E-03
(4) Sows, in individual pens	8.21E-03	1.32E-03	2.16E-02	3.47E-03
(5) Sows in groups	1.04E-02	1.67E-03	2.73E-02	4.40E-03
(6) Fattening pigs	6.77E-03	1.09E-03	1.78E-02	2.86E-03
(7) Laying hens in battery cages without treatment	1.21E-03	3.91E-04	3.19E-03	1.03E-03
(8) Laying hens in battery cages with aeration (belt drying)	1.36E-03	4.36E-04	3.56E-03	1.15E-03
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	2.17E-03	6.98E-04	5.70E-03	1.83E-03
(10) Laying hens in compact battery cages	1.36E-03	4.36E-04	3.56E-03	1.15E-03
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	3.45E-03	1.11E-03	9.06E-03	2.92E-03
(12) Broilers in free range with litter floor	1.32E-02	2.36E-03	3.47E-02	6.20E-03
(13) Laying hens in free range with grating floor (aviary system)	2.55E-03	8.21E-04	6.71E-03	2.16E-03
(14) Parent broilers in free range with grating floor	1.16E-02	2.07E-03	3.04E-02	5.43E-03
(15) Parent broilers in rearing with grating floor	2.51E-02	4.48E-03	6.59E-02	1.18E-02
(16) Turkeys in free range with litter floor	2.56E-02	4.58E-03	6.74E-02	1.20E-02
(17) Geese in free range with litter floor	1.92E-02	3.44E-03	5.06E-02	9.04E-03
(18) Ducks in free range with litter floor	2.71E-02	4.84E-03	7.12E-02	1.27E-02

ES-CA:

Concentrations in soil after ten years were calculated according to the Addendums for PT18 (WGV2015 and WGI2018) and for nitrogen standard application rates only. The emission to soil from the application of slurry/manure has been determined taking degradation and leaching to deeper soil layer into account for a period of 10 years. (agreed at BPC WGIV2017).

The corresponding half-lives for leaching from the topsoil layer are 2567 d in arable land (20 cm) and 642 d in grassland (5 cm). Due to the value for k_{leach} is derived from the soil depth, this value is different for arable and grass land.

$k_{total} = k_{degradation} + k_{leach}$

Input parameters for the $PECsoil_{10years}$ calculations considering degradation and leaching to deeper soil layers are listed in the table below:

Parameters	Symbol	Value	Unit	S/D/O/R
Fraction of rain water that infiltrates into soil	Finf_soil	0.25	-	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Rate of wet precitipation (700 mm/year)	RAINrate	1.92E-03	m/d	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for biodegradation in bulk soil	DT50biosoil	1.00E+6	d	CAR
First-order rate constant for leaching from soil layer (grassland)	kleach_gr	1.08E-03	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for leaching from soils (grassland)	DT50soil_gr	642.71	d	BPC WGIV2017
First-order rate constant for leaching from soil layer (arable land)	kleach_ar	2.70E-04	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for leaching from soils (arable land)	DT50soil_ar	2570.82	d	BPC WGIV2017
First-order rate constant for removal from top soil layer (grassland)	ktot_gr	1.08E-03	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (56)

First-order rate constant for removal from top soil layer (arable land)	ktot_ar	2.70E-04	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (56)

The areas of animal housing were corrected and the concentration of Iodate was calculated by multiplying the PIEC's of iodine/iodide by the factor 1.3782.

Iodine/Iodide		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
Type of housing/manure storage	cat-subcat	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Amount of active ingredient to be used for one application	Qai-prescr[kg]	0,6056	0,3281	0,1219	0,3619	0,4125	0,3788	0,8269	0,8269	0,7144	0,6581	0,8644	0,5119	0,9360	0,2419	0,3075	1,5075	0,9150	1,1363
Amount of active ingredient in relevant stream after one application	Qai-manure[kg]	0,3028	0,1641	0,0609	0,1809	0,2063	0,1894	0,4134	0,5788	0,3572	0,3291	0,4322	0,2559	0,4680	0,1209	0,1538	0,7538	0,4575	0,5681
Amount of active ingradient to be used for one application	Qai-STP[kg/d]	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	1,65E-01	0,00E+00	0,00E+00	1,73E-01	1,02E-01	0,00E+00	0,00E+00	0,00E+00	3,02E-01	1,83E-01	2,27E-01
Amount (maximum) of biocide in grassland	Qai-grass[kg]	3,03E-01	1,64E-01	6,09E-02	1,81E-01	2,06E-01	1,89E-01	4,13E-01	5,79E-01	3,57E-01	3,29E-01	4,32E-01	3,33E-01	4,68E-01	1,57E-01	2,00E-01	9,80E-01	5,95E-01	7,39E-01
Amount (maximum) of biocide in arable land	Qai-arab[kg]	3,03E-01	1,64E-01	6,09E-02	2,17E-01	2,48E-01	2,27E-01	4,13E-01	5,79E-01	3,57E-01	3,29E-01	4,32E-01	1,36E+00	4,68E-01	6,41E-01	8,15E-01	3,99E+00	2,42E+00	3,01E+00
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland After four manure applications	PIECgrs4-N[mg/kgwwt]	8,43E-03	4,30E-03	3,02E-02	1,82E-02	2,07E-02	1,47E-02	1,03E-02	1,44E-02	8,87E-03	7,32E-03	2,38E-02	1,01E-02	1,29E-02	7,11E-03	1,53E-02	1,92E-02	2,05E-02	1,45E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land	PIECars-N[mg/kgwwt]	2,11E-03	1,07E-03	7,54E-03	5,46E-03	6,22E-03	4,40E-03	2,57E-03	3,59E-03	2,22E-03	1,83E-03	5,96E-03	1,03E-02	3,23E-03	7,25E-03	1,56E-02	1,95E-02	2,09E-02	1,47E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after four manure applications on grassland taking into account degr	PIECgrs4-N_degr[mg/kgwwt]	3,10E-02	1,58E-02	1,11E-01	6,69E-02	7,63E-02	5,40E-02	3,77E-02	5,28E-02	3,26E-02	2,69E-02	8,77E-02	3,70E-02	4,75E-02	2,62E-02	5,63E-02	7,05E-02	7,53E-02	5,32E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after 10 years	PIECgrs-N[mg/kgwwt]	9,33E-02	4,76E-02	3,34E-01	2,01E-01	2,30E-01	1,63E-01	1,14E-01	1,59E-01	9,82E-02	8,10E-02	2,64E-01	1,11E-01	1,43E-01	7,87E-02	1,69E-01	2,12E-01	2,27E-01	1,60E-01
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land after 10 years	PIECars-N[mg/kgwwt]	1,41E-02	7,17E-03	5,04E-02	3,65E-02	4,16E-02	2,94E-02	1,71E-02	2,40E-02	1,48E-02	1,22E-02	3,98E-02	6,85E-02	2,16E-02	4,84E-02	1,04E-01	1,31E-01	1,39E-01	9,84E-02
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for grassland	PIECgw-grs-N[mg/L]	1,78E-02	9,09E-03	6,38E-02	3,85E-02	4,39E-02	3,10E-02	2,17E-02	3,04E-02	1,87E-02	1,55E-02	5,04E-02	2,13E-02	2,73E-02	1,50E-02	3,23E-02	4,06E-02	4,33E-02	3,06E-02
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for arable land	PIECgw-ars-N[mg/L]	2,69E-03	1,37E-03	9,62E-03	6,96E-03	7,94E-03	5,62E-03	3,27E-03	4,58E-03	2,83E-03	2,33E-03	7,60E-03	1,31E-02	4,12E-03	9,24E-03	1,99E-02	2,49E-02	2,66E-02	1,88E-02
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for grassland	PIECsw-grs-N[mg/L]	1,78E-03	9,08E-04	6,37E-03	3,85E-03	4,38E-03	3,10E-03	2,17E-03	3,04E-03	1,87E-03	1,55E-03	5,04E-03	2,13E-03	2,73E-03	1,50E-03	3,23E-03	4,05E-03	4,33E-03	3,05E-03
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for arable land	PIECsw-ars-N[mg/L]	2,69E-04	1,37E-04	9,61E-04	6,96E-04	7,93E-04	5,61E-04	3,27E-04	4,58E-04	2,82E-04	2,33E-04	7,60E-04	1,31E-03	4,11E-04	9,24E-04	1,99E-03	2,49E-03	2,66E-03	1,88E-03

Iodate		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
Type of housing/manure storage	cat-subcat	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Amount of active ingredient to be used for one application	Qai-prescr[kg]	0,8347	0,4522	0,1680	0,4987	0,5685	0,5220	1,1396	1,1396	0,9846	0,9070	1,1913	0,7055	1,2900	0,3334	0,4238	2,0776	1,2611	1,5660
Amount of active ingredient in relevant stream after one application	Qai-manure[kg]	0,4173	0,2261	0,0840	0,2494	0,2843	0,2610	0,5698	0,7977	0,4923	0,4535	0,5956	0,3527	0,6450	0,1667	0,2119	1,0388	0,6305	0,7830
Amount of active ingradient to be used for one application	Qai-STP[kg/d]	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	2,28E-01	0,00E+00	0,00E+00	2,38E-01	1,41E-01	0,00E+00	0,00E+00	0,00E+00	4,16E-01	2,52E-01	3,13E-01
Amount (maximum) of biocide in grassland	Qai-grass[kg]	4,17E-01	2,26E-01	8,40E-02	2,49E-01	2,84E-01	2,61E-01	5,70E-01	7,98E-01	4,92E-01	4,54E-01	5,96E-01	4,59E-01	6,45E-01	2,17E-01	2,75E-01	1,35E+00	8,20E-01	1,02E+00
Amount (maximum) of biocide in arable land	Qai-arab[kg]	4,17E-01	2,26E-01	8,40E-02	2,99E-01	3,41E-01	3,13E-01	5,70E-01	7,98E-01	4,92E-01	4,54E-01	5,96E-01	1,87E+00	6,45E-01	8,83E-01	1,12E+00	5,51E+00	3,34E+00	4,15E+00
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland After four manure applications	PIECgrs4-N[mg/kgwwt]	1,16E-02	5,92E-03	4,16E-02	2,51E-02	2,86E-02	2,02E-02	1,41E-02	1,98E-02	1,22E-02	1,01E-02	3,29E-02	1,39E-02	1,78E-02	9,80E-03	2,11E-02	2,64E-02	2,82E-02	1,99E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land	PIECars-N[mg/kgwwt]	2,90E-03	1,48E-03	1,04E-02	7,52E-03	8,58E-03	6,07E-03	3,54E-03	4,95E-03	3,05E-03	2,52E-03	8,22E-03	1,41E-02	4,45E-03	9,99E-03	2,15E-02	2,69E-02	2,88E-02	2,03E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after four manure applications on grassland taking into account degr	PIECgrs4-N_degr[mg/kgwwt]	4,27E-02	2,18E-02	1,53E-01	9,23E-02	1,05E-01	7,44E-02	5,20E-02	7,28E-02	4,49E-02	3,71E-02	1,21E-01	5,10E-02	6,54E-02	3,60E-02	7,75E-02	9,72E-02	1,04E-01	7,33E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after 10 years	PIECgrs-N[mg/kgwwt]	1,29E-01	6,56E-02	4,60E-01	2,78E-01	3,17E-01	2,24E-01	1,57E-01	2,19E-01	1,35E-01	1,12E-01	3,64E-01	1,54E-01	1,97E-01	1,08E-01	2,33E-01	2,93E-01	3,12E-01	2,21E-01
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land after 10 years	PIECars-N[mg/kgwwt]	1,94E-02	9,89E-03	6,94E-02	5,02E-02	5,73E-02	4,05E-02	2,36E-02	3,31E-02	2,04E-02	1,68E-02	5,49E-02	9,44E-02	2,97E-02	6,67E-02	1,43E-01	1,80E-01	1,92E-01	1,36E-01
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for grassland	PIECgw-grs-N[mg/L]	2,46E-02	1,25E-02	8,79E-02	5,30E-02	6,05E-02	4,28E-02	2,99E-02	4,19E-02	2,58E-02	2,13E-02	6,95E-02	2,93E-02	3,76E-02	2,07E-02	4,46E-02	5,59E-02	5,97E-02	4,21E-02
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for arable land	PIECgw-ars-N[mg/L]	3,70E-03	1,89E-03	1,33E-02	9,60E-03	1,09E-02	7,74E-03	4,51E-03	6,31E-03	3,90E-03	3,22E-03	1,05E-02	1,80E-02	5,67E-03	1,27E-02	2,74E-02	3,44E-02	3,67E-02	2,59E-02
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for grassland	PIECsw-grs-N[mg/L]	2,45E-03	1,25E-03	8,79E-03	5,30E-03	6,04E-03	4,27E-03	2,99E-03	4,18E-03	2,58E-03	2,13E-03	6,94E-03	2,93E-03	3,76E-03	2,07E-03	4,45E-03	5,59E-03	5,96E-03	4,21E-03
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for arable land	PIECsw-ars-N[mg/L]	3,70E-04	1,89E-04	1,32E-03	9,59E-04	1,09E-03	7,73E-04	4,51E-04	6,31E-04	3,89E-04	3,21E-04	1,05E-03	1,80E-03	5,67E-04	1,27E-03	2,74E-03	3,43E-03	3,67E-03	2,59E-03

PROPAN-2-OL		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
Type of housing/manure storage	cat-subcat	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Amount of active ingredient to be used for one application	Qai-prescr[kg]	1,5916	0,8623	0,3203	0,9510	1,0841	0,9954	2,1730	2,1730	1,8774	1,7296	2,2716	1,3452	2,4598	0,6356	0,8081	3,9617	2,4046	2,9861
Amount of active ingredient in relevant stream after one application	Qai-manure[kg]	0,1592	0,0862	0,0320	0,0951	0,1084	0,0995	0,2173	0,4346	0,1877	0,1730	0,4543	0,2690	0,2460	0,0636	0,0808	0,7923	0,4809	0,5972
Amount of active ingradient to be used for one application	Qai-STP[kg/d]	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	2,17E-01	0,00E+00	0,00E+00	2,27E-01	1,35E-01	0,00E+00	0,00E+00	0,00E+00	3,96E-01	2,40E-01	2,99E-01
Amount (maximum) of biocide in grassland	Qai-grass[kg]	1,59E-01	8,62E-02	3,20E-02	9,51E-02	1,08E-01	9,95E-02	2,17E-01	4,35E-01	1,88E-01	1,73E-01	4,54E-01	3,50E-01	2,46E-01	8,26E-02	1,05E-01	1,03E+00	6,25E-01	7,76E-01
Amount (maximum) of biocide in arable land	Qai-arab[kg]	1,59E-01	8,62E-02	3,20E-02	1,14E-01	1,30E-01	1,19E-01	2,17E-01	4,35E-01	1,88E-01	1,73E-01	4,54E-01	1,43E+00	2,46E-01	3,37E-01	4,28E-01	4,20E+00	2,55E+00	3,17E+00
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland After four manure applications	PIECgrs4-N[mg/kgwwt]	4,43E-03	2,26E-03	1,59E-02	9,56E-03	1,09E-02	7,71E-03	5,39E-03	1,08E-02	4,66E-03	3,85E-03	2,51E-02	1,06E-02	6,79E-03	3,74E-03	8,04E-03	2,02E-02	2,15E-02	1,52E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land	PIECars-N[mg/kgwwt]	1,11E-03	5,65E-04	3,96E-03	2,87E-03	3,27E-03	2,31E-03	1,35E-03	2,70E-03	1,16E-03	9,62E-04	6,27E-03	1,08E-02	1,70E-03	3,81E-03	8,19E-03	2,05E-02	2,19E-02	1,55E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after four manure applications on grassland taking into account degr	PIECgrs4-N_degr[mg/kgwwt]	4,48E-03	2,28E-03	1,60E-02	9,66E-03	1,10E-02	7,79E-03	5,45E-03	1,09E-02	4,71E-03	3,89E-03	2,53E-02	1,07E-02	6,86E-03	3,78E-03	8,12E-03	2,04E-02	2,18E-02	1,54E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for grassland after 10 years	PIECgrs-N[mg/kgwwt]	4,48E-03	2,28E-03	1,60E-02	9,66E-03	1,10E-02	7,79E-03	5,45E-03	1,09E-02	4,71E-03	3,89E-03	2,53E-02	1,07E-02	6,86E-03	3,78E-03	8,12E-03	2,04E-02	2,18E-02	1,54E-02
Concentration of the active ingredient in soil based on the nitrogen inmission estándar for arable land after 10 years	PIECars-N[mg/kgwwt]	1,11E-03	5,65E-04	3,96E-03	2,87E-03	3,27E-03	2,31E-03	1,35E-03	2,70E-03	1,16E-03	9,62E-04	6,27E-03	1,08E-02	1,70E-03	3,81E-03	8,19E-03	2,05E-02	2,19E-02	1,55E-02
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for grassland	PIECgw-grs-N[mg/L]	8,62E-03	4,39E-03	3,08E-02	1,86E-02	2,12E-02	1,50E-02	1,05E-02	2,10E-02	9,06E-03	7,48E-03	4,88E-02	2,06E-02	1,32E-02	7,27E-03	1,56E-02	3,92E-02	4,19E-02	2,96E-02
Concentration of the active ingredient in groundwater based on the nitrogen inmission estándar for arable land	PIECgw-ars-N[mg/L]	2,13E-03	1,09E-03	7,63E-03	5,52E-03	6,30E-03	4,46E-03	2,60E-03	5,19E-03	2,24E-03	1,85E-03	1,21E-02	2,08E-02	3,27E-03	7,33E-03	1,58E-02	3,96E-02	4,22E-02	2,98E-02
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for grassland	PIECsw-grs-N[mg/L]	8,62E-04	4,39E-04	3,08E-03	1,86E-03	2,12E-03	1,50E-03	1,05E-03	2,10E-03	9,06E-04	7,48E-04	4,88E-03	2,06E-03	1,32E-03	7,27E-04	1,56E-03	3,92E-03	4,19E-03	2,96E-03
Concentration of the active ingredient in surface water based on the nitrogen inmission estándar for arable land	PIECsw-ars-N[mg/L]	2,13E-04	1,09E-04	7,63E-04	5,52E-04	6,30E-04	4,46E-04	2,60E-04	5,19E-04	2,24E-04	1,85E-04	1,21E-03	2,08E-03	3,27E-04	7,33E-04	1,58E-03	3,96E-03	4,22E-03	2,98E-03

➢ ***Local PEC values for the emission pathway via STP***

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater from emission pathway via STP is considered negligible for Propan-2-ol because the emission factor to sludge by STP is 0. Therefore, only local PECs for Iodine are estimated for the emission pathway via STP:

- PEC $_{local\_soil}$ according to equation 66, chapter 2.3.8.5, Guidance BPR IV ENV B (2015);

Poultry systems	**Csludge**	**PEClocal$_{soil}$**	**PEClocal$_{groundwater}$**
	[mg.kg^{-1}]	**[mg.kg^{-1}]**	**[µg.L^{-1}]**
Iodine, Iodate, Iodide			
(8) Laying hens in battery cages with aeration (belt drying)	9.37E-03	4.98E-04	**0.16**
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	1.79E-02	9.50E-04	**0.31**
(12) Broilers in free range with litter floor	1.39E-02	7.37E-04	**0.24**
(16) Turkeys in free range with litter floor	4.16E-02	2.21E-03	**0.73**
(17) Geese in free range with litter floor	3.12E-02	1.66E-03	**0.55**
(18) Ducks in free range with litter floor	2.50E-02	1.33E-03	**0.44**

Values on bold are considered above the trigger value 0.1 µg/L for groundwater.

ES-CA:

PECs in soil was recalculated taking into account the following: for spreading of sewage sludge on arable land it is assumed that 100% of iodine is transformed into iodate and 14% into iodide (according to CAR). The molecular weight of 2 iodate ions is a factor of 1.3782 higher than the molecular weight of iodine, therefore the PECs for iodate were calculated by multiplying the PEC's of iodine by this factor.

Poultry systems	**PECsoil [mg.kg^{-1}]**	**PECgw [mg.L^{-1}]**
Iodine		
(8) Laying hens in battery cages with aeration (belt drying)	4.10E-01	7.83E-02
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	4.30E-01	8.20E-02
(12) Broilers in free range with litter floor	2.52E-01	4.84E-02
(16) Turkeys in free range with litter floor	7.47E-01	1.43E-01
(17) Ducks in free range with litter floor	4.53E-01	8.69E-02
(18) Geese in free range with litter floor	5.62E-01	1.08E-01
Iodide		
(8) Laying hens in battery cages with aeration (belt drying)	5.74E-03	1.10E-03
(11) Laying hens in free range with litter floor (partly litter floor. partly slatted)	6.02E-03	1.15E-03
(12) Broilers in free range with litter floor	3.53E-03	6.78E-04
(16) Turkeys in free range with litter floor	1.05E-02	2.00E-03

	(17) Ducks in free range with litter floor	6.34E-03	1.22E-03	
	(18) Geese in free range with litter floor	7.87E-03	1.51E-03	
	Iodate			
	(8) Laying hens in battery cages with aeration (belt drying)	5.65E-01	1.08E-01	
	(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	5.93E-01	1.13E-01	
	(12) Broilers in free range with litter floor	3.47E-01	6.67E-02	
	(16) Turkeys in free range with litter floor	1.03E+00	1.97E-01	
	(17) Ducks in free range with litter floor	6.24E-01	1.20E-01	
	(18) Geese in free range with litter floor	7.75E-01	1.49E-01	
	PROPAN-2-OL			
	(8) Laying hens in battery cages with aeration (belt drying)	1.96E-04	2.01E-04	
	(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	2.05E-04	2.10E-04	
	(12) Broilers in free range with litter floor	1.22E-04	1.25E-04	
	(16) Turkeys in free range with litter floor	3.58E-04	3.67E-04	
	(17) Ducks in free range with litter floor	2.17E-04	2.22E-04	
	(18) Geese in free range with litter floor	2.70E-04	2.77E-04	

PEC in groundwater

- ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the terrestrial compartment includes groundwater. PEC $_{groundwater}$ was assessed according to equation 26 and 28 of OECD ESD No. 14 and adapted to equation 37 of the Recommendation of the AHEE, Addendum to OECD ESD No. 14.

In accordance with the guidance presented in the TGD, Part B, for the groundwater risk assessment, the concentration in porewater is used for the initial groundwater assessment. The PEC in porewater ($PEC_{ground\ water}$) was calculated considering degradation processes in soil after 10 consecutive years of manure application, i.e., $PIEC_{10degr}$ was used as an input for soil concentration (in line with the WG(V) November, 2015 for risk assessment) using TGD equations for equilibrium partitioning.

Subcat (*i1*)	**PECgroundwater (µg/L)**			
	Iodine, iodate, iodide		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(1) Dairy cows	**0.78**	**0.25**	**35.44**	**11.41**
(2) Beef cattle	**0.23**	0.07	**10.54**	**3.39**
(3) Veal calves	**1.90**	**0.61**	**86.20**	**27.74**
(4) Sows, in individual pens	**2.70**	**0.43**	**122.59**	**19.73**
(5) Sows in groups	**3.42**	**0.55**	**155.42**	**25.01**
(6) Fattening pigs	**2.23**	**0.36**	**101.22**	**16.29**
(7) Laying hens in battery cages without treatment	**0.40**	**0.13**	**18.15**	**5.84**
(8) Laying hens in battery cages with aeration (belt drying)	**0.45**	**0.14**	**20.26**	**6.52**

Subcat (*i1*)	PECgroundwater (µg/L)			
	Iodine, iodate, iodide		Propan-2-ol	
	grass	arable	grass	arable
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	**0.71**	**0.23**	**32.41**	**10.43**
(10) Laying hens in compact battery cages	**0.45**	**0.14**	**20.26**	**6.52**
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	**1.13**	**0.36**	**51.51**	**16.58**
(12) Broilers in free range with litter floor	**4.34**	**0.78**	**197.24**	**35.27**
(13) Laying hens in free range with grating floor (aviary system)	**0.84**	**0.27**	**38.12**	**12.27**
(14) Parent broilers in free range with grating floor	**3.80**	**0.68**	**172.75**	**30.89**
(15) Parent broilers in rearing with grating floor	**8.24**	**1.47**	**374.70**	**66.99**
(16) Turkeys in free range with litter floor	**8.42**	**1.51**	**383.02**	**68.48**
(17) Geese in free range with litter floor	**6.32**	**1.13**	**287.55**	**51.41**
(18) Ducks in free range with litter floor	**8.90**	**1.59**	**404.67**	**72.35**

Values on bold are considered above the trigger value 0.1 µg/L for groundwater.

- ***Local PEC values for the emission pathway via STP***

PECs for groundwater was included in the table above in the estimation of the local PECs for the terrestrial compartment for the emission pathway via STP. This $PEC_{local\ groundwater}$ was estimated according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015) as a first worse-case estimation.

ES-CA:

Recalculated PECs values for groundwater were included in the tables above for both emission pathway via manure and via STP.

PEC in air

Following Iodine's CAR, exposure to air is not considered for Iodide and Iodate as they are assumed not to be volatile. Moreover, taking into account the high background values of iodine in air, emission to air resulting from application of iodine as disinfectant is not considered to be relevant.

Regarding propan-2-ol, the respective's AR stablishes that there are no ecotoxicological data on animal species for the air compartment available, no quantitative characterization of risk by comparison of the PECair to PNECair is possible. Furthermore, as the current intended use of the b.p. for PT3 is limited to indoor application and on basis of the available substance

information, the environmental risk of propan-2-ol for the atmosphere can be assumed as low too.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: According to the TGD on Risk Assessment (ECB Part II, 2003) there is currently no appropriate guidance to calculate a $PNEC_{air}$.
Therefore, the risk of its use can be considered acceptable for the atmosphere.

ES-CA:

Considering the high background concentrations of iodine in air, emission to air resulting from the application of iodine as a disinfectant is not considered to be relevant.

Regards the propan 2-ol taking into account that is a very volatile substance, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air (ENV 188, TAB 2021). In addition, there is not a standard procedure to derive a PNEC for air compartment and taking into account the low value of PEC vía STP, no environmental hazard is expected.

Sewage treatment plant (STP)

The following table shows the derived risk from the corresponding PEC for each scenario and substance:

Poultry systems	**$PEC/PNEC_{STP}$**		**HQi = $\Sigma(PEC/PNEC)_i$**
	Iodine	**Propan-2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	4.85E-03	3.70E-03	8.55E-03
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	9.25E-03	7.05E-03	1.63E-02
(12) Broilers in free range with litter floor	7.18E-03	5.47E-03	1.27E-02
(16) Turkeys in free range with litter floor	2.15E-02	1.64E-02	3.79E-02
(17) Geese in free range with litter floor	1.62E-02	1.23E-02	2.85E-02
(18) Ducks in free range with litter floor	1.29E-02	9.86E-03	2.28E-02

Conclusion: The risk assessment for sewage treatment plants resulted below 1 which indicates acceptable risk for this compartment.

ES-CA:

Recalculated risk assessment for sewage treatment plants.

Poultry systems	PEC/PNEC $_{STP}$				HQi = $\Sigma(PEC/PNEC)_i$
	Iodine	**Iodate**	**Iodide**	**Propan2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	0.02			0.0009	0.02
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.02			0.0009	0.02
(12) Broilers in free range with litter floor	0.01			0.0005	0.01
(16) Turkeys in free range with litter floor	0.04			0.0016	0.04
(17) Ducks in free range with litter floor	0.03			0.0010	0.03
(18) Geese in free range with litter floor	0.03			0.0012	0.03

Conclusion: The PEC/PNEC ratio for the STP was found to be less than 1 and thus not indicating an unacceptable risk to the STP.

Aquatic compartment

GERM-IOD product is intended to be used in the disinfection of floors, walls and ceilings and technical equipment in animal house by spraying or sprinkling methods. It is also intended to be used in footbaths for the disinfection of operator's footwear. Risk of contamination to the aquatic compartment comprises the risk to surface water and sediment after emission of the contaminant via wastewater through STP or WWTP and after manure application to soil.

Risk quotients for the different exposure scenarios for STP, surface water and sediment are presented below. The environmental exposure of Iodine, formulated as a 2.5% SL formulation and applied as liquid, was assessed in accordance with the Technical Guidance Documents (TGDs) and relevant OECD exposure scenario document for PT3 products for professional uses which let to generates Predicted Environmental Concentrations (PECs) and Predicted Initial Environmental Concentrations after manure discharges to all relevant compartments.

Surface water

- Derived from the emission pathway via manure/slurry

Subcat (*i1*)	PEC sw /PNECsw								HQi = Σ(PEC/PNEC)$_i$	
	Iodine		Iodate		Iodide		Propan-2-ol			
	grass	arable	grass	arable	grass	arable	grass	arable	grass	arable
(1) Dairy cows	0.13	0.03	0.003	0.001	0.09	0.022	0.001	0.000	0.22	0.053
(2) Beef cattle	0.04	0.01	0.001	0.000	0.03	0.006	0.000	0.000	0.07	0.016
(3) Veal calves	0.32	0.07	0.007	0.002	0.23	0.053	0.003	0.001	0.56	0.126
(4) Sows, in individual pens	0.46	0.05	0.009	0.001	0.32	0.038	0.004	0.001	0.79	0.09
(5) Sows in groups	0.58	0.07	0.012	0.001	0.41	0.048	0.006	0.001	**1.01**	0.12
(6) Fattening pigs	0.38	0.04	0.008	0.001	0.27	0.031	0.004	0.000	0.66	0.072
(7) Laying hens in battery cages without treatment	0.07	0.02	0.001	0.000	0.05	0.011	0.001	0.000	0.12	0.031
(8) Laying hens in battery cages with aeration (belt drying)	0.08	0.02	0.002	0.000	0.05	0.012	0.001	0.000	0.13	0.032
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	0.12	0.03	0.003	0.001	0.09	0.020	0.001	0.000	0.21	0.051
(10) Laying hens in compact battery cages	0.08	0.02	0.002	0.000	0.05	0.012	0.001	0.000	0.13	0.032
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.19	0.04	0.004	0.001	0.14	0.032	0.002	0.000	0.34	0.073
(12) Broilers in free range with litter floor	0.74	0.09	0.015	0.002	0.52	0.067	0.007	0.001	**1.28**	0.16
(13) Laying hens in free range with grating floor (aviary system)	0.14	0.03	0.003	0.001	0.10	0.023	0.001	0.000	0.24	0.054
(14) Parent broilers in free range with grating floor	0.64	0.08	0.013	0.002	0.46	0.059	0.006	0.001	**1.12**	0.142
(15) Parent broilers in rearing with grating floor	**1.40**	0.18	0.029	0.004	0.99	0.128	0.013	0.002	**2.43**	0.314
(16) Turkeys in free range with litter floor	**1.43**	0.18	0.030	0.004	**1.01**	0.131	0.014	0.002	**2.48**	0.317
(17) Geese in free range with litter floor	**1.07**	0.14	0.022	0.003	0.76	0.098	0.010	0.001	**1.86**	0.242
(18) Ducks in free range with litter floor	**1.51**	0.19	0.031	0.004	**1.07**	0.138	0.014	0.002	**2.63**	0.334

ES-CA: Recalculated risk assessment for surface water via manure/slurry

PEC/PNEC water		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
IODINE	GRASS	3,02	1,54	10,80	6,52	7,43	5,26	3,68	5,15	3,18	2,62	8,54	3,60	4,62	2,55	5,48	6,87	7,33	5,18
	ARABLE	0,46	0,23	1,63	1,18	1,34	0,95	0,55	0,78	0,48	0,40	1,29	2,22	0,70	1,57	3,37	4,22	4,51	3,18
IODATE	GRASS	0,04	0,02	0,15	0,09	0,10	0,07	0,05	0,07	0,04	0,04	0,12	0,05	0,06	0,04	0,08	0,10	0,10	0,07
	ARABLE	0,01	0,00	0,02	0,02	0,02	0,01	0,01	0,01	0,01	0,01	0,02	0,03	0,01	0,02	0,05	0,06	0,06	0,04
IODIDE	GRASS	2,15	1,09	7,68	4,63	5,28	3,74	2,61	3,66	2,26	1,86	6,07	2,56	3,29	1,81	3,89	4,88	5,21	3,68
	ARABLE	0,32	0,16	1,16	0,84	0,96	0,68	0,39	0,55	0,34	0,28	0,92	1,57	0,50	1,11	2,39	3,00	3,20	2,26
PROPAN 2 OL	GRASS	0,0003	0,0002	0,0011	0,0007	0,0008	0,0005	0,0004	0,0007	0,0003	0,0003	0,0017	0,0007	0,0005	0,0003	0,0006	0,0014	0,0015	0,0010
	ARABLE	0,0001	0,0000	0,0003	0,0002	0,0002	0,0002	0,0001	0,0002	0,0001	0,0001	0,0004	0,0007	0,0001	0,0003	0,0006	0,0014	0,0015	0,0011
HQi = Σ(PEC/PNEC)i	GRASS	5,21	2,65	18,64	11,24	12,81	9,07	6,34	8,87	5,48	4,52	14,73	6,22	7,97	4,39	9,45	11,85	12,65	8,93
	ARABLE	0,79	0,40	2,81	2,03	2,32	1,64	0,96	1,34	0,83	0,68	2,22	3,82	1,20	2,70	5,81	7,28	7,78	5,49

- Derived from the emission pathway via STP

Poultry systems	**PEC/PNEC$_{sw}$**				**HQi = Σ(PEC/PNEC)$_i$**
	Iodine	**Iodate**	**Iodide**	**Propan-2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	**1.91**	0.04	**1.36**	1.64E-04	**3.31**
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	**3.63**	0.08	**2.58**	3.12E-04	**6.29**
(12) Broilers in free range with litter floor	**2.82**	0.06	**2.01**	2.42E-04	**4.89**
(16) Turkeys in free range with litter floor	**8.46**	0.18	**6.02**	7.27E-04	**14.66**
(17) Geese in free range with litter floor	**6.35**	0.13	**4.52**	5.46E-04	**11.00**
(18) Ducks in free range with litter floor	**5.08**	0.11	**3.61**	4.37E-04	**8.80**

ES-CA: Recalculated risk assessment for surface water via STP

Poultry systems	**PEC/PNEC water**				**HQi = Σ(PEC/PNEC)$_i$**
	Iodine	**Iodate**	**Iodide**	**Propan2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	11,15	0,16	7,93	0,0003	19,24
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	11,69	0,16	8,31	0,0003	20,17
(12) Broilers in free range with litter floor	6,90	0,10	4,90	0,0002	11,90
(16) Turkeys in free range with litter floor	20,34	0,28	14,46	0,0006	35,08
(17) Ducks in free range with litter floor	12,37	0,17	8,80	0,0003	21,34
(18) Geese in free range with litter floor	15,34	0,21	10,90	0,0004	26,46

Sediment

- Derived from the emission pathway via manure/slurry

Subcat (*i1*)	**PEC /PNECsed**	
	Propan-2-ol	
	grass	**arable**
(1) Dairy cows	0.001	0.000
(2) Beef cattle	0.000	0.000
(3) Veal calves	0.003	0.001
(4) Sows, in individual pens	0.004	0.001
(5) Sows in groups	0.006	0.001
(6) Fattening pigs	0.004	0.000
(7) Laying hens in battery cages without treatment	0.001	0.000
(8) Laying hens in battery cages with aeration (belt drying)	0.001	0.000

Subcat (*i1*)	PEC /PNECsed	
	Propan-2-ol	
	grass	arable
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	0.001	0.000
(10) Laying hens in compact battery cages	0.001	0.000
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.002	0.000
(12) Broilers in free range with litter floor	0.007	0.001
(13) Laying hens in free range with grating floor (aviary system)	0.001	0.000
(14) Parent broilers in free range with grating floor	0.006	0.001
(15) Parent broilers in rearing with grating floor	0.013	0.002
(16) Turkeys in free range with litter floor	0.014	0.002
(17) Geese in free range with litter floor	0.010	0.001
(18) Ducks in free range with litter floor	0.014	0.002

- Derived from the emission pathway via STP

Poultry systems	**PEC/PNEC$_{Sed}$**
	Propan-2-ol
(8) Laying hens in battery cages with aeration (belt drying)	0.0002
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.0003
(12) Broilers in free range with litter floor	0.0002
(16) Turkeys in free range with litter floor	0.0007
(17) Geese in free range with litter floor	0.0005
(18) Ducks in free range with litter floor	0.0004

Conclusion:

Considering the potential risks for surface water derived from the evaluation made, it should be taken into account the fact that the natural background concentrations of Iodine in the aquatic compartment are higher (typically 0.02 mg/L) than the calculated PECs, although the $PNEC_{aquatic}$ value is lower, which demonstrates that the use of this product will not cause any risk to aquatic species in the environment. On the other hand, regarding the risk of the metabolite Iodide, it should be also taken into account that it has been considered that the 100% of Iodine is transformed into Iodide in the aquatic compartment (due to the lack of specific data from the CAR and from the a.s. supplier) and this assumption causes a clear overestimation of the risk for this metabolite .

According to BPR Guidance of R.A. vol. IV, Part B, active substances with a Koc lower than 500 cm^3/g are not probable to be adsorbed by the sediment. Therefore and following Iodine's CAR, RCR of this compartment was not evaluated because the environmental risk is not foreseeable.

Aquatic compartment can be considered out of risk.

ES-CA:

Conclusion

The PEC/PNEC values for iodine and/or iodide were found to be greater than 1 as a result of the application of slurry/manure on grassland and/or arable land and via STP. Even though the PEC/PNEC values exceed the trigger value of 1, the PEC values are still within

the range of the natural background concentrations of iodine in surface waters (0.5 -20 µg/L).

PEC value for sediment was not evaluated by ES-CA.

Terrestrial compartment

- Derived from the emission pathway via manure/slurry

Subcat (*i1*)	PEC/PNECsoil after one manure application on arable or four manure applications on grassland without degradation								HQi = $\Sigma(PEC/PNEC)_i$	
	Iodine		Iodate		Iodide		Propan-2-ol			
	grass	arable	grass	arable	grass	arable	grass	arable	grass	arable
(1) Dairy cows	0.259	0.065	0.010	0.003	0.710	0.178	0.016	0.004	1	0.25
(2) Beef cattle	0.077	0.019	0.003	0.001	0.211	0.053	0.005	0.001	0.3	0.074
(3) Veal calves	0.629	0.157	0.024	0.006	**1.727**	0.432	0.039	0.010	**2.42**	0.605
(4) Sows, in individual pens	0.895	0.112	0.035	0.004	**2.456**	0.307	0.056	0.007	**3.44**	0.43
(5) Sows in groups	**1.135**	0.142	0.044	0.006	**3.114**	0.389	0.071	0.009	**4.36**	0.546
(6) Fattening pigs	0.739	0.092	0.029	0.004	**2.028**	0.253	0.046	0.006	**2.84**	0.355
(7) Laying hens in battery cages without treatment	0.133	0.033	0.005	0.001	0.364	0.091	0.008	0.002	0.51	0.127
(8) Laying hens in battery cages with aeration (belt drying)	0.148	0.037	0.006	0.001	0.406	0.101	0.009	0.002	0.57	0.141
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	0.237	0.059	0.009	0.002	0.649	0.162	0.015	0.004	0.91	0.227
(10) Laying hens in compact battery cages	0.148	0.037	0.006	0.001	0.406	0.101	0.009	0.002	0.57	0.141
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.376	0.094	0.015	0.004	**1.032**	0.258	0.024	0.006	**1.45**	0.362
(12) Broilers in free range with litter floor	**1.440**	0.200	0.056	0.008	**3.951**	0.549	0.090	0.013	**5.54**	0.77
(13) Laying hens in free range with grating floor (aviary system)	0.278	0.070	0.011	0.003	0.764	0.191	0.017	0.004	**1.07**	0.268
(14) Parent broilers in free range with grating floor	**1.261**	0.175	0.049	0.007	**3.461**	0.481	0.079	0.011	**4.85**	0.674
(15) Parent broilers in rearing with grating floor	**2.735**	0.380	0.106	0.015	**7.507**	**1.043**	0.171	0.024	**10.5**	**1.462**
(16) Turkeys in free range with litter floor	**2.796**	0.388	0.109	0.015	**7.673**	**1.066**	0.175	0.024	**10.8**	**1.493**
(17) Geese in free range with litter floor	**2.099**	0.292	0.081	0.011	**5.761**	0.800	0.131	0.018	**8.07**	**1.121**
(18) Ducks in free range with litter floor	**2.954**	0.410	0.115	0.016	**8.107**	**1.126**	0.185	0.026	**11.4**	**1.578**

Subcat (*i1*)	PEC/PNECsoil after one manure application on arable or four manure applications on grassland with degradation								HQi = Σ(PEC/PNEC)$_i$	
	Iodine		Iodate		Iodide		Propan-2-ol			
	grass	arable	grass	arable	grass	arable	grass	arable	grass	arable
(1) Dairy cows	0.187	0.047	0.007	0.002	0.512	0.128	0.012	0.003	0.72	0.18
(2) Beef cattle	0.056	0.014	0.002	0.001	0.152	0.038	0.003	0.001	0.21	0.054
(3) Veal calves	0.454	0.113	0.018	0.004	**1.246**	0.311	0.028	0.007	**1.75**	0.435
(4) Sows, in individual pens	0.646	0.081	0.025	0.003	**1.772**	0.221	0.040	0.005	**2.48**	0.31
(5) Sows in groups	0.818	0.102	0.032	0.004	**2.246**	0.281	0.051	0.006	**3.15**	0.393
(6) Fattening pigs	0.533	0.067	0.021	0.003	**1.463**	0.183	0.033	0.004	**2.05**	0.257
(7) Laying hens in battery cages without treatment	0.096	0.024	0.004	0.001	0.262	0.066	0.006	0.001	0.37	0.092
(8) Laying hens in battery cages with aeration (belt drying)	0.107	0.027	0.004	0.001	0.293	0.073	0.007	0.002	0.41	0.103
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	0.171	0.043	0.007	0.002	0.468	0.117	0.011	0.003	0.66	0.165
(10) Laying hens in compact battery cages	0.107	0.027	0.004	0.001	0.293	0.073	0.007	0.002	0.41	0.103
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.271	0.068	0.011	0.003	0.744	0.186	0.017	0.004	**1.04**	0.261
(12) Broilers in free range with litter floor	**1.039**	0.144	0.040	0.006	**2.850**	0.396	0.065	0.009	**3.99**	0.555
(13) Laying hens in free range with grating floor (aviary system)	0.201	0.050	0.008	0.002	0.551	0.138	0.013	0.003	0.77	0.193
(14) Parent broilers in free range with grating floor	0.910	0.126	0.035	0.005	**2.497**	0.347	0.057	0.008	**3.5**	0.486
(15) Parent broilers in rearing with grating floor	**1.973**	0.274	0.077	0.011	**5.415**	0.752	0.123	0.017	**7.59**	**1.054**
(16) Turkeys in free range with litter floor	**2.017**	0.280	0.078	0.011	**5.535**	0.769	0.126	0.018	**7.76**	**1.078**
(17) Geese in free range with litter floor	**1.514**	0.210	0.059	0.008	**4.156**	0.577	0.095	0.013	**5.82**	0.808
(18) Ducks in free range with litter floor	**2.131**	0.296	0.083	0.011	**5.848**	0.812	0.133	0.019	**8.2**	**1.138**

Subcat (*i1*)	PEC/PNEC after 10 year consecutive application, degradation in soil included								HQi = $\Sigma(PEC/PNEC)_i$	
	Iodine		Iodate		Iodide		Propan-2-ol			
	grass	arable	grass	arable	grass	arable	grass	arable	grass	arable
(1) Dairy cows	0.201	0.065	0.008	0.003	0.552	0.178	0.013	0.004	0.77	0.25
(2) Beef cattle	0.060	0.019	0.002	0.001	0.164	0.053	0.004	0.001	0.23	0.074
(3) Veal calves	0.489	0.157	0.019	0.006	**1.342**	0.432	0.031	0.010	**1.88**	0.605
(4) Sows, in individual pens	0.695	0.112	0.027	0.004	**1.908**	0.307	0.043	0.007	**2.67**	0.43
(5) Sows in groups	0.882	0.142	0.034	0.006	**2.419**	0.389	0.055	0.009	**3.39**	0.546
(6) Fattening pigs	0.574	0.092	0.022	0.004	**1.576**	0.254	0.036	0.006	**2.21**	0.356
(7) Laying hens in battery cages without treatment	0.103	0.033	0.004	0.001	0.283	0.091	0.006	0.002	0.4	0.127
(8) Laying hens in battery cages with aeration (belt drying)	0.115	0.037	0.004	0.001	0.315	0.101	0.007	0.002	0.44	0.141
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	0.184	0.059	0.007	0.002	0.505	0.162	0.011	0.004	0.71	0.227
(10) Laying hens in compact battery cages	0.115	0.037	0.004	0.001	0.315	0.101	0.007	0.002	0.44	0.141
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.292	0.094	0.011	0.004	0.802	0.258	0.018	0.006	**1.12**	0.362
(12) Broilers in free range with litter floor	**1.119**	0.200	0.043	0.008	**3.070**	0.549	0.070	0.013	**4.3**	0.77
(13) Laying hens in free range with grating floor (aviary system)	0.216	0.070	0.008	0.003	0.593	0.191	0.014	0.004	0.83	0.268
(14) Parent broilers in free range with grating floor	0.980	0.175	0.038	0.007	**2.689**	0.481	0.061	0.011	**3.77**	0.674
(15) Parent broilers in rearing with grating floor	**2.125**	0.380	0.082	0.015	**5.833**	**1.043**	0.133	0.024	**8.17**	**1.462**
(16) Turkeys in free range with litter floor	**2.173**	0.388	0.084	0.015	**5.962**	**1.066**	0.136	0.024	**8.36**	**1.493**
(17) Geese in free range with litter floor	**1.631**	0.292	0.063	0.011	**4.476**	0.800	0.102	0.018	**6.27**	**1.121**
(18) Ducks in free range with litter floor	**2.295**	0.410	0.089	0.016	**6.299**	**1.126**	0.144	0.026	**8.83**	**1.578**

ES-CA: Recalculated risk assessment for soil. There are only included the PEC/PNEC after 10-year consecutive application, degradation in soil included.

PEC/PNEC soil		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
IODINE	GRASS	7,91	4,03	28,31	17,08	19,46	13,77	9,63	13,48	8,32	6,87	22,37	9,44	12,11	6,67	14,35	18,00	19,21	13,56
	ARABLE	1,19	0,61	4,27	3,09	3,52	2,49	1,45	2,03	1,25	1,04	3,37	5,80	1,83	4,10	8,82	11,06	11,81	8,34
IODATE	GRASS	0,42	0,22	1,51	0,91	1,04	0,74	0,52	0,72	0,44	0,37	1,20	0,50	0,65	0,36	0,77	0,96	1,03	0,73
	ARABLE	0,06	0,03	0,23	0,17	0,19	0,13	0,08	0,11	0,07	0,06	0,18	0,31	0,10	0,22	0,47	0,59	0,63	0,45
IODIDE	GRASS	21,70	11,06	77,68	46,86	53,41	37,79	26,42	36,99	22,83	18,84	61,39	25,90	33,24	18,31	39,38	49,38	52,73	37,22
	ARABLE	3,27	1,67	11,71	8,48	9,66	6,84	3,98	5,58	3,44	2,84	9,26	15,93	5,01	11,26	24,21	30,36	32,41	22,88
PROPAN 2 OL	GRASS	0,0090	0,0046	0,0323	0,0195	0,0222	0,0157	0,0110	0,0220	0,0095	0,0078	0,0511	0,0215	0,0138	0,0076	0,0164	0,0411	0,0439	0,0310
	ARABLE	0,0022	0,0011	0,0080	0,0058	0,0066	0,0047	0,0027	0,0054	0,0023	0,0019	0,0126	0,0217	0,0034	0,0077	0,0165	0,0414	0,0442	0,0312
HQi = Σ(PEC/PNEC)i	GRASS	30,05	15,31	107,53	64,87	73,94	52,32	36,58	51,21	31,60	26,09	85,01	35,87	46,02	25,34	54,51	68,38	73,01	51,54
	ARABLE	4,53	2,31	16,22	11,74	13,38	9,47	5,52	7,72	4,77	3,93	12,82	22,06	6,94	15,58	33,52	42,05	44,90	31,70

- Derived from the emission pathway via STP

Poultry systems	**PEC_{soil} / $PNEC_{soil}$**			**HQi = Σ(PEC/PNEC)$_i$**
	Iodine	**Iodate**	**Iodide**	
(8) Laying hens in battery cages with aeration (belt drying)	0.042	0.002	0.116	0.16
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.080	0.003	0.221	0.304
(12) Broilers in free range with litter floor	0.062	0.002	0.171	0.235
(16) Turkeys in free range with litter floor	0.187	0.007	0.514	0.708
(17) Geese in free range with litter floor	0.141	0.005	0.386	0.532
(18) Ducks in free range with litter floor	0.113	0.004	0.309	0.426

ES-CA: Recalculated risk assessment for soil via STP.

Poultry systems	**PEC/PNEC soil**				**HQi = Σ(PEC/PNEC)$_i$**
	Iodine	**Iodate**	**Iodide**	**Propan2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	34,75	1,86	1,33	0,0004	37,94
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	36,44	1,95	1,40	0,0004	39,79
(12) Broilers in free range with litter floor	21,36	1,14	0,82	0,0002	23,32
(16) Turkeys in free range with litter floor	63,31	3,39	2,43	0,0007	69,12
(17) Ducks in free range with litter floor	38,39	2,05	1,47	0,0004	41,92
(18) Geese in free range with litter floor	47,63	2,55	1,83	0,0005	52,01

Conclusion: In most of the cases, the calculated RCR values in soil are below 1 for iodate, iodide and iodine with the exception of punctual cases where RCR values are slightly above 1. In the rest of all scenarios, the risk is considered acceptable.

Considering the potential risks for soil derived from the evaluation made, it should be taken into account the fact that the natural background concentrations of Iodine in the soil compartment are higher (global mean value 5 mg/kg) than the calculated PECs, although the PNECsoil value is much lower, which demonstrates that the use of this product will not cause any risk to terrestrial species in the environment. On the other hand, regarding the risk of the metabolite Iodide, it should be also taken into account that it has been considered that the 100% of Iodine is transformed into Iodide in the terrestrial compartment (due to the lack of specific data from the CAR and from the a.s. supplier) and this assumption causes a clear overestimation of the risk for this metabolite.

ES-CA:

Conclusion
The risk assessment for the soil compartment revealed that the PEC/PNEC values for iodine, iodate and/or iodide related to the exposure vía the STP as well as the PEC/PNEC values for iodide, iodide and/or iodate related to the arable and grass land exceed the trigger value of 1. However, the corresponding PECs are below the natural background concentrations of iodine in soil (0.5-20 mg/kg dwt). So, it can be concluded that the use of the product does not pose an unacceptable risk to the soil compartment.

Groundwater

Exposure to groundwater may arise from different routes depending on the application pattern of the product:

- *Emission via wastewater to STP* leading to releases to soil via sewage sludge deposition in agricultural soil and, subsequently, to groundwater (indoor application in animal housing and further release of wastewater/slurry and in domestic/commercial/industrial areas with wet cleaning of treated surfaces)
- *Emission via manure application* leading to releases to agricultural and grassland soil and subsequently, to groundwater (indoor application in animal housing).

Subcat (*i1*)	**PECgroundwater (µg/L)**			
	Iodine, iodate, iodide		**Propan-2-ol**	
	grass	**arable**	**grass**	**arable**
(1) Dairy cows	**0.78**	**0.25**	**35.44**	**11.41**
(2) Beef cattle	**0.23**	0.07	**10.54**	**3.39**
(3) Veal calves	**1.90**	**0.61**	**86.20**	**27.74**
(4) Sows, in individual pens	**2.70**	**0.43**	**122.59**	**19.73**
(5) Sows in groups	**3.42**	**0.55**	**155.42**	**25.01**
(6) Fattening pigs	**2.23**	**0.36**	**101.22**	**16.29**
(7) Laying hens in battery cages without treatment	**0.40**	**0.13**	**18.15**	**5.84**
(8) Laying hens in battery cages with aeration (belt drying)	**0.45**	**0.14**	**20.26**	**6.52**
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	**0.71**	**0.23**	**32.41**	**10.43**
(10) Laying hens in compact battery cages	**0.45**	**0.14**	**20.26**	**6.52**
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	**1.13**	**0.36**	**51.51**	**16.58**
(12) Broilers in free range with litter floor	**4.34**	**0.78**	**197.24**	**35.27**
(13) Laying hens in free range with grating floor (aviary system)	**0.84**	**0.27**	**38.12**	**12.27**
(14) Parent broilers in free range with grating floor	**3.80**	**0.68**	**172.75**	**30.89**
(15) Parent broilers in rearing with grating floor	**8.24**	**1.47**	**374.70**	**66.99**
(16) Turkeys in free range with litter floor	**8.42**	**1.51**	**383.02**	**68.48**
(17) Geese in free range with litter floor	**6.32**	**1.13**	**287.55**	**51.41**
(18) Ducks in free range with litter floor	**8.90**	**1.59**	**404.67**	**72.35**

Conclusion:

According to Directive 2006/118/EC, the maximum allowed concentration of a chemical in groundwater is 0.1µg/L. First tier risk assessment was performed for the product GERM-IOD according to the relevant emission scenarios (OECD exposure scenario document for PT3 products for professional uses. PECgw values are above the limit value in same cases of scenarios assessed where emission occurs after STP/WWTP sludge application in soil and further leachate to groundwater of the active substance. Application in poultry facilities according to the application patterns for footbaths proposed is safe with regards to the groundwater compartment. On the other hand PECgw values obtained for animal housing are above the trigger value of 0.1µg/L and in some cases (i.e. ducks) above the mean natural background concentration of 1µg/L. In any case, they are still below the maximum natural background concentration of 70µg/L. Therefore, no risk is expected for this compartment. However PECgw concentrations derived for propan-2-ol are above the trigger value so a second tier 2 is developed by using FOCUS PEARL.

It is important to bear in mind that both Iodine and propan-2-ol are regarded as readily biodegradable in soil with a DT50 below of 30 days. In order to refine the risk derived from the scenarios of disinfection before, PECgw was calculated using FOCUS PEARL 4.4.4. The following input data as worse case Scenario 1 (i1=18) – Indoor application at ducks in free range with litter floor, for both substances: Iodine and Propan-2-ol.

The application dosage to use in FOCUS PEARL for each substance is estimated by the following equation:

Dosage applied in PEARL (kg/ha/year) for grassland scenario = PIECgrass4-N x DEPTHgr x RHOsoil_wet x 0.01 = PIECgrass4-N x 0.85

Dosage applied in PEARL (kg/ha/year) for arable land scenario = PIECarab x DEPTHarable x RHOsoil_wet x 0.01 = PIECarab x 3.4

Where:

PIECgrass4-N is the $PIEC_{soil,grassland}$, estimated according equation 24 from ESD Addendum 2015 for four manure application events with no degradation.

PIECars is the $PIEC_{soil,arableland}$ is the initial concentration of the active substance in soil of arable land after 1 manure/slurry application based on nitrogen immission standard for arable land [mg/kg] according to OECD ESD PT18 No.14 (2006) and to the Addendum (Nov.2015).

DEPTHgr is the default value for mixing depth with soil, grassland by spreading (0.05 m).

RHOsoil_wet is the density of wet bulk soil (1700 $kg.m^{-3}$).

- *Grassland:*

Iodine: Appl_rate = 3.1E-02 x 0.05 x 1700 x 0.01 = 0.02635 kg/ha/year

Propan-2-ol: Appl_rate = 8.14E-02 x 0.05 x 1700 x 0.01 = 6.92E-02 kg/ha/year

- *Arable land:*

Iodine: Appl_rate = 4.84E-03 x 3.4 = 0.0164 kg/ha/year

Propan-2-ol: Appl_rate = 1.27E-02 x 3.4 = 0.043 kg/ha/year

The appl_rates before and the following chemical parameters are used for FOCUS PEARL simulations.

Parameter	substance	Value	Unit	Origin
Molar mass	Iodine	253.81	[g.mol-1]	S
	Propan-2-ol	60.09		
Solubility in water (at test temperature)	Iodine	290	[mg.L-1]	S
	Propan-2-ol	1E+05		
Molar enthalpy of dissolution		27	[kJ.mol-1]	D
Vapour pressure (at test temperature)	Iodine	40.7	[Pa]	S
	Propan-2-ol	5780		
Molar enthalpy of vaporisation		95	[kJ.mol-1]	D
Diffusion coefficient in water		4.3E-05	[m2.d-1]	D
Gas diffusion coefficient		0.43	[m2.d-1]	D
Reference temperature to degradation, vaporization and dissolution		20	[ºC]	D
Exponent for the effect of liquid (degradation moisture relationship)		0.7	[-]	D
Sorption to soil organic carbon (Koc or Kom) (Kom = Koc / 1.724)	Iodine	96.17	[$dm^3.kg^{-1}$]	S
	Propan-2-ol	1.91		
Exponent of the Freundlich-Isotherm (1/n)		0.9	[-]	D/S
DT50 (20°C)	Iodine	30	[d]	S
	Propan-2-ol	30		
Arrhenius activation energy		65.4	[kJ.mol-1]	D
Plant uptake factor		0	[-]	D

Outputs below show the predicted 80th concentrations for each substance in groundwater:

Concentration closest to the 80th percentile [µg·L^{-1}]				
Ground land Scenarios	**Iodine**		**Propan-2-ol**	
	Alfalfa (grassland)	**Maize (arable land)**	**Alfalfa (grassland)**	**Maize (arable land)**
Châteaudun	0.000000	0.000000	**1.922871**	**0.906530**
Hamburg	0.000004	0.000000	**7.082559**	**0.249585**
Jokioinen	0.000000	-	**12.237135**	-
Kremsmünster	0.000000	0.000000	**2.984838**	**0.396537**
Okehampton	0.000002	0.000000	**3.462985**	**0.640977**
Piacenza	0.000000	0.000000	**2.225491**	**0.118663**
Porto	0.000000	0.000000	**1.085180**	0.040406
Sevilla	0.000000	0.000000	**0.192086**	0.002192
Thiva	0.000000	0.000000	**0.314302**	0.065421

Values on bold are considered above the trigger value 1E-04 mg/L

Outputs above disclose acceptable risk for groundwater compartment at three locations Porto, Sevilla and Thiva under arable land scenario. Propan-2-ol is considered of concern for groundwater compartment at this stage when it is compared with the trigger value 1E-4 mg/L. However, as it occur with Iodine, the natural background concentration of propan-2-ol could be above this trigger value, which could mean an acceptable risk for this compartment.

ES-CA: Recalulated PECs values for the groundwater via manure/slurry

PECgw[µg/L]		Dairy cows (1)	Beef cattle (2)	Veal calves (3)	Sows, in individual pens (4)	Sows in groups (5)	Fattening pigs (6)	Laying hens in battery cages without treatment (7)	Laing hens in battery cages with aeration (belt drying) (8)	Laying hens in batters cages with forced drying (deep pit, high rise) (9)	Laying hens in compact battery cages (10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (11)	Broilers in free range with litter floor (12)	Laying hens in free range with grating floor (aviary system) (13)	Parent broilers in free range with grating floor (14)	Parent broilers in rearing with grating floor (15)	Turkeys in free range with litter floor (16)	Ducks in free range with litter floor (17)	Geese in free range with litter floor (18)
IODINE	GRASS	17.83	9.09	63.80	38.49	43.87	31.04	21.70	30.38	18.75	15.48	50.43	21.28	27.30	15.04	32.34	40.56	43.31	30.57
	ARABLE	2.69	1.37	9.62	6.96	7.94	5.62	3.27	4.58	2.83	2.33	7.60	13.08	4.12	9.24	19.88	24.93	26.62	18.79
IODATE	GRASS	24.57	12.52	87.93	53.04	60.46	42.78	29.91	41.87	25.84	21.33	69.50	29.32	37.63	20.72	44.57	55.90	59.69	42.13
	ARABLE	3.70	1.89	13.26	9.60	10.94	7.74	4.51	6.31	3.90	3.22	10.48	18.03	5.67	12.74	27.40	34.37	36.69	25.90
IODIDE	GRASS	17.83	9.09	63.80	38.49	43.87	31.04	21.70	30.38	18.75	15.48	50.43	21.28	27.30	15.04	32.34	40.56	43.31	30.57
	ARABLE	2.69	1.37	9.62	6.96	7.94	5.62	3.27	4.58	2.83	2.33	7.60	13.08	4.12	9.24	19.88	24.93	26.62	18.79
PROPAN 2 OL	GRASS	8.6187	4.3930	30.8457	18.6068	21.2098	15.0073	10.4919	20.9838	9.0644	7.4825	48.7582	20.5729	13.1996	7.2700	15.6364	39.2189	41.8751	29.5605
	ARABLE	2.1325	1.0869	7.6319	5.5244	6.2973	4.4557	2.5959	5.1918	2.2427	1.8513	12.0638	20.7522	3.2659	7.3333	15.7727	39.5607	42.2400	29.8182
HQi = Σ(PECgw)i	GRASS	68.84	35.09	246.38	148.62	169.41	119.87	83.80	123.62	72.40	59.77	219.11	92.45	105.43	58.07	124.90	176.24	188.18	132.84
	ARABLE	11.21	5.72	40.13	29.05	33.11	23.43	13.65	20.67	11.79	9.74	37.75	64.94	17.17	38.56	82.94	123.80	132.18	93.31

ES-CA: Recalulated PECs values for the groundwater via STP.

Poultry systems	PECgw [µg/L]				**HQi = Σ(PEC/PNEC)$_i$**
	Iodine	**Iodate**	**Iodide**	**Propan2-ol**	
(8) Laying hens in battery cages with aeration (belt drying)	78.30	107.91	1.10	0.20	187.51
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	82.00	113.01	1.15	0.21	196.37
(12) Broilers in free range with litter floor	48.40	66.70	0.68	0.13	115.91
(16) Turkeys in free range with litter floor	143.00	197.08	2.00	0.37	342.45
(17) Ducks in free range with litter floor	86.90	119.77	1.22	0.22	208.10
(18) Geese in free range with litter floor	108.00	148.85	1.51	0.28	258.63

Conclusion

For the risk assessment for groundwater, the maximum permissible concentration for pesticides laid down in by Directive 98/83/EC is usually applied (limit value of 0.1). According to the definition of "pesticide" in the Directive, this limit value apply to organic compounds and relevant metabolites or breakdown or reaction products, respectively. So, this limit value is not applicable for iodine. Thus, a qualitative risk assessment for groundwater was carried out by comparing the PECs for groundwater with the natural background concentration of iodine reveling that the corresponding PECs sometimes are above the natural background concentrations of iodine in groundwater (1-70 µg/L) but never are above the extreme up of 400 µg/L. So, it can be concluded that the use of the product does not pose an unacceptable risk to the groundwater compartment.

Regards Propan-2-ol, the concentration is greater than the drinking water threshold trigger value of 0.1 µg/ L in both scenarios (via slurry/manure and STP). Following discussions at WG-VII-2018 it was agreed that the following argument forms an acceptable weight of evidence approach to support FOCUS PEARL not offering an appropriate tier 2 refinement for these proposed uses of propan-2-ol.

The FOCUS PEARL model was developed for the determination of groundwater concentrations related to the application of plant protection products (PPP) on agricultural land. Accordingly, the model assumptions for the nine locations rely on e.g. soil properties that are representative for agriculturally used areas in Europe. The unlimited applicability of the model for the very diverse field of biocidal applications is thus questionable. For biocidal applications where the release of active substances to the environment is related to the application of sewage sludge or manure/slurry to agricultural land, the applicability of FOCUS PEARL might be given. In the present case, where volatile compounds are present for which the model is might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.

This discussion is supported by the conclusion at the 21st BPC meeting that if not all nine scenarios show a safe use and the applicability of the models for the substance evaluated can

be questioned, a qualitative approach could be applied using expert judgment in a weight of evidence approach.

An acceptable risk of propan-2-ol to groundwater is therefore expected.

Primary and secondary poisoning

Direct uptake of Iodine after application of GERM-IODin indoor premises is not likely. However, Iodine reaching environmental compartments such as water or soil leads to specific compartment organisms such as fish and earthworms.

Secondary poisoning is of special relevance for substances with a log Kow ≥ 4.5, whereas Iodine's Kow is lower than 3 which indicate that Iodine has a low potential for bioaccumulation in organisms.

ES-CA:

According to the AR for Iodine (Sweden 2013) the bioaccumulation potential for an inorganic substance, as Iodine, is not considered relevant. Furthermore, it was concluded that there was no concern regarding primary and secondary poisoning through the use of Iodine in disinfectants, as the amounts which were released were considered to be negligible compared to the natural occurring background concentrations and the fact that Iodine is an essential element (e.g. for the functioning of the thyroid hormone synthesis).

Mixture toxicity

ES-CA:

Mixture toxicity was not necessary, risk assessments on iodine, iodine species and SoCs are considered to represent a worst-case. However, it can be a good additional information.

Two components of GERM-IOD formulation are considered of concern for the environmental compartment, iodine as the active substance and Propan-2-ol. In view of that, mixture toxicity is foreseeable, and the following screening step is developed:

Screening step

Screening Step 1: Identification of the concerned environmental compartments. These compartments have already been identified in the point "Fate and distribution in exposed environmental compartments".

Screening Step 2: Identification of relevant substances

Summary of available ecotoxicological data of a.s and SoC (mg/L)		
	Relevant component (a.s)	***Relevant SoC***

	Iodide	Iodate	Iodine	Propan-2-ol
Content in the product [w/w %]	2.5	2.5	2.5	6.57
Concerned Aquatic compartment				
Fish LC50	3780	220	1.67	8692
Fish NOEC (21d)	-	-	-	-
Daphnia magna LC50 (48 hr)	0.83	58.5	0.59	2285
Daphnia magna NOEC	-	-	-	141
Algae ErC50 (72 hr)	-	-	1.3	10500
Algae EbC50 (72 hr)	-	-	0.62	-
Algae NOEC (72 hr) (biomass)	-	-	-	-
Algae NOEC (72 hr) (growth rate)	-	-	-	-
Concerned STP compartment (microorganisms)				
Activated sludge EC10 (3 hrs)	-	-	290	1000
Concerned soil compartment (mg/kg d.wt)				
Earthworms LC50 (14 days)	-	-	1000	-
Earthworms NOEC	-	-	125	-

Based on these data of table below, Toxic Units (TU) are calculated for all two product components according to Equation 121 (TUi= Ci/ECxi) from BPR Vol. IV (October 2017):

Toxic units (TU) for each component					
	Relevant component (a.s)			***Relevant SoC***	ΣTU
	Iodide	**Iodate**	**Iodine**	**Propan-2-ol**	
Content in the product [w/w %]	2.5	2.5	2.5	6.57	
Concerned Aquatic compartment					
Fish LC50	0.00	0.01	1.50	0.00	1.51
Fish NOEC (21d)	-	-	-	-	0.00
Daphnia magna LC50 (48 hr)	3.01	0.04	4.24	0.00	7.29
Daphnia magna NOEC	-	-	-	0.05	0.05
Algae ErC50 (72 hr)	-	-	1.92	0.00	1.92
Algae EbC50 (72 hr)	-	-	4.03	-	4.03
Algae NOEC (72 hr) (biomass)	-	-	-	-	0.00
Algae NOEC (72 hr) (growth rate)	-	-	-	-	0.00
Concerned STP compartment (microorganisms)					
Activated sludge EC50 (3 hrs)	-	-	0.01	0.01	0.02
Concerned soil compartment					
Earthworms LC50 (14 days)	-	-	0.003	-	0.003
Earthworms NOEC	-	-	0.02	-	0.02

Finally, the relative TU are calculated according to Equation 122 (rel TU*i* = (TU*i*/ΣTU)/100) from BPR Vol. IV (October 2017). This value gives the weigth of each substance in the ecotoxicological properties of the b.p.:

Summary of relative toxic units (relative TU)

	Relevant component (a.s)			***Relevant SoC***
	Iodide	**Iodate**	**Iodine**	**Propan-2-ol**
Content in the product [w/w %]	2.5	2.5	2.5	6.57
Concerned Aquatic compartment				
Fish LC50	0.04	0.75	99.15	0.05
Fish NOEC (21d)	-	-	-	-
Daphnia magna LC50 (48 hr)	41.29	0.59	58.09	0.04
Daphnia magna NOEC	-	-	-	100.00
Algae ErC50 (72 hr)	-	-	99.97	0.03
Algae EbC50 (72 hr)	-	-	100.00	-
Algae NOEC (72 hr) (biomass)	-	-	-	-
Algae NOEC (72 hr) (growth rate)	-	-	-	-
Concerned STP compartment (microorganisms)				
Activated sludge EC50 (3 hrs)	-	-	56.75	43.25
Concerned soil compartment				
Earthworms LC50 (14 days)	-	-	100.00	-
Earthworms NOEC	-	-	100.00	-

According to this calculation iodine, iodide and Propan-2-ol have to be regarded as relevant for mixture toxicity assessment for aquatic compartment whilst only iodine should be considered as relevant for soil compartment as the a.s. accounts for more than 99% of the toxicity of the mixture.

Screening Step 3: Screen on synergistic interactions

Screening step	
Y	Significant exposure of environmental compartments? (**Y**/N)
Y	Number of relevant substances >1? (**Y**/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/**N**)
	Accordig to Guidance on BPR VolIV-Env Parts B+C (vers 2.0 – October 2017), no synergism interactions are expected between the active substance and the SoC (none of them are included in Appendix 11 of the guidance mentioned before and after extensive bibliography source, no data has been found about it). In view of that, the environmental risk assessment of the biocidal product GERM-IOD must be based on the active substance in its forms of Iodine and idodide and in the substance propan-2-ol.

Overall conclusion on the risk assessment for the environment of the product
• The risk assessment for **sewage treatment plants** indicates a safe use for the b.p. • The risk assessment for **surface water** indicates, for some sub-scenarios, values of iodine higher than the PNEC. However, these PEC estimations are below its natural

background concentration. In view of that, surface water compartment can be considered out of concern.

- The risk assessment for **sediment** indicates a safe use for the b.p.
- The risk assessment for **soil** indicates acceptable risk for the scenarios i1=1, 2, 7-10 and 13. The rest of sub-scenarios showed values of Iodine and Iodide slightly above the respective PNECsoil. It is important to take into account that the natural background concentrations of Iodine in the soil compartment are higher (global mean value 5 mg/kg) than the calculated PECs, although the PNECsoil value is much lower, which demonstrates that the use of this product will not cause any risk to terrestrial species in the environment. On the other hand, regarding the risk of the metabolite Iodide, it should be also taken into account that it has been considered that the 100% of Iodine is transformed into Iodide in the terrestrial compartment (due to the lack of specific data from the CAR and from the a.s. supplier) and this assumption causes a clear overestimation of the risk for this metabolite. In view of that, a safe use can be assumed for the b.p.
- The risk assessment for **groundwater** discloses acceptable risk for all scenarios when the active substance Iodine is considered.

  When Propan-2-ol is taken into account, acceptable risk is obtained for those scenarios where residues are emitted directly to STP, because high percentage of both active substances is considered degradated. Then, poultry sytems sub-scenarios of scenario [1] where local emission is done via waste water scenarios, are deemed at safe.

  In addition, for those sub-scenarios, where release to soil is done as manure/slurry, acceptable risk is foreseen for arable scenarios at Porto, Sevilla and Thiva for a dilution rate of 1.5%.
- For all scenarios, no risk for the **secondary poisoning** is identified.

The following Risk Mitigation Measure is proposed for those scenarios where it may be applied in order to avoid any potential risk for soil or groundwater compartment:

To protect groundwater and soil organisms, application of this product is restricted to areas with a hard standing. Spills and residues containing the product need to be discharged to the sewer with connection to a sewage treatment plant.

ES-CA:

When the product is released to the sewer no unacceptable risk is expected for micro-organisms in the municipal sewage treatment plant, for aquatic organisms in freshwater and for terrestrial organisms in soil. PEC/PNEC ratios are >1, however, the concerned PEC values are well below or within the natural background concentration (ranges).

PECs in groundwater are well above the threshold of 0.1 µg/L. The limit value for pesticides of 0.1 µg/L specified in the Drinking Water Directive 98/83/EC is not applicable for Iodine and its Iodine species since the definition for pesticides is limited to organic substances. The calculated Iodine concentrations are sometimes above the natural background concentration range of 1-70 µg/L, but no exceed the extremes up of 400 µg/L. Although, it must be taken into account that a very worst case was considered in the risk assessment.

Regarding indirect exposure of Iodine via run-off from treated areas after slurry/manure application on grassland and arable land, the PECs for freshwater are within the range

and for soil they are below the typical natural background concentration, indicating that no unacceptable risk for the aquatic and soil compartment is to be expected. All calculated PEC_{GW} values after slurry/manure application on grassland and arable land regarding Iodine are well above the 0.1 µg/L threshold and acceptable human intake limits but below the extremes up value of 400 µg/L of the natural background concentrations. Furthermore, it was concluded that there was no concern regarding primary and secondary poisoning through the use of Iodine in disinfectants.

Aggregated exposure (combined for relevant emmission sources)
Not required

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

Not applicable as the biocidal product is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant

3 ANNEXES[12]

3.1 List of studies for the biocidal product (family)

See PAR confidential for more information.

12 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.2 Output tables from exposure assessment tools

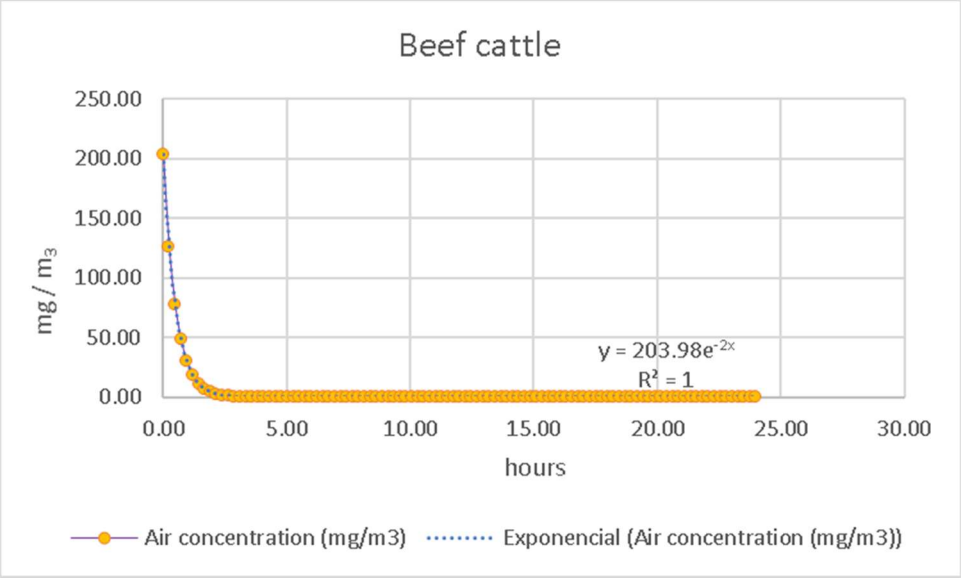
Human Risk Assessment

Exposure Assesment GERM-IO

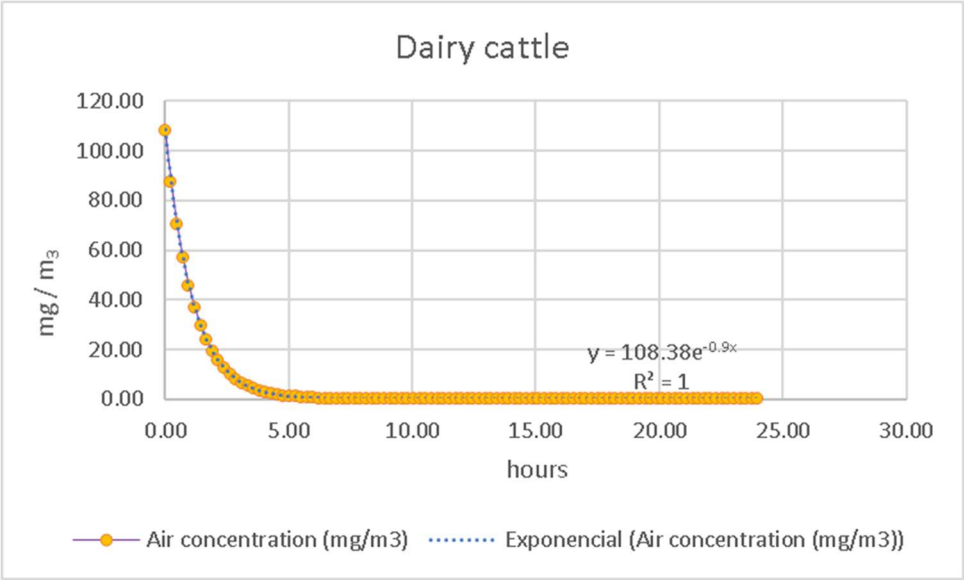
DRA_Livestock Exposure Calculator

Air concentration vs. time for the 6 representative animal species (graphics extracted from ConsExpo web simulations)

a) <u>Beef cattle</u>

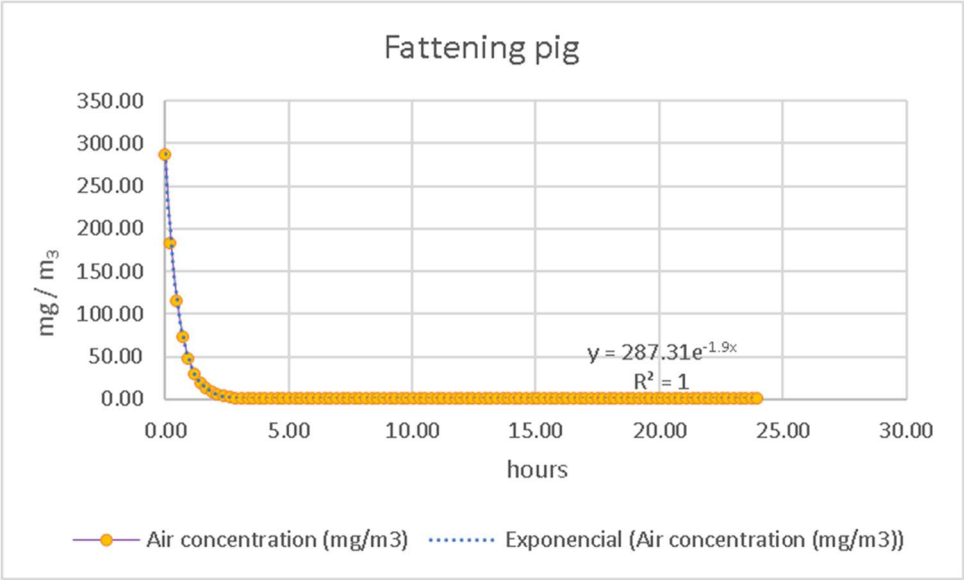


b) <u>Dairy cattle</u>

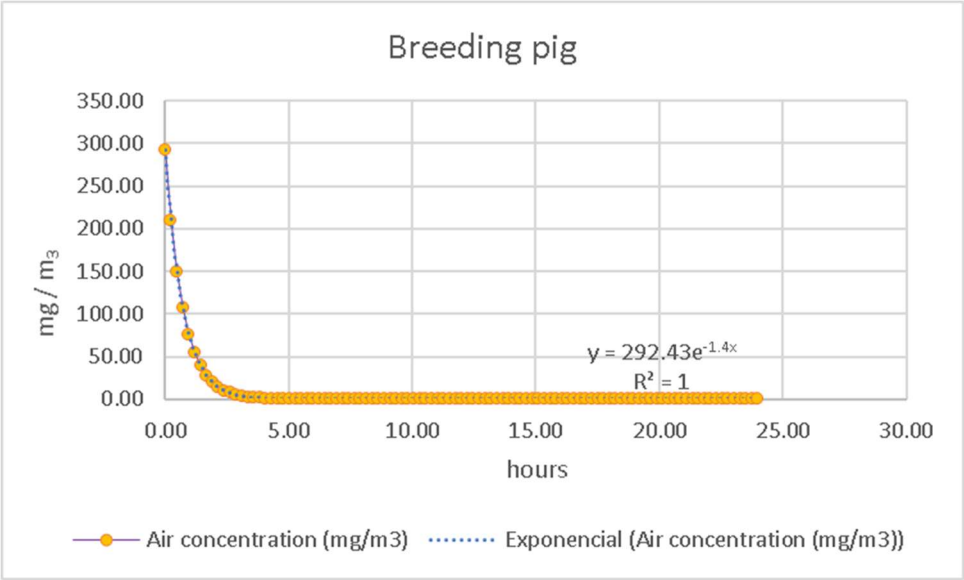


Beef cattle: for x = 24, y = 203.98*exp(-2*24)= 2.91E-19 mg/m^3
Dairy cattle: for x = 24, y = 108.38*exp(-0.9*24)= 4.49E-08 mg/m^3

c) <u>Fattening pig</u>

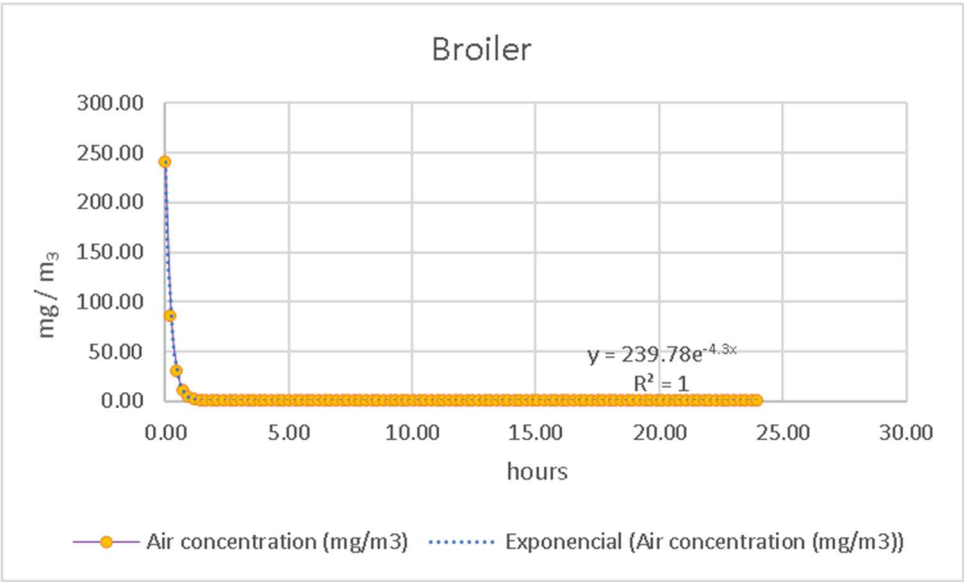


d) <u>Breeding pig</u>

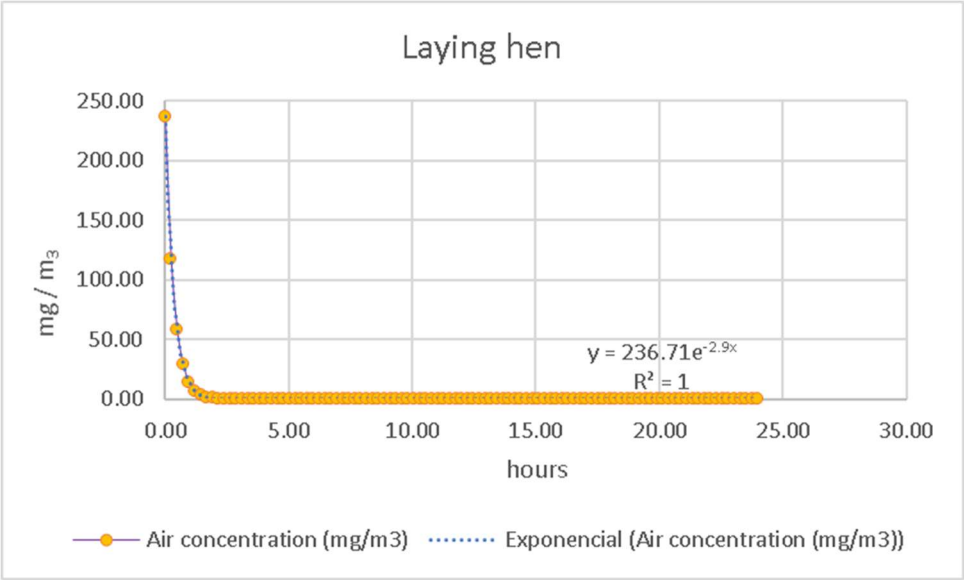


Fattening pig: for x = 24, y = 287.31*exp(-1.9*24)= 4.51E-18 mg/m^3
Breeding pig: for x = 24, y = 292.43*exp(-1.4*24)= 7.47E-13 mg/m^3

e) <u>Broiler chicken</u>



f) <u>Laying hen</u>



Broiler chicken: for x = 24, y = 239.78*exp(-4.3*24)= 3.64E-43 mg/m^3
Laying hen: for x = 24, y = 236.71*exp(-2.9*24)= 1.41E-28 mg/m^3

Environmental Risk Assessment

Scenario [1]: Animal housing

1. Local PEC values for the emission pathway via manure/slurry

In order to cover as many animal scenarios as possible, all the animals contemplated in the guide have been considered in a first stage to calculate the amount of component used in the accommodation or storage of manure for an application. This amount has been calculated as follows:

Qai_prescri= Amount of product prescribed to be used x content of active ingredient / (Area to be treated x 1000000) [Kg] (eq. 10 of OECD ESD. No. 14)

The amount to the manure after one application is estimated following equation 14 of OECD ESD No. 14, which takes into account the fraction release to the manure in function of the type of application and type of animal housing:

Qai = Qai_prescri x Fslurry/manure [kg] (eq. 14 of OECD ESD. No. 14)

The next step consist in the estimation of the substance's amount discharged to the soil over the manure's storage period for grassland and arable land. This estimation takes into account the number of biocides application during manure storage period (Napp_manure) for grass and for arable land which have been estimated according Sections 2.2-2.3 of the OECD ESD No.14 Addendum (2015) and taken into account the use frequency of the biocidal product:

Estimation of number of applications during manure storage (reference: OECD ESD No.14 Sections 2.2-2.3 of the Addendum (2015))

				sows (i1=4, 5, 6)	poultry (i1= 12, 14-18)	veal (i1=1, 2, 3)	Laying hens (i1=7-11, 13)	
number of land application for arable land	Nlapp_arab	[-]	1					d
number of prescribed maximum repeated biocide treatments	Napp_bioc	[-]		2	9	1	1	S
land application interval for arable land	Tar_int	[d]	365					D
period between biocide treatments	Tbioc_int	[d]		183	41	365	365	S
manure storage time arable land in new scenario	Tmanure_int_ar	[d]	212					D
number of biocide applications during manure storage period	**Napp_bio_manure_ar**	[-]		1	5	1	1	O

				sows (i1=4, 5, 6)	poultry (i1= 12, 14-18)	veal (i1=1, 2, 3)	Laying hens (i1=7-11, 13)	
number of repeated treatments prescribed in grassland	Napp prescr			2	9	1	1	S
period between biocide treatments	Tbioc_int	[d]		183	41	365	365	S
land application interval for arable land	Tgr_int	[d]	53					D
maximum number of applications during manure storage period of manure to be spread on grassland	**Napp_manure_gr**	[-]		1	2	1	1	O

Once Napp_manure are calculated for each soil (grass and arable). The correspondent Qai for grassland and arable land was estimated considering equations 16 and 17 respectively from the OECD ESD No. 14.

Qai_grass = Qai x Napp_manure_gr (eq. 16 of OECD ESD. No. 14)

Qai_arab = Qai x Napp_bio_manure_ar (eq. 17 of OECD ESD. No. 14)

The next step consists to estimate the Nitrogen production (Qnitrog_grass and Qnitrog_arab) during the manure storage period for each housing and soil type. This calculation takes into account the number of animals (Nanimal), the Nitrogen production from each animal (Qnitrog) and the default values of Manure application time interval for grassland (Tgr_int=53 d) and arable land (Tar_int = 212 d). These estimations are carried on by following the equations 20 and 21 from OECD ESD No.14.

Qnitrog-grass = Nanimal x Qnitrog x Tgr_int (eq. 20 of OECD ESD. No. 14)

Qnitrog-arab = Nanimal x Qnitrog x Tar_int (eq. 21 of OECD ESD. No. 14)

- **Estimation of PEC soil after one manure application on arable land and four manure applications on grassland without degradation.**

Taken into account section 3.2 from OECD ESD No.14 Addendum 2015, the PIECsoil for grassland after four application events without degradation is estimated (PIECgrass_4-N). This calculation takes into account the nitrogen immission standard for one year on grassland (QN_gr), the estimated nitrogen production during the manure storage period (Qnitro-grass), the mixing with soil in grassland (DEPTHgr) and the density of wet bulk soil (RHOsoil).

PIECgrass_4-N = (Qai_grass x QN_gr x 100) / (Qnitro-grass x DEPTHgr x RHOsoil)

(eq. 24a Addendum 2015 of OECD ESD No. 14).

Following ENV162 of TAB ENV (2019), the total initial concentration of the substance in soil after four manure application events considering all prescribed biocide applications and without taking degradation in soil into account is estimated as:

PIECgrass_4-N-total = (PIECgrass_4-N x Napp_presc) / (Napp_manure_gr x Nlapp_grass)

(eq. 24a Addendum 2015 of OECD ESD No. 14 + ENV 162 of TAB-ENV 2019).

Where Nlapp_grass is the default number of manure applications for grassland (4 applications) and Napp_presc is the maximum number of disinfectant applications in one year.

PECsoil after one manure application on arable land is calculated according equation 25 from OECD ESD No.14.

PIECara_N = (Qai_arab x QN_ar x 100) / (Qnitro-arab x Nlapp_arab x DEPTHar x RHOsoil)

(eq. 25 of OECD ESD No. 14).

Where Nlapp_arab is the default number of manure applications for arable land (1 applications).

- **Estimation of PEC soil after one manure application on arable land and four manure applications on grassland with degradation.**

Following section 3.3 of Addendum OECD ESD No. 14, PIEC soil for grassland is calculated by considering degradation process of the substance in soil. To do it the following intermediate equations are followed:

$Kdeg_{soil}$ = Ln(2) / DT50_biosoil (eq. 6 OECD ESD No.14)

$Fsoil_{grass}$ = (1- ($e^{-Kdegsoil \times Tgr\text{-}int}$)$^{Nlapp\_grass}$) / (1- $e^{-Kdegsoil \times Tgr\text{-}int}$) (eq. 7a Addendum 2015 of OECD ESD No.14)

PIECgrass_4_degr-N = PIECgrass_4-N x $Fsoil_{grass}$ (eq. 9 of OECD ESD No.14, considering the eq.24b Addendum 2015 OECD ESD No.14)

For PIEC of arable land, similar process has been carried on:

$Fsoil_{arab}$ = (1- ($e^{-Kdegsoil \times Tar\text{-}int}$)$^{Nlapp\_arab}$) / (1- $e^{-Kdegsoil \times Tar\text{-}int}$) (eq. 8 from OECD ESD No.14)

PIECarab_degr-N = PIECarab_N x $Fsoil_{grass}$ (eq. 9 from OECD ESD No.14)

- **Estimation of PEC soil after 10 year consecutive application, degradation in soil included.**

For **arable land**, the initial concentration in soil of arable land after 10 years of manure application, taking degradation into account has been estimated according to Section 3.4 of Addendum 2015 of OECD ESD No.14.

$Fsoil_{ars\_10}$ = (1-($e^{(-kbio\_soil \times Tar\_int\_10)Nlapp\_arab\_10}$))/(1-$e^{(-kbio\_soil*Tar\_int\_10)}$) (eq.8a Addendum 2015 of OECD ESD No.14)

Where $Fsoil_{ars\_10}$ is the fraction of active remaining in arable soil after 10 year of manure application.

Then according to updated eq. 25 of Addendum 2015 of OECD ESD No.14, the initial concentration in soil of arable land after 10 years of manure application, taking degradation into account (PIECars_10_degr-N) is estimated:

PIECars_10_degr-N = PIECars-N x $Fsoil_{ars\_10}$ (eq. 25a Addendum 2015 of OECD ESD No.14)

For **grassland**, the initial concentration in soil of grassland after 10 years of manure application, taking degradation into account has been estimated according to Section 3.5 of Addendum 2015 of OECD ESD No.14.

In this case, an interval of 206 days between last (of four) manure application and the first application of a new series (Tgr_int_NoManure) is taken into account.

The fraction of substance remaining in grassland soil, after 365 days after the first (of four) manure spreading events (Fsoilgrs2) is estimated according to eq.35 of Section 3.5 at Addendum 2015 OECD ESD No.14:

$Fsoil_{grs2}$ = $e^{-Kdegsoil \times Tgr\text{-}int\_NoManure}$ (eq.35 Addendum 2015 OECD ESD No.14)

PIECgrs10_degr-N is estimated according eq.36 form Addendum 2015 OECD ESD No.14:

$$PIECgrs_{10\_degr} - N_{i1,i2,i3,i4} = PIECgrs_{4\_degr} - N_{i1,i2,i3,i4} \cdot \left[1 + \sum_{n=1}^{9} Fsoil_{grs2}{}^{n}\right]$$

- **Estimation of PEC groundwater.**

The concentration in porewater is used for the initial groundwater assessment. The PEC in porewater is calculated from PIECgrs10_degr–Ni1,i2,i3,i4 using TGD equations for equilibrium partitioning. These equations are also applied in the ESD for PT18 in Equations 26 – 29. The appropriate equation here is shown for reasons of clarity:

$$PIECgrs_{10\_degr}\text{ - gw - }N_{i1,i2,i3,i4} = \frac{PIECgrs_{10\_degr} - N_{i1,i2,i3,i4} * RHOsoil_{wet}}{K_{soil\text{-}water} * 1000}$$

- **Estimation of PEC surfacewater.**

The concentration in surface water used for the initial assessment is calculated by dividing PIECgrs10_degr–gw–Ni1,i2,i3,i4 by a dilution factor of 10. This is represented by Equation 27 from the ESD, in which DILUTION run-off is set to a value of 10.

- **Estimation of PEC sediment.**

The concentration in surface water used for the initial assessment is calculated according to equation 50 from chapter 2.3.8.4 of BPR IV-ENV part B (2015).

$$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000$$

2. Local PEC values for the emission pathway via STP

As it was mentioned before, this section considers those sub-scenarios of poultry housing where emission is done via STP. The following table shows the sub-scenarios where a fraction of 0.1 to STP is considered according ESD guidance:

- Laing hens in battery cages with aeration (belt drying)
- Laying hens in free range with litter floor (partly litter floor, partly slatted)
- Broilers in free range with litter floor
- Turkeys in free range with litter floor
- Geese in free range with litter floor
- Ducks in free range with litter floor

The amount of substance that reaches STP is estimated according to equation 34 form OECD ESD No.14

Qai = Fwastewater x Qai_prescri [kg.d-1] (eq.34 OECD ESD No-14)

Then, concentration in untreated wastewater is estimated following equation 32 form BPR Vol IV- Part B (2015).

$$Clocal_{inf} = \frac{Elocal_{water} \cdot 10^6}{EFFLUENT_{stp}}$$

This concentration is considered emitted directly to STP so PECstp can be deemed as Clocalinf (eq. 39 form BPR Vol IV- Part B (2015)).

PECstp = $Clocal_{inf}$ (eq.39 BPR Vol IV- Part B (2015))

Following RIVM-VSP report 14245c02 (2017), fraction of emission directed to water by STP (Fstp_water) and faction of emission directed to sludge by STP (Fstp_sludge) are obtained from EUSES 2.1.2 as EUES Simple Treat.

Fstp_water = 0.122

Fstp_sludge= 4.19%.

Then, Clocal_eff is estimated following eq. 33 from chapter 2.3.7.1 of BPR Vol IV- Part B (2015):

$Clocal_{eff}$ = $Clocal_{inf}$ x Fstp_water (eq. 33 BPR Vol IV- Part B (2015))

PECsurfacewater is estimated following equation 45 of BPR Vol IV- Part B (2015)

PECsw = $$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}) \cdot DILUTION}$$ (eq. 45 BPR Vol IV- Part B (2015))

PECsediment is estimated following equation 50 of BPR Vol IV- Part B (2015)

PECsed = $$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000$$ (eq. 50 BPR Vol IV- Part B (2015))

PECsoil is calculated according to equations 55 and 66 from BPR Vol IV- Part B (2015), after Csludge and $Csludge_{soil10}$ estimations:

Csludge = Amount of substance reaching STP x Fstp_sludge x 1000000/ SLUDGERATE

$Csludge_{soil10}$= $$Csludge_{soil\,10}\,(0) = Csludge_{soil\,1}\,(0) \cdot \left[1 + \sum_{n=1}^{9} Facc^{n}\right]$$ (eq.62 BPR vol IV-Part B (2015))

PECsoil = $$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{k\,T}\left[C_{soil}(0) - \frac{D_{air}}{k}\right] \cdot \left[1 - e^{-kT}\right]$$ (eq.55 BPR vol IV-Part B (2015))

PECgroundwater is calculated according to equations 19 from OECD ESD No.14:

PECgw = $$PIECwater = \frac{PIEClocal_{soil} * RHOsoil_{wet}}{K_{soil-water} * 1000}$$ (eq. 19 OECD ESD No.14)

The following tables, shows the outputs obtained for each substance at scenario [1]:

Iodine

- ***for the emission pathway via manure/slurry***

type of housing	Fraction to the manure	Area	Volume	Number of animals	Nitrogen production/animal	Number of biocides application during manure storage period		Number of prescribed maximum repeated biocides treatments according to information given by the applicant	Amount of active ingredient to be used in housing or manure storage for	Amount to the manure after one application	Amount of ai discharged to the soil over the manure's storage period.		Nitrogen production during the manure storage period	
	Fslurry/manure			Nanimal	Qnitrog	Napp-manure		$Napp_{prescr}$	Qai_prescri	Qai	Qai-grass	Qai-arab	Qnitrog-grass	Qnitrog-arab
	(-)	m²	m³	(-)	kg	(-)		(-)	kg	kg	kg	kg	kg	kg
						grass	arable				grass	arable	grass	arable
Dairy cows	0.50	1170	9630	100	3.39E-01	1	1	1	2.19E-01	1.10E-01	1.10E-01	1.10E-01	1796	7185
Beef cattle	0.50	370	3063	125	2.88E-01	1	1	1	6.94E-02	3.47E-02	3.47E-02	3.47E-02	1909	7637
Veal calves	0.50	160	590	80	2.38E-02	1	1	1	3.00E-02	1.50E-02	1.50E-02	1.50E-02	101	404
Sows, in individual pens	0.50	560	1960	132	7.11E-02	1	1	2	1.05E-01	5.25E-02	5.25E-02	5.25E-02	497	1989
Sows in groups	0.50	710	2480	132	7.11E-02	1	1	2	1.33E-01	6.66E-02	6.66E-02	6.66E-02	497	1989
Fattening pigs	0.50	600	2110	400	3.04E-02	1	1	2	1.13E-01	5.63E-02	5.63E-02	5.63E-02	645	2580
Laying hens in battery cages without treatment	0.50	750	2810	21000	2.02E-03	1	1	1	1.41E-01	7.03E-02	7.03E-02	7.03E-02	2248	8993
Laying hens in battery cages with aeration (belt drying)	0.50	750	2810	21000	1.81E-03	1	1	1	1.41E-01	7.03E-02	7.03E-02	7.03E-02	2015	8058
Laying hens in batters cages with forced drying (deep pit, high rise)	0.80	750	2810	21000	1.81E-03	1	1	1	1.41E-01	1.13E-01	1.13E-01	1.13E-01	2015	8058
Laying hens in compact battery cages	0.50	750	2810	21000	1.81E-03	1	1	1	1.41E-01	7.03E-02	7.03E-02	7.03E-02	2015	8058
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.30	1430	5360	10000	1.71E-03	1	1	1	2.68E-01	8.04E-02	8.04E-02	8.04E-02	906	3625
Broilers in free range with litter floor	0.30	1110	4170	20000	1.56E-03	2	5	9	2.08E-01	6.24E-02	1.25E-01	3.12E-01	1654	6614
Laying hens in free range with grating floor (aviary system)	0.50	1270	4780	20000	1.71E-03	1	1	1	2.38E-01	1.19E-01	1.19E-01	1.19E-01	1813	7250
Parent broilers in free range with grating floor	0.50	390	1458	7000	2.98E-03	2	5	9	7.31E-02	3.66E-02	7.31E-02	1.83E-01	1106	4422
Parent broilers in rearing with grating floor	0.50	500	1880	9000	1.37E-03	2	5	9	9.38E-02	4.69E-02	9.38E-02	2.34E-01	653	2614
Turkeys in free range with litter floor	0.30	3330	12500	10000	4.82E-03	2	5	9	6.24E-01	1.87E-01	3.75E-01	9.37E-01	2555	10218
Geese in free range with litter floor	0.30	2500	9380	10000	4.82E-03	2	5	9	4.69E-01	1.41E-01	2.81E-01	7.03E-01	2555	10218
Ducks in free range with litter floor	0.30	2000	7500	10000	2.74E-03	2	5	9	3.75E-01	1.13E-01	2.25E-01	5.63E-01	1452	5809
Reference										formula 14	formula 16	formula 17	formula 20	formula 21

type of housing	ESD Addendum 2015 3.2 PIECsoil,grassland, four manure application events, no degradation (equation 24a)	PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland Without degradation					PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland With degradation					PECsoil and PEC/PNEC after 10 year consecutive appliaction, degradation in soil included					based on nitrogen immision standards	based on nitrogen immision standards	PIEC surface water (mg/L) for grassland	PIEC surface water (mg/L) for arable land	PIEC sediment (mg/kg dwt) for grassland	PIEC sediment (mg/kg dwt) for arable land
	PIECgrass4-N	based on nitrogen immision standards					based on nitrogen immision standards					based on nitrogen immision standards										
	mg/kg	PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio			PIEC groundwater (µg/L)	PIEC groundwater (µg/L)				
	grass	grass	arable	grass	arable	max	grass	arable	grass	arable	RCRmax	grass	arable	grass	arable	RCRmax	Grassland	Arable	derived from surfacewater by using an AF of 10	derived from surfacewater by using an AF of 10	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)
Dairy cows	1.22E-02	3.05E-03	7.63E-04	0.710	0.178	0.710	2.20E-03	5.51E-04	0.512	0.128	0.512	2.37E-03	7.64E-04	0.552	0.178	0.552	0.78	0.25	7.79E-05	1.81E-05	3.42E-04	7.93E-05
Beef cattle	3.63E-03	9.08E-04	2.27E-04	0.211	0.053	0.211	6.55E-04	1.64E-04	0.152	0.038	0.152	7.06E-04	2.27E-04	0.164	0.053	0.164	0.23	0.07	2.32E-05	5.38E-06	1.02E-04	2.36E-05
Veal calves	2.97E-02	7.43E-03	1.86E-03	**1.727**	0.432	1.727	5.36E-03	1.34E-03	**1.246**	0.311	1.246	5.77E-03	1.86E-03	**1.342**	0.432	1.342	1.90	0.61	1.90E-04	4.40E-05	8.31E-04	1.93E-04
Sows, in individual pens	2.11E-02	1.06E-02	1.32E-03	**2.456**	0.307	2.456	7.62E-03	9.52E-04	**1.772**	0.221	1.772	8.21E-03	1.32E-03	**1.908**	0.307	1.908	2.70	0.43	2.70E-04	3.13E-05	1.18E-03	1.37E-04
Sows in groups	2.68E-02	1.34E-02	1.67E-03	**3.114**	0.389	3.114	9.66E-03	1.21E-03	**2.246**	0.281	2.246	1.04E-02	1.67E-03	**2.419**	0.389	2.419	3.42	0.55	3.42E-04	3.97E-05	1.50E-03	1.74E-04
Fattening pigs	1.74E-02	8.72E-03	1.09E-03	**2.028**	0.253	2.028	6.29E-03	7.86E-04	**1.463**	0.183	1.463	6.77E-03	1.09E-03	**1.576**	0.254	1.576	2.23	0.36	2.23E-04	2.58E-05	9.76E-04	1.13E-04
Laying hens in battery cages without treatment	6.25E-03	1.56E-03	3.91E-04	0.364	0.091	0.364	1.13E-03	2.82E-04	0.262	0.066	0.262	1.21E-03	3.91E-04	0.283	0.091	0.283	0.40	0.13	3.99E-05	9.26E-06	1.75E-04	4.06E-05
Laying hens in battery cages with aeration (belt drying)	6.98E-03	1.75E-03	4.36E-04	0.406	0.101	0.406	1.26E-03	3.15E-04	0.293	0.073	0.293	1.36E-03	4.36E-04	0.315	0.101	0.315	0.45	0.14	4.45E-05	1.03E-05	1.95E-04	4.54E-05
Laying hens in batters cages with forced drying (deep pit, high rise)	1.12E-02	2.79E-03	6.98E-04	0.649	0.162	0.649	2.01E-03	5.04E-04	0.468	0.117	0.468	2.17E-03	6.98E-04	0.505	0.162	0.505	0.71	0.23	7.13E-05	1.65E-05	3.13E-04	7.26E-05
Laying hens in compact battery cages	6.98E-03	1.75E-03	4.36E-04	0.406	0.101	0.406	1.26E-03	3.15E-04	0.293	0.073	0.293	1.36E-03	4.36E-04	0.315	0.101	0.315	0.45	0.14	4.45E-05	1.03E-05	1.95E-04	4.54E-05
Laying hens in free range with litter floor (partly litter floor, partly slatted)	1.78E-02	4.44E-03	1.11E-03	**1.032**	0.258	1.032	3.20E-03	8.00E-04	0.744	0.186	0.744	3.45E-03	1.11E-03	0.802	0.258	0.802	1.13	0.36	1.13E-04	2.63E-05	4.97E-04	1.15E-04
Broilers in free range with litter floor	1.51E-02	1.70E-02	2.36E-03	**3.951**	0.549	3.951	1.23E-02	1.70E-03	**2.850**	0.396	2.850	1.32E-02	2.36E-03	**3.070**	0.549	3.070	4.34	0.78	4.34E-04	5.59E-05	1.90E-03	2.45E-04
Laying hens in free range with grating floor (aviary system)	1.31E-02	3.28E-03	8.21E-04	0.764	0.191	0.764	2.37E-03	5.92E-04	0.551	0.138	0.551	2.55E-03	8.21E-04	0.593	0.191	0.593	0.84	0.27	8.38E-05	1.95E-05	3.68E-04	8.53E-05
Parent broilers in free range with grating floor	1.32E-02	1.49E-02	2.07E-03	**3.461**	0.481	3.461	1.07E-02	1.49E-03	**2.497**	0.347	2.497	1.16E-02	2.07E-03	**2.689**	0.481	2.689	3.80	0.68	3.80E-04	4.90E-05	1.67E-03	2.15E-04
Parent broilers in rearing with grating floor	2.87E-02	3.23E-02	4.48E-03	**7.507**	**1.043**	7.507	2.33E-02	3.23E-03	**5.415**	0.752	5.415	2.51E-02	4.48E-03	**5.833**	**1.043**	5.833	8.24	1.47	8.24E-04	1.06E-04	3.61E-03	4.66E-04
Turkeys in free range with litter floor	2.93E-02	3.30E-02	4.58E-03	**7.673**	**1.066**	7.673	2.38E-02	3.31E-03	**5.535**	0.769	5.535	2.56E-02	4.58E-03	**5.962**	**1.066**	5.962	8.42	1.51	8.42E-04	1.09E-04	3.69E-03	4.76E-04
Geese in free range with litter floor	2.20E-02	2.48E-02	3.44E-03	**5.761**	0.800	5.761	1.79E-02	2.48E-03	**4.156**	0.577	4.156	1.92E-02	3.44E-03	**4.476**	0.800	4.476	6.32	1.13	6.32E-04	8.15E-05	2.77E-03	3.58E-04
Ducks in free range with litter floor	3.10E-02	3.49E-02	4.84E-03	**8.107**	**1.126**	8.107	2.51E-02	3.49E-03	**5.848**	0.812	5.848	2.71E-02	4.84E-03	**6.299**	**1.126**	6.299	8.90	1.59	8.90E-04	1.15E-04	3.90E-03	5.03E-04
Reference	formula 24a	formula 24a + ENV162	formula 25									Equation 25a - page 12.					formula 26		formula 27		equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)

- ***for the emission pathway via STP***

type of housing	Fraction to STP	ELOCAL_WWTP																		
	Fwastewater	Qai_prescri	Amount of a.i. reaching STP	EFFLUENT SPT	Clocal_inf	PECstp	RCR STP	Fstp_water (fraction of emission directed to water by STP)	Fstp_sludge (fraction of emission directed to sludge by STP)	Clocal_eff	PECsw	RCR SW	PECsed	RCR Sed	Csludge	$Csludge_{soil10}$	PEClocalsoil	RCR Soil	PEClocalgroundwater
	(-)	kg	kg.d-1	[l.d-1]	[mg.l-1]	[mg.l-1]		[-]	[-]	[mg.l-1]	[mg.l-1]		mg.kgdt		[mg.kg-1]	[mg.kg-1]	[mg.kg-1]		[µg.L-1]
Dairy cows	0.00	2.19E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Beef cattle	0.00	6.94E-02	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Veal calves	0.00	3.00E-02	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Sows, in individual pens	0.00	1.05E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Sows in groups	0.00	1.33E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Fattening pigs	0.00	1.13E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages without treatment	0.00	1.41E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages with aeration (belt drying)	0.20	1.41E-01	2.81E-02	2E+06	0.014	0.014	0.00	0.8	0.2	1.13E-02	1.12E-03	0.04	4.93E-03	-	9.37E-03	9.37E-03	4.98E-04	0.12	0.16
Laying hens in batters cages with forced drying (deep pit, high rise)	0.00	1.41E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Laying hens in compact battery cages	0.00	1.41E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.20	2.68E-01	5.36E-02	2E+06	0.027	0.027	0.01	0.8	0.2	2.15E-02	2.14E-03	0.08	9.41E-03	-	1.79E-02	1.79E-02	9.50E-04	0.22	0.31
Broilers in free range with litter floor	0.20	2.08E-01	4.16E-02	2E+06	0.021	0.021	0.01	0.8	0.2	1.67E-02	1.66E-03	0.06	7.30E-03	-	1.39E-02	1.39E-02	7.37E-04	0.17	0.24
Laying hens in free range with grating floor (aviary system)	0.00	2.38E-01	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Parent broilers in free range with grating floor	0.00	7.31E-02	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Parent broilers in rearing with grating floor	0.00	9.38E-02	-	2E+06	-	-	-	0.8	0.2	-	-	-	-	-	-	-	-	-	-
Turkeys in free range with litter floor	0.20	6.24E-01	1.25E-01	2E+06	0.062	0.062	0.02	0.8	0.2	5.00E-02	4.99E-03	0.18	2.19E-02	-	4.16E-02	4.16E-02	2.21E-03	0.51	0.73
Geese in free range with litter floor	0.20	4.69E-01	9.38E-02	2E+06	0.047	0.047	0.02	0.8	0.2	3.75E-02	3.75E-03	0.13	1.64E-02	-	3.12E-02	3.12E-02	1.66E-03	0.39	0.55
Ducks in free range with litter floor	0.20	3.75E-01	7.50E-02	2E+06	0.038	0.038	0.01	0.8	0.2	3.00E-02	3.00E-03	0.11	1.32E-02	-	2.50E-02	2.50E-02	1.33E-03	0.31	0.44
Reference			formula 34 (ENV/JM/MONO(2006)4		equation 32, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 38, Guidance BPR IV ENV B (2015)		Generally, obtained from EUSES simple treat (obtained from EUSES). In this case this values were taken from CMK's CAR		equation 33, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 45 Guidance BPR IV ENV B (2015) PECsw = Clocal_water		equation 50 Guidance BPR IV ENV B (2015)		equation 39 Guidance BPR IV ENV B (2015)		equation 55 and 66 Guidance BPR IV ENV B (2015)		equation 56 Guidance BPR IV ENV B (2015)

Propan-2-ol

- ***for the emission pathway via manure/slurry***

type of housing	Fraction to the manure	Area	Volume	Number of animals	Nitrogen production/animal	Number of biocides application during manure storage period		Number of prescribed maximum repeated biocides treatments according to information given by the applicant	Amount of active ingredient to be used in housing or manure storage for	Amount to the manure after one application	Amount of ai discharged to the soil over the manure's storage period.		Nitrogen production during the manure storage period	
	Fslurry/manure			Nanimal	Qnitrog	Napp-manure		$Napp_{prescr}$	Qai_prescri	Qai	Qai-grass	Qai-arab	Qnitrog-grass	Qnitrog-arab
	(-)	m²	m³	(-)	kg	(-)		(-)	kg	kg	kg	kg	kg	kg
						grass	arable				grass	arable	grass	arable
Dairy cows	0.50	1170	9630	100	3.39E-01	1	1	1	5.77E-01	2.88E-01	2.88E-01	2.88E-01	1796	7185
Beef cattle	0.50	370	3063	125	2.88E-01	1	1	1	1.82E-01	9.12E-02	9.12E-02	9.12E-02	1909	7637
Veal calves	0.50	160	590	80	2.38E-02	1	1	1	7.88E-02	3.94E-02	3.94E-02	3.94E-02	101	404
Sows, in individual pens	0.50	560	1960	132	7.11E-02	1	1	2	2.76E-01	1.38E-01	1.38E-01	1.38E-01	497	1989
Sows in groups	0.50	710	2480	132	7.11E-02	1	1	2	3.50E-01	1.75E-01	1.75E-01	1.75E-01	497	1989
Fattening pigs	0.50	600	2110	400	3.04E-02	1	1	2	2.96E-01	1.48E-01	1.48E-01	1.48E-01	645	2580
Laying hens in battery cages without treatment	0.50	750	2810	21000	2.02E-03	1	1	1	3.70E-01	1.85E-01	1.85E-01	1.85E-01	2248	8993
Laying hens in battery cages with aeration (belt drying)	0.50	750	2810	21000	1.81E-03	1	1	1	3.70E-01	1.85E-01	1.85E-01	1.85E-01	2015	8058
Laying hens in batters cages with forced drying (deep pit, high rise)	0.80	750	2810	21000	1.81E-03	1	1	1	3.70E-01	2.96E-01	2.96E-01	2.96E-01	2015	8058
Laying hens in compact battery cages	0.50	750	2810	21000	1.81E-03	1	1	1	3.70E-01	1.85E-01	1.85E-01	1.85E-01	2015	8058
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.30	1430	5360	10000	1.71E-03	1	1	1	7.05E-01	2.11E-01	2.11E-01	2.11E-01	906	3625
Broilers in free range with litter floor	0.30	1110	4170	20000	1.56E-03	2	5	9	5.47E-01	1.64E-01	3.28E-01	8.20E-01	1654	6614
Laying hens in free range with grating floor (aviary system)	0.50	1270	4780	20000	1.71E-03	1	1	1	6.26E-01	3.13E-01	3.13E-01	3.13E-01	1813	7250
Parent broilers in free range with grating floor	0.50	390	1458	7000	2.98E-03	2	5	9	1.92E-01	9.61E-02	1.92E-01	4.80E-01	1106	4422
Parent broilers in rearing with grating floor	0.50	500	1880	9000	1.37E-03	2	5	9	2.46E-01	1.23E-01	2.46E-01	6.16E-01	653	2614
Turkeys in free range with litter floor	0.30	3330	12500	10000	4.82E-03	2	5	9	1.64E+00	4.92E-01	9.85E-01	2.46E+00	2555	10218
Geese in free range with litter floor	0.30	2500	9380	10000	4.82E-03	2	5	9	1.23E+00	3.70E-01	7.39E-01	1.85E+00	2555	10218
Ducks in free range with litter floor	0.30	2000	7500	10000	2.74E-03	2	5	9	9.86E-01	2.96E-01	5.91E-01	1.48E+00	1452	5809
Reference										formula 14	formula 16	formula 17	formula 20	formula 21

type of housing	ESD Addendum 2015 3.2 PIECsoil,grassland, four manure application events, no degradation (equation 24a)	PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland Without degradation					PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland With degradation					PECsoil and PEC/PNEC after 10 year consecutive appliaction, degradation in soil included					based on nitrogen immision standards	based on nitrogen immision standards	PIEC surface water (mg/L) for grassland	PIEC surface water (mg/L) for arable land	PIEC sediment (mg/kg dwt) for grassland	PIEC sediment (mg/kg dwt) for arable land
	PIECgrass4-N	based on nitrogen immision standards					based on nitrogen immision standards					based on nitrogen immision standards										
	mg/kg	PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio			PIEC groundwater (µg/L)	PIEC groundwater (µg/L)				
	grass	grass	arable	grass	arable	max	grass	arable	grass	arable	RCRmax	grass	arable	grass	arable	RCRmax	Grassland	Arable	derived from surfacewater by using an AF of 10	derived from surfacewater by using an AF of 10	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)
Dairy cows	3.21E-02	8.02E-03	2.01E-03	0.016	0.004	0.016	5.79E-03	1.45E-03	0.012	0.003	0.012	6.23E-03	2.01E-03	0.013	0.004	0.013	35.44	11.41	3.54E-03	8.23E-04	3.03E-03	7.03E-04
Beef cattle	9.55E-03	2.39E-03	5.97E-04	0.005	0.001	0.005	1.72E-03	4.31E-04	0.003	0.001	0.003	1.85E-03	5.97E-04	0.004	0.001	0.004	10.54	3.39	1.05E-03	2.45E-04	9.01E-04	2.09E-04
Veal calves	7.81E-02	1.95E-02	4.88E-03	0.039	0.010	0.039	1.41E-02	3.52E-03	0.028	0.007	0.028	1.52E-02	4.88E-03	0.031	0.010	0.031	86.20	27.74	8.62E-03	2.00E-03	7.36E-03	1.71E-03
Sows, in individual pens	5.55E-02	2.76E-02	3.47E-03	0.056	0.007	0.056	2.00E-02	2.50E-03	0.040	0.005	0.040	2.16E-02	3.47E-03	0.043	0.007	0.043	122.59	19.73	1.23E-02	1.42E-03	1.05E-02	1.22E-03
Sows in groups	7.04E-02	3.52E-02	4.40E-03	0.071	0.009	0.071	2.54E-02	3.17E-03	0.051	0.006	0.051	2.73E-02	4.40E-03	0.055	0.009	0.055	155.42	25.01	1.55E-02	1.80E-03	1.33E-02	1.54E-03
Fattening pigs	4.58E-02	2.29E-02	2.86E-03	0.046	0.006	0.046	1.65E-02	2.07E-03	0.033	0.004	0.033	1.78E-02	2.86E-03	0.036	0.006	0.036	101.22	16.29	1.01E-02	1.17E-03	8.65E-03	1.00E-03
Laying hens in battery cages without treatment	1.64E-02	4.11E-03	1.03E-03	0.008	0.002	0.008	2.96E-03	7.41E-04	0.006	0.001	0.006	3.19E-03	1.03E-03	0.006	0.002	0.006	18.15	5.84	1.82E-03	4.21E-04	1.55E-03	3.60E-04
Laying hens in battery cages with aeration (belt drying)	1.83E-02	4.59E-03	1.15E-03	0.009	0.002	0.009	3.31E-03	8.27E-04	0.007	0.002	0.007	3.56E-03	1.15E-03	0.007	0.002	0.007	20.26	6.52	2.03E-03	4.70E-04	1.73E-03	4.02E-04
Laying hens in batters cages with forced drying (deep pit, high rise)	2.94E-02	7.34E-03	1.83E-03	0.015	0.004	0.015	5.29E-03	1.32E-03	0.011	0.003	0.011	5.70E-03	1.83E-03	0.011	0.004	0.011	32.41	10.43	3.24E-03	7.52E-04	2.77E-03	6.43E-04
Laying hens in compact battery cages	1.83E-02	4.59E-03	1.15E-03	0.009	0.002	0.009	3.31E-03	8.27E-04	0.007	0.002	0.007	3.56E-03	1.15E-03	0.007	0.002	0.007	20.26	6.52	2.03E-03	4.70E-04	1.73E-03	4.02E-04
Laying hens in free range with litter floor (partly litter floor, partly slatted)	4.66E-02	1.17E-02	2.92E-03	0.024	0.006	0.024	8.41E-03	2.10E-03	0.017	0.004	0.017	9.06E-03	2.92E-03	0.018	0.006	0.018	51.51	16.58	5.15E-03	1.20E-03	4.40E-03	1.02E-03
Broilers in free range with litter floor	3.97E-02	4.47E-02	6.20E-03	0.090	0.013	0.090	3.22E-02	4.47E-03	0.065	0.009	0.065	3.47E-02	6.20E-03	0.070	0.013	0.070	197.24	35.27	1.97E-02	2.54E-03	1.69E-02	2.17E-03
Laying hens in free range with grating floor (aviary system)	3.45E-02	8.63E-03	2.16E-03	0.017	0.004	0.017	6.23E-03	1.56E-03	0.013	0.003	0.013	6.71E-03	2.16E-03	0.014	0.004	0.014	38.12	12.27	3.81E-03	8.85E-04	3.26E-03	7.56E-04
Parent broilers in free range with grating floor	3.48E-02	3.91E-02	5.43E-03	0.079	0.011	0.079	2.82E-02	3.92E-03	0.057	0.008	0.057	3.04E-02	5.43E-03	0.061	0.011	0.061	172.75	30.89	1.73E-02	2.23E-03	1.48E-02	1.90E-03
Parent broilers in rearing with grating floor	7.54E-02	8.48E-02	1.18E-02	0.171	0.024	0.171	6.12E-02	8.50E-03	0.123	0.017	0.123	6.59E-02	1.18E-02	0.133	0.024	0.133	374.70	66.99	3.75E-02	4.83E-03	3.20E-02	4.13E-03
Turkeys in free range with litter floor	7.71E-02	8.67E-02	1.20E-02	0.175	0.024	0.175	6.25E-02	8.69E-03	0.126	0.018	0.126	6.74E-02	1.20E-02	0.136	0.024	0.136	383.02	68.48	3.83E-02	4.94E-03	3.27E-02	4.22E-03
Geese in free range with litter floor	5.79E-02	6.51E-02	9.04E-03	0.131	0.018	0.131	4.70E-02	6.52E-03	0.095	0.013	0.095	5.06E-02	9.04E-03	0.102	0.018	0.102	287.55	51.41	2.88E-02	3.71E-03	2.46E-02	3.17E-03
Ducks in free range with litter floor	8.14E-02	9.16E-02	1.27E-02	0.185	0.026	0.185	6.61E-02	9.18E-03	0.133	0.019	0.133	7.12E-02	1.27E-02	0.144	0.026	0.144	404.67	72.35	4.05E-02	5.22E-03	3.46E-02	4.46E-03
Reference	formula 24a	formula 24a + ENV162		formula 25								Equation 25a - page 12.					formula 26		formula 27		equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)

- ***for the emission pathway via STP***

type of housing	Fraction to STP	ELOCAL_WWTP																	
	Fwastewater	Qai_prescri	Amount of a.i. reaching STP	EFFLUENT SPT	Clocal_inf	PECstp	RCR STP	Fstp_water (fraction of emission directed to water by STP)	Fstp_sludge (fraction of emission directed to sludge by STP)	Clocal_eff	PECsw	RCR SW	PECsed	RCR Sed	Csludge	$Csludge_{soil10}$	PEClocalsoil	RCR Soil	PEClocalgroundwater
	(-)	kg	kg.d-1	[l.d-1]	[mg.l-1]	[mg.l-1]		[-]	[-]	[mg.l-1]	[mg.l-1]		mg.kgdt		[mg.kg-1]	[mg.kg-1]	[mg.kg-1]		[µg.L-1]
Dairy cows	0.00	5.77E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Beef cattle	0.00	1.82E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Veal calves	0.00	7.88E-02	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Sows, in individual pens	0.00	2.76E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Sows in groups	0.00	3.50E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Fattening pigs	0.00	2.96E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages without treatment	0.00	3.70E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages with aeration (belt drying)	0.20	3.70E-01	7.39E-02	2E+06	0.037	0.037	0.00	0.125	0	4.62E-03	4.62E-04	0.00	3.95E-04	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Laying hens in batters cages with forced drying (deep pit, high rise)	0.00	3.70E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Laying hens in compact battery cages	0.00	3.70E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.20	7.05E-01	1.41E-01	2E+06	0.070	0.070	0.01	0.125	0	8.81E-03	8.81E-04	0.00	7.52E-04	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Broilers in free range with litter floor	0.20	5.47E-01	1.09E-01	2E+06	0.055	0.055	0.01	0.125	0	6.84E-03	6.84E-04	0.00	5.84E-04	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Laying hens in free range with grating floor (aviary system)	0.00	6.26E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Parent broilers in free range with grating floor	0.00	1.92E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Parent broilers in rearing with grating floor	0.00	2.46E-01	-	2E+06	-	-	-	0.125	0	-	-	-	-	-	-	-	-	-	-
Turkeys in free range with litter floor	0.20	1.64E+00	3.28E-01	2E+06	0.164	0.164	0.02	0.125	0	2.05E-02	2.05E-03	0.00	1.75E-03	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Geese in free range with litter floor	0.20	1.23E+00	2.46E-01	2E+06	0.123	0.123	0.01	0.125	0	1.54E-02	1.54E-03	0.00	1.32E-03	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Ducks in free range with litter floor	0.20	9.86E-01	1.97E-01	2E+06	0.099	0.099	0.01	0.125	0	1.23E-02	1.23E-03	0.00	1.05E-03	0.00	0.00E+00	0.00E+00	0.00E+00	0.00	0.00
Reference			formula 34 (ENV/JM/MONO(2006)4		equation 32, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 38, Guidance BPR IV ENV B (2015)		Generally, obtained from EUSES simple treat (obtained from EUSES). In this case this values were taken from CMK's CAR		equation 33, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 45 Guidance BPR IV ENV B (2015) PECsw = Clocal_water		equation 50 Guidance BPR IV ENV B (2015)		equation 39 Guidance BPR IV ENV B (2015)		equation 55 and 66 Guidance BPR IV ENV B (2015)		equation 56 Guidance BPR IV ENV B (2015)

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Summary of the efficacy studies are presented in part 2.2.5.5. and in IUCLID part 6.7.

3.6 Confidential annex

Please see the copnfidential PAR for more information.