

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Iodine based products CID LINES NV

ECHA/BPC/237/2019

Adopted

11 December 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of the biocidal product family

Iodine based products CID LINES NV

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family: Iodine based products CID LINES NV

Authorisation holder: CID LINES

Active substance common name: Iodine, including polyvinylpyrrolidone iodine

Product types: 3 and 4

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 13th of August 2015, recorded in R4BP3 under case number BC-BY019142-30, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 28 May 2019. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-33) and its Working Groups (WG September 2019). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on 11 December 2019.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family may be expected to fulfil the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family 'Iodine based products CID LINES NV' consists of products containing the active substance iodine/PVP-iodine for disinfection of teats. Iodine is formulated into the products either as pure iodine (0.25%-3.0%) or as PVP-iodine (2.5%-10%, corresponding to 0.3 – 1.2% iodine). Fatty alcohol ethoxylated and phosphoric acid are identified as substances of concern due to their classification for certain human endpoints.

The biocidal product family (BPF) consists of 12 meta SPCs, each containing 1 or 2 products:

Use # 1.1 – *meta* SPC 1: PT3 – Concentrated Teat disinfectants, post-milking, Iodine

Use # 2.1 – *meta* SPC2: PT3 – RTU Teat disinfectants, post-milking, Iodine

Use # 3.1 – *meta* SPC 3: PT3 – RTU Udder disinfectants, Iodine

Use # 4.1 – *meta* SPC 4: PT3 – RTU Teat disinfectants, Post-milking, Iodine

Use # 4.2 – *meta* SPC 4: PT3 – RTU Udder disinfectants, Iodine

Use # 5.1 – *meta* SPC 5: PT3 – RTU Teat disinfectants, Post-milking, PVP-Iodine

Use # 6.1 – *meta* SPC 6: PT3 – RTU Udder disinfectants, PVP-Iodine

Use # 7.1 – *meta* SPC 7: PT4– Concentrated Surface disinfectants in kitchen and in food industry, Iodine

Use # 7.2 – *meta* SPC 7: PT3– Concentrated Surface disinfectants for veterinary use, Iodine

Use # 8.1 – *meta* SPC 8: PT4 – Concentrated Surface disinfectants in kitchen and in food industry, Iodine

Use # 8.2 – *meta* SPC 8: PT3 – Concentrated Surface disinfectants for veterinary use Iodine

Use # 9.1 – *meta* SPC 9: PT4 - Concentrated– Cleaning in place disinfectants, Iodine

Use # 10.1 *meta* SPC 10: PT3 – Concentrated teat disinfectants, Post-milking, Iodine

Use # 11.1 – PT3 – RTU teats disinfectants, Post-milking, Iodine

Use # 12.1 – *meta* SPC12: PT3 – RTU Teat disinfectants, Post-milking, Iodine

Physio-chemical properties and analytical methods

Products within the family are all dark brown liquids with a pungent odour. The pH range of the products throughout the family is wide, at approximately pH 1 for the CIP products to 6 for the skin disinfectants. The products within the family are water based and therefore generally have a density of approximately 1.

Although the products within the family are stabilised, the degradation of iodine exceeded 10% in some studies (meta SPCs 2, 3, 9, 11 and 12). This is acceptable as efficacy trials provided show products can be adequately stored for the proposed shelf-life of 24 months and remain efficacious. All products within the family have a shelf-life of 24 months, with the exception of those of meta SPC 5, for which a shelf-life of 18 months was set.

Products should generally be protected from high temperatures (storage ≤ 40 °C) as well as low temperatures (> 0 °C).

At renewal of the authorization, the applicant should submit data on the stability (appearance, seepage) of the packaging during storage as this was noted as a deficiency.

Based on the classification and labelling related information, meta SPCs 7, 8 and 9 are classified as corrosive to metals (H290). Products are not oxidising, explosive or flammable.

An adequate titration method was provided for determination of the iodine content in all representative products. For substances of concern, no methods were provided as they are not expected to be formed during storage.

Efficacy

This product family contains 12 meta SPCs with teat-, udder-, CIP- and surface-disinfectants, respectively.

For teat disinfection, post milking, all tested products of the iodine product family demonstrated a bactericidal, yeasticidal and virucidal efficacy at the intended use concentrations of 0.25% to 0.33% iodine or 3% PVP-iodine in 5 minutes.

Standard lab tests (EN 1656, EN 1657, EN 14675) under test conditions defined for teat disinfection have been applied to demonstrate the efficacy. Furthermore, as a standard simulated-use test is not available, a modified EN 16437 has been used to demonstrate efficacy against microbes attached to artificial skin.

For udder disinfection the bactericidal and yeasticidal efficacy was demonstrated at 0.3% iodine or 10% PVP-iodine in 5 minutes. Laboratory tests (EN 1656, EN 1657, EN 16437 simulated skin test) under dirty conditions at 30 °C have been applied to demonstrate the efficacy.

Bactericidal, yeasticidal and virucidal efficacy was demonstrated for PT 3 iodine based disinfectants at the following iodine concentrations: 0.025%, 0.025% and 0.035% in 30 minutes.

Bactericidal and yeasticidal efficacy was demonstrated for PT 4 iodine based disinfectants at the following iodine concentrations: 0.015% and 0.0125% in 15 minutes. CIP disinfectants for PT 4 have a bactericidal and yeasticidal activity at 0.00125% iodine at 5 and 15 minutes, respectively. For surface disinfection and CIP standard laboratory tests for PT 3 and 4 have been applied.

It can be concluded that all products in this family are efficacious, when used in accordance with the use instructions proposed in the SPC.

Human Health

For the purpose of the human health risk assessment, exposure to iodine arising from professional use of iodine products and via the diet was compared with the relevant upper limit (UL) values for iodine for adults (600 µg/day) and infants (200 µg/day). If the resulting exposure was below the iodine UL it was considered that the risks are acceptable.

The industrial user is exposed during pouring or pumping of the product to allow dilution of the product (meta SPC7-9) and during application by spraying on surfaces (meta SPC7 and 8).

The professional user is exposed during mixing and loading, application, and cleaning of the teats and the equipment. In addition, exposure from the biocidal use of these products can arise via the diet. The general public are also exposed via the diet through consumption of milk from treated cows following biocidal use. The human health exposure assessments are based on model calculations using models and default values from the HEAdhoc Recommendation no. 13 (Jan. 2017). Post-milking teat disinfection (meta SPC 1, 2, 4, 5, 10, 11, and 12) skin disinfection (meta SPC3, 4, and 6) is assessed.

For meta SPCs intended for post-milking treatment, the following is reflected in the risk mitigation measures (RMM) section of the SPC: in case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection. This RMM has been agreed upon previously by the BPC when discussing other UAs on iodine-based products for teat disinfection.

Additionally, surface disinfection in animal housing (meta SPC 7, 8) and CIP disinfectant for milking parlours (meta SPC 9) is assessed. The professional user is exposed during pouring or pumping of the product to allow dilution of the product (meta SPC 7-9) and during application by spraying on surfaces (metaSPC 7 and 8).

Furthermore, at the BPC Human Health Working Group IV 2017, it was decided that the consumer risk assessment should not only consider the iodine exposure resulting from teat treatment with iodine-containing disinfectants, but also exposure to iodine from other sources. According to the European Food Safety Authority, milk and other dairy products are by far the main source of iodine in the human diet. However, it is noted that the level of iodine in milk varies greatly across Europe and is only partly due to teat treatment with iodine-containing disinfectants. The main non-biocidal factors influencing the level of iodine in milk are the dairy cattle diet (i.e. drinking water and grass), the use of iodine feed supplements, farming practices, seasonal variations and milk processing technologies. Other non-biocidal sources of iodine in the human diet include eggs, grain products, fish and iodized salt.

In order to undertake the consumer risk assessment, the Human Health Working Group, agreed harmonised values for background levels of iodine in milk and other dietary sources, as well as the approach to be taken for the consumer exposure assessment. The agreed background levels of iodine were 200 µg/L iodine from milk (EFSA monitoring data¹ and the O'Brien study, 2013²) and from sources other than milk, 185 µg/day for adults and 96 µg/day for children (UK retail survey of iodine in UK produced dairy foods³).

¹ EFSA Journal 2013;11(2):301.

² O'Brien et al. Iodine concentrations in milk. Irish Journal of Agricultural Food and Research 52: 209-216, 2013.

³ FSIS 02/08, 16 June 2009.

It should be noted that the regulation of iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the BPC. Where unacceptable risks are identified as a result of consideration of total dietary intake of iodine in addition to exposure arising from biocidal use, a risk management decision cannot be taken in isolation with respect to the biocides use only. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward.

Industrial user risk assessment

Industrial use, surface disinfection and CIP disinfectants used in food industry (PT4): metaSPC7, 8 and 9

Products in meta SPC 7 and 8 include uses for surface disinfection and products in meta SPC9 are intended for CIP disinfectant in food industry (PT 4). Products for industrial use are classified for local effects (meta SPC 7: H318 'Causes serious eye damage', meta SPC 8: H315 'Causes skin irritation' and H318 'Causes serious eye damage' and meta SPC 9: H314 'Causes severe skin burns and eye damage'). Therefore, both local effects assessment and a systemic risk assessment to iodine, including dietary intake from milk and other dietary sources have been performed.

Based on this risk assessment, risk from the industrial use of products included in meta SPC 7-9 are acceptable when including the following RMM:

Meta SPC 7 PT 4:

- During pouring of the concentrated product: wear chemical resistant gloves and eye/face protection;
- During pumping of the product: wear chemical resistant gloves and eye/face protection;
- During spraying of the product: wear chemical resistant gloves, coated coverall.

Meta SPC 8 PT 4:

- During pouring and pumping of the concentrated product: wear chemical resistant gloves, coverall and eye/face protection;
- During spraying of the product: wear chemical resistant gloves and coated coverall, and eye/face protection;
- During spraying of the product: Wear chemical resistant gloves, coated coverall.

Meta SPC 9 PT 4:

- During pouring and pumping of the concentrated product: wear chemical resistant gloves, coverall and eye/face protection.

Professional user risk assessment

Professional use, post-milking teat disinfection (PT3): meta SPC 1, 2, 4, 5, 10, 11, and 12

Risk from the professional use of products included in meta SPC 1, 2, 4, 5, 10, 11, and 12 are acceptable when wearing the following RMM:

Meta SPC 1 and 10 PT 3:

- For mixing and loading of the product: wear chemical resistant gloves and eye/face protection;
- For manual spraying application: Wear chemical resistant gloves.

Meta SPC 2, 5, 11 en 12, PT 3:

- For manual spraying application: wear chemical resistant gloves;
- For manual dipping application: no PPE is necessary for safe use.

Professional use, skin disinfection (PT3): meta SPC 3, 4, and 6

Risk from the professional use of products included in meta SPC 3, 4 and 6 are acceptable when wearing the following RMM:

Meta SPC3 PT 3:

- For manual spraying application on cows and sows: wear chemical resistant gloves.

Meta SPC4 PT 3:

- For manual spraying application on cows and sows: no PPE is necessary for safe use.

Meta SPC6 PT 3:

- For manual spraying application on cows and sows: wear chemical resistant gloves.

Professional use, surface disinfection – animal housing (PT 3): meta SPC 7 and 8

Products in meta SPC 7 and 8 include uses for surfaces disinfection in animal housing.

Products for professional use are classified for local effects (metaSPC7: H318 'Causes serious eye damage' and metaSPC 8: H315 'Causes skin irritation' and H318 'Causes serious eye damage'). Therefore, both local effects assessment and a systemic risk assessment to iodine, including dietary intake from milk and other dietary sources have been performed.

Based on this risk assessment, risk from the professional use of products included in meta SPC 7 and 8 are acceptable when wearing the following RMM:

Meta SPC 7 PT 3:

- During pouring and pumping of the concentrated product: wear chemical resistant gloves, coated coverall and eye/face protection;
- During spraying of the product: Wear chemical resistant gloves and an impermeable coverall.

Furthermore, the following RMM needs to be added:

- Due to potential concern for human health, the professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes. Only use one kind of Iodine-containing product per day.

Meta SPC 8 PT 3:

- During pouring and pumping of the concentrated product: wear chemical resistant gloves, coverall and eye/face protection;
- During spraying of the product: wear chemical gloves and impermeable coverall.

Furthermore, the following RMM needs to be added:

- Due to potential concern for human health, the professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes. Only use one kind of Iodine-containing product per day.

Professional use, CIP disinfectants used in milking parlours (PT4): meta SPC 9

Products included in meta SPC 9 used as CIP disinfectants in milking parlours (PT 4) and are classified for local effects (H314 'Causes severe skin burns and eye damage'). The professional user is only exposure to the concentrated product. In line with the TAB (TOX14, WG-III-2016), exposure to corrosive products must be avoided by means of PPE and RMM and a systemic risk assessment is not considered necessary. Therefore, only a local effects assessment has been performed.

Risk from the professional use of products included in metaSPC9 are acceptable when including the following RMM:

Meta SPC 9 PT 4:

- During pouring and pumping of the concentrated product: wear chemical resistant gloves, coverall and eye/face protection.

Additional conclusions on BPF

For the professional use for teat disinfection on cows and for skin disinfection on cows PPE is necessary. Furthermore, for the professional use for teat disinfection and the disinfection of animal housing use of PPE or PPE/RPE is necessary. Based on combined exposure, taking into account iodine from dietary exposure per use, products in this BPF cannot be used at the same time, as otherwise the UL would be exceeded. Therefore the following risk mitigation measure needs to be included: only use one kind of Iodine-containing product per day.

Consumer risk assessment

Dietary risk via iodine residues in milk due to teat disinfection and due to background iodine residues in milk and other dietary sources has been assessed for both adults and children. When only exposures arising from the biocidal use are considered, acceptable risks are identified for both adults and toddlers following post-milking application. However, when exposure arising from the biocidal use and total dietary intake are considered, an acceptable risk is identified for adults but an unacceptable risk is identified for toddlers following post-milking application. It should be noted that the unacceptable risk identified for toddlers is mainly due to exposure to iodine from sources other than the biocidal use, accounting for 94% of the iodine UL. A more elaborate discussion and proposal is included in the conclusions of this BPC opinion (see below).

Furthermore, dietary risk via iodine residues from other uses was assessed:

- Udders of cows and of pigs are disinfected a few days before and one day after respectively calving and farrowing. Milk will be used for newborns and the mother will not go to the slaughterhouse. Therefore, no exposure to residues due to this use is envisaged. Additionally, the udder disinfection will be equal to the teat disinfection scenario, therefore covered by the assessment for teat disinfection.
- Dietary exposure for humans by indirect exposure by eating livestock from animal treated housing. As the calculated residues exposure of 203 µg/d and 36 µg/d for respectively adults and toddlers are well below their UL when based on worst case assumptions (i.e. 600 µg/d and 200 µg/d), no adverse health effects are expected after indirect exposure to residues by eating food from animal origin from animal treated use included in meta SPC 7 and 8.
- Dietary exposure for humans by indirect exposure to food that has been in contact to treated surfaces. Based on the results from a provided residue study, the residues found on the inox surface was below the quantification limit of analytical method (3 ppm equal to 0.0003%). Therefore, no adverse health effects are expected after indirect exposure to residues by surfaces treated with products included in meta SPC 7 and 8.
- Dietary exposure for humans by indirect exposure to food from treated CIP installations or to food from treated milking equipment. Based on the results from a provided residue study, the residues found on the inox surface was below the quantification limit of analytical method (3 ppm equal to 0.0003%). Therefore, no

adverse health effects are expected after indirect exposure to residues by CIP installations and milking equipment treated with products included in meta SPC 9. Additionally, as scenario 5 does not lead to additional iodine exposure, no combined assessment of scenario 1 (milk from teat disinfection) and scenario 5 is considered necessary.

Animal exposure

Teat disinfection

Total exposure estimates for dairy cows exceed the human UL in terms of mg/kg bw day, but are below the UL for farm animals as derived from the EFSA 2013 opinion on the safety and efficacy of Iodine compounds (E2) as feed additives. In this opinion it was also concluded that the Iodine level in edible tissues/products is generally found to be highest in milk and not in meat. In line with this also EMEA (European Agency for the Evaluation of Medicinal Products) concluded within their summary report on Iodine-containing products used for veterinary medicine, that only small increases in serum Iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue Iodine concentrations. In addition, Iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products. Consequently the risk from post-milking teat disinfection with the products included in meta SPC 1, 2, 4, 5, 10, 11, and 12 is considered acceptable also with regard to animal health.

Skin disinfection

The exposure assessment according to the DRAWG draft guidance for biocides was carried out for the skin disinfection of udders of cows or sows before delivery (considering the worst case meta SPC 6, maximal total iodine concentration 1.8%), which is considered representative also for the use for skin disinfection included in meta SPC 3 and 4 (total iodine 0.5 – 1.45%). Furthermore, exposure was corrected in Tier 2 with a dermal absorption rate of 12% assumed for humans (WGVII 2018). This value for animal exposure was discussed and agreed upon at WGVII 2018 for a comparable application. The exposure estimate for fattening pig and breeding pig are below the resp. animal UL, and therefore considered acceptable. Consequently, the risk from skin disinfection within meta SPC 3, 4 and 6 is considered acceptable with regard to animal health protection.

Surface disinfection animal housing

The exposure assessment for animal house spraying application according to the DRAWG draft guidance for biocides was corrected with tier 2 using a dermal absorption rate of 12% as for humans. The exposure-estimate for laying hen resulted in 75% of the respective UL which is considered acceptable. The exposure-estimate for dairy cattle resulted in 82% of the respective UL which is also considered acceptable. The exposure estimate for calf appears to be 113% of the respective UL and the exposure estimate for pigs appears to be 174% of the respective UL. However, the risk for calves and pigs from animal house disinfection residues is nevertheless considered acceptable, since:

- the animal specific limit values were derived from maximum content of Iodine in feed allowed for animal health protection. However, the calves and pigs would experience the exceedance only once in their life-time;
- the exposure estimate is quite conservative. After disinfection, the stables are kept empty for usually 14 days for drying and heating. Within that time, a very considerable amount of Iodine will evaporate. This aspect was not considered in the exposure estimate.

Therefore, the risk for animal health from exposure due to animal house spraying application (meta SPC 7 and 8) appears acceptable for laying hen, dairy cattle, calf and pig.

Therefore, the following RMM need to be included to conclude safe use for animals:

- stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs;
- feeding troughs must be covered during application.

Environment

Teat disinfectants and disinfectants for animal housing are released to the environment due to spillage during application, cleaning of the applied equipment and surfaces, and dripping from animal's teats and udders. As most dairy farms are not connected to the public sewer, residues are predominantly discharged to the manure storage and eventually to soils when manure is applied as a fertiliser. Release from the food industry is via the sewer to surface water, sediments, and soils. Iodine is not volatile and is persistent as it does not degrade biologically or abiotically. Depending on the redox conditions and acidity, iodine will be transformed into iodide or iodate. Both species exist in water, but iodate is the dominant species in soils.

When residues are released to the municipal sewer, no unacceptable risks are identified for micro-organisms in the sewage treatment plant. However, emission from the food industry results in predicted environmental concentrations (PECs) in surface that exceed the predicted no-effect concentrations (PNECs). The highest concentration (6.12 µg/L) is however within the natural background concentration (0.5-20 µg/L). The expected concentration in sediment (0.298 mg/kg wwt) is also below the natural background concentration of 6 mg/kg. The iodine concentrations in soils after distribution of sewage sludge on land does result in an exceeding of the PNEC, but no unacceptable risks are expected as soils are aerobic and therefore iodine is transformed into iodate for which the PEC is well below the PNEC. Emission to individual waste water treatment systems, however, may result in malfunctioning of the installation as such systems are vulnerable for high loads of biocides due to their size. Diluted residues and waste water must be discharged to the sewer where legally allowed or to the manure storage.

Emission to manure from both teat disinfectants and stable disinfection results in levels up to 1.93 µg/L iodine in surface water adjacent to agricultural soils due to runoff, resulting in PEC PNEC ratios up to 8.74. In addition, concentrations in groundwater above the 0.1 µg/L threshold are indicated (up to 19.4 µg iodine/L). The calculated concentrations for iodine are nevertheless within the natural background range of 0.5–20 µg/L for surface water and 1-70 µg/L for groundwater. Because iodine is a natural occurring compound and many uncertainties exist in the applied methodology (as appropriate models for runoff to surface water and leaching to groundwater are not available for inorganic substances like iodine), the background concentration has been accepted as a threshold which must not be exceeded. From an environmental perspective the application of iodine-based teat disinfectants is therefore acceptable. No risk mitigation measures are necessary.

Overall conclusion

Overall, when exposure arising from biocides use is considered in isolation, no unacceptable risks are identified for professional users if appropriate PPE is worn or for the general public as a result of the consumer risk assessment. Once exposure from biocides use is considered in conjunction with total dietary exposure of iodine, acceptable risks are still identified for professional users if appropriate risk mitigation measures are in place and for adults following exposure to iodine in the diet. However, an unacceptable risk is identified for toddlers which is mainly due to exposure from non-biocidal sources of iodine accounting for 94% of the UL for toddlers.

The regulation of iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the BPC. Unacceptable risks have been identified as a result of consideration of total dietary intake of iodine in addition to exposure arising from biocidal use. Thus it is not considered appropriate to take risk management decisions in isolation with respect to the biocides use to address concerns that arise from the risk assessment. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward.

It is noted that the impact of taking into account total dietary exposure of iodine is not a new issue. In an EFSA scientific opinion intakes were reported to exceed the UL 2-fold for adults and 4-fold for toddlers with the current authorised maximum contents of total iodine in complete feed of 5 mg/kg. As a result of these exceedances, the FEEDAP Panel of EFSA recommended a reduction for iodine in feed of 2 mg/kg. However, even this reduced value would lead to exceedance of the iodine UL of the high consuming toddler (160% of the UL).

The following elements were taken into consideration for a decision on the authorisation of iodine teat disinfection products:

- The reference values for iodine of 600 µg/d for adults and 200 µg/d for children are not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. Furthermore, it is noted that effects that were taken into account for the derivation of the limit values were considered marginal and not associated with clinical effects. Moreover, the assessment factor taken into account is relatively high for a nutrient. It is further noted that WHO derived a value of 1000 µg/d for people in general but not for children specifically. Therefore, the limit values used in this assessment are considered conservative.
- The estimated intakes are based on theoretical worst case levels of iodine in milk and were calculated based on a chronic exposure, which was considered to be the most appropriate based on how the UL was derived. Furthermore, it is noted that the SCF (from which the UL for adult and toddler are included in the CAR for iodine) also reports adapted UL values for older children. As the estimated residue levels of iodine in milk are based on a worst case assessment and the data are based on short term consumption studies, then the intakes seen in reality may not be of concern if the lifelong exposures from varying sources of food were considered.
- The actual amount of iodine intake in the EU is highly variable and difficult to estimate, as levels of iodine intake depend on the geographical location, the soil, people's diet, the season, farming practices, iodine fortification of feed for dairy animals, iodine supplementation programs and other factors. From iodine supplementation programs,

monitoring data on iodine nutrition will become available and a clearer picture of the iodine status across Europe will emerge. It has been discussed in the CA-meeting whether the generation of additional data on residue levels from teat disinfection in milk should be requested from applicants for post-authorisation. However, in the September 2017 CA meeting it was agreed that such a requirement cannot be imposed to the applicants for product authorisation.

To summarise, taking all information into consideration and noting that:

- the assessment is based on worst case theoretical levels of iodine in milk, using a conservative limit value and using worst case short term exposure studies for long term exposure;
- 94% of UL for toddlers in the dietary assessment is due to background levels in milk and other dietary sources not related to biocidal use;
- exceedance of the UL is reported based on dietary intake (without teat disinfection) and the biocidal use itself is not responsible for the exceedance of the UL for toddlers;
- the major contributor of iodine in milk is feed, due to natural sources and/or supplements;
- the authorized maximum iodine of 5 mg/kg content in feed leads to 400% of the UL for toddlers;

The BPC considers that using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not by themselves present an unacceptable risk to human and animal health nor the environment.

b) Presentation of the biocidal product/biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance iodine contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family in accordance with Article 23 of the BPR is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

It is proposed that biocidal product family shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

For the co-formulant identified as potentially having ED properties, a process under REACH will be triggered by the eCA (the Netherlands) in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final⁴.

At renewal of the authorization, the applicant should submit data on the stability (appearance, seepage) of the packaging during storage.

oOo

⁴ The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation (Note agreed by Member States' Competent Authorities for Biocidal Products).