Amendments to the Norwegian authorisation of the Union Authorised biocidal product family – BPF_Iodine_VET - EU-0020540-0000

We refer to your amendments of the implemented decision in EEA countries and Switzerland (EE-AAT) to the authorisation of the biocidal product family BPF_Iodine_VET - EU-0020540-0000, R4BP 3 Case numbers BC-WM064604-18, BC-VN064607-11, BC-KX064610-15 and BC-FQ064613-28. The Norwegian Environment Agency hereby amends the Norwegian authorisation.

Background
Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Product Regulation, BPR) is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

According to Article 17(6) of the BPR, the authorisation holder of a Union Authorisation shall notify the Agency and the Commission of each product within the biocidal product family at least 30 days before placing it on the market.

The amendment of the implemented decision concerns a notification of a new product in Meta SPC 4 and 5, to the biocidal product family.

Meta SPC 4:

Product name: FINK – Io Dip 15
Trade name(s): FINK – Io Dip 15
Euter-Dip
FINK – Euter-Dip PVP-D
Active substance(s): Iodine (CAS no. 7553-56-2.)
Product type: PT 3 - Veterinary hygiene
Authorisation number with suffix: EU-0020540-0014 1-4
**Meta SPC 5:**

- **Product name:** FINK – Io Dip 30
- **Trade name(s):** FINK – Io Dip 30
- Io Dip 30
- Iodine Dip 30
- ST – Io Dip
- DESINTEC MH Iodine Film
- Iodine Dip 3000
- Iodine Dip

- **Active substance(s):** Iodine (CAS no. 7553-56-2.)
- **Product type:** PT 3 - Veterinary hygiene
- **Authorisation number with suffix:** EU-0020540-0015 1-5

- **Product name:** FINK – Io Dip 50
- **Trade name(s):** FINK – Io Dip 50
- Io Dip 50
- Iodine Dip 50
- Iodine Dip 5000
- IODOPLUS 5000

- **Active substance(s):** Iodine (CAS no. 7553-56-2.)
- **Product type:** PT 3 - Veterinary hygiene
- **Authorisation number with suffix:** EU-0020540-0013 1-5

- **Product name:** YODIN RTU
- **Trade name(s):** YODIN RTU
- **Active substance(s):** Iodine (CAS no. 7553-56-2.)
- **Product type:** PT 3 - Veterinary hygiene
- **Authorisation number with suffix:** EU-0020540-0016 1-5

**Evaluation**

The evaluation of the Norwegian Environment Agency is that the applied for amendments to the authorisation of the biocidal product family BPF_Iodine_VET are in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

**Decision**

The Norwegian Environment Agency hereby accepts the amendment to the Norwegian authorisation of the Union Authorised biocidal product family BPF_Iodine_VET.

No other change(s) than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the terms and conditions as stated in the authorisation letter dated 18.02.2020 apply.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP 3.
Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation numbers to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser