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5.1.2.e @urpl.gov.pl; 5.1.2.e (FOD VVVL - SPF SPSCAE)' <5.1.2.e@health.fgov.be>;  
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**Ämne:** SV: PT19 - application of art. 19(5)

Dear 5.1.2.e

Thank you for lifting this issue, as it promotes greater harmonizations across assessments! And apologies for not responding earlier, we wanted to double check the assessment and thus needed to await the access to R4BP3.

For the two products mentioned, only Buiten reikwijdte verzoek is applied for in Norway. And even after the last update of the PAR it is not fully clear to us which uses (age category, application) of this product may be authorised according to article 19(1), and which used we must consider authorising under article 19(5). Hence, we have just sent a message to CA BE to ask if they can make a clear overview of uses to be authorized under article 19(1) and which uses need to be authorized under article 19(5), as this is important in order to determine if the same conditions apply in Norway.

On a general basis, we agree with Sweeden that this is a complex issue.

We have gone through authorized products in Norway and there is a large variance in at what ages the different DEET products can be used, how much product to be applied and where the product should be applied. Also, there are different assessment performed by rMSs and also different uses applied by applicants.

As both Sweden and Denmark have responded, we also have quite short summers, and most people use long trousers and long-sleeved shirts when travelling in areas where there is a high density of mosquitoes. Hence an additional refinement/recalculation of the human health exposure assessment by using a reduced skin area might be a way forward, if needed. However, when refining the risk assessment, it is important to remember that the dose used in the efficacy studies must still be covered by human health risk assessment, also a more detailed review of whether there exists comparable alternatives is needed.

For some DEET products, including the RNL for Buiten reikwijdte verzoek both ticks and mosquitos are listed as target organisms. As there is an increase of vector borne diseases by ticks in Norway and thus there is a higher need for ticks protection, authorisation according to article 19(5) could be relevant. However, as the efficacy guidance clearly state that "PT19 biocides against ticks can only claim to repel or attract (in order to trap) the target organisms, not to prevent the diseases", and also considering the scope of BPR not being in conflict with directive for medicinal products for human use (i.e. when claiming to prevent disease in human beings), we are a bit reluctant to use article 19(5) with this as the main argument.

We are wondering whether 5.1.2.e could elaborate about the discussion on DEET they are planning on initiating?

Best regards,

5.1.2.e

Senior Adviser, Chemicals Section

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**Fra:** 5.1.2.e <5.1.2.e @kemi.se>

**Sendt:** fredag 10. januar 2025 10:56

**Til:** 5.1.2.e <5.1.2.e @ctgb.nl>

**Kopi:** 5.1.2.e <5.1.2.e @miljodir.no>; 5.1.2.e <5.1.2.e @kemi.se>;

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**Emne:** Sv: PT19 - application of art. 19(5)

Dear 5.1.2.e

We find this to be a complex matter, both when it comes to assessing the need for stronger DEET products but also as we yet do not have a clear established process/method at our agency on how to handle 19(5) assessments. We do not have the same system as in DK where the ministry is involved in these assessments, but we as competent authority has the full responsibility.

We are just about to initiate a discussion on DEET so at this stage we do not have a final position, however the arguments presented by 5.1.2.e regarding clothing seems reasonable also for Swedish conditions. It could also be questioned whether 90 days exposure is relevant for Swedish conditions with quite short

summers. Also we have an increasing number of vector borne diseases by ticks in Sweden, and these are also affecting children, so we have to take also this into consideration when assessing the need.

Lastly we are not sure whether other PT 19 products with other active substances could be a better alternative to DEET-products, both for the use on adults and children. And as all active substances still have not been fully evaluated makes this even more difficult to assess. We also have products with ethyl butylacetylaminopropionate authorised for use on children from 2 years of age, we do not know whether these products could be considered to be a full substitute for products with DEET. If you have any information regarding this, we would really be grateful if you could share it.

Kind regards,

/5.1.2.e

5.1.2.e

The Swedish Chemicals Agency

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**KEMI**  
Kemikalieinspektionen

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**Från:** 5.1.2.e <5.1.2.e @mst.dk>

**Skickat:** den 8 januari 2025 14:00

**Till:** 5.1.2.e <5.1.2.e @ctgb.nl>; 5.1.2.e @miljodir.no; 5.1.2.e <5.1.2.e @kemi.se>; 5.1.2.e <5.1.2.e @kemi.se>; 5.1.2.e @inail.it; 5.1.2.e @sanita.it; 5.1.2.e @urpl.gov.pl

**Kopia:** 5.1.2.e (FOD VVVL - SPF SPSCAE)' <5.1.2.e @health.fgov.be>; 5.1.2.e @health.fgov.be' <5.1.2.e @health.fgov.be>; 5.1.2.e @health.fgov.be' <5.1.2.e @health.fgov.be>; 5.1.2.e @tukes.fi

**Ämne:** SV: PT19 - application of art. 19(5)

Dear 5.1.2.e

In DK we visited this issue back in 2020 (I think) at the renewal of one of the Buiten reikwijdte verzoek products. The product showed risk for all ages (adults, ages below 12, and 2 years old). Our Ministry decided that PT19 assessments on HH does not really apply a realistic situation for the conditions in Denmark, as long sleeved shirts and trousers will likely be used in situations with many mosquitoes, hence we can

calculate on a reduced skin area – the new calculated AEL for the reduced skin area has to be acceptable and the label shall include an RMM regarding what body parts the product can be applied on and that long trousers and long sleeved should be worn to prevent mosquito bites. If this is done we can use 19(5) for PT19 products.

Unfortunately it was not described in this opinion from our ministry how to deal with a risk for children.

In the Buiten reikwijdte verzoek product, I can see that we have not approved the use on kids age below 12, and we expect to do the same for this product, meaning we would only approve the uses that are anyways 19(1) (above 12 years/adults), but we have to get clarification from our ministry first, which we are working on.

Our understanding is that even if we only approve the 19(1) uses we should still follow RMS if they use 19(5) and therefore use 19(5) ourselves (which is a bit weird when we then only approve 19(1) uses).

Best regards

5.1.2.e

**Fra:** 5.1.2.e) <5.1.2.e [ctgb.nl](mailto:ctgb.nl)>

**Sendt:** 8. januar 2025 10:51

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**Emne:** PT19 - application of art. 19(5)

**[EKSTERN E-MAIL]** Denne e-mail er sendt fra en ekstern afsender.

Vær opmærksom på, at den kan indeholde links og vedhæftede filer, som ikke er sikre.

Dear colleagues,

I am approaching you in the frame of the renewal of the PT19 products based on N,N-diethyl-meta-toluamide.

I chose to approach you as a selection of the member states that have received an NA-RNL for Buiten reikwijdte verzoek (Buiten reikwijdte verzoek in refMS BE) and/or Buiten reikwijdte verzoek (Buiten reikwijdte verzoek in refMS BE).

For these renewals, the applicant has provided new efficacy tests as requested. We had hoped that this would show efficacious use at lower use rates. However, now that the peer review has ended, it has become clear that there is still a risk for human health – either for the whole product (the Buiten reikwijdte verzoek product), or only the use on adults, 1x/day can be authorised (the Buiten reikwijdte verzoek product). Member states will have to decide whether they will apply art 19(5) in order to keep these products on the market.

In NL we are currently discussing our approach and are not yet certain what exactly we will do. And although it is a strictly national decision whether or not to apply art. 19(5), we are interested to know what other members are intending to do. It matters to us whether all member states apply art. 19(5), or whether only a few do so.

Therefore, we would be very grateful if you could indicate whether you plan to apply art. 19(5), or whether you will only grant authorisations for safe products and uses (art 19(1) only). If you could very briefly explain the background/motivation of your decision it would be even more helpful. It would also be interesting to know in case you are still involved in discussions, just like us.

Thank you very much in advance for any information you might be able to share.

Kind regards,

5.1.2.e

Ctgb NL

PS For BE (in copy), we already know that they will authorise under art 19(5).

I have also copied FI (5.1.2.e) in, just for information, as I know that for another product you have applied art 19(5) (OFF! 5.1.2.e).

5.1.2.e

5.1.2.e

Ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

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