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Health Board
Paldiski maantee 81
EE - 10617 Tallinn
Estonia

Beerse, 1st March 2024
Ref: DMcK/GV/20240301

Dear Sir/Madam,

We would like to request clarification on how the Biocides Competent Authority for Estonia will approach the situation described below, regarding grace periods for the sale and use of biocidal products containing an active substance which is subject to a non-approval decision.

Situation:
Hypothetical Biocidal Product X (BPX) contains Active Substance Y (ASY), which is in the Review Programme of BPR, but not yet approved. Thus, BPX is marketed in Estonia under the national transitional scheme as permitted under Article 89(2) of BPR. If a decision is taken not to approve ASY under BPR, Article 89(2) foresees that a Member State may continue to apply its current system to permit BPX to be placed on the market for up to 12 months after the date of the decision, and for a further grace period of 6 months to be allowed to use up BPX.

We would be grateful for your responses to the following questions:

1. In this situation, will Estonia apply a grace period of 12 months, following the decision for non-approval of ASY, for placing BPX on the market, as foreseen in BPR? If not, what grace period will be applied?
2. In this situation, will Estonia apply an additional grace period of 6 months following the grace period for placing BPX on the market, for using stocks of BPX, as foreseen in BPR? If not, what grace period will be applied?
3. What additional grace period will Estonia apply for placing treated articles containing BPX on the market, following the grace period for using up stocks of BPX?

May we kindly ask you to send your response by email to Greet Vanhove (gvanhove@its.jnj.com).

We look forward to hearing from you.

Yours sincerely,

Adrian Gray (signed on his behalf by Greet Vanhove – Admin. Support Regulatory Affairs)
Global Head Regulatory Affairs
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