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Development of Legislation and Other instruments

Comments by the Swedish Chemicals Agency on guidance on the concept of negligible exposure, in Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market

The interpretation of the concept of negligible exposure in Annex II of Regulation (EC) No 1107/2009 has been a subject for discussion at meetings arranged by the Commission and others in the past.

When the concept was introduced in the negotiations of the regulation, the main objectives set forth with the new cut-off criteria for approval of active substances were:

1. To ensure a high level of protection of both human and animal health and the environment, taking into account the precautionary principle (Recital 8).
2. To strengthen the harmonisation objectives by establishing approval criteria at the community level (Recital 9).
3. To speed up the approval process. At that time, long discussions had taken place on a limited number of very problematic substances resulting in extensive delays in decision making. The idea was that a procedure should be adopted where decisions for active substances could be taken based on critical properties identified during the hazard identification. This would provide an elegant solution to the protracted discussions that had taken place previously regarding the uncertainties for risk assessment of such substances (Recitals 8, 10 and 12).
4. A hazard based procedure was also in line with the ambition to achieve a more predictable process for all parties (Recital 12).

When introduced by the Commission, the concept of negligible exposure was perceived as a way to exclude certain exceptional cases from the cut-off approach. The objective was not to allow for general derogations. This is expressed by the final legal texts saying that "*unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is the product is used in closed systems or in other conditions excluding contact with humans …*".

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We now have the impression that there is a discussion on negligible exposure as a way to derogate from the hazard based procedure, by introducing a more risk based one. In practice, such an approach would hollow out the cut-off criteria as such and ultimately jeopardize the high level of protection of human health and the environment stipulated by the regulation.

It has been argued that, from a technical point of view, it is not possible to define absolutely closed systems and that "no exposure" may probably not exist in practise. We agree with this view, but one relevant conclusion could therefore be that negligible exposure may not be a realistic scenario at present. Nevertheless, we cannot exclude that there will be technical solutions in the future with exposure scenarios that can be described as such. Negligible exposure should not be used as a derogation to keep certain critical substances on the market in order to control a serious danger to plant health. Such derogations should instead be referred to parts of the regulation explicitly intended for these derogations, as provided for in Article 4.7 and the emergency clause in Article 53.