

CropLife Europe's comments on Sweden's TRIS Notification Ordinance amending the Pesticides Ordinance (2014:425). Notification Number: 2020/682/S

The proposal by the Ministry of Environment of Sweden prohibits the use of plant protection products (PPPs) in pastureland, recreational public areas (i.e., public parks, gardens, pre-schools, and playgrounds), communal garden areas, non-professional greenhouses and in plants within the home environment. Environmental sanctions are also introduced for non-compliance.

CropLife Europe believes that this proposal neglects the fact that PPPs, for both professional and non-professional uses, can only be authorised after adhering to very strict authorisation conditions that limit risks and ensure adequate protection of the end user and the environment. In the case of PPPs for non-professional uses, authorisation conditions are often even stricter than those for the professional users to compensate the lack of expertise by amateurs (exposure models, adapted packaging, additional safety measures, lower toxicity profiles, increased safety margins, etc.). Therefore, the risks that this proposal associates to the use of PPPs in the specific areas have no foundation, as explained by the Swedish Crop Protection Association in 'annex 1' of this document.

In addition to the above-mentioned, please find below the [main industry concerns on the legislative proposal](#):

1. Lack of communication, absence of a transition period and overall uncertainty

The proposal argues that because a report on the limitation of non-professional use of chemical plant protection products in Sweden (Report 4/17, no M2017/01318/Ke) was published by the Ministry in 2017, the market should not be deemed to be 'unprepared for the changes as such'. However, an indication that there might be a limit in the future does not translate into a future 'blanket ban' on PPPs in consumer and some professional uses. Therefore, companies are indeed unprepared for these unexpected changes introduced by this proposal in such a short-time frame. Similarly, the affected companies and other key stakeholders were not informed directly, or invited to provide their insights, by the Swedish authorities in charge of drafting this proposal. Indeed, comments were provided but only after the publication was made of the Ministry's intentions.

As, according to the text, companies should have been prepared for the implementation of such changes, no transitional period has been established by the Ministry. The absence of a transitional period has made it very difficult for companies in all parts of the supply chain to react and adapt to the potential changes. The timing for entering comments into TRIS for the Kemi proposal (daughter law) 'Regulations amending the Swedish Chemicals Agency's regulations (KIFS 2008:3) on pesticides' as notified under TRIS 2020/409/S was, initially, the 1st of October 2020. However, this timeline was then extended to 1st January 2021 and then closed for contributions before the deadline. The second TRIS notification, as mentioned in the title, 'Notification Ordinance amending the Pesticides Ordinance (2014:425)', has an implementation date of 1st February 2021 with the end of standstill for submitting contributions to TRIS set for the 3rd of February. Timelines are just not realistic and if this is to be implemented on the Swedish market industry, retailers need at least a minimum of a year to act in a sensible way. So, the implementation date should be somewhere in 2022.

The Ministry, in their proposal, sets the standard of the ban simply on a basis of active substances. They consider that no active substances should be allowed for non-professional and professional users in some areas. Indeed, they also do not consider how the active substance is formulated in a product and how it is presented to the user. Any scientific approach relies on a realistic (often worst case) assessment of the risk. Here, it appears that no assessment of the risk of the products has been done by the Ministry. Just a complete and blanket ban, which is counter to the principles of 1107/2009.

The Ministry, in their proposal, then give Keml an authority to grant exemptions to some actives. The active substances proposed in the exemption by Keml are again not based on a risk assessment approach but purely based on hazard. Moreover, there is not information in place specifying when, how or under which criteria these exceptions will be made.

This uncertainty, together with the lack of overall communication, is affecting new and old products as well as products that are currently being developed or evaluated. Therefore, either a minimum transitional phase or clear guidelines should be put in place for companies to prepare from a development and business point of view. Indeed, it should be reminded that PPPs are a seasonal business and products are now being manufactured/packaged and distributed for sale in 2021 without knowing what to expect.

2. Non-compliance with the provisions on the protection of property and freedom of business

The ban proposal foresees an implementation as from February 2021, without any transitional period (being the end of standstill for the 'ban proposal' the 3rd of February). This would target directly new products and products being evaluated adding an **element of unfairness**: manufacturers are constantly developing solutions and investing money in products with better profiles (e.g., composition, packaging, regulatory fees, etc.) to further reduce risk to the users, bystanders, or the environment. Concerned applicants will see their application rejected because of the new provisions, **which would not only be contradictory to the principles of proportionality, legal certainty, and protection of legitimate expectations but also to the protection of property and freedom of business mentioned in the proposal.**

The document explains how this new legislation should not be considered a restriction on the protection of property and the freedom to conduct business as it is motivated by an urgent general interest, namely the protection of the human health and the environment. Therefore, according to the text, the proposal must be weighed against the interests of individual traders. Nonetheless, PPPs undergo the most rigorous approval process ensuring the safety of humans and the environment. Therefore, the alleged 'urgent general interest' that this proposal stands by and by which it justifies the non-compliance with the provisions on the protection of property and freedom of business is unfounded.

Our industry heavily invests in R&D and stewardship projects to produce safe solutions for the environment, human and animal health. CropLife Europe believes that efforts should instead be devoted to the implementation of a strict and independent monitoring system for overseeing the uptake of good practices. Prohibiting the use of PPPs will only lead to the undesired consequence of significantly increasing the risk of use of illegal products, i.e., use of unauthorised PPPs (e.g., designed for professional use or from another country via online purchase) or use of unsuitable solutions (e.g., bleach, gasoline, home-made recipes). In fact, 'Acetic Acid' has been included in Keml's list of exemptions to the ban for this very reason. Therefore, once again, authorities should ensure that products are approved in accordance with the appropriate risk assessment methodologies rather than with a blanket ban purely based on hazard.

3. No alignment with 1107

The Regulation 1107/2009/EC provides for a possibility to prohibit the use of a plant protection product. This is, however, described as an emergency measure and can only be instated if a substance constitutes a serious risk to human or animal health or the environment. In this case, a

'serious risk' could not be demonstrated by the proposal as explained throughout this document. Therefore, the use ban is **not in accordance with the requirements to impose such ban under the emergency measure clause of the Regulation**.

Moreover, if the consequences of the proposal are considered (which basically results in the authorisations being obsolete), it can be argued that the proposal factually revokes all authorisations. It is our view that the proposed ban of the use of all plant protection products is **in violation with the substance-based approach** of the Regulation (as all substances will be banned by default unless exceptions).

4. No initial compliance with TRIS procedural requirements and regulations

The TRIS procedure requires Member States to notify their draft acts ("technical regulations") with the aim of preventing barriers in the internal market. According to Art 1(1)(f) of the TRIS Directive technical regulation means technical specifications and other requirements or rules on services [...] as well as laws, regulations, or administrative provisions of Member States, except those provided for in Article 7, prohibiting the manufacture, importation, marketing or use of a product [...].

The proposal already provided a ban to use PPPs in certain areas. However, this 'mother law' was not initially notified to TRIS. Instead, the first TRIS notification (2020/409/S) was only intended for the exemption of certain substances (being this exemption only a possibility: 37a§ "*The Swedish Chemicals Agency may issue regulations on exemptions from the prohibitions in §§ 37–37 for active substances in plant protection products that are deemed to pose a limited risk to human health and the environment*".) In the event that Keml had not adopted any regulations that exempt specific substances, the general prohibition, which laid down in the proposal or 'mother act', would have still been effective.

Not notifying first the general ban or 'mother law' to TRIS has caused general confusion to manufacturers, applicants, distributors, sellers and customers for over four months. Moreover, will the 'daughter law' on 'regulations amending the Swedish Chemicals Agency's regulations (KIFS 2008:3) on pesticides' (TRIS 2020/409/S) be re-issued? If yes, what would that actually mean in terms of timing or further expectations?

Annex 1 – Position paper of Swedish Crop Protection Association

Remissyttrande

Ert Dnr: M2020/00660/R

Vårt Dnr: SV/04/20

Miljödepartementet

Rättssekretariatet,

Naturskydd och prövningssystem

Förbud mot användning av växtskyddsmedel inom vissa områden och miljöstraffavgift för överträdelse av förbuden

Svenskt Växtskydd har fått rubricerad promemoria på remiss från Miljödepartementet. Vi har följande synpunkter.

Svenskt Växtskydds ställningstaganden i korthet

- Svenskt Växtskydd avstyrker förslaget i sin helhet
- Svenskt Växtskydd menar att det saknas skäl som motiverar förslaget

Förslaget

I promemorian föreslås ändringar i den svenska bekämpningsmedelsförordningen. De ändringar som föreslås innebär att all användning av växtskyddsmedel förbjuds på tomtmark, inom koloniträdgårdsområden, i växthus som inte används yrkesmässigt samt på krukväxter i hemmiljö. Den idag gällande tillståndsplikten för yrkesmässig användning av växtskyddsmedel tas bort på skolgårdar, lekplatser, tomtmark för flerfamiljshus samt i parker och trädgårdar dit allmänheten har tillträde. I stället införs förbud mot all användning av växtskyddsmedel också inom dessa områden. För överträdelser av förbuden föreslås miljöstraffavgifter.

Svenskt Växtskydds synpunkter

Svenskt Växtskydd kan inte i promemorian, eller någon annanstans, uppfatta några miljömässiga eller andra skäl till att införa de föreslagna förbuden. Vi avstyrker därför förslaget i sin helhet.

Som skäl för förbuden nämns i promemorian:

- Minskad risk för människors hälsa
- Minskad risk för förorening av yt- och grundvatten
- Minskad risk för insekter, fåglar och däggdjur

Svenskt Växtskydd menar att ingen av dessa skäl motiveras på ett tillfredsställande sätt.

Minskad risk för människors hälsa:

De skäl som anges i detta avsnitt är synnerligen generella och torde kunna gälla många hälsorisker, kemiska eller andra, i vårt samhälle. Kemiska växtskyddsmedel beskrivs därför också som en potentiell hälsorisk. Svenskt Växtskydd tänker inte ange några exempel men vi vill bestämt mena att det finns andra risker där potentialen är högre.

Minskad risk för förorening av yt- och grundvatten:

Idag är endast ett fåtal växtskyddsmedel godkända för privat användning. I syfte att förbättra kunskapsläget avseende riskerna för yt- och grundvatten vid privat användning utfördes under år 2018 en studie där dagvattenprover från olika lokaler i tätbebyggda områden analyserades. I CKB rapport 2019:2 redovisas resultaten från den studien. Där framgår att användningen av glyfosat kan leda till läckage till omgivande vattenmiljöer, men att de halter man finner av glyfosat eller dess nedbrytningsprodukt AMPA är långt under den bedömningsgrund som finns för glyfosat och det riktvärde som gäller för AMPA. Bedömningsgrunder och riktvärden bestäms av en anledning och överskrids värdena kan åtgärder behöva vidtas. Är emellertid halter långt under dessa värden saknas sådana skäl. Några andra underlag än ovan nämnda rapport berörs inte i promemorian. Skälet kan därmed inte anges som motiv för ytterligare reglering.

Minskad risk för insekter, fåglar och däggdjur:

När det gäller detta skäl saknas helt underlag. De produkter som skulle omfattas av ett förbud är företrädesvis ogräsmedel och inte toxiska för insekter. Att de inte får vara skadliga för bin är idag ett bestämt krav för att överhuvudtaget kunna godkännas. Vad avser fåglar och däggdjur finns varken någon förklaring i promemorian eller någon relevans i sak.

Bilaga IV i Northern Zone Guidance Document avseende klass 3-produkter, för icke-professionell användning i Sverige, samt reglerna i §20 i 3 kap. KIFS 2008:3 innebär omfattande krav som ett växtskyddsmedel måste uppfylla för att godkännas. Dessa stränga krav ställs alltså redan idag för att skydda människor och miljö när det gäller växtskyddsmedel som ska användas av icke-utbildade användare. Så länge dessa krav är uppfyllda anser Svenskt Växtskydd att skäl till att ytterligare begränsa användningen saknas.

Svenskt Växtskydd anser vidare att när det gäller den användning av växtskyddsmedel som nu föreslås förbjudas är det för användaren fullt tillräckligt med den information som redan idag finns på medlens förpackningar. Där ska i enlighet med gällande regler anges hur produkten ska användas för att på bästa möjliga sätt skydda människors hälsa och miljön.

Svenskt Växtskydd

Anders Normann
Verksamhetsledare