

How an inconsistent ban is endangering the secure environment for industrial research

- Switzerland is rightly proud of its status as a location for research. A research location lives on innovations. And it lives on a stable environment. This also applies to crop protection. It takes around ten years to discover a new active substance and overcome all the safety hurdles. And a new active substance costs around CHF 260 million.
A reliable regulation environment is of central importance for a research location.
- Crop protection products are highly beneficial. They make possible regional agricultural production. They protect harvests from diseases and pests. Besides the benefits of innovation, safety for humans and the environment is of central importance. Industry ensures this in the course of the research process. **The authorities monitor safety in the approval process. They establish clear legal criteria.**
- These clear criteria include **low limits in ground water for the active substances of crop protection products**. The very low limit is 0.1 µg/l – one tenth of a millionth of a gram per litre.
- Not only the active substances of crop protection products but their degradation products are subject to very low limits. A distinction is made here between “relevant degradation products” and “non-relevant degradation products”. Degradation products are also called metabolites. **“Relevant” degradation products can be biologically active. They may have negative impacts on humans and the environment. “Relevant” metabolites are subject to more stringent limits than “non-relevant” metabolites.**

The limit for “relevant” degradation products (metabolites): max. 0.1 µg/l

The maximum value for “non-relevant” degradation products (metabolites): max. 10 µg/l

- **At the start of 2020, the active substance chlorothalonil was banned in Switzerland.** This is a fungicide which has tried and tested for years. This crop protection product has great benefits. It is used for example to combat speckled leaf blotch in wheat and is the most effective agent against leaf spot in cereals. Another important consideration is that when battling plant diseases and pests, farmers must have access to a range of agents. As with medication, this prevents the development of resistance. Chlorothalonil is an important resistance breaker, notably due to its mode of action.
- **Syngenta has appealed against the decisions of the authorities to ban the use of chlorothalonil and to significantly lower the limits for its degradation products in groundwater.** This was because, based on several scientific studies, the Swiss Federal Food Safety and Veterinary Office (FSVO) concluded in its own expert opinion from early December 2019 that the degradation products of chlorothalonil are not relevant and thus should be classified as non-harmful to humans and the environment. Nevertheless, just two weeks later, the authorities made the completely unexpected decision to ban further use of the active ingredient in Switzerland from January 1, 2020, and to classify all degradation products as “relevant.” For Syngenta, this is incomprehensible from a scientific perspective and has major implications, particularly for farmers and the agricultural industry. The company therefore took legal action against the decision. The main ruling is still pending.
- **The precipitate ban of chlorothalonil by the authorities in Switzerland is inconsistent and disproportionate in view of the great benefits of chlorothalonil for farmers.** There were mainly two metabolites of chlorothalonil found in the ground water. One of these is R471811, the other R417888. Metabolite R471811 had already been classified as “non-relevant” by the FSVO in the relevance test in June/August 2019, while

Facts about the ban on chlorothalonil in Switzerland

R417888 was initially classified as “relevant” because it could not be proved to be harmless. **As a result of more recent studies, however, the FSVO concludes in its relevance test of 3 December 2019 that the metabolite R417888 is also “non-relevant”.**¹ Based on the current classification by the authorities, both metabolites mainly found are “non-relevant”.

- **Recognition that the metabolites R471811 and R417888 are “non-relevant” leads to the conclusion that the higher limit of 10 µg/l applies to these metabolites.** Both metabolites are well below this limit at all measuring stations. Accordingly, there is no breach of limits. The authorities are contradicting themselves here with conflicting statements of their own criteria and the recognition that R471811 and R417888 are “non-relevant”.
- **The authorities are clearly aware of the contradictions.** They are saying that the distinction between “relevant” and “non-relevant” metabolites no longer applies to chlorothalonil because the initial active substance, i.e. chlorothalonil, is classified by the EU as a known or presumed human carcinogen.²
- **However, this is doubly wrong.**
 - Chlorothalonil is classified by the EU in category 2. The European Chemicals Agency (ECHA) is responsible for possible review of the classification. The Swiss authorities are aware of the prevailing EU classification.³
 - Even if an active substance such as chlorothalonil is more stringently classified, a metabolite is not necessarily relevant. This is not the case where sufficient data is available showing that the metabolite does not have the properties.⁴ In the case of chlorothalonil metabolites, the authorities have this data. Expert opinions show that the two cited metabolites are “non-relevant” – and are accordingly not hazardous to humans and the environment. The Swiss Federal Food Safety and

¹ Source: «Relevanzprüfung der Grundwassermetaboliten der Produkte mit dem Wirkstoff Chlorothalonil im Rahmen der (teil-)gezielten Überprüfung. Beurteilung der im Rahmen des rechtlichen Gehörs eingereichten toxikologischen Informationen (*Relevance test of ground water metabolites of products containing the active substance chlorothalonil in a (partial) specific examination. Evaluation of the toxicological information submitted to the legal hearing*), Federal Department of Home Affairs, 3 December 2019

² The EU divides chemical substances into the following categories:

Category 1: Known or presumed human carcinogens

- **Category 1A:** known to have carcinogenic potential for humans, (classification is largely based on human evidence)
- **Category 1B:** presumed to have carcinogenic potential for humans, (classification is largely based on animal evidence)

Category 2: Suspected human carcinogens

³ It is true that a change in the classification of chlorothalonil is under discussion at the EU. However, the classification in category 2 is still valid.

⁴ Evaluation of relevance

The relevance of metabolites predicted to be present in ground water in concentrations exceeding 0.1 µg/l is evaluated in three stages. Such a metabolite is classified as relevant if

1 the metabolite has pesticidal action, or

2 the parent substance is classified as toxic, carcinogenic or mutagenic and at the same time there is not sufficient data for the metabolite showing that the metabolite does not have this property, or

3 information on the toxicological properties of the metabolite shows that this must be classified as toxic, carcinogenic or mutagenic.

(Source: “Relevanz von Pflanzenschutzmittel-Metaboliten im Grund- und Trinkwasser”, (*Relevance of pesticide metabolites in ground water and drinking water*), Federal Department of Economic Affairs, Education and Research document of 31 January. 2020)

Facts about the ban on chlorothalonil in Switzerland

Veterinary Office (FSVO) has confirmed this in its own relevance test of 3 December 2019.

There is accordingly absolutely no reason for the authorities to ride roughshod over the legal distinction between “relevant” and “non-relevant” metabolites and simply designate all chlorothalonil metabolites as “relevant”.

- The fact is that the ban on chlorothalonil is inconsistent and disproportionate. The ban is a dangerous precedent for Switzerland as a research location. **The ban is a danger to the stable and reliable environment for the researching agricultural industry and planning security for farmers who have to use crop protection products to secure their harvests.** The uncertainty poses a danger to a reliable approval process in Switzerland and inhibits innovation. This is why Syngenta has appealed the ban. Companies must defend themselves against arbitrary and disproportionate decisions – among other reasons, so that their future innovations reach the Swiss market.
- **The inconsistent decision also results in a lack of transparency and misleads the public.** The responsible Swiss Federal Food Safety and Veterinary Office (FSVO) is failing to publicise decisive information, such as the relevance test of 3 December 2019, and is contradicting its own evaluation by announcing – for reasons which are beyond comprehension – that all the metabolites found in ground water must comply with the limit of 0.1 µg/l, whether they are classified as “relevant” or “non-relevant”. This procedure is leading to uncertainty and careless misinformation of the public.