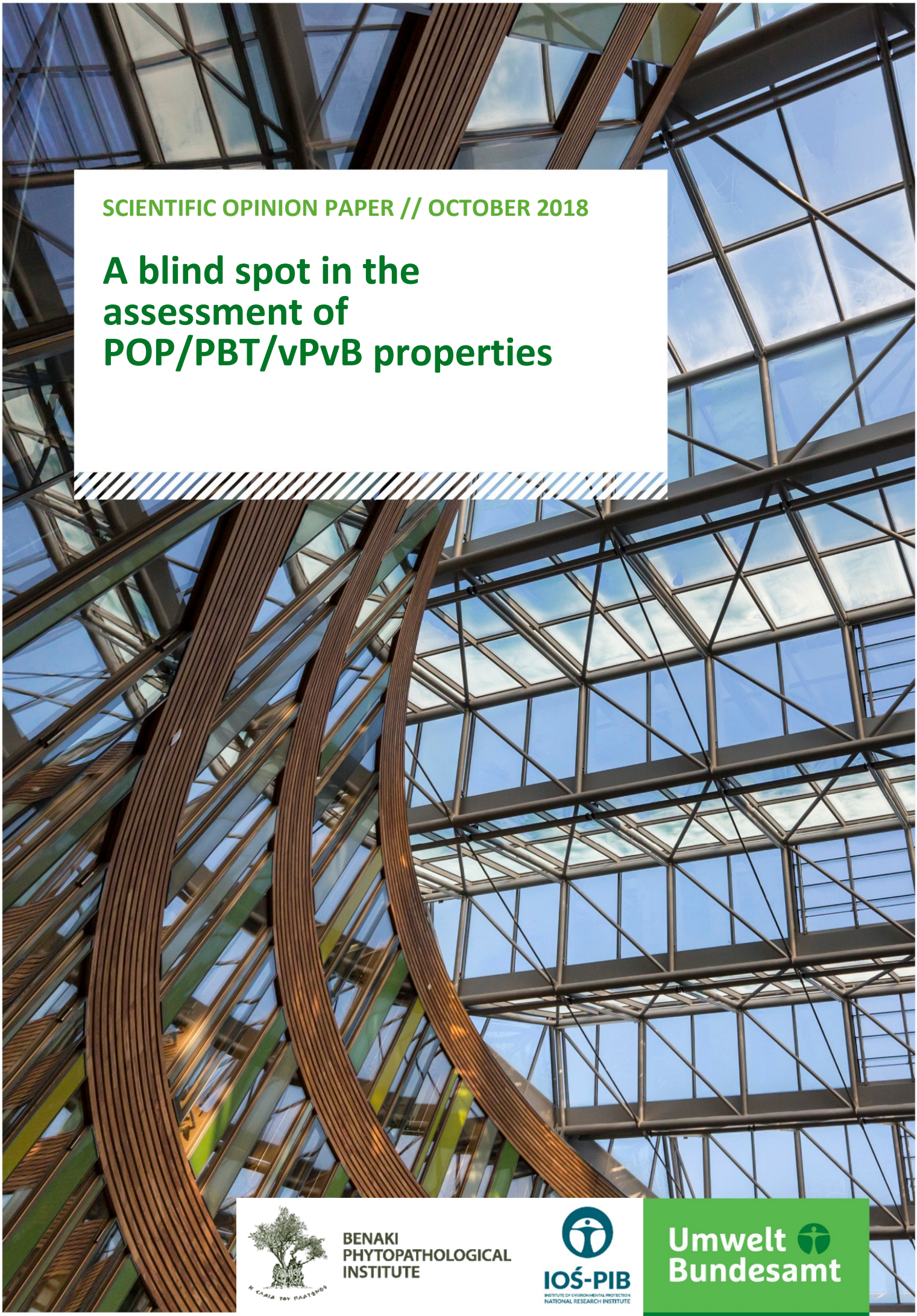

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A blind spot in the assessment of POP/PBT/vPvB properties

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- Federal Environment Agency (Germany)

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by

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Section IV 1.3 Plant Protection Products

On behalf of the German Environment Agency

A blind spot in the assessment of POP/PBT/vPvB properties: Transformation products of plant protection products

This paper relates to the assessment of transformation products (i.e. metabolites, degradation or reaction products), which are formed from plant protection products. Currently, the 'REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues' is underway. Therefore, we think, it is a good point in time to address a detail in Regulation (EC) No. 1107/2009 which is not in line with other substance regulations, i.e.

- Regulation (EC) No. 1907/2006 for REACH
- Regulation (EC) No. 726/2004 for medicinal products, and
- Regulation (EC) No. 528/2012 for biocides.

Where do we see a blind spot?

Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market requires an assessment of 'an active substance, safener or synergist' with regard to long range transport, persistence (P), bioaccumulation (B) and toxicity (T) (Annex II, 3.7). This hazard-based approach follows the precautionary principle laid down in Article 1 (4) and prohibits the approval of substances that fulfill the POP, PBT, or vPvB criteria.

However, the Regulation contributed to a blind spot: Also transformation products can be hazardous substances. Meanwhile, they are not yet covered within the POP/PBT/vPvB assessment and the approval criteria for active substances.

An academic or a real problem?

One example of a blind spot appeared in a recent assessment of the active substance etoxazole (which is used against mites and ticks). Etoxazole is transformed to a substance very similar in structure, called R-13. This transformation product is formed both in water and in soil in relevant concentrations. According to degradation data for soil and estimations for sediment, R-13 is considered very persistent (vP) in the environment. Besides, according to estimations R-13 is also very bioaccumulative (vB). Thus, this transformation product fulfills the criteria of vPvB substances – without any consequences yet.

What about other substance regulations?

At the same time, transformation products are indeed examined in the POP/PBT/vPvB assessment within REACH, for both human and veterinary medicinal products, in the assessment of biocides, and in the Stockholm Convention on Persistent Organic Pollutants. For example, the placing on the market of DDT (dichlorodiphenyltrichloroethane) was also limited due to the transformation product DDE (dichlorodiphenyldichloroethylene) which is also very persistent and very bioaccumulative (vPvB).

Is there any solution?

We have serious concerns to limit the POP/PBT/vPvB assessment to the active substance and to ignore transformation products completely. At least transformation products occurring in a relevant amount should be included in the assessment and the approval criteria in the same way as active substances, which is already described in the Regulation.

In order to foster harmonisation between the EU regulations for substances and their environmental assessment, we suggest to extend in the future the POP/PBT/vPvB assessment of plant protection products also to *metabolites occurring in a relevant amount* (please refer to 3.7.1, 3.7.2, and 3.7.3 in Annex II of the Regulation (EC) No. 1107/2009).

And what is a relevant amount?

Criteria for 'relevance' were laid down in the 'Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414 EEC' (SANCO/221/2000 –rev.10- final; 25 February 2003) and were later included in Regulations (EC) No. 283/2013 and No. 284/2013.

We suggest, that the term 'relevant amount' is defined under no. 32 in Art. 3 or in 3.7. of Annex II of the Regulation (EC) No. 1107/2009, like this:

'Relevant amount' means an amount of a metabolite, if the metabolite fulfils one of the following conditions:

(a) it accounts for more than 10 % of the amount of active substance added, at any time during the studies;
(b) it accounts for more than 5 % of the amount of active substance added in at least two sequential measurements;
(c) the maximum of formation is not reached at the end of the study but accounts for at least 5 % of the active substance at the final measurement.