Ten years on, how is the health of ECHA's Biocidal Products Committee?

INSIGHT INTERVIEW

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Erik van de Plassche, chair of the Biocidal Products Committee, gives Chemical Watch's senior biocides reporter, Vanessa Zainzinger, his personal reflections on the BPC's first decade and how to make a better system

Europe BPR

The biocidal products regulation (BPR) ushered in plenty of changes when it became effective in 2013. One of them was the introduction of the expert Biocidal Products Committee, run by ECHA, that would deliver opinions on all the major processes under the ambitious new law.

Ten years down the line, the BPC is a well-oiled machine, known for providing recommendations so solid they are almost always rubber-stamped by the European Commission. It is hard to imagine the EU's legal framework for biocides without the BPC's opinions at the heart of substance approvals, Union authorisations and legal disputes.

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In 2013, Erik van de Plassche had just joined ECHA, after coordinating technical and scientific support for the implementation of the biocidal products directive (BPD) at the Joint Research Center. He was immediately tasked with setting up the committee, a body he has chaired ever since.

Now, as he prepares to leave the agency at the end of July, he looks back on bringing the BPC to life ten years ago. "It was a challenge to set it all up, get the first meetings running, and learn how to bring all the member states to a consensus," he recalls. "We could use a little bit of experience from the existing REACH committees, like RAC [risk assessment committee] and MSC [member state committee], but had to make up our own processes and set it up from scratch, in a relatively short time."

A daunting task

Van de Plassche says the most daunting part of starting the committee was the ambitious goal of processing and adopting 50 opinions on existing active substances every year. The ongoing biocides review programme was notoriously slow under the BPD, but when it became a regulation in 2012, it was envisaged that with the help of a committee, the process could be speeded up and the overdue programme could be brought to completion.

"We thought we would meet the target, or at least that we would get close to it," van de Plassche remembers. And they did, in the beginning. The BPC adopted 49 opinions on active substances in 2015 and 45 in 2016. But by 2019, the number had slipped to just nine, as it became clearer that the review programme would be much harder to finish than regulators had hoped.

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In retrospect, the Commission's overambition is striking. It had expected the BPC would have processed 1,725 opinions – including on active substance approvals, Union authorisations and mutual recognition disputes – by 2023. In reality, the committee has adopted 391 opinions so far.

Van de Plassche says it was the introduction of the criteria for identifying endocrine disrupting properties that stopped progress in its tracks. The additional testing required has

added years to the evaluation of substances, he says. The BPC has had to delay conclusions on the assessment of dozens of substances to identify whether they meet the new criteria. Initially, it lacked an agreed methodology to assess if the criteria for endocrine disruptors have been met or not. Now there is official guidance, but the assessment process remains hindered by a lack of test methods and limited laboratory capacity. On top of this, for substances meeting the criteria, a risk assessment has to be carried out where no agreed methodology is currently available.

The BPC

The first meetings of ECHA's Biocidal Products Cmmittee (BPC) in 2013 were a milestone for the new biocidal products regulation (BPR), which envisaged Echa speeding up the European Commission's review programme and giving expert opinions on all active substances to be used in biocidal products.

Each member state can appoint one representative to the BPC which provides opinions on:

- applications for approval, and renewal of approval, of active substances;
- applications for inclusion in the BPR Annex I list of low-risk active substances;
- identification of active substances that are candidates for substitution;
- applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations; and
- scientific and technical matters concerning mutual recognition.

Simplifying

Over the years, van de Plassche has been an advocate of simplifying the BPR to avoid increasing delays in the review programme and other processes. As he prepares to leave ECHA, complexity remains a buzzword.

"The BPR is at least as complex as other legislation, such as REACH, but with a fraction of the resources to deal with it," he says. The small biocides teams in regulatory authorities are consistently overloaded with work, he says, trying to juggle more than 60 different processes under the BPR, while implementing their national systems for biocides that still run in parallel to the EU legal framework. While everybody is firing on all cylinders, he says, there is no time to reflect on whether the system is really running as it should.

"What we see is more and more delays in the review programme and a backlog of dossiers that doesn't seem to disappear," he says. He expects upcoming new requirements – for example, the guidance for assessing the risk of biocides to pollinators that ECHA will soon finalise – will keep making matters worse. "Almost always when you have a new element it leads to a new assessment, combined with new data needed. Our assessments will by default keep becoming more complex."

But changing this, he says, will "take some bold decisions." He has several suggestions, including mirroring the plant protection products regulation. This also had a long-running review programme, and like that sector, the biocides sector could introduce a hazard-based traffic light system that would see existing substances temporarily approved without a full assessment. "We would approve all active substances in the review programme, but establish a list of endpoints and assess exclusion and substitution criteria," van de Plassche explains.

He further suggests that regulators steer clear of introducing new technical scientific requirements and scrap the assessment of metabolites and impurities for the first approval of an existing active substance. Regulators could accept all reference specifications and that hazard data is covered by these specifications for the first approval, he suggests.

On top of this, all renewals of active substances should be delayed until 2035, van de Plassche suggests. "Renewals are a mini review programme," he says. "They take a lot of resources from member states and we are already seeing delays to renewals because current approvals will expire before the authorities can process the renewal application. It is a huge problem that all these processes are running at the same time."

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Meanwhile, regulators could think about redistributing dossiers between member states. "Some member state competent authorities do not have the resources to finalise their review programme dossiers; not now and not in the next five years," he says. "So other member states or ECHA may need to take over."

To van de Plassche, it is important that the Commission, ECHA, member states and industry look at the options above and jointly consult on the way forward. "We need to get together to find a way out that is acceptable to all," he says.

If nothing changes, van de Plassche is "almost convinced" that the six-year extension to the review programme, which was recently agreed, will not be sufficient. And as a result, he says, the market will suffer from a lack of innovation while companies don't have the capacity to put resources into new chemistries that could make biocides more sustainable. At the same time, existing active substance will keep disappearing from the market. Thirteen percent of the BPC's opinions recommend non-approval, and 30% of currently used actives are meeting the exclusion or substitution criteria.

'Proudest moments'

Looking back, van de Plassche also sees many achievements in the BPC's eventful first ten years. He highlights the first Union authorisation – adopted in 2017, for two biocidal products containing iodine/PVP-iodine – as one of his proudest moments, as well as the renewal of rodenticides, where the committee managed to coordinate a bumper response to the comparative assessment of anticoagulants with non-chemical alternatives and integrated pest management.

Joost van Galen will succeed Van de Plassche on 1 August. He has been working for ECHA since 2019 after a role as project leader for authorisations of biocides at the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb). He will chair his first BPC meeting in September.

Van Galen inherits an experienced, well-functioning committee, van de Plassche says. But he also notes the challenges that lie ahead. Like many parts of ECHA, the BPC will increasingly struggle with resource constraints as its remit expands and it takes on further tasks. An expected surge in minor and major change applications for biocidal product authorisations will become a significant stream of work, van de Plassche expects, coupled with the upcoming substance and Union authorisation renewal work.

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"Sometimes you wonder if that’s feasible for one committee," he says, as he hints at a provision in the BPR that allows for two BPCs to split the different procedures and workstreams. Other busy committees, such as the RAC, have previously had to restructure to cope, he says.

For now, however, the BPC can cope and remains one of the best functioning parts of the EU’s legal framework for biocides, and van Galen will be "stepping on a moving train", van de Plassche says.

"Everyone is very well adapted to this machinery and knows exactly what to do." Chairing the BPC, and guiding it to this place, has been a privilege, he says. "It’s been a very enriching experience. It was a challenge to set it up but as you go along, you realise that what you’re doing has an impact – you’re an important player in the biocides world."