Biocide Regulations – Life Before the BPR

By Hannah Leach

If you're new to the world of biocides and the Biocidal Products Regulation (EC) No 528/2012 (also known as the BPR) you might hear people refer to the BPD, 98/8/EC, identified and notified actives, review regulations and Annex I approvals and wonder what they mean…. This brief history of the biocides legal requirements before the BPR will help answer some of your questions.

****To receive direct notification of our news and articles, please opt-in to our e-newsletter, distributed once every two months****

What was the BPD?

The Biocidal Products Directive 98/8/EC (also known as the BPD) entered into force on 14th May 2000 and was the first EU wide scheme under which biocides were regulated and assessed for their safety to people, animals and the environment. A fundamental aim of the BPD was to harmonise the EU market for biocidal active substances and products. Once a biocidal product was authorised under the Directive in one EU Member State that authorisation could then be recognised in all other Member States.

Since the BPD was written as a 'directive', each EU Member State was then responsible for implementing the BPD into their national law.

What was Annex I of the BPD?

Annex I of the BPD contained all the **biocidal active substances** that had been assessed and approved for use in biocidal products. The ultimate aim of companies submitting active substance BPD dossiers was to gain '**Annex I inclusion**'. The equivalent under the BPR is referred to as the '**Union list of approved active substances**'.

[It is important not to confuse Annex I of the BPD with Annex I of the BPR. Annex I of the BPR refers to the list of active substances that can be used in products eligible for the 'simplified authorisation procedure'.]

The biocides review programme under the BPD

Biocidal active substances which were on the market before the BPD entered into force (14th May 2000) were referred to as '**existing active substances**'.

'**New biocidal active substances**' are those which were not on the EU market prior to the 14th May 2000. New active substances need to be assessed and approved before biocidal products containing them can be placed on the EU market.

From the date of entry into force, it was optimistically expected that the BPD review programme would last for 10 years and that by 2010 all the existing biocidal actives would have been approved. When it became obvious that this was not possible, the deadline was extended to 14th May 2014. Under the BPR, the deadline to approve all actives was then extended even further to 31st December 2024.

The review programme for existing active substances was governed by five EU Commission review regulations. The First Review Regulation ((EC) No 1896/2000) requested that industry either:

Hannah Leach; Regulatory Specialist Biocides

a. identify existing active substances placed on the market for use in biocidal products. Biocidal products containing active substances which had been identified (but not notified) could continue to be marketed until 1st September 2006; or
b. notify their intention to support an active substance through the review programme for potential inclusion in Annex I of the BPD. Biocidal products containing notified active substances could continue to be marketed for the notified product types until the active had been reviewed and an approval decision published.

The Fifth Review Regulation ((EC) No 1451/2007) updated and replaced the second, third and fourth review regulations. The key point to know is that this review regulation contains the definitive list of the identified active substances under the BPD and is the list often referred to by evaluating authorities with regards to the efficacy considerations of biocidal products.

The active substances were reviewed by product type and were separated into four priority lists which specified the deadlines for submission of the active substance dossiers for each supported product type:

Priority List	**Deadline for dossier submission**	**Product Type***
1st List	28th March 2004	PT8 Wood preservatives
		PT14 Rodenticides
2nd List	1st May 2006	PT16 Molluscicides
		PT18 Insecticides, acaricides and products to control other arthropods
		PT19 Repellents and attractants
		PT21 Antifoulants
3rd List	1st August 2007	PT1 Human hygiene biocidal products
		PT2 Private area and public health area disinfectants and other biocidal products
		PT3 Veterinary hygiene biocidal products
		PT4 Food and feed area disinfectants
		PT5 Drinking water disinfectants
		PT6 In-can preservatives
		PT13 Metal working fluid preservatives
4th List	1st November 2008	PT7 Film preservatives
		PT9 Fibre, leather, rubber and polymerised materials preservatives
		PT10 Masonry preservatives
		PT11 Preservatives for liquid-cooling and processing systems
		PT12 Slimicides
		PT15 Avicides
		PT17 Piscicides
		PT20 Preservatives for food or feedstocks *[later removed]*
		PT22 Embalming and taxidermist fluids
		PT23 Control of other vertebrates *[later re-named as PT20]*

* correct at the time of publication of the lists

The Rapporteur Member States (RMS) responsible for the review of each active substance dossier are detailed in Annex II of the Fifth Review Regulation.

Replacement of the BPD

The Biocidal Products Regulation (EC) No 528/2012 (BPR) was adopted on 22nd May 2012 and was applicable from 1st September 2013.It repealed and replaced the BPD. As a result of its status as a regulation, the BPR was automatically applicable in all EU Member States and so there was no requirement to implement the law into the national legislation. The Commission also took the opportunity to extend the work programme for the review of all existing biocidal active substances until 31st December 2024. Other key differences between the BPD and the BPR include *inter alia*:

- Exclusion and substitution criteria
- Union authorisation of biocidal products
- Frame formulations replaced by the concept of 'product families'
- Option for simplified authorisation procedure
- Use of biocidal products now included
- New requirements for treated articles
- Managed by ECHA
- List of active substance suppliers (Article 95 list) to prevent free-riders
- Mandatory data-sharing

How can Eurofins Help?

The Biocides Regulatory team here at Eurofins have worked together since 2005 and gathered extensive knowledge on the world of Biocides from the early days of the BPD right through to successful biocidal product authorisations under the BPR. If you require any assistance with your biocidal active or product approvals then please do not hesitate to contact Owen Pryce (owenpryce@eurofins.com).

Hannah Leach; Regulatory Specialist Biocides