Evaluation of Active Substances:

The Industry Experience

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2nd April 2015

150 years

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1 | Status Quo – where are we are where do we need to go?

2 | Industry experience - qualifications

3 | Extra requirements now in place for A.S. manufacturers

4 | Public consultations

5 | Article 95 – importance of being on the list

6 | Summary

Status Quo

- 1998 - Directive addressed the need to regulate the biocidal products market
- 2002 – confirmation of participation
- 2006 – first wave of dossiers submitted
- 2009 – first approvals
- 2010 – first extension to programme
- 2013 – ECHA take over running of programme
  - Aim of making 50 PT/AS decisions per year
- 2024 – programme to be completed

Status as of end of March 2015

source: source: CA-March15-Doc 5 2 - Progress of the RP of AS

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- Number of AS/PT decisions:

112

- Number of active ongoing AS/PT evaluations by ECHA:

100

- ECHA effect – AS/PT decisions since 1st September 2013:

34

- Number of AS/PT decisions still to take (approx):

450

Communicated timelines to completion

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Priority List	Product Type	Evaluation	Start BPC opinion
1	8, 14, 16, 18, 19, and 21	31/12/2015	31/03/2016
2	3, 4 and 5	31/12/2016	31/03/2017
3	1 and 2	31/12/2018	31/03/2019
4	6 and 13	31/12/2019	31/03/2020
5	7, 9 and 10	31/12/2020	31/03/2021
6	11, 12, 15, 17, 20 and 22	31/12/2022	31/09/2023

Challenges

- For industry and member states in continuing approach
  - Retention of expertise
- Market distortion in the PTs
- Heavy fee burden for some biocidal product manufacturers
- Negative decisions – impacting business

BASF is celebrating its 150th anniversary in 2015

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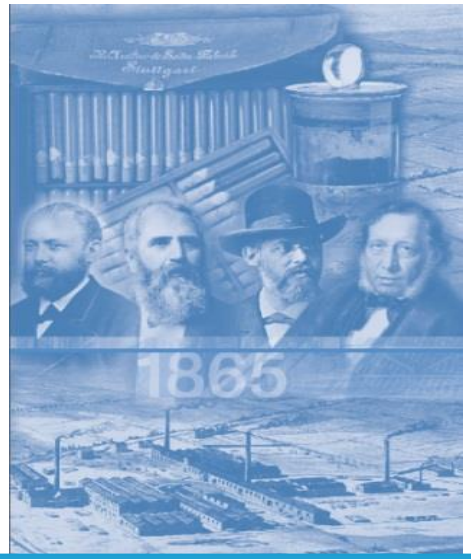

1865 2015 The future…

Chronology of BASF history

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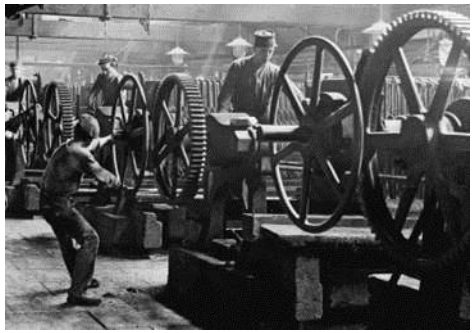

1865 – 1901
The age of dyes

1902 – 1924
The Haber-Bosch-Process and the age of fertilizers

1925 – 1944
New high-pressure syntheses

1945 – 1964
From new beginnings to the plastic age

1965 – 1989
The road to becoming a transnational company

1990 – 2015
Sustainable start to the new millennium

Chronology of BASF history

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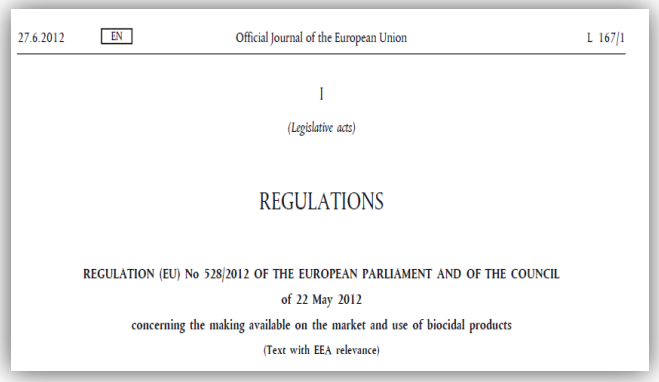
2002 – 202? The Age of Biocides



27.6.2012 EN Official Journal of the European Union L 167/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 May 2012
concerning the making available on the market and use of biocidal products
(Text with EEA relevance)

BASF Biocide Curriculum Vitae

- Number of Active Substances supported: 13 (18 in total for Group)
- Number of Product Types: 9
- Number of AS/PT approvals granted: 9 (still opinions)
- Number of AS/PT decisions still be made: 28
- Start of workprograme: 2002
- Expected date of completion: 2024

Extra Challenges for AS manufacturers

- New exclusion criteria and substitution criteria
- Evaluation or consideration of use in Treated Articles
- Harmonised classification and labelling
- IUCLID
- Age of submitted data
- Data sharing and negotiations
- Agreements and contracts
- Documentation of negotiations
- Importance of the 1st of September 2013 in the dossier evaluation

Substitution/Exclusion Candidate – what does this mean?

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- Aim is to encourage the use of active substances with a better tox and environmental profiles
- A new requirement under BPR

Exclusion Criteria (Article. 5)

- Active Substance will not be approved if:
  - CMR 1A and 1B
  - Endocrine Disrupters
  - PBTs (persistent, bioaccumulative and toxic) and vPvB
- If no alternative for PT exists and non-approval would be detrimental to human health, animal health or the environment - AS can be authorised for up to 3 years only.
- Not to be approved for consumer uses

Candidate for substitution (Article 10)

- A substance will qualify as a candidate for substitution if certain criteria are fulfilled, for example:
  - One of the exclusion criteria but may be approved due to lack of alternative
  - 2 out of 3 PBT criteria
  - is a Respiratory sensitisers (R42)
  - Acceptable Daily Intake, Acute reference dose or acceptable operator exposure level significantly lower than other AS for same PT and use.
  - Significant proportion of non-active isomers or impurities
- Length of initial approval for active substance will not be the full 10 years
  - Substances do not qualify for Union Authorisation

Extra steps in the Active Substance Evaluation: Public Consultation

- If the conclusion of the evaluation of any active substance shows that it meets the substitution criteria, according to Article 10, more information is necessary
  - These substances must be further evaluated before approval is granted.
- The further evaluation will take place as a public consultation, whereby any interested third party can submit information to ECHA (European Chemicals Agency) on viable alternatives or substitutes to the active substance under review.
  - 60 day consultation
- This process is very new but it will be increasingly used should more active substances progress through the BPR review programme and qualify as either a substitution

Public Consultation: Experience

- Suitable data is to be submitted – different approach to REACh SEA analysis
  - ALL alternatives are considered for that use
- As of March 2015:
  - Number of public consultations that have occurred: 12
  - Number of PTs involved: 14
  - Amount of data submitted: varied – for 4 substances no data was submitted
  - Percentage of BPC Opinions affected: 34%

(Ref: ECHA doc on experience in public consultation, Nov 2014, BPC-8-2014-06)

Implications for a substitution candidate at Product Authorisation

- If Active Substance is a substitution candidate – a comparative assessment **will** take place
  - Comparison of the product vs other approved products on the market
- A comparative assessment can **only** be done if:
  - Other BPS have already been approved in that country for that PT
  - The BPs on the market must show more than 3 modes of action in killing bacteria/fungi/moulds/yeasts etc.
    - If answer is no – evaluation can not be done for risk of developing antimicrobial resistancy
- The product approval will not be 10 years – most likely shorter than the AS approval
- Fees!
  - More frequent reapproval and comparative assessment fees

Implications of comparative assessment

- BPR timelines have been brought in line with the original submission deadlines
- Aim under BPD – to review the most urgently needed AS and PTs
- Review of remaining AS has been brought in line with the original submission deadlines
- Aim under BPR – to make comparative assessment easier for the PTs

Reality of comparative assessment

- HOWEVER, not all Member States worked according to this logic!
  - Some Member States were quick and have reviewed all AS/PTs
  - Some of the substances have now been branded as Substitution Candidate
  - For some products there are no alternatives in the product type
  - AS will no longer receive the full 10 years approval
  - BPs will not receive the full 10 years
  - Some active substances, which are ‘fortunate‘ to be with slower MSs will qualify but much later in the programme
- Skewing of the market

Pragmatic approaches to comparative assessment

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- Due to the way in which Member States approached the review – not straightforward to evaluate all PTs together
  - PT6 substances are starting to come through
  - Each A.S. is being evaluated independently
  - 50% of sensitising AS s are in this group
  - Deadline for PT 6 review is 2020
  - By 2020 the choice for PT6 may be considerably smaller
  - If some groups of substances are removed – not many alternatives
- For this group of actives an alternative approach needs to be considered to ensure that the market can still work!
- Approach already proposed for PT 14 and PT 21

Important confirmations:
Importance of the Article 95, Manufacturers of Active Substances List

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- Article 95 is an overview of all active substance suppliers and product suppliers who have submitted a valid dossier and are allowed to stay on the market
- All biocidal product manufacturers need to use authorised substance suppliers at the latest from 1st September 2015
  - An approved supplier has to be used even if the Active Substance is not approved on the 1st September 2015

What do Biocidal Product Manufacturers need to have?

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- Transparency of supply chain to supplier in Art. 95 List
- Confirmation of supplier status
- Do not necessarily need a Letter of Access
- Otherwise Member States will police and cancel registrations

Example from UK:

EU Biocides Regulation 528/2012 (EU BPR) – Impact of the Article 95 list on biocidal products made available on the UK market under the Control of Pesticides Regulations (COPR)

From 1 September 2015, a biocidal product cannot be made available on the EU market unless either the substance supplier or the product supplier is included in the Article 95 list for the product type to which the product belongs. Have you checked your supplier is listed?

By 1 September 2015, **all** companies making biocidal products available on the UK market must have evidence their supplier is included in the Article 95 list. This evidence should include written confirmation of the source of the active substance formulated within the product and a link to the source's entry on ECHA's Article 95 list.

HSE does not intend to be prescriptive as to exactly what that evidence should comprise as we believe industry should have a degree of flexibility on this issue, but you should have documentation demonstrating a clear, auditable trail showing the supply of the active substance used in your product is from a specific Article 95 listed company – for example that could be a Letter of Intent to Supply or a similar document from the Article 95 listed company; copies of paperwork such a contract between the companies for the supply of that substance; or invoices/delivery notices etc. If a company is making the biocidal product available on the market and also the Article 95 listed company for the active substance in the product, a simple written confirmation of the fact that they will only be using their own source of the active substance will suffice.

ALL COPR Approval Holders need to submit evidence to HSE to prove that the supplier of the active substance in their product(s) or the product supplier is included in the Article 95 list.

If HSE DOES NOT receive this information on your product(s) by 1 September 2015, the approval conditions relating to the advertisement, sale and supply of your product(s) will be REVOKED.

NO phase out period for the advertisement, sale and supply of your product(s) on the UK market can be granted.

The approval conditions relating to the storage, use and disposal of your product(s) will continue subject to the provisions of Article 89(2), 3(b) and 4(b) of EU BPR.

All other companies making biocidal products available on the UK market must have the required evidence and must provide it to HSE or Enforcement Authorities if requested.

Have you submitted your evidence yet? If you haven't send it to our usual address.

BPR – a life enhancing experience?

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- BPR is and will remain a challenge - need to focus on the positive:
- Work-life Balance
- Health
  - ECHA now in lead – more resources, tighter time lines – need to keep up!
- Learning
  - new documentation, data sharing – develop new skills
- Patience
  - Time lines have been extended - not over soon
- Security
  - Biocides is a job for life!

Thank you for your attention!

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