BIOCIDAL PRODUCT DOSSIER EVALUATION PROCEDURES

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INTRODUCTION

Regulation EU N° 528/2012 (BPR)

CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

Biocidal products shall not be made available on the market or used unless authorised in accordance with the Regulation. In the article 19 of BPR the conditions for an authorisation of a biocidal product are well described.

TOPICS

National authorisaton procedure

Mutual recognition procedure

Other procedures

Pre-submission meetings

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National Authorisation Procedure (1)
BPR

1) Applicant submit an application to the receiving Competent Authority.

2a) The receiving competent authority shall inform the applicant of the fees payable and shall reject the application if the applicant fails to pay the fees within 30 days.

2b) Upon receipt of the fees payable under, the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

National Authorisation Procedure (2)
BPR

3a) Within 30 days of acceptance, the receiving Competent Authority shall validate the application.

3b) Where the receiving Competent Authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

3c) The receiving Competent Authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements.

National Authorisation Procedure (3)
BPR

4) The receiving Competent Authority shall decide whether to grant an authorisation in accordance with Article 19 within 365 days of the validation of an application.

Within the 365-day period, the receiving competent authority shall:

- draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the 'assessment report');
- send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days;
- take due account of those comments when finalising its assessment.

National Authorisation Procedure (1)

Italy

1. The Ministry of Health (MoH) manages the acceptance of the application through the R4BP3.

2. At the same time, the MoH perform the first completeness check of the information submitted by the applicant and send a letter of commitment for the evaluation to the National Institute of Health (ISS).

3. The ISS receives the letter of assignment for the evaluation and it accesses to the IUCLID dossier and related information on the R4BP3.

4. The dossier is assigned to the national experts on biocidal products evaluation for a technical-scientific check (20 days).

National Authorisation Procedure (2)

Italy

5. A request for additional information can be sent to the applicant in case of data gaps (30 days).

6. If no additional information are required, the evaluation starts (3-4 months).

7. The product assessment report (PAR) and the Summary of product characteristics are drafted considering the evaluation performed by the national experts.

8. The documentation related to the opinion on the authorization of the biocidal product is uploaded on the R4BP3 and sent to the MoH.

National Authorisation Procedure

First Stage

DRAFT risk assessment/DRAFT PAR

List of studies

MSDS

Letter(s) of access

Justification for data waiving

Second Stage

Summary of product characteristics (SPC) in english/italian

Italian labels according to the SPC

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MUTUAL RECOGNITION PROCEDURE (1)

BPR

An application for Mutual Recognition in parallel (MRP) is made after the decision to approve the active substance is adopted and at the same time as the initial NA application. A reference Member State (RMS) and one or more Concerned Member States (CMS) are involved at the same time.

An application for Mutual Recognition in sequence (MRS) can be made at any point after the national authorisation is granted in the reference MS, on the condition that it is still valid.

MUTUAL RECOGNITION PROCEDURE (2)
BPR

The RMS shall be responsible for the evaluation of the application and it has 365 days to draft the PAR and the SPC.

A 90 days commenting period is expected and the CMSs can provide their written comments on DRAFT PAR/SPC.

Within this 90 days period, the CMS shall agree on the summary of biocidal product characteristics.

MUTUAL RECOGNITION PROCEDURE (3)
BPR

Within 30 days of reaching agreement, the reference Member State and each of the CMSs shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

If no agreement is reached within the 90-day, each Member State that agrees to the summary of biocidal product characteristics may authorise the product accordingly.

MUTUAL RECOGNITION PROCEDURE (4)
BPR

Article 35

Referral of objections to the coordination group

If any of the CMSs considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the RMS, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

60 days to reach an agreement on the authorisation of the biocidal product

MUTUAL RECOGNITION PROCEDURE (5)
BPR

Article 36

Referral of unresolved objections to the Commission

If the Member States fail to reach agreement within the 60-day period the RMS has to inform the Commission.

The Commission may ask the Agency for an opinion on scientific or technical questions raised by Member States and adopt a decision.

The CMSs and the RMS shall comply with the decision within 30 days of notification by the Commission.

MUTUAL RECOGNITION PROCEDURE (1)
ITALY

1. The Ministry of Health (MoH) manages the acceptance of the application through the R4BP3.

2. At the same time, the MoH perform the first completeness check of the information submitted by the applicant and send a letter of commitment for the evaluation to the National Institute of Health (ISS).

3. The ISS receives the letter of assignment for the evaluation and accesses to the related information on the R4BP3.

MUTUAL RECOGNITION PROCEDURE (2)
ITALY

4. The documentation drafted by the RMS (PAR and SPC) is evaluated and, eventually, written comments are provided to the RMS.

5. The documentation related to the opinion on the authorization of the biocidal product is uploaded on the R4BP3 and sent to the MoH.

MUTUAL RECOGNITION PROCEDURE

Less information than a National authorization are required, in order to finalize the evaluation.

The evaluation is based in the first evaluation performed by the RMS.

SPC in English/Italian and Italian labels are always required.

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OTHER PROCEDURES

Renewals of the authorizations, same biocidal product applications and administrative changes are managed directly by the MoH.

Changes on biocidal product, both major and minor changes, are managed by the ISS after a letter of assignment by the MoH. In this case, the procedure in similar to the evaluation of an authorization, but with a low number of experts involved.

COMPARATIVE ASSESSMENT (1)

Art. 23 del BPR → **Comparative assessment**

Art. 24 del BPR → ***Technical Guidance Notes*** **(TGN)**

Technical Guidance Notes (TGN): *CA-May15-Doc.4.3.a – Final*

COMPARATIVE ASSESSMENT (2)

Where an active substance is identified as a candidate for substitution, the Member State should carry out a comparative assessment to check whether other authorised biocidal products, non-chemical control or prevention methods that present a significantly lower overall risk for human health, animal health and the environment are available.

If there is already an authorised product, which is sufficiently effective, presents no other significant economic or practical disadvantages and does not affect the occurrence of resistance in the target organism, the new product will be restricted or prohibited.

COMPARATIVE ASSESSMENT (3)

1) Screening Phase

1.a) Chemical diversity assessment

2) Tier I – Comparison to eligible alternative BPs

2.a) Tier I-A – comparison of elements available at SPC level

2.b) Tier I-B – detailed comparison

3) Tier II - comparison to eligible non-chemical alternatives

3.a) Assessment of "sufficiently effective"

3.b) Assessment of significant economic or practical disadvantages

3.c) Assessment of significantly lower overall risk for human health, animal health and the environment

3.d) Overall conclusion of Tier II

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PRE-SUBMISSION MEETINGS (1)

Future applicants for authorisation may request a pre-submission information session with MSs to clarify regulatory and procedural issues related to the authorisation application process.

The pre-submission information sessions aim to give future applicants for authorisation the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process.

PRE-SUBMISSION MEETINGS (2)

1. The applicant asks to the MoH for an authorization to proceed with a pre-submission meeting.

2. Letter of assignment to the ISS by the MoH.

3. A form is sent to the applicant to provide questions on future application (max 10) in order to involve the experts and organize the meeting.

4. The pre-submission information session (2 hours).

THANK YOU
FOR YOUR ATTENTION