MAKING A DECISION ON MARKETING THE BIOCIDAL PRODUCT
CASE STUDY FOR A PT18

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CASE STUDY (PT18)

Situation:

2 application for national authorisation with related mutual recognition in parallel

3 application for national authorisation

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Application for a Mutual Recognition in Parallel of an insecticide/acaricide, intended to be used against crawling and flying insects (cockroaches, ants, flies, mosquitoes, including tiger mosquitoes) and arachnids, as ticks and dust mites, by professional and non-professional users in indoor and outdoor areas.

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WHAT TO DO?

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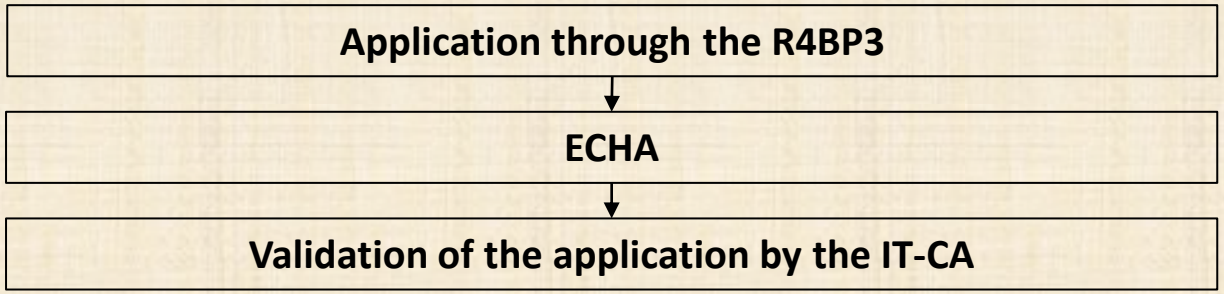

The application has to be controlled in order to check if all required documents have been submitted.

Completeness check for compliance with the data requirements according to the most recent guidelines.

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Pre-evaluation check by the national experts

Dossier check in order to verify if all the information reported by the applicant are correct.

Missing information have to be requested.

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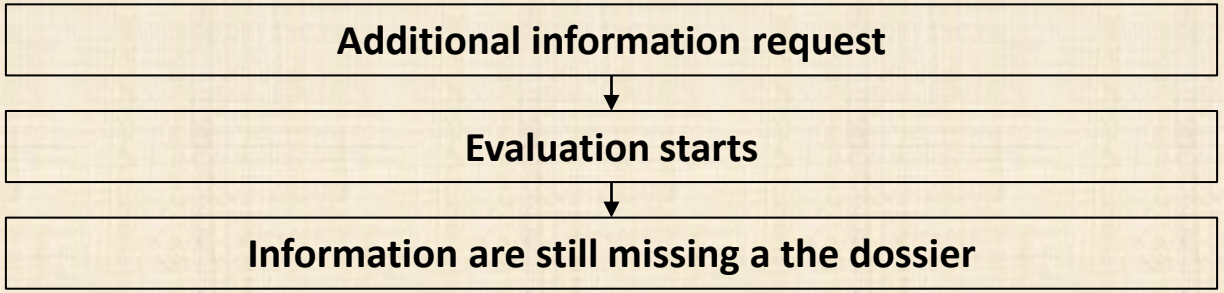

A second request for missing data should be sent to the applicant.

All the data requirements have to be covered by the dossier and scientifically valid justification must be submitted in case of data waiving.

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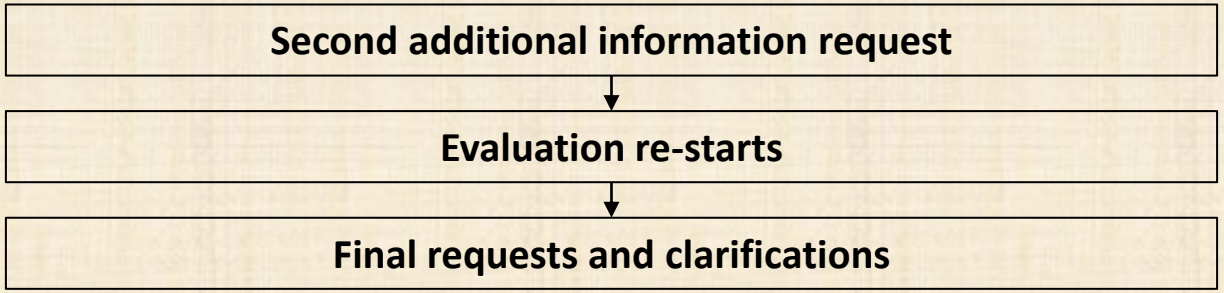

When the evaluation is finalized, a DRAFT PAR and SPC have to be prepared.

CMSs can provide their written comments on the DRAFT documents.

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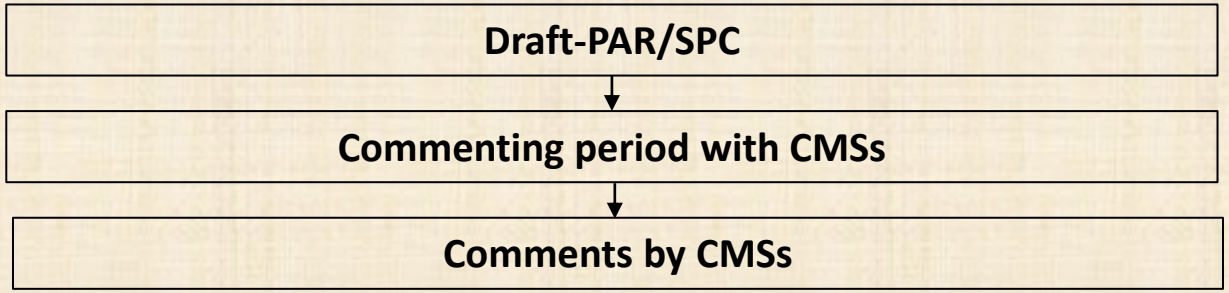

A reply for each open point has to be submitted by the RMS.

National experts are involved in the procedure.

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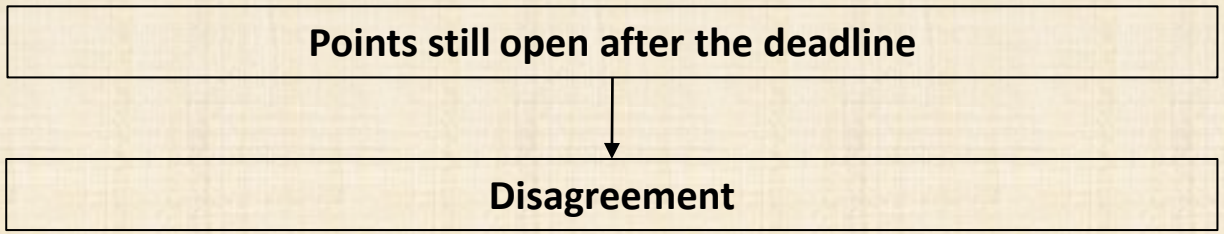

All the still open points have to be discussed at the Coordination Group in order to reach an agreement.

Usually, teleconferences are organized to discuss the open points.

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All the open points can be closed after the agreement.

PAR and SPC must comply with the decision of the Coordination Group and have to be revised accordingly.

After the revision the evaluation is concluded and the authorization can be granted by the RMS and all the CMSs involved within 30 days.

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Situation:

4 applicants

5 application requests and 5 biocidal dossier submitted

The dossier has been developed in task-force and all the applicant submitted different application for each product.

5 letter of assignment for the evaluation of these product

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Number of products
2 involved in NA-MRP with Italy as RMS
3 for a NA-APP

Intended uses
>10

Authorised uses
1

Evaluation time
ca. 14 mesi

Comments received by the CMSs
>130 (for each of 2 products involved in the)

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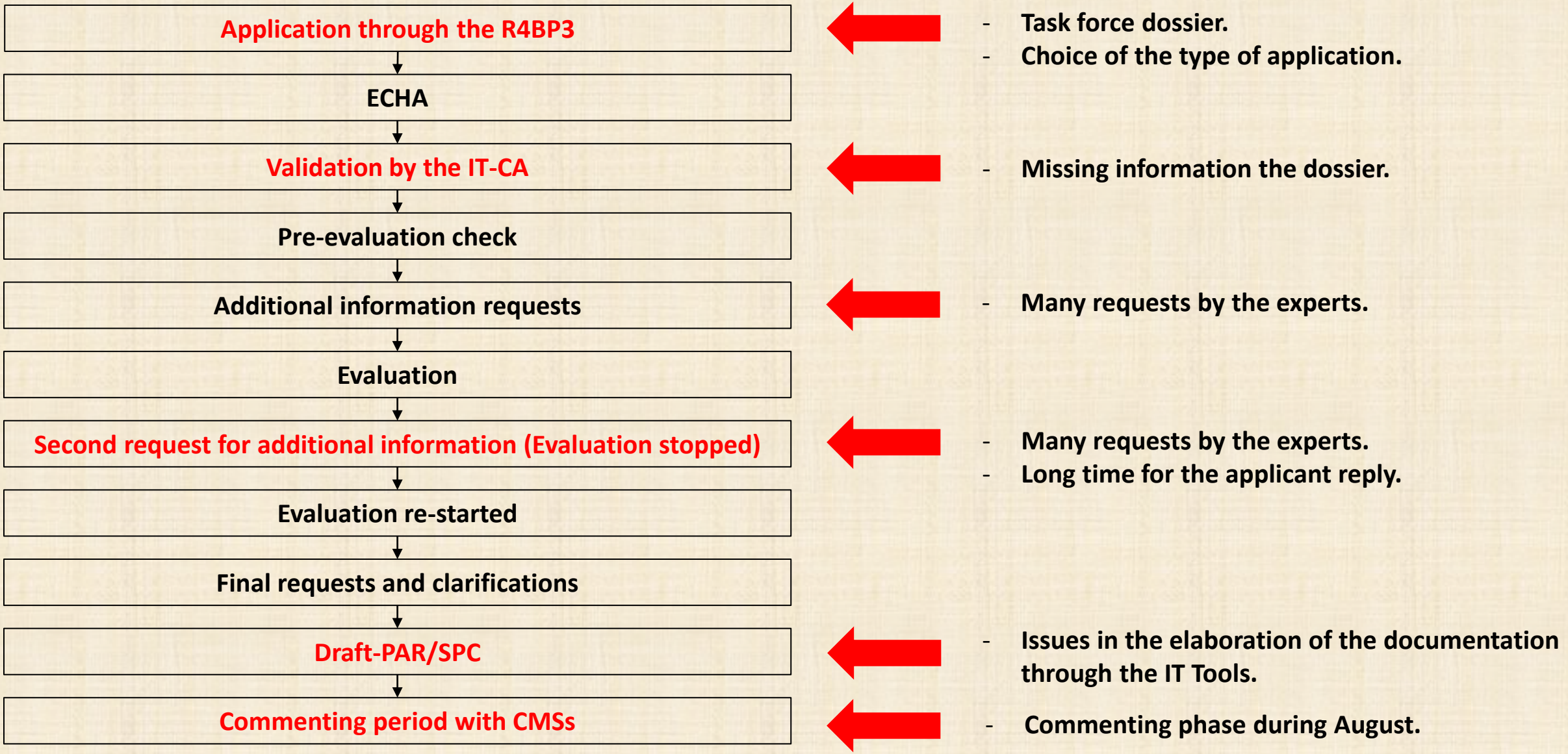

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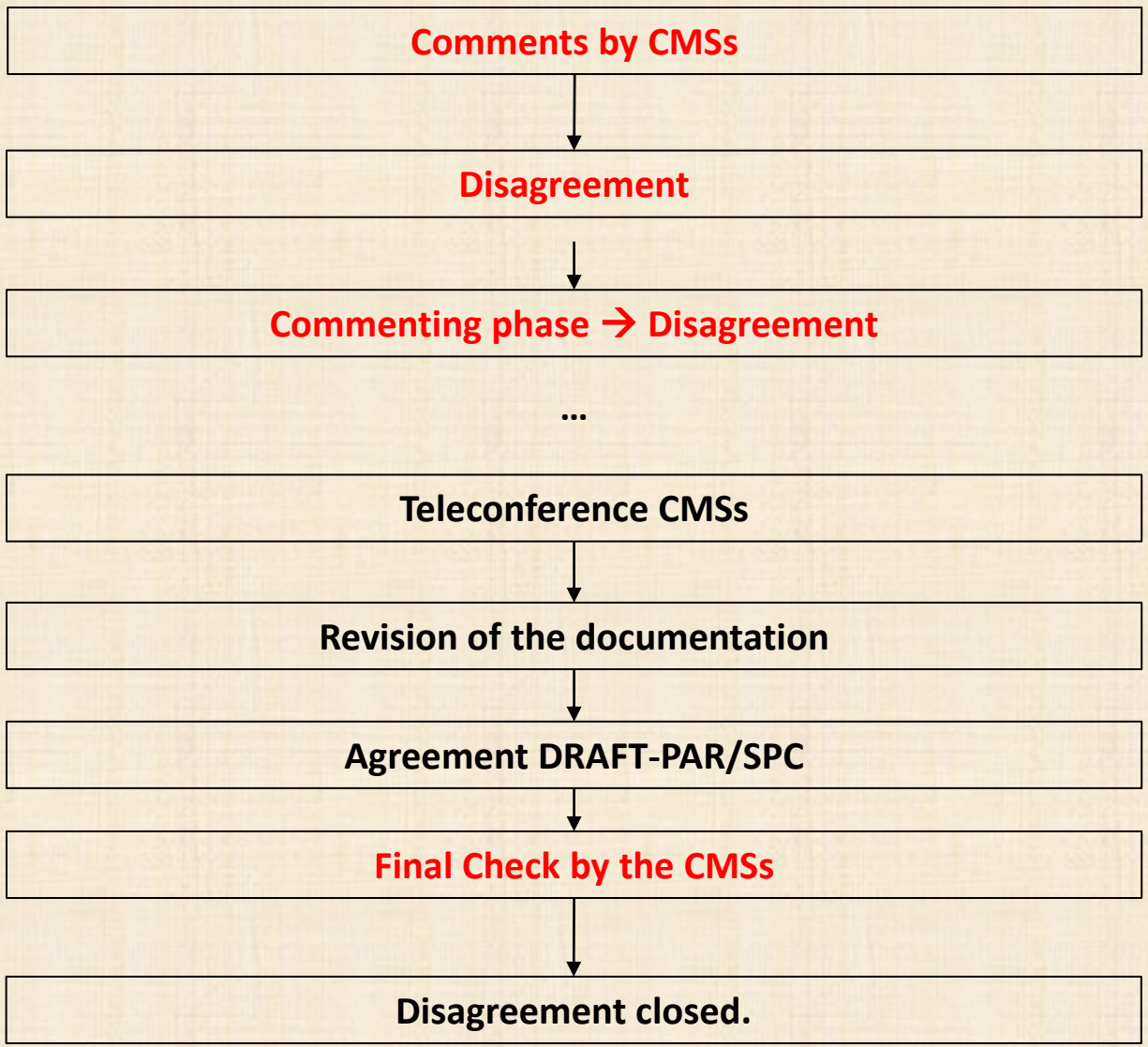

- Many comments received by the CMSs
- No reply within the deadline.
- Change of the procedure.
- Problem to log into the IT Tools.
- Delay in the finalisation of the related documents.

THANK YOU
FOR YOUR ATTENTION