The Turkish Journal of Occupational / Environmental Medicine and Safety

Vol:1, Issue Supplement 2 Web: http://www.turjoem.com ISSN : 2149-4711 Oral Presentation

P20. NATIONAL ACTIVITY FOR BIOCIDES SUBSTANCES AND PRODUCTS

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Active substances activity

The Unit of Hazard Evaluation of Preparations and Mixtures of the National center for Chemicals of the Istituto Superiore di Sanità is responsible for evaluating the biocidal active substances and products.
In the Unit a scientific secretariat (SECR) has been established with the aim to coordinate the activitiesand they are also involved in the evaluation of the active substances trough several actions:
-The documentation (original dossier; CARs; Commenting tables) is uploaded on the shared folder managed by the IT department;
-SECR informs the experts that a new dossier/documentation has been submitted and uploaded on the folder providing general information on pathway for retrieving the documents, the deadline for finalizing the assessment;
-Internal meetings are organized for discussing critical issues came up during the evaluation, for prioritizing the activities;
-In drafting the CAR (and any other evaluation reports), the experts modify directly the original documentations previously saved on a specific subfolder, and all the revisions are made in track changes;
-An overall editorial revision is carried out after the finalization of the assessment;
-Experts communicate by emails for informing colleagues on critical issues came up during the evaluation.

The active role of ECHA ensures an effective and close cooperation with eCA:
-the Dossier manager provides scientific support in the identification of the critical issues;
-helpful contribute from BPC SECR in drafting the Draft Opinions and the Assessment Reports in compliance with the provisions in the BPR (risk management measures, restrictions and/or operation controls to be put in place when a potential risk can occur);

The exact timing established for each step of the peer review allows eCA to plan the activities and set up the priority, coordinating with other ECHA committees and/or expert groups involved in specific issues, such as:

- RAC for the harmonized classification; ED Expert Group in case the active may have endocrine disrupting properties and PBT Expert Group when PBT/vPvB criteria are met.
As to be compliant with the BPR/BPD requirements the eCA fully revises the evaluation submitted by the Applicant in the originally dossier but often no endorsed guideline is used; limited number of scenarios have been evaluated respect to the intended uses claimed in the dossier; data are waived on the basis of questionable rationale; several documents to be provided during the different evaluation steps, such as: First Draft CAR / Consolidated RCOM Table / Draft Final CAR / Assessment Report / Draft Opinion / Combined CARs / CLH report/ etc.

Products evaluation

An additional panel of experts is in charge of products evaluation.
National activity related to authorization and mutual recognition are described.
Uncertainty in the submission of the additional information/studies from the applicant are often responsible for the delay in finalizing the assessment, and the eCA is requested to revise the assessment when NEW guideline or format are endorsed, causing additional burden of work; no formal disagreement have been received till now at national level.