The importance of the problem formulation step in the risk assessment process for LMOs

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Abstract

Problem formulation (PF) is a systematic planning step that identifies the key factors to be considered in a particular risk assessment. PF enables transparency by explicitly stating and framing the assumptions essential for the safety evaluation. PF is the crucial basis for the entire risk assessment process. The key steps hereby are a) identifying operational protection goals, b) defining plausible pathways to harm, c) formulating risk hypotheses about the likelihood and severity of such events, d) identifying the information useful to test the risk hypotheses, and e) developing a plan to acquire adequate data for hypothesis testing. The main products of problem formulation are a conceptual model and a detailed analysis plan. Originating from chemical risk assessment, the methodology of PF is now the integral part in all areas of regulatory safety evaluation, especially in environmental risk assessments. A more explicit use of PF is required for LMOs, to take account of their specific properties on a case-by-case basis. A crucial step in PF is the identification of the hazards associated with induced genetic modification of the specific LMO based on a comparative approach. Comparison of any characteristics of the LMO contrasting those of the appropriately selected comparator(s) enables the identification of differences that may lead to new or changed levels of harm. These differences are then theoretically assessed in the problem formulation process in order to identify the potential (environmental) consequences. Case-specific factors to be considered are: a) the biology and ecology of the parental organism, b) the introduced traits, c) the intended uses of the LMO, d) the scale and frequency of possible release into environment, e) the receiving environment, and f) the interactions among these variables enabling an increased establishment and spread of the LMO. Only those new characteristics which have the potential to cause harm will need to be assessed. Therefore, it is the LMO's potential effect different to an adequate comparator on agreed protection goals that counts for PF.

Key words: problem formulation, LMO, hazard identification, (environmental) risk assessment