Proposed new text to add to RA\_Training\_Manual\_rev11DEC2013 (perhaps as a new Annex or immediately following the text now found at Line 1443 or Line 1675.)

The manual and roadmap guidance documents both mention only briefly that the amount of information needed for an environmental risk assessment of an LMO can be influenced by whether the environmental release is a small-scale, confined release versus a large-scale unconfined release. For novice and expert risk assessor alike, it is crucial that this be elaborated upon in a way that does not give the impression that researchers will have a lot of information in the earliest stages of basic research or research that is intended to be part of variety development for LM plants. It is hoped that this information in the Manual will avoid the unintended consequence of discouraging researchers in the public sector universities and institutes from using LM plants in their research – a loss which would deny mankind of a proven, vital tool for crop variety development and environmental protection.

This brief section of the Manual is intended to clarify some of the main distinctions between small-scale confined and large scale unconfined environmental releases, both the size of the release and the duration of the release. This can be illustrated in the case of environmental releases LM plants by looking at the extensive experience in several countries that have conducted environmental risk assessments for both types of environmental releases for the same LM plant.

In the case of small-scale, confined releases for LM plants the information needed for the risk assessment typically includes a brief description of the plant species, gene(s) inserted, and the environment (location, size, and duration of the release). In such releases, potential environmental impacts are limited, because the LM plant has limited interaction with the environment.

Several countries have more detailed information online about their specific approaches for small-scale confined environmental releases (often called field tests), and these countries also have information that allows for a comparison with the types of information needs for large-scale unconfined releases with LM plants that would be typical of commercial production for a new variety.

[Note to authors: It is important that this distinction be clear in the manual and guidance documents. This is something that the AHTEG should elaborate upon in their work over the coming months.]

The simple table below may provide a starting point for further elaboration of this concept.

|  |  |  |
| --- | --- | --- |
|  | **Small-scale confined** | **Large-scale unconfined** |
| 1. Plant  | Species, variety  | Species, variety |
| 2. Gene(s) | Genes, promoters, terminators, introns, etc | Genes, promoters, terminators, introns, etc.Copy number (limited use but sometimes useful), expression levels of gene products,  |
| 3. Environment | Location, size, and duration of the confined release site; means of physical and/or biological confinement during the course of the environmental release  | Environments where the plant will likely be grown Other organisms in those environments that are likely to interact with the plant  |