



CASE STUDY 11:

A medical researcher seeks information about application of the Advance Informed Agreement procedure

Objective:

To determine if the Advance Informed Agreement procedure applies in particular instances

References:

Biosafety Protocol

BCH Module 1: Introduction to the Cartagena Protocol on Biosafety

Scenario:

You are working for a Competent National Authority and have been contacted by a medical researcher who intends to start some new research. She wishes to import some supplies and wants to know if the Advance Informed Agreement (AIA) Procedure will apply to her.

- (i) A line of genetically engineered knock-out mice¹ for cancer research in a contained facility.
- (ii) Five genetically modified rice plants that have been modified to express a protein that will be planted in a small plot on university grounds that can be harvested and used to produce a medically important pharmaceutical ('biopharming').

¹ A genetically engineered mouse that has had one or more of its genes made inoperative (i.e. have been "knocked out" of the mouse).



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TRAINER NOTES

Training Objective:

Understand the application of the AIA procedure.

Requirements:

Cartagena Protocol on Biosafety or access to the BCH if printed version of the Protocol is not available.

Notes:

- Users can work singly or in groups for this exercise.
- This exercise may be used to spark discussion regarding the complications surrounding use of the phrase “intentional introduction into the environment”, which is not defined by the Protocol. It must be read in context of other Protocol provisions, for example Article 7 (which clearly excludes LMO-FFPs; although the biopharming in this example does involve processing, they are also intended for planting) and the contrasting definition of “contained use” in Article 3(b).
- You may wish to note that some LMOs may also be given specific exclusions from the AIA procedure under Article 7.4.