**To**: GMO contact list

**Subject**: Consultation for a medicinal product for human use containing or consisting of a GMO - [name of product (INN)]

**Message:**

Dear colleague,

This is to inform you that a marketing authorisation application for [name of product (INN)] has been received by the European Medicines Agency. The [Committee for Advanced Therapies] [Committee for Medicinal Products for Human Use] considers that the product contains or consists of genetically modified organisms (“GMOs”).

Brief description of the product: [add description]

In accordance with Article 6 of Council Regulation (EEC) No. 726/2004, necessary consultations will be held with the Competent Authorities established under Council Directive 2001/18/EC with respect to the evaluation of environmental aspects.

The procedure for evaluation started on [add date] and the evaluation timetable is attached.

The consultation with the Competent Authorities will start on [add date]; by which EMA will send to the Competent Authorities the Module 1.6.2, the Rapporteur assessment report on the environmental risk assessment (ERA) and a consultation form.

The consultation deadline to receive the Competent Authorities comments will be: [add date]

Should you have any questions on the above please do not hesitate to contact me.

Yours sincerely,

[Add NAME]

Product Lead

European Medicines Agency

Attachments:

Evaluation timetable