

Biology documents

Environmental risk/safety assessments of genetically modified (GM) or genetically engineered (GE) plants are based on a broad body of knowledge and experience with the untransformed species (variety, etc.), i.e. familiarity with the conventional crop plant. The intent of a biology document is to describe portions of this body of knowledge directly relevant to risk/safety assessment in a format readily accessible to regulators.

The biology document is not an environmental risk/safety assessment of the species. Rather, the document provides an overview of pertinent biological information of the untransformed species to help define the baseline and scope (the comparator against which transformed organisms will be compared), in the risk/safety assessment of the transformed organism. Biology documents are not detailed crop handbooks or manuals of agricultural or silvicultural practice or economic botany, but rather focus on the biological information and data that may be clearly relevant to the assessment of newly transformed plants.

Biology documents are categorised into several sections. The sections range from species specific information to information on the potential effects of the crop species on human health and biosafety. The information contained in the biology document is essentially an assessment of the information pertinent to the environmental risk assessment from collective peer reviewed sources. In addition, a useful list of references and appendices are usually included at the end of each document.

Competent authorities such as the [Canadian Food Inspection Agency \(CFIA\)](#) and the [Australian Office for the Gene Technology Regulator \(OGTR\)](#) have developed comprehensive databases on relevant biology documents. The [Organisation of Economic Cooperation and Development's \(OECD's\)](#) consensus documents for the work on harmonising the regulatory oversight in biotechnology are probably one of the best resources available to risk assessors.

The OECD's consensus biology documents relevant to South African GM crops can be accessed directly here:

1. [Maize](#)
2. [Cotton](#)
3. [Soybean](#)