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Abstract

The risk assessment process – the voice of the scientist

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Under the Directive 2001/18/EC on releases to the environment, genetically modified plants are assessed for their safety to human health and the environment. Data supplied by the notifier are assessed initially by the competent authority at Member State level before being considered at the European level for marketing consents (Part C releases). The EC Scientific Committee on Plants (SCP) is consulted by the Commission for advice and risk assessments on specific dossiers and to provide up-to-date evaluation of emerging scientific results. Since its establishment in 1997 the Scientific Committee on Plants, consisting of independent scientists around Europe, has published some 115 opinions on the internet (http://europa.eu.int/comm/food/fs/sc/scp/index_en.html) covering its dual remit of advice on plant protection products (under Directive 91/414/EEC) and genetically modified organisms (under Directive 90/220/EEC and now 2001/18/EC). 32 published GMO opinions arise from risk assessments of specific dossiers, guidance documents and individual questions posed to the Commission on GM issues. The newly established European Food Safety Authority is taking over this role and a Scientific Panel on Genetically Modified Organisms will replace the SCP in Spring 2003.

The case by case scientific risk assessment consists of sequential steps to identify characteristics which may cause adverse effects: evaluate their potential consequence, assess the likelihood of occurrence and estimate the risk posed by each identified characteristic of the GMO. The risk assessment is guided by an initial comparative analysis with appropriate non-GM comparator and aims to identify intended and any unintended effects of the genetic transformation. Jointly, experts from the SCP, the Scientific Committee on Food (SCF) and the Scientific Committee on Animal Nutrition (SCAN) have produced a guidance document for notifiers which systematically summarises the strategy and data for risk assessment. This includes molecular characterisation, comparative analysis, environmental assessment, food and feed safety assessment, allergenicity, wholesomeness and derived animal products. Following a public consultation on the Internet, the draft document is currently under revision and will shortly be published in final form by the overarching EC Scientific Steering Committee.