An Overview of Online Databases and Web-based Resources Related to the Biosafety of Genetically Modified Crops

By W. Craig[1], M. Araya Quesada, R. Lewandowski[2], G. Degrassi and D. Ripandelli

Biosafety Unit, International Centre for Genetic Engineering and Biotechnology, Area Science Park, Padriciano 99, 34149 Trieste, Italy. [1]corresponding author (craig@icgeb.org).

[2]Present address: Center for Interdisciplinary Research in Pediatric Critical Illness and Injury (CIRPCII), Children's Memorial Research Center (CMRC), 2430 N. Halsted Street Chicago, Il 60614, USA.

Abstract

Due to heightened awareness of global environment degradation over the last decade, biosafety, now a major scientific field, has come to the forefront of world attention. It encompasses knowledge and expertise from a wide range of scientific disciplines, including molecular biology, plant breeding, genetics, plant pathology, agronomy, weed science, and ecology. In protecting the environment and human health, the harmonisation and coordination of initiatives in biotechnology and biosafety of derived products are important driving forces behind the activities of international organisations dealing with regulatory aspects, dissemination of information and capacity-building. This review draws together the majority of online databases and information resources of particular relevance to the biosafety of genetically modified crops (and their products), giving a brief description of their content, aims, and limitations (where present). It provides a snapshot of the current status of web-based information, and discusses some of the contributing factors in determining public opinion on the possible risks and safety issues deriving from the use of biotechnology.

Keywords: *biosafety, databases, Internet, websites, dissemination of information, Genetically Modified Organisms (GMOs), Living Modified Organisms (LMOs), transgenes, GM crops*

Riassunto

In seguito all'aumento delle preoccupazioni derivanti dal degrado ambientale nell'ultimo decennio, la biosicurezza, oggi riconosciuta come un importante campo scientifico, ha catturato l'attenzione del pubblico a livello mondiale. Abbraccia conoscenza ed esperienza di un'ampia gamma di discipline scientifiche, incluse la biologia molecolare, il miglioramento

genetico delle piante, la genetica, la patologia vegetale, l'agronomia, il diserbo, l'ecologia, per citarne alcune. Per proteggere l'ambiente e la salute umana, l'armonizzazione ed il coordinamento delle iniziative in biotecnologia e in biosicurezza dei prodotti da essa derivati sono importanti forze trainanti dietro le attività di organizzazioni internazionali che si occupano di aspetti inerenti la regolamentazione, l'informazione e la formazione o "costruzione di capacità". Scopo di questo articolo è raccogliere la maggior parte delle banche dati "on-line" e le fonti di informazione di particolare interesse per la biosicurezza degli organismi geneticamente modificati (ed i loro prodotti), dando una breve descrizione del loro contenuto, degli scopi e dei limiti (quando presenti). Viene cosi fornita un'istantanea dello stato attuale delle informazioni disponibili nel web, e discussi alcuni dei fattori che contribuiscono a determinare l'opinione pubblica sui possibili rischi e sugli elementi di sicurezza derivanti dall'uso delle biotecnologie.

1. INTRODUCTION

Heightened global environmental awareness and concern over accelerating ecological degradation during the latter quarter of the 20th Century resulted in a desire by the international community to push the protection of the environment higher up the political agenda. These efforts came to fruition in 1992 with the Convention on Biological Diversity (CBD; Secretariat of the Convention on Biological Diversity, 1992), and more recently with the advent of the Cartagena Protocol on Biosafety (CPB; Secretariat of the Convention on Biological Diversity, 2000), which came into force in 2003 and has 159 signatory countries to date (May 2010). The latter derived from the request for procedures to be developed to address the safe transfer, handling and use of any LMO ("living modified organism"; used interchangeable with "genetically modified organism" [GMO] in this paper) resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity (Article 19.3, CBD). Parties to the CPB lacking a cohesive biosafety policy, especially a number of developing countries, undertook, or are currently undertaking, a number of initiatives to put a national regulatory framework in place. This has resulted in a great demand for biosafety-related information, training programmes, and capacity-building projects.

This period of heightened political activity in environmental protection coincided with a concomitant rise in genetically modified (GM) crop

cultivation. Since 1996, the global area of GM crops under cultivation has grown at around 7 % per annum. The estimated total global cultivated area of approved GM crops in 2009 was 134 million hectares. Further, 90 % (13 million) of the farmers growing GM crops are small and resource-poor in developing countries (James, 2009). Among the top 10 GM crop-growing countries by area, neither the USA, Argentina, Canada, Uruguay, nor Australia are Parties to the CPB. At the same time, many developing countries that have ratified the CPB are still in the process of elaborating a regulatory framework governing the import or cultivation of GM crops. This has led to the current situation where different strategies and standards have been adopted at the national level, caused by the different infrastructures available in developed and developing countries, and has resulted in much confusion and difficulty in harmonising environment and trade agreements and regulations.

Biosafety in the context of the CPB is used to describe efforts to reduce or eliminate the potential risks resulting from biotechnology and its products. It has similarly been defined as "*the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms*" (Zaid, 2001). Relevant scientific disciplines that underpin biosafety studies include molecular biology, plant breeding, genetics, plant pathology, agronomy, weed science, entomology and ecology, amongst others. Therefore a large amount of scientific knowledge and data has a direct impact on biosafety, and it can be a difficult process to collate this information in a credible way in order to create a balanced view.

One of the major problems within the scientific debate on GMOs relates to informational limitations. Most of the available scientific information regarding GMOs is held by corporate organisations and research institutions whose motives are sometimes questioned, as they are viewed in some quarters as having a strong financial interest in ensuring that GMOs are perceived as positive contributions to human well-being. On the other hand, some of the most well publicised opposition to GMOs has sometimes taken the form of high profile press announcements that do not stand up under scrutiny (Young, 2004). It seems apparent that, whilst the basic underlying science continues to be contested, there is a continuing need for impartial organisations to play a role in compiling, coordinating,

and making available unbiased and reliable information on biosafety from different countries. Such widespread dissemination of scientific information should be a prerequisite in all biosafety undertakings.

Some useful sites concerning biotechnology and biosafety databases have been reviewed, with descriptions and comments on the information provided (Degrassi *et al.*, 2003). This article aims to augment that review in light of the recent, seemingly exponential, growth of online biosafety activity, including a revision of website content and addresses where necessary. The authors have collated the various databases and resources into categories to reflect the numerous concerns that have arisen from the commercial release of GMOs: a) general concerns, including the various legislation and regulation approaches, ethical issues (eg. labelling), GM detection and traceability, intellectual property rights, and socio-economical concerns; b) risks to animal and human health, that include issues of toxicity, allergenicity, quality and safety of food and feed; c) risks to the environment, including the susceptibility of non-target organisms, the potential for horizontal transfer to non-GM species, and any resulting changes to biodiversity; and d) risks to agriculture, especially the evolution of any resistance/tolerance of target organisms to the GMO, the development of multi-herbicide-tolerant weeds, and necessary changes to pest/weed management. The review ends with the inclusion of those databases and information resources which support biosafety activities, as well as those currently under development.

It should be noted that this review is not intended to be a complete listing of all biosafety-related databases and resources, but has concentrated on those found by the authors to be useful in their daily biosafety activities. The described databases were accessed throughout March 2010, and all remarks are based on observations made during that period. It is recognised that the Internet is a dynamic entity, therefore the databases described below may have undergone updating since our assessment was made.

2. GENERAL CONCERNS

Several websites offer useful entry-points to a diversity of biosafety data. These "one-stop shops", contain huge collections or listings of relevant informatic tools and links to other sites. The availability of information on these websites is often exhaustive and so comprehensive that this article

will focus only on the databases that they host, and the reader is advised to visit the relevant homepage so that they may explore further the additional biosafety information provided.

2.1. Central Portal of the Biosafety Clearing-House (CBD-BCH)

The **CBD-BCH** (http://bch.cbd.int/), hosted by the CBD Secretariat, Montreal, Canada, is a major repository of biosafety information. The BCH claims to be "*an information exchange mechanism established by the CPB to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, LMOs*". To be of use to all parties, the portal is available in all official UN languages, however English is the predominant language. To date, a number of relevant national regional and international databases are interoperable with the CBD-BCH, and searching the over-abundance of available records at the site has been facilitated by separating the records into smaller groups (found at http://bch.cbd.int/database/), each with their individual search mechanism. Groups are categorised as either: (a) National Records - with links to national contacts, laws and regulations, country decisions and other communications, roster of experts; or (b) Reference Records - submitted by general BCH users, with links to registries of LMOs, genes and organisms, capacity building activities, a directory of international organisations involved in biosafety, the biosafety information resource centre, and also a scientific bibliographic database focused entirely on biosafety (more later). Information in the BCH is owned and updated by either the Governments or the users themselves (after registration at https://bch.cbd.int/user/signin.shtml?returnurl=%2fmanagementcentre%2fdefault.shtml). Authorised "National Focal Points" and users can enter, supplement and update their information in the Central Portal through support provided in the BCH's "Management Centre". This intermediary allows for the screening and verification of information before it is made available online.

As with any undertaking of this magnitude, problems were encountered early on regarding the timeliness of the portal content. The CBD Secretariat acknowledged that "*the usefulness of the information available in the Biosafety Clearing-House is […] somewhat constrained by a lack of certainty regarding its completeness. [G]iven that it is widely known that some of the missing information is currently available, it seems reasonable to assume that there may be internal constraints delaying the timely*

provision of information to the Biosafety Clearing-House that should be addressed at a national level" (CBD, 2005a). These apparent 'teething-troubles' are currently being addressed and rectified, and as an introduction to biosafety activity at the national level around the globe, the website is unparalleled.

2.2. Food and Agriculture Organization of the United Nations (FAO)

The FAO is involved in assisting its member countries, particularly developing countries, to reap the benefits derived from the application of new technologies, including biotechnology, in agriculture, forestry and fisheries. With this in mind, the FAO, in association with the organisations responsible for international standard setting in sanitary and phytosanitary matters, has developed the **International Portal on Food Safety, Animal and Plant Health** (http://www.ipfsaph.com/) to provide a single access point for authorised official international and national information on food safety, animal health and plant health related to the the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Information can be browsed in a number of ways, including by cross-sectoral themes such as "Biotechnology/GMOs" for which there are currently more than a thousand records of various legislation/regulations, agreements, decisions, guidelines, manual/training materials, and reports from around the world (of which 1044 are specific to GMOs). Each record is classified by commodity, country, source and type of information, with more than 42,000 records in November 2009.

2.3. International Centre for Genetic Engineering and Biotechnology (ICGEB)

Although each national regulatory authority may have their own online databases for storing and disseminating risk assessment (RA) documents (see below), it is a difficult and time-consuming activity to collate documents from different countries. With this in mind, the ICGEB maintains an informatic tool, the **Risk Assessment Searching Mechanism** (RASM; http://rasm.icgeb.org), which is an online collection of RA documents related to official government decisions concerning the commercial release of GMOs, irrespective of the individual authority's CPB signatory status. To date, it contains over 800 records of RA documents, relating to 186 different transgenic events from 21 plant species issued by 29 official authorities, of which more than 75 % of records are from non-CPB party authorities. Typical government sources include national/regional food standard authorities,

environmental protection agencies and departments of agriculture. Most records provide additional links to specific databases (described below) when relevant, for example information concerning OECD unique identifiers, transgene sequences and patents (if any). The website also hosts a bibliographic database and a database of biosafety research, both of which are described later.

2.4. Organisation for Economic Cooperation and Development (OECD)

The OECD plays an important role in work towards the international harmonisation of regulatory oversight in modern biotechnology, primarily to ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of the technology. The OECD created the BioTrack Online website to provide information on environmental, food and feed safety issues relating to modern biotechnology. The home page focuses on the regulatory oversight of modern biotechnology products in OECD member countries, which includes information related to major legislative developments, documents, links to other related web sites, and online databases of modern biotechnology products, as well as field trials.

The **Database for Products Derived Using Modern Biotechnology** (http://www2.oecd.org/biotech/) now incorporates OECD unique identifiers added to relevant records. The purpose of the unique identifier is to link information from the OECD product database with those from the various interoperable systems. With over 100 records, the aim of the database is to share information of GM crops ("transformation events") approved, or in the process of being approved, for commercialisation. The database allows full text searching, and also for search results of listed organisms to be sorted by the unique identifier (130), organism (14), company (12), or country of the approval (11). Links included with each record (where available) are the relevant OECD "biology" or "food/feed" consensus documents (described below), and websites of the approval authorities and their decisions. The database relies on data provided on a voluntary basis, both by authorities in OECD member countries and by certain institutions that either have developed or are currently developing products. This leads to a few omissions and some missing links in the inventory, but otherwise provides a comprehensive picture of currently available GM crops.

Key supporting documents are the **OECD Biotechnology Consensus Documents** (http://www.oecd.org/document/51/0,3343,en_2649_34387_1889395_1_1_1_1,00.html) which comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits, and are updated to take into account new knowledge on the topic. At the present time, consensus documents have been published on the biology of: Bananas and Plantains; Cotton; Lodgepole Pine; Douglas Fir; Native North American Larches - Subalpine Larch, Western Larch and Tamarack; Jack Pine; Western White Pine; Chili Peppers, Hot Peppers and Sweet Peppers; Oyster Mushroom; Papaya; Sunflower; European White Birch; Maize; Stone Fruits; Eastern White Pine; Sugar Beet; Soya bean; Rice; White Spruce; Noway Spruce; Bread Wheat; and Oilseed rape. The OECD has also published consensus documents with relevance to food and feed safety aspects of major crops (described below).

Similar 'biology' documents are also offered by the Office of the Gene Technology Regulator, Australian Government (Risk Assessment References, http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1); the Canadian Food Inspection Agency (CFIA; Biology Documents, Companion Documents for Directive 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, http://www.inspection.gc.ca/english/plaveg/bio/dir/biodoce.shtml); and the National Bureau of Plant Genetic Resources, New Delhi, India (http://www.nbpgr.ernet.in/download/Document%20on%20Biology%20of%20Rice.pdf).

2.5. European Union (EU)'s Joint Research Centre (JRC) "Biotechnology & GMOs" Information website

Under the EU mandate to provide scientific support for the development and implementation of the EU biotechnology regulations, the Joint Research Centre (JRC) plays a leading role in the harmonisation of technical GM issues. This latter role is implemented at the Biotechnology and GMOs Unit of the JRC in Ispra, Italy. Amongst its numerous activities is the reception of all summary notifications of deliberate field trial releases (SNIFs) and the weekly updating of the **SNIF database** (http://gmoinfo.jrc.ec.europa.eu/). The database is the repository of all notifications, and related RA reports when available, from across the EU after 17

October 2002 when the new Council Directive 2001/18/EC came into force. Permission to release a GMO is authorised by individual member countries competent authorities following a favourable evaluation of the accompanying RA documentation. The database is structured so that SNIFs can be found under the notification number. Data relating to country, publication date, name of the institute or company, project title and final report are provided for each SNIF. The website is also linked to the **Member States national websites** (http://gmoinfo.jrc.ec.europa.eu/links_ms.aspx), the **GMO Panel of the European Food Safety Authority** (http://www.efsa.europa.eu/en/panels/gmo.htm), the European Commission's **Community register of genetically modified food and feed** (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) and **Laboratory for GM Food and Feed** (http://gmo-crl.jrc.ec.europa.eu/), as well as the **Institute for Health and Customer Protection** (IHCP; http://ihcp.jrc.ec.europa.eu/).

The **Molecular Biology and Genomics Unit** (http://mbg.jrc.ec.europa.eu/) is one of the five scientific units at the IHCP, and provides the JRC with scientific and technical support to policy development under the EC regulatory framework for GMOs. Among the several information sources provided through the home page is the **GMO Methods Database** (http://mbg.jrc.ec.europa.eu/home/ict/methodsdatabase.htm) which has been designed to allow user-friendly access to information on methods of GMO analysis. It contains more than 300 different DNA-based (PCR) or protein-based (ELISA) assay procedures, and supports the implementation of European legislation on GMOs. Available data includes: (i) General information on the GMO (i.e., producer company, host plant species, engineered trait) and the corresponding method (i.e. method scope (qualitative/quantitative, screening/identification), assay type (single, nested, multiplex etc.) and level of specificity (trait, construct, or event- specificity); (ii) Core data for carrying out PCR or ELISA analysis; (iii) Information on Certified Reference Material (CRM) and plasmid standards; (iv) References of the published articles or validation reports and the corresponding web link or PDF file (when available); (v) Detailed information on the performance of the method and its validation status (i.e. description of the experimental scheme, levels tested and the corresponding set of descriptive statistic values as well as international standard organisations to which the method has been submitted or

accepted (i.e. ISO, AOAC, CEN etc.); (vi) Printable PDF files with the description of the experimental design and data analysis of validation trials, extraction protocols, reactions set up and amplification conditions for PCR analysis.

2.6. Information System for Biotechnology (ISB)

The ISB (http://www.nbiap.vt.edu/) is maintained by the Agricultural Experiment Station at Virginia Tech, Virginia, USA as part of the National Biological Impact Assessment Program administered by the United States of America's Department of Agriculture (USDA) Cooperative State Research, Education, and Extension Service. Amongst the many services provided on its webpage is the **Annotated Database of WWW Sites Pertaining to Agricultural/Environmental Biotechnology** (http://www.nbiap.vt.edu/othersites/indexlinksdblevel1.cfm). Some of the almost 100 listed sites are true databases aimed at storing data, documents and other information, with a retrieval system that allows easy and efficient access to stored data, while others simply contain general information. The ISB site also offers a searchable **Environmental Releases Database** (http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm) of information on applications for USA field tests of GMOs maintained by the Animal and Plant Health Inspection Service (APHIS) of the USDA. These records are also available directly from the United States of America's Regulatory Agency Review Database (below). Additionally, the ISB site provides a series of links to **international field trial sources** (http://www.nbiap.vt.edu/cfdocs/globalfieldtests.cfm).

2.7. Centre for Environmental Risk Assessment (CERA)

The Center for Environmental Risk Assessment (CERA; http://cera-gmc.org/) was established by the non-profit International Life Sciences Institute Research Foundation (ILSI RF) in March 2009. Their website is data-rich, attractive and well-managed, and offers free access to information on the implementation of biosafety systems, including case studies for food and environmental safety assessments. Also provided on the website are two databases. The first, the **GM Crop Database** (http://www.cera-gmc.org/?action=gm_crop_database&) is a database of safety information on all GM plant products that have received regulatory approval worldwide. Each record describes a transformation event, and contains the OECD unique identifier, a descriptor, a synopsis of regulatory approvals, and product-specific background information. Links are given to the relevant

authority's legal and decision documents, as well as contact information. The second database is a searchable library of biosafety-related citations in key topic areas and is described later.

2.8. National Biosafety Websites and Databases

At the global level, the previously-mentioned CBD-BCH also contains a sub-database of **National Biosafety Websites and Databases** (http://bch.cbd.int/database/contacts/) where links to websites, some still under development, which act as, or similar to, national biosafety clearing houses (N-BCHs) can be found. Of note amongst the vast collection of available national biosafety websites are the following.

Representing the country growing the greatest quantity of GM crops (James, 2009), and therefore containing one of the largest collections of related biosafety information, the **United States Regulatory Agencies Unified Biotechnology Website** (http://usbiotechreg.nbii.gov/) disseminates information, *inter alia*, related to capacity-building, the assistance it offers to countries regarding the implementation of National Databases, national laws and regulations, and the roles of governmental agencies with contacts details. Additionally, the website hosts the **US Database of Completed Regulatory Agency Reviews** (http://usbiotechreg.nbii.gov/database_pub.asp) of GM crop plants intended for food or feed, with appropriate approval and RA documents of the government agencies in the USA that are responsible for the safety evaluation. These agencies are APHIS, the Environmental Protection Agency, and the Department of Health and Human Services' Food and Drug Administration. According to USA law, depending upon the product characteristics, each GM crop may be subject to review by one or more of these agencies.

In Australia, the Office of the Gene Technology Regulator at the Department of Health and Ageing oversees the national scheme for regulating GMOs (http://www.ogtr.gov.au/). Here, data regarding field trial sites, post-harvest monitoring, protocols, compliance and RA reports, and GM products being used in the country can be found. Using an innovative and pioneering approach, each GM field trial site can be located by searching a **database** (http://www.maps.ogtr.gov.au/) under differing categories; state, local government area, GMO crop type, licence or map. The results are then graphically represented on a map, showing the precise trial location along

with relevant nearby environmental, geographical, and physical features (eg. rivers, roads, towns and land use). These maps allow farmers to be aware of any trials in proximity to their fields. In addition, there are records of the sites undergoing post-harvest monitoring.

2.9. Commercial Company Databases

Databases and other information-sharing tools have also been developed by commercial companies to address the information needs of different user communities such as consumers, industry and universities. The main plant science industries provide information regarding the commercial status of their GM products to the Biotechnology Industry Organisation (BIO), Washington DC, USA. Using this data, BIO has developed the **Commercial Status of Certain Agricultural Biotechnology Products** database (http://www.biotradestatus.com/), with the proviso that the data is made public for informational purposes only. Currently seventy products have been classified into one of the following three categories; (i) Commercialised - available for sale in at least one country, (ii) Last Seed Sales - this is the last year that seed for this product was sold for commercial use, and (iii) Never Commercialised – the product has never been made available for sale. The retrieval mechanism allows records to be selected according to company, crop, OECD Unique Identifier, and event name.

2.10. GMO Detection

We have previously mentioned and described the JRC GMO methods database. A similar database, the **GMO detection methods database** (GMDD; http://gmdd.shgmo.org/) has been developed in Shanghai, China. The database provides detailed information of nucleic acid-based and protein-based methods, including primer sequences, amplicon length, endogenous reference gene primers, validation information, PCR programs and references etc. In addition, the database also contains information on GMO insertion sequences and certified reference materials.

2.11. GMO Labelling

The International Service for the Acquisition of Agri-biotech Applications (ISAAA), New York State, USA, provides the information service **Global Knowledge Center on Crop Biotechnology** (CropBiotech Net; http://www.isaaa.org/kc/) regarding the global status of crop biotechnology products and issues, communication materials and links to other information sources. Worthy of a visit on this site is the section dedicated to **International Approaches**

to Labelling (http://www.isaaa.org/kc/Publications/htm/articles/Labeling/countries.htm). Current labelling policies in nineteen countries are provided through links identified by national flags, complete with relevant links to key documents.

2.12. Stewardship Breakdown

Knowledge of proven routes of adventitious mixtures of GM and non-GM commodities, as well as unintended GMO presence in the environment is invaluable for the improvement of biosafety risk management and monitoring procedures. The **GM Contamination Register** (http://www.gmcontaminationregister.org/) is a joint initiative by GeneWatch UK and Greenpeace International to record all incidents of such stewardship breakdowns arising from the intentional or accidental release of GMOs. Only publicly-documented incidents are recorded in the database, the sources of which include peer-reviewed scientific articles, national newspapers and media, and press releases from governments, industry and non-governmental organisations. The register can be searched using a query form with one or more search criteria, such as region/continent and country, category of incident, the GMO involved and when the accident occurred. Although there are concerns over the impartiality of some of the information provided, as well as the balance of cover given, it is seen as a useful resource to highlight possible deficiencies in GM management strategies.

3. HUMAN AND ANIMAL HEALTH

3.1. Organisation for Economic Co-operation and Development (OECD)

In the area of food and feed safety, **OECD consensus documents** have been published (http://www.oecd.org/document/9/0,3343,en_2649_34391_1812041_1_1_1_1,00.html) on the nutrients, anti-nutrients or toxicants, information of the product's use as a food/feed and other relevant information. At the present time, the following consensus documents have been published: Cassava; Tomato; Sunflower; Cultivated Mushroom (*Agaricus bisporus*); Alfalfa and Other Temperate Forage Legumes; Barley; Cotton; Rice; Bread Wheat; Maize; Potatoes; Sugar Beet; Soya bean; and Low Erucic Acid Rapeseed.

3.2. Crop Composition Database

As part of the regulatory process for possible commercial release, a detailed

RA of the GM plant is undertaken, during which the receiving non-GM plant species characteristics serve as a baseline with which the transgenic plant is compared. Information obtained from food and feed crop composition studies is used to assess similarities and differences in important nutrients and anti-nutrients. The International Life Sciences Institute (ILSI), Washington DC, USA has developed a publicly-accessible database of crop composition data by compiling their existing analytical data. Their **crop composition database** (http://www.cropcomposition.org/) contains data for assessing the compositional equivalence of new crop varieties, as well as documenting the broad natural variability in the composition of conventional crops. The database has 70,000 data points on 102 nutritionally important analytes (eg. amino acids, carbohydrates, fatty acids, fibre, minerals, vitamins, etc.) for maize, cottonseed and soya bean samples obtained from controlled field trials in multiple locations worldwide. The database is searchable on a number of attributes including analyte, matrix, year of harvest, and field location.

3.3. Protein Allergenicity Databases

Allergen sequence databases have become essential tools used in bioinformatic analyses during the safety assessments of GM foods. The oldest of these databases is the **Bioinformatics for Food Safety database** (BIFS; http://www.iit.edu/~sgendel/fa.htm) at the National Centre for Food Safety and Technology, Chicago, USA (Gendel, 1998). This database takes a broad approach to sequence inclusion because it was initially constructed to support allergenicity assessments for GM foods and as a tool for testing and validating query methods. The database is structured in three parts to allow the identification of complete, non-redundant data sets for food allergens, non-food allergens and wheat gluten sequences, respectively. The online database has been updated several times in the last few years, and now also includes links to the Pfam protein structural database (Bateman *et al.*, 2004).

The Food Allergy Research and Resource Program (FARRP) **Protein Allergen Database** (http://allergenonline.com/) at the University of Nebraska, USA contains a list of publicly-known allergens. As with the BIFS database, each entry is identified by the source organism, protein name, allergen designation (if available) and is linked (through a Gene Identifier number) to an accession in Entrez (at NCBI, described below). FARRP allows users to compare a sequence to an allergen database on-line (using the FastA program). The

database contains a comprehensive list (1386 sequence entries; database current version 9, released on January 2009) of unique proteins of known and putative allergens (food, environmental and contact) and gliadins that may cause celiac disease. Some entries are from published studies demonstrating clear clinical cause and effect for some individuals with a history of allergy to the source material, whilst others are where the authors of an abbreviated note or a sequence database entry claim that protein is an allergen or binds IgE without published proof. However, proteins that are merely similar in sequence to an allergen (homologues) are not included in the database.

Allermatch (http://www.allermatch.org/), hosted by the Wageningen University and Research Centre, The Netherlands, is a unique website where the amino acid sequence of a protein of interest can be compared with sequences of allergenic proteins. It can automatically predict the potential allergenicity of proteins using bioinformatics approaches as recommended by the Codex Alimentarius Commission and FAO/WHO Expert consultation on allergenicity of foods derived through modern biotechnology. The unique features of the Allermatch website allow the user in a user-friendly and time-saving manner to enter the input sequence and retrieve, with a few mouse-clicks, the outcomes of interest in an accurate, concise, and comprehensible format. The database was last updated on December 2005 and contains 368 entries from SwissProt and 681 entries from the International Union of Immunological Societies and the World Health Organization.

The **Structural Database of Allergenic Proteins** (SDAP; http://fermi.utmb.edu/SDAP/) of the University of Texas Medical Branch, USA is a Web server that integrates a database of allergenic proteins with various computational tools that can assist structural biology studies related to allergens. SDAP is aimed at being a tool in the investigation of the cross-reactivity between known allergens, in testing the FAO/WHO allergenicity rules for new proteins, and in predicting the IgE-binding potential of genetically modified food proteins. Using this service, it is possible to retrieve information related to an allergen from the most common protein sequence and structure databases (e.g. SwissProt, PIR, NCBI, PDB), to find sequence and structural neighbours for an allergen, and to search for the presence of an epitope other the whole collection of allergens.

4. ENVIRONMENT

4.1. Biodiversity Databases

In order to be able to assess the potential environmental impact of GM crops, especially with regard to possible impacts on biodiversity, it is essential to know beforehand what diversity is already present. To this end, many databases are available, but only three of the more comprehensive and accessible examples will be highlighted here.

The Global Biodiversity Information Facility (GBIF), Copenhagen, Denmark is an international non-profit organisation which provides free and universal access to data records that are being shared via the GBIF network and regard the world's biodiversity. GBIF created a **data portal** (http://data.gbif.org) which provides access to a collation of over 85 million records from a number of countries and organisations. Data can be found for: (i) species or other group of organisms; (ii) species recorded in a particular country; and (iii) a data publisher, dataset or data network. Two types of data are currently being shared through the GBIF Network: (i) Species occurrence records (based on specimens and observations), with information about the occurrence of species at particular times and places, and (ii) Names and classifications of organisms, with information on the names (both scientific and common) used for species and on the classification of those organisms into taxonomic hierarchies.

Plant Resources of Tropical Africa (PROTA; http://www.prota.org), an international, not-for-profit foundation, is currently involved in synthesising dispersed information on approximately 7,000 useful plants of Tropical Africa and to providing wide access to the information through *inter alia*, online databases. The database currently houses 1169 review articles, outlining the origin, taxonomy, related wild species, biology, agricultural and traditional uses, major pest species, cooking requirements, etc. related to these plants.

The **PLANTS database** (http://plants.usda.gov/), maintained by the Department of Agriculture of the USA (http://www.usda.gov/), is an example of a national directory, providing standardised information concerning the vascular plants, mosses, liverworts, hornworts, and lichens of its territories (USDA, NRCS, 2005). It includes names, plant symbols, checklists, distributional data, species abstracts, characteristics, images, plant links,

references, crop information, and automated tools. It also provides downloadable species checklists for each state.

4.2. Invasiveness

The **Global Invasive Species Database** (GISD; http://www.issg.org/database/) aims to increase awareness about invasive alien species and to facilitate effective prevention and management activities. It is managed by the Invasive Species Specialist Group of the Species Survival Commission of the IUCN-World Conservation Union. The GISD focuses on invasive alien species that threaten native biodiversity and covers all taxonomic groups from micro-organisms to animals and plants in all ecosystems. Species information is either supplied by or reviewed by expert contributors from around the world. Such information is essential in order to alert risk assessors to possible alterations in invasiveness of any sexually-compatible species of released GMOs, should transgenic DNA sequences be incorporated in the wild or semi-natural environment.

4.3. Out-Crossing Potential

The Gene Flow Project (http://www.bioversityinternational.org/scientific_information/themes/conservation_and_use/gene_flow_project.html) was funded by GTZ and realised in collaboration with CIAT and Universidad del Valle (Cali, Colombia). Its goal is to provide objective information to guide basic and scientifically sound decision-making. The project produced the following outputs:

A) World Maps of Crop Wild Relatives (CWR) and Gene Introgression (http://www.bioversityinternational.org/scientific_information/themes/conservation_and_use/gene_flow_project_maps.html), where maps were produced showing the regions where crops are likely to occur in the same areas with their sexually compatible wild relatives. The visual presentation shows areas where gene flow and introgression may be an issue and hence could benefit from closer scrutiny.

B) A Database of Gene Flow Bibliography (http://www.bioversityinternational.org/scientific_information/themes/conservation_and_use/gene_flow_project_literature_database.html). The database is in excel format and contains crop-specific bibliographic information related to gene flow and crop wild relatives. The database contains over 2,500 references, and is searchable by: author, date of publication, type of publication and crop species.

4.4. Bt Toxin

Insect resistance conferred by *Bacillus thuringiensis* (*Bt*) genes represents the second most popular introduced trait, after herbicide tolerance, in GM crops such as maize, cotton and potato (James, 2009). The ongoing discovery of new *Bt* toxin genes and the rapid accumulation of information on their insecticidal activities have prompted the development of a couple of *Bt*-specific databases.

The **Nontarget Effects of Bt Crops** database (http://delphi.nceas.ucsb.edu/btcrops/), hosted by the National Center for Ecological Analysis and Synthesis, California, USA includes details of the methods and results for a large number of studies that have assessed the effects upon nontarget invertebrates of crops transformed with Bt genes. Access to this data has facilitated scientists in carrying out and publishing a number of meta-analysis to determine the possible impact of Bt crops (in these cases, aubergine, cotton, maize, potato and rice) on non-target invertebrates.

The Canadian Forest Service has constructed a **Database on Bt Toxin Specificity** (http://www.glfc.forestry.ca/bacillus/) of published data on insecticidal activity of *Bt* delta-endotoxin genes. The database is limited to spore-free preparations of crystal proteins or toxins that were bioassayed individually (i.e., cloned gene products or toxins purified from single gene strains). Genetically-altered toxin proteins are not included (with the exception of minor modifications to enhance expression or protein stability, e.g. cry9Ca1). The database links effective dose estimates for the toxin proteins with information on various factors which may affect toxicity. Those factors include: the host used for toxin gene expression; how the protein inclusions were purified; if and how the toxins were activated, solubilised or purified; the method used for toxin protein quantification: the species and stage of the insect that were bioassayed; the type of bioassay used; general bioassay conditions; and parameter used to assess toxicity. The search engine allows information retrieval based either on *Bt* toxin bioassays or 237 individual *cry* genes. The search outcome is a list table including the insect species used for the bioassay of the specified toxin, the method used for the bioassay and its result, and the bibliographic reference for each bioassay/toxin gene.

5. AGRICULTURE

5.1. Herbicide Resistance Databases

During 1996 to 2009, herbicide tolerance has consistently been the dominant cultivated GM trait (James, 2009), with more than 300 transformation events authorised for commercial release by National Competent Authorities from around the world (ICGEB, unpublished). In the evaluation of possible environmental risk and the devising of GM management strategies, information concerning the evolution of herbicide-resistant weeds (derived from both conventional and GM agricultural practises) along with their environmental and agricultural impact throughout the world is especially useful.

The **Worldwide Herbicide Resistant Weeds Database** (http://www.weedscience.org/) is the result of an on-going survey undertaken by a global collaboration between weed scientists, and is chaired in Oregon, USA. It currently holds information concerning 334 resistant biotypes, 190 species (113 dicots and 77 monocots) and over 300,000 fields. These include reports of weeds resistant to those herbicides associated with GM crop cultivation; bromoxynil (eg. Brominal, Buctril), glyphosate (eg. Roundup, Touchdown) and chlorsulfuron (Glean, Telar). So far there are no records of resistance to phosphinothricin (eg. Bialaphos, Basta, Liberty). Additionally, the website provides a gallery of images of the main weed species, statistics related to the distribution of main herbicide-resistant weeds worldwide, relevant publications and other educational materials for free download.

Agricultural companies such as Monsanto and Syngenta are stepping up efforts to educate farmers about the proper use of Roundup Ready crops, which are genetically modified to resist glyphosate herbicide. If the crops are irresponsibly planted, weeds that are resistant can appear, reducing the value of the system. The aim of the two websites that they have independently developed, www.weedresistancemanagement.com and www.resistancefighter.com, respectively, is to disseminate information on the proper use of the herbicide to prevent the appearance of resistant weeds.

5.2. Pest Management

The University of California Statewide **Integrated Pest Management Program**

(UC IPM; http://www.ipm.ucdavis.edu/PMG/crops-agriculture.html) develops and promotes the use of integrated, ecologically sound pest management programs in California, USA. Although not deploying GMOs themselves, their site offers insights into the diversity of current agricultural practices, as well as the development of pest management strategies that can also be adopted by those farmers growing GM crops. Their website offers information on more than 60 crops, including the toxicities of relevant pesticides to natural enemies and honey bees, descriptors of invertebrate and weed pests, and diseases (incidence, symptoms, management/control methods), and a gallery of natural enemies with description. UC IPM Pest Management Guidelines are also available for free download for each crop.

The **Arthropod Pesticide Resistance Database** (APRD; http://www.pesticideresistance.org/) is a website hosted by Michigan State University, USA, providing access to information on the development of pesticide resistance in arthropods. The database can be searched by anonymous users but only authorised users can submit a case to the database. It is a public service for use by resistance management practitioners around the world, and as such, researchers are encouraged to contact the website management with any resistance information they might have. The database reports of resistance cases from 1914 to the present, when the resistance was first discovered for a specific time and place. Pesticide resistance is a dynamic, evolutionary phenomena therefore the significance of the data contained in the database is in relation to the time and place where it was reported.

6. DATABASES SUPPORTING BIOSAFETY ACTIVITY

6.1. Scientific literature

Peer-reviewed scientific studies comprise a major component that underpins the decision-making process concerned with the environmental release of any GMO. To facilitate easy access to relevant published data, a number of initiatives have taken up this challenge.

The afore-mentioned ICGEB biosafety website also maintains the searchable **Bi[bli]osafety Database** (http://bibliosafety.icgeb.org/) which is a collection of scientific studies on biosafety and RA in biotechnology, with monthly updates distributed to members (free subscription). As of March 2010, the

database contained more than 9600 records (full reference with abstracts) of scientific articles published in international peer-reviewed journals since 1990. To assist access to the full version of an article each record contains the corresponding author's Email address and/or a DOI (Digital Object Identifier - a unique string which links directly to the article on the journal website). All articles are selected and classified by ICGEB scientists in accordance with the major concern in relation to the environmental release of GMOs. The database is also interoperable with the CBD-BCH website, and as such, is the bibliographic resource provided on those pages (http://bch.cbd.int/database/bibliographic-references/).

A similar tool is **CERA's** searchable library of biosafety-related citations, the Bibliographic Database (http://cera-gmc.org/index.php?action=bibliography_database). The records can be accessed by searching in the following fields: "source", "year(s) published", "author(s)" and/or "keywords". A full citation is given for all records, but no forwarding link to the actual article. Additional in house publications can be found on the CERA publications page (http://cera-gmc.org/index.php?action=publications).

The Commission "Green Biotechnology" of the Union of the German Academies of Sciences and Humanities, in the framework of the Inter-Academy Panel GMO-Initiative, has collected and made available approximately 240 publications on various aspects of GM crops (http://www.akademienunion.de/publikationen/literatursammlung_gentechnik/english.html). This collection, which does not claim to be complete, contains a number of extensive reviews produced by organisations such as the Royal Society, the International Council for Science, the US National Center for Food and Agricultural Policy, the Australian Bureau of Agriculture, the FAO, the Nuffield Council of Bioethics, as well as introductions to the CPB by the World Conservation Union and the UN Secretariat of the CBD. Global Reviews of Commercialized Transgenic Crops published by the International Service for the Aquisition of Agri-Biotech Applications (ISAAA) give a detailed summary of global applications of Green Biotechnology in Agriculture. One focus of this collection is on reports about the application of Green Biotechnology in developing countries.

Additionally, the **Database of the Safety and Benefits of Biotechnology** (http://croplife.intraspin.com/) is hosted by CropLife International - an organisation

with a Brussels-based secretariat representing the plant science industries. The purpose of the database is to enable access to credible scientific information about the demonstrated benefits associated with the use of agricultural biotechnology products, and about their safety. The database therefore maintains a biased positive approach to biotechnology, but this does not impact on the impartiality of the scientific content of the studies presented. At the present time the database contains only 161 papers (in downloadable pdf file format), and are divided into six main categories: agronomic, safety and health, socio-economic, environmental, developing countries, and co-existence.

Another web-based bibliographic database is the **bEcon** (http://www.ifpri.org/book-637/node/5339), a selective collection of peer-reviewed applied economics literature that assesses the impacts of GM crops in developing countries. Developed by researchers at the International Food Policy Research Institute (IFPRI), bEcon focuses on four major research questions addressed in the literature: (i) What are the (potential, actual) advantages of GM crops for farmers? (ii) What are consumers willing to pay for non-GM products, and how will their preferences affect the market? (iii) What are the magnitude and distribution of the economic benefits resulting from the adoption of GM crops in a particular industry (sector)? (iv) What is the international distribution of economic benefits resulting from the adoption and trade of GM crops? The database is updated on a regular basis as new publications become available as well as through direct contributions from authors and researchers.

6.2. Biotechnology and Biosafety Research

The FAO has developed the **FAO-BioDeC** database (http://www.fao.org/biotech/inventory_admin/dep/default.asp) to gather, store, organise and disseminate updated baseline information on the state-of-the-art of crop biotechnology products and techniques that are either in use or in the pipeline in developing countries. The database comprises around 2000 entries from 70 developing countries, including countries with economies in transition. The database gives an overview of the different stages of adoption and development of these biotechnologies in the different countries and regions. As well as information on GMOs, it also contains information on other biotechnological products such as those obtained by micropropagation, *in vitro* regeneration, embryo rescue, random amplified

polymorphic DNA, amplified fragment length polymorphism, and *in vitro* germplasm conservation and exchange. Records can be searched using a combination of selected fields such as product or technology, trait or specific technique used, species, country, region, institution and status of the development process (that is, experimental phase, field trials, or commercialisation). Its aim is to "*assist in identifying needs and gaps in agricultural research, whilst at the same time offering the opportunity to have a closer look at programmes in neighbouring countries to identify potential partners for collaborative undertakings*". The efforts expended in establishing such a database are commendable, however the records lack any contact information, and it is therefore left to the visitor to track it down from other sources.

Also available through the ICGEB biosafety website is the **BiosafeRes database** (http://www.icgeb.org/~gmores/prod/index.php) which was developed to enhance communication regarding past and present GMO biosafety research. The database is a worldwide, web-based, free and public-access database of past and current research projects in GMO Biosafety. It aims to improve communication within the scientific community, and thus clearly facilitates development of more and better worldwide collaborative research ventures in this field by encouraging synergy. It is a useful tool for those seeking scientific expertise on GMO biosafety research, and also for journalists and the general public seeking further information in this area, and it is also aimed at facilitating the task of researchers in developing countries wishing to increase contact with scientists elsewhere, and to develop collaborative projects with them. Biosafety research project leaders worldwide are encouraged to enter their projects directly into the database. It currently holds descriptions of more than a hundred biosafety research projects.

A similar database, the **ABC Database** (http://ifpri.catalog.cgiar.org/abc/index.htm) has been developed with the aim of creating an enabling environment that fosters research, cooperation and technology transfer and comprehensively reviewing and updating information on the status of public sector biotechnology research and development (R & D) pipelines. The database contains information about the objectives and results of public research in agricultural biotechnology, with the aim to inform all interested stakeholders and to facilitate collaboration in public research. The

database is a collaborative initiative of the IFPRI and the Public Research and Regulation Initiative (PRRI), in concert with public research institutes and other organisations worldwide. The information in the database is provided by public researchers who can enter information about their research directly into the database.

GMO Safety (http://www.gmo-safety.eu), supported by the German Federal Ministry of Education and Research, provides up-to-date clear and intelligible information about current and past biosafety research into GM plants. The information portal is designed to make research findings on the environmental safety of GM plants accessible to the interested public and to contribute towards objective, responsible opinion-forming. The sections 'Maize', 'Grain', 'Potatoes', 'Oilseed rape', 'Woody plants', 'Monitoring' and 'Gene transfer' provide comprehensive basic information about the key BMBF-funded research areas. A database with summaries of research topics, methods and results ('Database') is supplemented by exciting insights into the everyday working lives of researchers ('Science live'), background reports on individual topics ('Focus') and news stories on everything to do with biological safety research both in Germany and at the international level ('News'). The 'Debate' section is designed to enliven the discussion about green genetic engineering by offering new perspectives and surprising points of view – this section regularly presents interesting texts on scientifically and socially relevant topics. There is also a glossary with key terms, a photo database and a schools portal (German only) with suggestions for teachers.

6.3. Glossaries

Efficient communication and discussions at the inter-governmental level, along with the dissemination and sharing of information, can often be hampered by the use of inappropriate terminology, especially with regard to GMOs. In addressing the problem, the FAO has also developed the **FAO Glossary of Biotechnology for Food and Agriculture** (http://www.fao.org/biotech/index_glossary.asp), a useful tool for acquiring general information and consolidating terminology in biotechnology. The glossary is available in multi-language versions (Arabic, English, French, Spanish, Russian, Vietnamese and Serbian) and contains a searchable tool providing a comprehensive list of more than 3000 terms and acronyms used regularly in biotechnology in food and agriculture.

Another similar resource is the online version of Technomic Publishing's **Glossary of Biotechnology Terms"** (http://biotechterms.org/) which is intended as a general introduction to assist individuals who seek to gain an understanding of the terminology as it is currently used. Additionally, a glossary is provided on the Colorado State University, USA website, **Transgenic Crops: An Introduction and Resource Guide** (http://www.colostate.edu/programs/lifesciences/TransgenicCrops/). It is available in two language versions, English and Spanish, and can be found by following the relevant links. Although not updated since January 2006, it is still a useful tool for the information contained.

6.4. Molecular Databases

Molecular databases are essential to those people involved in protein analysis that may impinge on GM biosafety. **The Sequence Platform for the Phylogenetic Analysis of Plant Genes** (SPPG, http://bioinformatics.psb.ugent.be/cgi-bin/SPPG/index.htpl), hosted by the Flanders Interuniversity Institute for Biotechnology (VIB), Belgium is an integrated sequence repository that combines expressed sequence tag (EST) sequence data with protein information from 32 different plant species (Vandepoele and Van de Peer, 2005). SPPG allows the identification of possible host plant homologues to introduced transgenes, based on individual genes, gene families, gene families combined with their phylogenetic tree, and sequence similarity (BLAST).

Access to sequence data is crucial for the detection, identification, and RA of GMOs, and is provided by search engines, such as the Sequence Retrieval System (SRS) of the **EMBL nucleotide sequence database** (http://www.ebi.ac.uk/embl/), Expert Protein Analysis System (ExPASy) of the **SwissProt annotated protein sequence database** (http://www.expasy.org/), the Life Sciences Search Engine (Entrez) of the **GenBank Nucleotide Sequence database** (http://www.ncbi.nlm.nih.gov/Genbank/GenbankSearch.html) and Getentry of the **DNA Data Bank of Japan** (http://www.ddbj.nig.ac.jp/). Similarly, there are numerous databases that address general toxicological issues (e.g. U.S. National Library of Medicine, http://www.toxnet.nlm.nih.gov/), and the "*Bad Bug Book*", http://www.cfsan.fda.gov/~mow/intro.html). Although they were not initially created to reflect potential toxicity resulting from a genetic modification, they are particularly relevant to food safety.

Another website, **123 Genomics** (http://www.123genomics.com/) is incredibly comprehensive, and provides a large number of links related to genomics and bioinformatics, most of them freely-available on the Internet. The bookmarks are grouped into 18 major categories. One such category is **Sequence Databases** (http://123genomics.com/databases.html), which itself is divided into DNA and RNA, Protein, Carbohydrate, and Model Organisms. Another category is **Other Resources** (http://www.123genomics.com/files/others.html), which provides links to patent information, biology- and chemistry-related topics, as well as dictionaries, encyclopaedias, and thesauri amongst many others.

6.5. Patent Sites

Patents represent another important source of information on biotechnology that may be important in the decision-making process and RA. In fact, the increasing use of intellectual property in Life Sciences has resulted in a growing number of patents protecting the outcomes of new biotechnological R & D, not only the product itself, but also the biotechnological methods, DNA constructs, and processes for production of biological products. Several on-line databases have been established to allow free access to patent information.

The CAMBIA-BIOS Patent Resource site has a wealth of information on agricultural biotechnology patents. It was developed by CAMBIA, Australia and includes a free full-text **Life Science Patent Database** (http://www.patentlens.net/patentlens/quick.html) and an analysis of major patent positions on *Agrobacterium*-mediated transformation of plants. The database contains over 1,500,000 life science patents and patent applications from the Patent Cooperation Treaty (PCT), United States Patent and Trademark Office (US-PTO), Australian and European Patent Office databases. Another database, **Agricultural Biotechnology Intellectual Property** (http://www.ers.usda.gov/data/AgBiotechIP/), available on the USDA Economic Research Service webpages, identifies and describes utility patents on inventions in biotechnology and other biological processes that are used in food and agriculture, and that were issued in the USA between 1976 and 2000. The database also provides information about the ownership of these patents, whether patents are held in the public or private sector, and any changes in patent ownership due to firm mergers, acquisitions and spin-off businesses. A third useful electronic resource for patent searchers,

the **DNA Patent Database** (DPD; http://dnapatents.georgetown.edu/) based at Georgetown University, Washington DC, USA allows free searching of full text and analysis of all DNA patents issued by the US PTO. Patents included in the DPD were identified by virtue of PTO classification and the presence of keywords such as "DNA" within the body of the patent.

To complement the data available in the CAMBIA and USDA-ERS patent databases described above, the **Public Intellectual Property Resource for Agriculture** (PIPRA; http://www.pipra.org/) is developing a database that will provide an overview of IPR currently held by the public sector, including up-to-date information about licensing statuses. Access to the database is currently restricted to PIPRA members, however public access will be available once it has been reviewed and the necessary improvements have been implemented.

6.6. Risk Assessment

The **Biosafety assessment tool** (BAT; http://english.genok.org/biosafety_assessment_tool), developed jointly by the Biosafety Forecast Service of the Norwegian Institute of Gene Ecology (GenØk), Norway and the Integrated Research in Biosafety (INBI), New Zealand, is a new database aimed to provide support for those who are performing risk assessments. It is intended to be accessible to specialists and non-specialists and to assist users to identify relevant risk issues when performing risk assessment. The BAT is arranged into three primary sections: 1) Practical Assessment, to compose a submission or review of a GMO application; 2) Topic Guides, to provide background information; and 3) Checklist, to complete the risk evaluation.

7. CONCLUSION

It is generally agreed that the public should play a more active role in the biosafety decision-making process, but this is highly dependent upon a number of contributing factors, most importantly of which are; the access to and availability of relevant biosafety information, knowledge-sharing in suitable formats to allow for an understanding by a non-technical audience, and the raising of science education standards so that people are capable of making informed decisions.

The web-based databases and resources outlined above are all accessible

to anyone who has efficient access to the internet, and all play a significant role in raising biosafety awareness and the dissemination of information. However, generally speaking, these resources are primarily conceived and publicised as tools for use by policy-makers, bureaucrats, academics and companies rather than for the population at large. To date, a limited number of attempts have been made to make the information more accessible to a wider audience, of which GMO Safety is a particularly good example, by publicising the biosafety resources more widely, or by explaining the practical implications of particular rules, using less technical language, or including glossaries of key terms.

Although Internet access is becoming more feasible and universal each year, free large-scale access still represents a problem, especially in the developing world. Internet-based sources of information are often of little use to policy-makers and bureaucrats, let alone ordinary citizens, in countries that have a poor information and communication technology (ICT) infrastructure. In such countries, information needs to be available via alternative technologies that may include paper documents by mail and fax or a telephone hotline as well as CD-ROM and web-based information (Lasseur, 2000; Zaid *et al.*, 2001). This is being addressed by several of the above biosafety database providers.

Global public opinion, on the whole, seems to be either ambivalent towards, or accepting of, the benefits (potential and real) brought about by biotechnology, apart from in Europe where it seems to be aggressively against GMOs (and in particular GM crops). European anxiety and the resultant scepticism have derived from the deeper structural and institutional problems of biotechnology development (Parr, 2005). A recent analysis of European public disquiet over the prospect of GM food concluded that this scepticism seems to have its origins in similar attitudes despite national cultural differences. The attitudes were not driven by "risk" in the scientifically understood sense of hazard and probabilities, but were much more about institutional and cultural responsibilities (Marris *et al.*, 2001).

The level of education, religion, socio-economic factors, pressure by NGO environmental groups, and government policy all play a role in shaping public opinion concerning biotechnology. The incorporation of appropriate public awareness programmes into educational systems requires not

only a significant revision of curricula and re-organisation of academic departments related to life sciences and biotechnologies, but also the development of the necessary manpower who are able to understand and communicate the different aspects of biotechnology. Urgently needed is active interdisciplinary cooperation in research and development, both in universities and industries, cooperation involving biochemists, bioengineers, mathematicians, computational scientists, systems analysts and specialists in bioinformatics. Bio-scientists and biotechnologists must acquire more sensitive awareness of civil societal concerns and the ability to communicate with private citizens, politicians and the media (Hulse, 2004). Scientific literacy, informal dissemination of impartial information through the public media, clear standards, food labelling, reducing the extent of exaggerated expectations, allowing the public to be part of the decision-making process, and the reliability of information are all equally important in order to have a clear picture of the benefits and risks of biotechnology (Sharma, 2002). It is advised however that any new initiative addressing these issues should be well co-ordinated in order to avoid duplication of efforts and energies, and to promote a fuller coverage of available knowledge and reduce existing gaps. It is hoped that publications such as this will contribute in their own small way to improving the availability of biosafety information to a wider audience.

8. REFERENCES

Bateman A, **Coin** L, **Durbin** R, **Finn** RD, **Hollich** V, **Griffiths-Jones** S, **Khanna** A, **Marshall** M, **Moxon** S, **Sonnhammer** ELL, **Studholme** DJ, **Yeats** C & **Eddy** SR 2004. The Pfam Protein Families Database. *Nucleic Acids Research.* Database Issue 32, D138-D141.

Degrassi G, **Alexandrova** N & **Ripandelli** D 2003. Review: Databases on Biotechnology and Biosafety of GMOs. *Environmental Biosafety Research* 3: 145–160.

Gendel S 1998. Sequence Databases for Assessing the Potential Allergenicity of Proteins Used in Transgenic Foods. *Advances in Food and Nutrition Research* 42: 63-92.

Hulse J H 2004. Biotechnologies: Past History, Present State and Future Prospects. *Trends in Food Science & Technology* 15: 3–18.

James C 2009. Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2009. *ISAAA Briefs,* No. 41. ISAAA, Ithaca, NY, USA. Available at http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp. Accessed online March 2010.

Lasseur, C. J. (2000). Public Information and Public Participation in National Biosafety Frameworks. *The Hague*, The Netherlands: Ministry of Housing, Spatial Planning and the Environment.

Marris C, **Wynne** B, **Simmons** P & **Weldon** S 2001. Public Perceptions of Agricultural Biotechnology in Europe. Final Report of the PABE Research Project. Available at http://www.lancs.ac.uk/depts/ieppp/pabe/docs/pabe_finalreport.pdf. Accessed online March 2010.

Parr D 2005. Will Nanotechnology Make the World a Better Place? *Trends in Biotechnology* 23(8): 395-398.

Secretariat of the Convention of Biological Diversity 1992. *Convention on Biological Diversity.* Secretariat of the Convention of Biological Diversity, Montreal, Canada. Available at http://www.biodiv.org/doc/legal/cbd-en.pdf. Accessed online March 2010.

Secretariat of the Convention of Biological Diversity 2000. *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes*. Secretariat of the Convention of Biological Diversity, Montreal, Canada. Available at http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf. Accessed online January 2006. Accessed online March 2010.

Secretariat of the Convention of Biological Diversity 2005. Operation and Activities of the Biosafety Clearing-House. Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety. Second Meeting. Montreal, Canada, 30 May–3 June 2005. Agenda Item 5. UNEP/CBD/BS/COP-MOP/2/3. Secretariat of the Convention of Biological Diversity, Montreal, Canada. Available at http://www.biodiv.org/doc/meetings/bs/mop-02/official/mop-02-03-en.pdf. Accessed online March 2010.

Sharma KK, **Sharma** HC, **Seetharama** N & **Ortiz** R 2002. Development and Deployment of Transgenic Plants: Biosafety Consideration. *In Vitro Cellular and Developmental Biology – Plant* 38: 106 – 115.

USDA, NRCS 2005. The PLANTS Database, Version 3.5. Data compiled from various sources by Mark W. Skinner, National Plant Data Center, Baton Rouge, LA 70874-4490 USA. Available at http://plants.usda.gov. Accessed online March 2010.

Vandepoele K & **Van de Peer** Y 2005. Exploring the plant transcriptome through phylogenetic profiling. *Plant Physiology* 137: 31-42.

Young T 2004. Genetically Modified Organisms and Biosafety: A Background Paper for Decision-Makers and Others to Assist in Consideration of GMO Issues, (p. xi+56). IUCN- The World Conservation Union, Gland, Switzerland and Cambridge, UK.

Zaid A, **Hughes** HG, **Porceddu** E & **Nicholas** F 2001. Glossary of Biotechnology for Food and Agriculture. A Revised and Augmented Edition of the Glossary of Biotechnology and Genetic Engineering. Publishing and Multimedia Service. Food and Agriculture Organization of the United Nations (FAO), Rome, Italy.