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COMMISSION

Community Research



SEVENTH FRAMEWORK
PROGRAMME

DRAFT

Networking and database technology

FP7 Collaborative Project
GRACE 311957

Preliminary Author List:
S. Unger, S. Kecke, W. Craig

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GRACE

GMO Risk Assessment and
Communication of Evidence

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1. Introduction

The main programme activities of the GRACE project have been designed to:

- a) elaborate and implement systematic, transparent and inclusive reviews of existing evidence of potential health, environmental and socio-economic impacts (risks and benefits) of GM plants (GMPs) or food and feed derived from GMPs, and;
- b) consider the design, execution and interpretation of results of animal feeding trials as well as *in vitro* studies for assessing the safety of GM food and feed.

These key activities will yield valuable and accessible information on the main issues associated with GMPs for risk assessors, risk managers, policy makers, scientists, technology developers, other stakeholders and the general public. This information will be hosted in an online central access point specially designed and constructed for the project, the primary database of which will be sustained by the Julius Kühn Institut (JKI) after the end of the project.

GRACE is committed to giving high priority to consulting professional users (mainly GMO risk assessors and risk managers, policy-makers) and a broad range of stakeholders throughout the entire project. Their input will influence the design, content and output of the reviews and central access point. This networking and consultation on both the process and the outputs of the project with the scientific community, users and stakeholders as well as the broader public will be achieved by a range of different approaches, of which the current stakeholder consultation is the first concerning the central access point.

GRACE is actively seeking interested stakeholders with a high degree of work-related experience in using relevant online informatic tools in support of the risk assessment and/or risk management of GMPs. A small number of the identified professional users and stakeholders will be invited to form a Feedback Group, to be consulted via video conference, during the development of the GRACE central access point to ensure its eventual relevance to the wider biosafety community and interested members of the public.

2. Requirements and objectives of the GRACE activity in networking and database technology

Many websites contain information from reviews on GM crops and supply useful links to data sources. However, few of these databases document the review process or the quality evaluation of the risk assessment studies in a detailed and transparent format. A primary objective of GRACE is to improve the availability of scientific information concerning GM plants for professional users and the wider stakeholder community. Therefore, GRACE will establish an open-access database that will:

- provide a central access point for relevant information on the risk assessment of GM plants;
- allow continuous updating and inform risk managers and other stakeholders about the current risk status of certain GM plants;
- host all of the data established by GRACE (review protocols, quality assessment of the reviewed data and outcomes from the GRACE reviews, evaluation reports, recommendations for future implementations);
- provide guidance for good quality reviews;
- include unpublished studies and reports.

To implement such a rich information source, the GRACE database will be linked to a range of online informatic tools, research organisations, initiatives and institutions, both within and outside the EU, which serve as sources of data for GRACE project activities. The sustainability of the database and review process beyond the lifetime of GRACE will be supported by the German Federal Ministry of Food, Agriculture and Consumer Protection, whilst management oversight will be provided by the project co-ordinator (JKI).

3. System requirements

Formally, the term "database" refers to the data itself and supporting data structures. A "database management system" (DBMS) is therefore a suite of computer software providing the interface between users and a database or databases. Because they are so closely related, the term "database" when used casually often refers to both a DBMS and the data it manipulates. The GRACE database will not only host data in a structured framework, but will also be accessible through a DBMS tailored to the needs of the end users. The GRACE database will therefore provide:

- reliable central master data storage
- easy-to-use web application
- different user types with tailored access and editing rights
- for permitted users, the web interface should easily facilitate:
 - data downloading;
 - data uploading;
 - entering new records;
 - updating records;
 - revision control for all the changed data, and;
 - import and export of literature data (references).

4. Business requirements

The GRACE database will be a central access point for all relevant information on the risk and benefit assessments of GM plants. It is envisaged that the web space will be divided into 3 main areas:

Area 1: Central access point for all relevant information on the risk assessment of GM plants

- A comprehensive overview of key online informatic tools and sources, including a short description of each (examples provided in Table 1).
- The capability to search linked 3rd-party databases, where permission to do so has been negotiated.

Area 2: Review database

- To host all of the data collected by GRACE (review protocols, inclusion/exclusion criteria, data extracted in the GRACE review process, evaluation reports, recommendations for future implementations).
- Will archive the compiled modules from each stage of the systematic reviews and evidence maps (see Figure 1 and Appendix).
- Will ensure that a read-only copy of the data underpinning the published systematic reviews and evidence maps is archived for posterity.
- Will allow future access to the data sets, to facilitate the revision of any of the systematic reviews when new data is generated.
- Will provide guidance for evidence synthesis.

Area 3: Animal feeding trials and alternative *in vitro* studies

- Will document the evaluation of the GRACE animal feeding trials and alternative *in vitro* studies for the assessment of GMO impacts on human health.

5. Software development and database technology

The database will be developed using open-source software. Figure 2 illustrates the proposed database interaction. Registered user (e.g. reviewer/reader) will be able to access the GRACE database over the Internet (WWW) from their computer using their browser of choice (e.g. Mozilla Firefox, Chrome, Internet Explorer), and using the web application developed by the GRACE project.

Table 1. Examples of online informatic tools and information sources

Type of informatic tool/information	Example(s)
<i>Databases of scientific literature</i>	
PubMed comprises more than 22 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites.	
	www.ncbi.nlm.nih.gov/pubmed
Provides a search of scholarly literature across many disciplines and sources, including theses, books, abstracts and articles.	
	www.scholar.google.com
The database is a searchable collection of scientific studies on biosafety and risk assessment in biotechnology. It is updated monthly and the new records are immediately distributed by email to freely subscribed users. The database contains a comprehensive collection of many thousands of records (full reference with abstracts) of scientific articles published since 1990. The database is also interoperable with the central portal of the Biosafety Clearing House, hosted by the Convention on Biological Diversity.	
	http://bibliosafety.icgeb.org
<i>Crop biology documents</i>	
Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology	
	www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm
OGTR Risk Assessment References	
	www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1
<i>Crop composition database</i>	
	www.cropcomposition.org

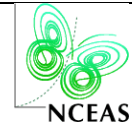
Crop composition documents

Consensus Documents for the Work on the Safety of Novel
Foods and Feeds



www.oecd.org/science/biotrack/consensusdocumentsfortheworkonthesafetyofnovelfoodsandfeeds.htm

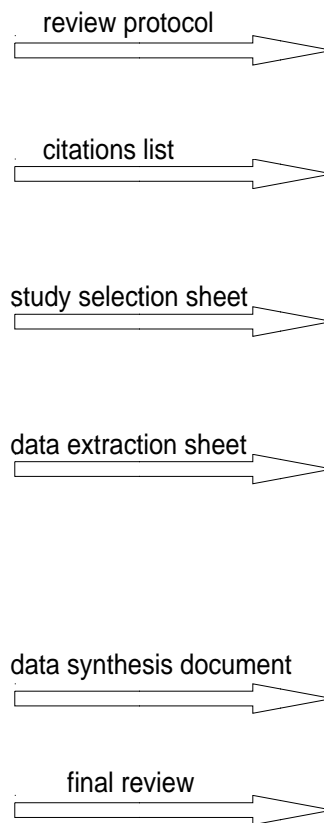
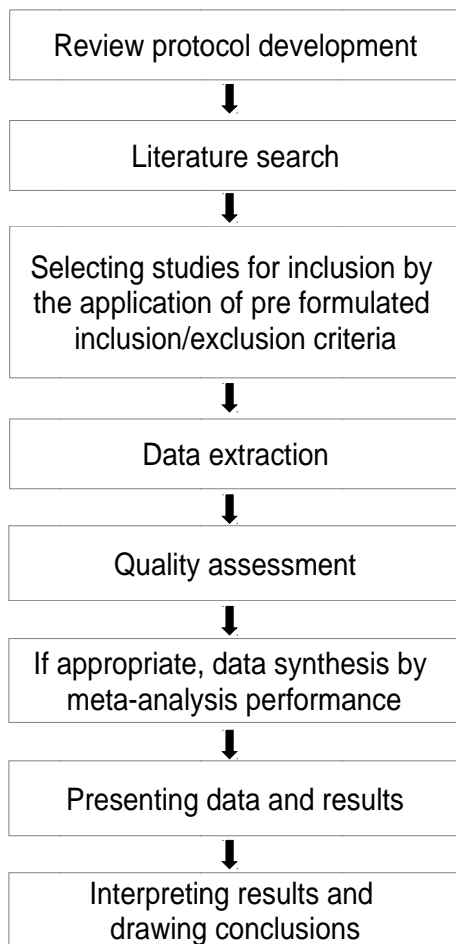
Database of environmental data



<http://btcrops.nceas.ucsb.edu>

Review database

Review process



Review database



Figure 1. Review process and review database

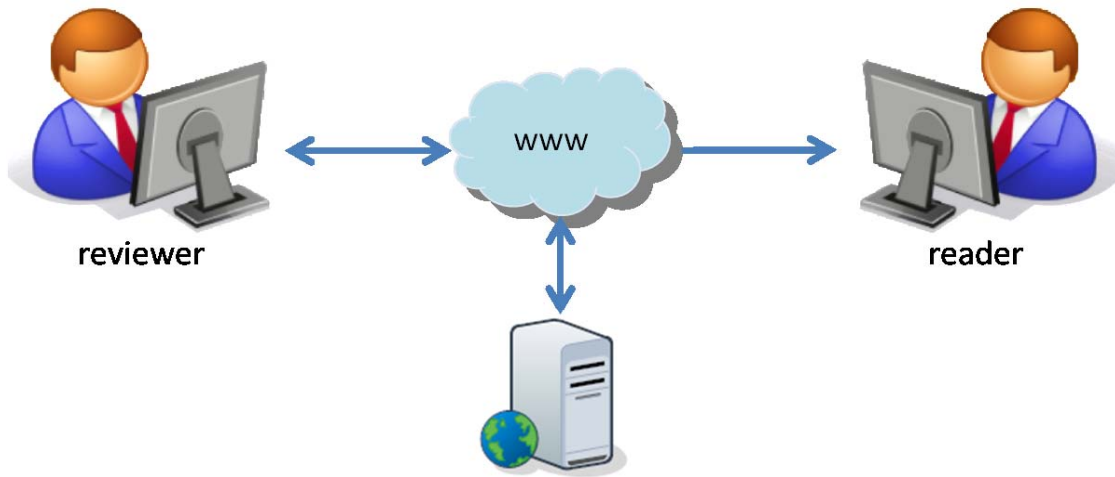


Figure 2. User - database interaction

Appendix

Review protocol development

Reviewer / review team	Reader / stakeholder
<ul style="list-style-type: none"> • entering review (protocol) relevant data, e.g.: <ul style="list-style-type: none"> ➢ question ➢ question type (PI/ECO, PIT, PO) and assigning the parts of question to type items ➢ review type (SR, EM) ➢ abstract 	<ul style="list-style-type: none"> • searching for reviews • view review protocol or download as PDF

Literature search

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> • add/create/change combining search terms => search string • document search process: <ul style="list-style-type: none"> ➢ which source/database ➢ what search terms and combinations ➢ state of the search • upload references as RIS file which is exported by reference management software (e.g. EndNote) 	<ul style="list-style-type: none"> • view combining search terms or search string • view search process or download as PDF • view and download references as RIS file

Study selection

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> • document study selection process: <ul style="list-style-type: none"> ➢ screening process (e.g. title, abstract, full text) ➢ inclusion/exclusion criteria ➢ quantity of studies on every screening process ➢ reasons for exclusion <p>or</p> <ul style="list-style-type: none"> • upload final spreadsheet for study selection 	<ul style="list-style-type: none"> • view study selection or download as spreadsheet • filtering study selection according to: <ul style="list-style-type: none"> ➢ title screening ➢ abstract screening ➢ full text screening ➢ critical appraisal • download outcome

Data extraction

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> document data extraction process in a protocol upload final spreadsheet, the data extraction sheet 	<ul style="list-style-type: none"> view all information of data extraction form download data extraction form view data of data extraction download data extraction file

Quality assessment

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> document quality criteria development, e.g. identified biases 	<ul style="list-style-type: none"> download outcome of quality assessment

Data synthesis via meta-analysis (if appropriate)

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> document meta-analysis entering publication bias upload results of data synthesis (e.g. excel spreadsheet, word file, PDF) 	<ul style="list-style-type: none"> view meta-analysis information view publication bias download provided data synthesis file

Presenting/interpreting data and results and drawing conclusions

Reviewer / review team	Reader / Stakeholder
<ul style="list-style-type: none"> upload final review paper 	<ul style="list-style-type: none"> download final review paper