



2013

# HolyRisk Data Management

**USER GUIDE** 



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#### Introduction 1

This document is a user guide describing how to use the HolyRisk Data Management (DM) software. This guide will concentrate on the main functions of the system. If you would like to have more precision on technical aspect, please refer to the HolyRisk Data Management technical guide.



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#### About HolyRisk Data Management 2

### 2.1 Overview

### 2.1.1 What is HolyRisk DM ?

The HolyRisk Data Management software is the result of an interdisciplinary (social sciences, risk analysis, computer science), comparative (US/EU) and empirical study that investigates how food safety policies are influenced by the scientific uncertainty embedded in the risk assessment reports.

The HolyRisk Data Management software allows to code relevant risk assessment (RA), risk management (RM) and impact assessment documents (IA) and store them in the HolyRisk Database.

Both HolyRisk Data Management software and HolyRisk Database are licensed. For more information, see the license section.

### 2.1.2 Contributors to HolyRisk Data Management

- INRA Met@risk research unit
- JIFSAN Joint Institute for Food Safety and Applied Nutrition, University of Maryland / The Food and Drug Administration (FDA)

### 2.1.3 Credits

The HolyRisk Data Management software has been developed during the HolyRisk research project. It has been granted by the French National Research Agency<sup>1</sup> (ANR) (ANR-09-BLAN-0314).

### 2.2 License

### 2.2.1 HolyRisk Data Management License

The current stable version of the HolyRisk Data Management software (including the HolyRisk database structure) is 1.0 (December 2013). It is distributed under the AFFERO GPL V3 license.



http://www.gnu.org/licenses/agpl-3.0.en.html

### 2.2.2 HolyRisk Database license

The current stable version of the HolyRisk Database is 1.0 (December 2013). It is distributed under the Creative Commons Attribution-ShareAlike 4.0 International License.



http://creativecommons.org/licenses/by-sa/4.0/

<sup>&</sup>lt;sup>1</sup> http://www.agence-nationale-recherche.fr/



### 2.2.3 Warnings

HolyRisk Data Management software has been developed during the HolyRisk research project. Some features were needed only at one point in the project and future evolution of the program or the database may not have been applied to them. It is especially the case for comparing codings.

If you need to use such features, you'll need to check them before using them.

### 3 Getting started

### 3.1 Installation and system requirements

HolyRisk Data Management is a web application. It is accessible using a recent web browser (Google Chrome, Firefox...) and an Internet connection. The user doesn't have to install anything on its computer.

If troubleshooting are encountered, please try to update your web browser or test with another one. You may also need to empty your web browser cache. We advise against using Internet Explorer.

### 3.2 HolyRisk DM at a glance

### 3.2.1 Overview

Here is a short description of HolyRisk DM user interface. It is composed of 4 zones:

- The Header circled in purple on the figure below
- The Quick Access circled in red on the figure below
- The Data Panel circled in green on the figure below
- The Footer circled in blue on the figure below

menu				
Database user guide and content	HolyRisk Data	Management	Glossary:	#INRA
				SCIENCE & IMPACT
Quick Access te ready the panel Hazard Europe/US Uncertainty Variables Image Impact Assessment (IA) Risk Assessment (RA) Quick Access		Da	ata Panel	
Terms of Use Licenses References Contact	Footer			



Header

### 3.2.2 The header

On the header, you have several buttons:



### 3.2.2.1 Database user guide and content

Click on the "Database user guide and content" to get the document describing the database and how to use the Holyrisk DM software.

menu			A 1
Database user guide and content	HolyRisk Data Management	Glossary:	-
Data extraction +		Search a document	

### 3.2.2.2 The "Data extraction" button

E	Database user guide and content	
logo	ut	
Data	a extraction -	
	Global number of documents	
	RA (1 variable - 1 column / 1 doc - X lines)	
	RM (1 variable - 1 column / 1 doc - X lines)	▶
	RA (1 variable - X columns / 1 doc - 1 line)	
	RM (1 variable - X columns / 1 doc - 1 line)	
	IA (1 variable - X columns / 1 doc - 1 line)	

It is a drop-down menu giving you access to the following features:

- Global number of documents
- Extraction of RA and RM codings: each document dispatched on X lines
- Extraction of RA, RM, IA codings: each document on 1 line.

All the extraction features generate csv file, i.e. a plain text file with data separated by a semi-column.

#### 3.2.2.3 The Glossary

The glossary describes a list of terms that can be useful to code the documents. It is a drop-down list. Click on the arrow to expand it, select a term in the list: its definition is displayed in a pop-up window.



Glossary:		Glossary
	$\sim$	
ono/one		Acronym:
BMDL/ BMCL		NOAEL
BMR		Signification:
IEDI		No observed adverse effect level
IESTI		
LED10	_	Explication:
LOAEL		Greatest concentration or amount of an agent, found by experiment or
LOEL/LEL		functional capacity, growth, development or life span in an organism, system or
ML Method/MLE		(sub) population.
MOE		
MOS		
MRL		
NOAEL		
PBPK Model		
PMTDI		ok
0.7147	*	

### 3.2.2.4 The "Search a document" button

When you click on the "Search a document" button, a pop-up window is displayed. Use this window to enter your search criteria on the left in the "Search parameters" area and get the corresponding documents on the right, in the "Search results" area.

Search a document		8	×
Search parameters	Search results		
Type of document to search: RA RM IA Documents must match: ALL parameters I ANY parameters of the same type Search parameter: Value: Call Remove Search Parameter Parameter	Туре	Coding title	
	0 documents found		
		Show linked documents Open in Quick Access	

### Search parameters

1. Specify the type(s) of documents to search using the check boxes.



2. Use the "Search parameter" drop-down list to get the list of the available criteria. Choose one



Search parameter:	
Agent of hazard	
Agent of hazard	
Category	
Country	
Uncertainty variable	
Year	

3. Then the "Value" drop-down list is updated with the possible values corresponding to the previously specified parameter

3-monochloro-propane-1,2-diol (3-MCPD)	
BSE	
acrylamide	
aflatoxins	
ammelide	
ammeline	
anisakis simplex	
arsenic	
avian influenza	
azaspiracid	
bacillus Anthracis	
bacillus cereus	
bacillus spp	
bisphenol A	
boron	[

4. Click on Add to validate your choice. It is added in the bottom of the "search parameters" area.



ype of document to search:
🛚 RA  VIRM 🔲 IA
ocuments must match:
) ALL parameters ( ) ANY parameters of the same type
earch parameter:
~
alue:
~
Add
Parameter
Agent of hazard = 3-monochloro-propane-1,2-diol (3-MCPD)

To remove a criterion, check the box next to it and click on emove

5. If you specify more than one criterion, you can decide to search for documents that match all the criteria or just one of them. Choose the appropriate radio button.

Documents must ma	atch:
ALL parameters	<ul> <li>ANY parameters of the same type</li> </ul>

- 6. To run the search, click on Search
- > Search results

The documents corresponding to your search criteria are displayed on the right in the "search results" area.

	arch results	
	Туре	Coding title 🔺
8	RA Document title : Statement of the	3-MCPD esters_EFSA_2008_XC_valid e Scientific Panel on Contaminants in the Food chain (CONTAM) on a
Đ	RM	CertainContaminants 1881/2006 AF
Ð	RM	 Multiple Contaminants_EC Reg2007_AF
	3 documents found	
	3 documents found	Show linked documents Open in Quick Access
docu	<b>3 documents found</b> ument in the result table th	Show linked documents Open in Quick Access en click on Open in Quick Access to edit the document.



### 3.3 The Quick Access



The "Quick Access" is the tool to navigate through the documents available in HolyRisk Data Management.

It is composed of 3 tabs, "Hazard", "Europe/US" and "Uncertainty variables", allowing you to browse the documents.

The documents are organized in a hierarchy that is different depending on the tab you are. For example, on the "Hazard" tab, documents will be sorted by:

- 1. Type: RA, RM or IA
- 2. Category of hazard : biohazard or contaminant
- 3. Hazard: for example, for biohazard, you will see BSE, avian influenza, etc.
- 4. Document name: the short name of the document is displayed next to the  $\stackrel{\smile}{=}$  icon
- 5. Coding name: a document may have been double coded. All the coding are grouped under the document name.



### To open a coding, click on a coding name

### 3.4 The Data Panel

The "Data Panel" is where the information are stored. It is composed of different tabs depending on the kind of document considered.



Data Panel							
General Information Hazard Identification Ha	azard Characterization	Exposure Assessment	Risk Chara	acterization	Uncertainty and Judgment Variables	Recom	nendation
Opinion of t	the scientific commited	e on food on 3-Monoc	hloro-propa	ane-1,2-dio	ol(3-MCPD)		
Document ID							
Agent of hazard in the RA	Publication Year:			Publi	sher:		
	2001	2001 Coding title:		Euro	opean Commission	~	
Agent	Coding title:			Туре	Type of committee:		
3-monochioro-propane-1,2-diol (3-MCPD)	3 monochloro propane_SCF_2001_G Number of contributors:				~	~	
🕤 Add			Num	Number of pages:			
Country:				5			
Europe	Number of author	Number of authors:		Num	Number of pages mentioning the hazard:		
Expert committee:							
SCF	Number of authors disclosing (conflict of) interest:		Num	Number of pages of references:			
				1	1		
				Aver	age number of references per page	:	
				7			
Detionals of the DA			_	_			
Information on the request							

Data Panel for a RA document

a Panel					
cument description Type of measure	Judgment/Uncertainty variables	Links to documents			
COMMISSION REGULATION (EC) No 333/2007					
cument description					
Agent of hazard in the RM	Coding title:		Date		
Agent	Multiple Contamin	ants_EC Reg2007_AF	Day: Month: Year:		
3-monochloro-propage-1 2-diol (3-MCPD)	Document issued b	y:	28 🗘 3 🍣 2007	~	
cadmium	European Commis	sion (EC)			
inorganio Tin	Document number	:	Cost/Benefit Analysis		
Inorganic Tin	333/2007	v	Cost/Benefit analysis:		
lead	Type:		No	~	
mercury	EC Regulation	Regulation Uncertainty analysis:			
📀 Add	Country:		No	~	
oes the RM act provide background informa	Europe	~			
marts:					
mpacts:					

Data Panel for a RM document

### 3.5 The Footer

On the "Footer" you will find:

- Terms of use of the HolyRisk Data Management
- Licenses: the licenses for the HolyRisk Data Management software and the HolyRisk Database
- References: the publications to cite if you want to make reference to the HolyRisk Data Management software or the HolyRisk Database. You will also find the list of publications related to the HolyRisk research project
- Contact: the e-mail to contact members of the HolyRisk project



## 4 Structure and content of the HolyRisk Database

### 4.1 The risk assessment (RA) documents

The records represent a single hazard per document. Therefore documents covering multiple hazards are represented by as many records as hazards are described in the document. The coding then refers to discussions of a particular hazard. We decided to take RAs issued after 2000 to 2010.<sup>2</sup>

Currently, the database contains 252 records of which 177 are full records (named "coded" in the DB) and 75 are partial records with basic identifying information only (named "not coded" in the DB). Not coded records were included to represent all RAs mentioned in the RM documents linked to the full record RAs but they are ignored in the analyses.

Each risk assessment record has nine sections each can be accessed with a tab on the Data Panel. They are as follows:

### 4.1.1 General Information

This section contains data that identify the document including its title, year of publication, publisher, length in number of pages, number of contributors, authors, and references etc. It also includes information on the request for the RA, the nature and objective of the document, and some other general information such as its structure, the group and food product at risk, the main source of contamination, and the health effects of the hazard including genotoxicity, the number of cases and incidents of illnesses and number of deaths along with the geographical areas affected.

This is where the original document can be downloaded in a PDF form.

### 4.1.2 Hazard Identification

Here the diseases caused by the hazard are coded using the ICD-10 nomenclature.

### 4.1.3 Hazard Characterization

This section, for contaminants gives a detailed description of the food, populations and the agent of hazard considered, as well as the type oftoxicity reference value (TRV) used, its value, as well as the studies cited, and the critical effects considered in this part of the RA. For biohazards, it records if there is a dose-response section.

### 4.1.4 Exposure Assessment

This section describes the type of exposure assessment reported, the type of exposure estimate, population and food considered, the values of the consumption and exposure estimate.

### 4.1.5 Risk Characterization

Here we code data like the margin of safety, if mentioned, comparison with the TRV, the likelihood that the TRV is exceeded and health concern level.

### 4.1.6 Variable Occurrences

This section lists the occurrence of Uncertainty and Judgment variables linking them to particular sentences in the text. The uncertainty variables focus on the substantive sources of expressed scientific uncertainty. We intended to capture the kind of informational problem that created the uncertainty. We were concerned only with final uncertainty, uncertainty that remained in the mind of the panel and we were not interested in flaws and problems in studies that the panel reviewed but dismissed in light of

 $<sup>^2</sup>$  EFSA was created in 2002, before that the Scientific Committee on Food carried out most risk assessments for the European Commission.



better evidence. Therefore we coded only the summaries and conclusions of the documents and, if they contained a special section called uncertainty analysis, we coded that too. There were a few documents that did not have conclusions and/or summaries. If these were short documents, we coded the entire text. If they were longer, we identified the section where final uncertainties were communicated. We also did not second-guess the panels or approach their work in a critical fashion. The uncertainty variables are simply descriptions of what the scientists thought remained uncertain, after all the evidence had been considered. While our ultimate unit is the sentence, the coders had to consider the wider context to code the sentence or sentences properly.

Each uncertainty variable has three attributes: its magnitude (high, low, undetermined), whether it is quantified (no, probability estimate, default uncertainty factor, estimated uncertainty factor) and, finally, if uncertainty is quantified, the value given.

Judgment variables describe how the panel judges the weight of the evidence and it follows more closely the language they use to do so. There are five judgment variables.

We created a detailed coding manual for both uncertainty and judgment variables, that provide definition, explanation, examples and counterexamples for each variable.

We tested our coding scheme using supervised machine learning. This process caught a few mistakes that upon further considerations we reclassified.

### 4.1.7 Recommendation

Here the recommendations of the RA panel are categorized and listed. We distinguish between two types of recommendations. One points to lack of sufficient knowledge and -- therefore, implicitly or explicitly – refers to uncertainties elsewhere in the RA. Those we code in a way that it could be mapped on the uncertainty variables. For instance, recommending "Additional long-term data on the hazard's effect" indicates there is some problem with making "Inference in time," or calling for "Standardization/Harmonization of data" suggests that "Comparability of data" is an issue. <sup>3</sup>

The second type of recommendation is the one that urges specific RM interventions managing the hazard itself. Here we use the same codes that will be used to code the RM action taken in RM documents (e.g., destroying the product, labeling, informing the consumers etc.). We also code if precaution is mentioned in the recommendations, and if they make general recommendations for reducing exposure.

### 4.1.8 Linked Documents

This section lists all the linkages to other RAs, RMs and IAs.

### 4.1.9 Keywords Occurrences

The last section is generated by the computer that lists the occurrence of a list of keywords related to uncertainty, classified and counted. This section is machine generated.

<sup>&</sup>lt;sup>3</sup>We found that the relationship between uncertainty and recommendations were quite tenuous.



### 4.2 The risk management (RM) documents

HolyRisk includes 174 risk management records. Each represents one document and have four sections that can be accessed with a tab on the Data Panel.

They are as follows:

### 4.2.1 Document Description

This section lists the hazards covered in the document. It gives the date it was issued and the type of the RM document with all its identifying information.

This is where the original document can be downloaded in a PDF form.

### 4.2.2 Type of Measure

Here one finds the description of the measures in the document, their type, the hazard they refer to, the time frame for execution and where it can be found in the text.

### 4.2.3 Uncertainty and Judgment Variables

This section registers if precaution is mentioned in the document, if hedging is present and if there is any open reference to uncertainty of any kind.

### 4.2.4 Links

This section lists all the linkages to other RMs, RAs and IAs.

### 4.3 The impact analysis (IA) documents

There are nine IA records currently in the database, four from the EU and five from the US, two are about contaminants and seven about biohazards.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2001	1	11.1	11.1	11.1
	2004	3	33.3	33.3	44.4
	2005	1	11.1	11.1	55.6
	2011	3	33.3	33.3	88.9
	2012	1	11.1	11.1	100.0
	Total	9	100.0	100.0	

### Impact Assessments by date of publication

The IAs were issued between 2001 and 2012. Three records cover not one but three hazards. Each record has four sections. They are as follows:

### 4.3.1 Background Information

This section includes information about what hazard is discussed, when and which institutions, in which country issued the document, the stated objective of the IA, what RM measure it refers to, what stakeholders are identified, and what policy options are chosen.

### 4.3.2 Impact Analysis

The impact analysis is coded in four areas: public health, economic, social and environmental. For each, the record includes the method used, including the method of estimating costs and benefits.



### 4.3.3 Uncertainty Analysis on Public Health

If uncertainty is explicitly expressed it is coded using the uncertainty ontology and judgment variables.

### 4.3.4 Links to Documents

Here one finds the links of this document to RMs, RAs and other.

