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Highly Integrated Information Systems for Automated Biological Risk Assessment of the Contained Use of Pathogenic Organisms within the Geneva Region

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Abstract

The intent of the project was to automate biologic risk management data exchange between the Swiss federal information system (ECOGEN) and the Geneva cantonal information system on the industrial environment (SI/GEI). Using adapted sorting criteria, all the selected projects on the contained use of pathogens were submitted to risk calculations as part of the application of the Geneva risk project called the Cantonal Risk Register (CCR) incorporating GIS risk representation. A unique method to quantify the risk of the contained use of pathogenic organisms was developed that is easy to use, comprehensible, reproducible, and allows for the automated import of data, risk calculation and export to GIS-visualization tools.

1. Introduction

The Ordinance on Contained Use of Organisms (CO) regulates activities involving the contained use of genetically modified or pathogenic organisms in Switzerland. The Ordinance on Major Hazards (OMA) regulates the prevention and management of accident in facilities using genetically modified or pathogenic organisms for activities of classes 3 and 4 are carried out. In the Canton of Geneva, the Geneva Labor Inspectorate (OCIRT) is the competent authority that handles these responsibilities, with a focus on the control of adherence to safety measures and monitoring of installations. In order to fulfill this obligation, OCIRT decided to develop a new thematic layer of information in the framework of the Geneva Risk application (CCR). The Geneva Risk project deals mainly with the risk of industrial installations that fall under the Ordinance on Major Accidents (OMA) (Susini et al. 2004, Jansen et al. 2005). Our goals were to complete our application in order to fulfill our duty to control all the major hazard facilities (with chemical and biological risk potential) and to get a comparison of the different kinds of industrial risks (chemical and biological) in the Canton, in order to set up priorities in monitoring installations, and to enhance further the preparedness of emergency response and land-use practices. Special GIS representations will be used in order to inform the public.

This project deals only with the activities involving pathogenic organisms regulated by the CO that could affect human health and plants. For the purpose of our study, the pathogenic organisms must be part of a notified application being classified from class 2 to 4 activity, and taking place in a research, diagnostic or production facility. Genetically modified organisms will be looked at during a later stage of the project.

The Federal Coordination Centre for Biotechnology is the entry and exit point for all notifications and permit applications that fall under the Ordinance on the Contained Use of Organisms (English translation not legally binding, [CO](#)) and the Ordinance on Occupational Safety in Biotechnology (OOSB). All the notifications and permits are managed by the federal ECOGEN information system. ECOGEN enables the comprehensive exchange of electronic data between all the parties involved, extending from the on-line registration of the notification or permit application by the project owner to the processing by the different authorities. (Krähenbühl and Freund 2004).

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ECOGEN is a federal information system that is used in accordance with the Swiss Containment Ordinance CO (regulation of 25 August 1999 on the contained use of organisms, SR 814.912). Within the scope of the CO, all institutes, companies and organizations which intend to carry out projects involving pathogenic or genetically modified organisms belonging risk group 1 to 4 in a contained system must notify these projects (risk group 2) or apply for a permit (risk group 3-4).

The goals of our project include the automation of the import of the Geneva region project data from ECOGEN to the SI/GEI, the automated filtering of those projects for risk calculations depending on the given criteria and those for submission to OMA regulations (projects from class 3 and 4, and some class 2 depending on the damage potential), risk calculations, and the GIS risk representation in the cantonal risk register (CCR). To reach this aim, there was the need to develop a quantified risk analysis method for the contained use of organisms that is easy to use and comprehensible, and an integrated information system that allows for the automated import of data, risk calculation and export to GIS-visualization tools.

This project was developed in partnership with the Federal Coordination Centre for Biotechnology of Switzerland (<http://www.contactbiotech.ch>), the Geneva labor inspectorate-section of environmental affairs from the Geneva state (www.geneve.ch/ocirt/environnement_entreprises) and two private companies (Basler & Hofmann and GamaSoft).

2. Methods

There is, to the best of our knowledge, no method available to quantify the risk of handling pathogenic micro-organisms in clinical, research, and environmental laboratories, production plants etc.. Based on the IAEA-approach to rapidly assess and prioritize industrial risks, a simple risk model to quantify the risk of pathogens to lab workers and their contact persons outside the facility was developed for different types of activities like diagnostic, food diagnostic, research laboratories, and production installations. Risk is understood as a function of probability and damage. The probability component of handling pathogens in a facility was calculated using a base incidence of laboratory infections derived from the literature. For a given facility, this base probability was multiplied by bonus and penalty factors, which depend on the type and risk class of the activity, the nature of the pathogens handled, the size of the laboratory (area and number of staff) and safety measures implemented. The damage component was estimated using a simple epidemiological model consisting of reproduction rate, morbidity, and mortality. Numeric data for the different factors were obtained from the literature. The risk model (which includes calculations for collective and individual risks) covers both routine event scenarios, namely infection routes via lab workers, contaminated material and wastes as well as accident related scenarios, namely fire and earthquakes. We developed also a scenario dealing with an environmental accident caused by the escape of an organism capable of causing disease on ornamental trees. The methodology developed also makes it possible to quantify and visualize the utility of the technical and organizational safety measures. The companies having a highly developed safety culture clearly obtain better results with the risk calculations than those which have gaps as regards safety. The plausibility of the occupational and environmental risk calculated was checked against statistical occupational hazards in the US and Switzerland. This verification step showed that the method gives comprehensible results (Gmünder and Susini, to be published).

We had to set up a dataset allowing the risk calculation, and we identified 42 data fields of information that were necessary to be filled up for a notified project in a plant, in order to proceed with the appropriate risk calculations. It is important to note that not all the data obtained from the ECOGEN file could be used directly for our risk calculation. Actually only three data fields were used: type of activity, risk class and presence of pathogens. Twelve other values necessary for the calculations must be selected by the user, for example, number of employees, availability and implementation of a biosafety policy and appropriate safety measures. The rest of the necessary data (probabilities, frequencies, damage and kind of risk) are provided by the system and can be chosen by the user from dynamic tables. The user is guided by

a sequential flow diagram. The import of the ECOGEN file will be done on a regular basis of three times a week, for this exchange, complex interactions between cantonal and federal safety protection firewalls had to be solved. Once an import of data from ECOGEN has been completed, the SI/GEI exports data of inspections and controls done by inspectors on the notified projects on its part to ECOGEN. The industrial environment and risk management process for the Geneva state is automated through highly integrated information systems. The new solution, which supports CO and OMA regulations, biological risks calculation and GIS representations, is outlined in Fig. 8 which depicts the high level components of the system and how they interact to implement the CO & OMA processes.

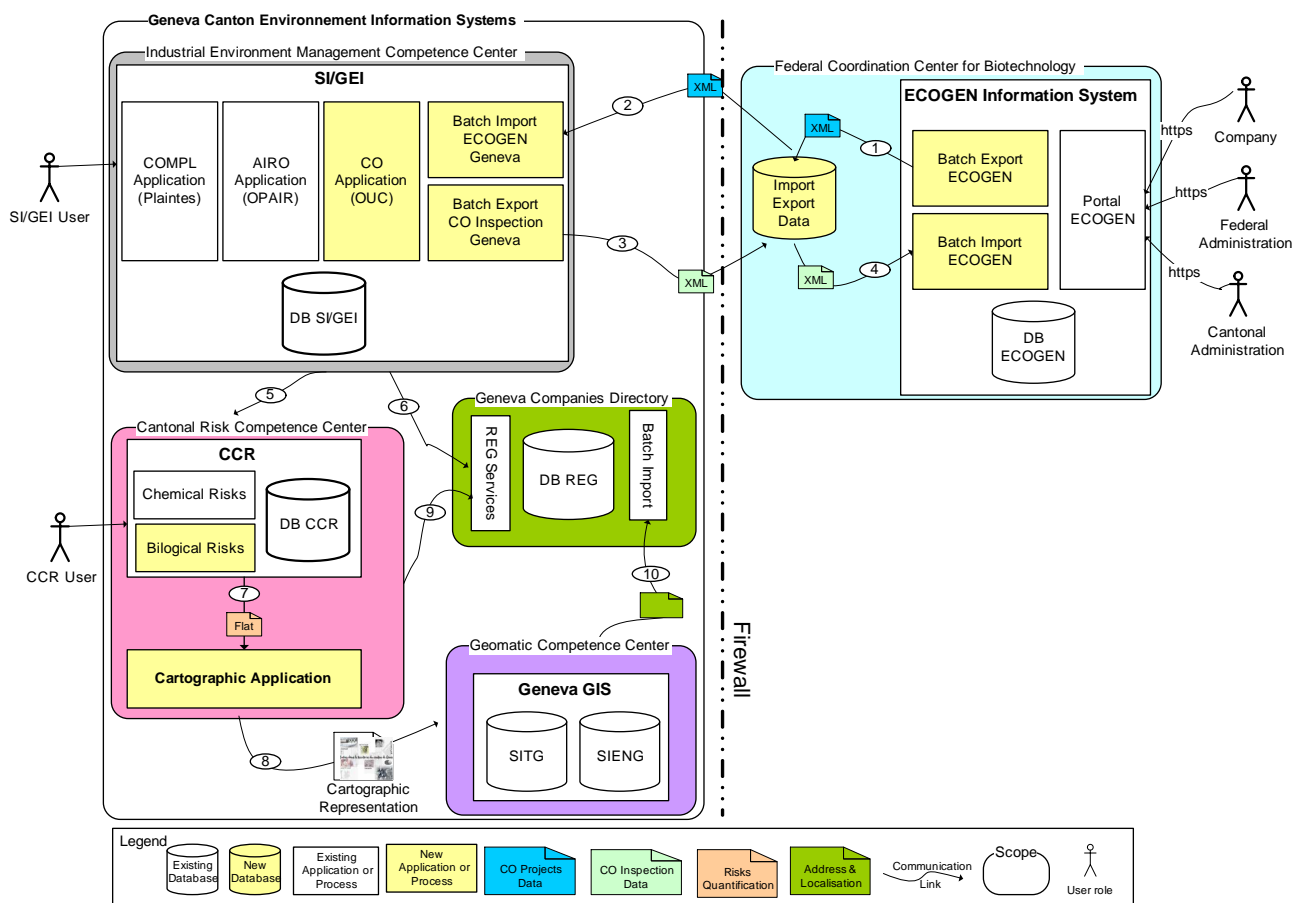


Fig. 8: Geneva Industrial Environment & Risk Management Systems

The link between the biological risk calculation method explained above to the outlined system below is evident in the following four steps. The complete process flow is explained in detail in Table 1 and the process flow of a single project can be followed by this sign ① in the figure 1 with his description in the table 1.

First step: we automatically import from ECOGEN a set of data containing all the notified projects of the canton and process them within the SI/GEI application.

Second step: the CCR application gets from the SI/GEI application a subset of ECOGEN projects data based on a predefined filtering criteria (dangerousness and submission to OMA) based on the following parameters: Type of activity, Risk class and Presence of pathogens.

Third step: the Biological Risks application does the following :

- gets the IAEA parameters from the user
- calculate all intermediary risks
- calculate the total risks
- F/N analysis and data export for cartographic presentation

Fourth step: cartographic application gets the export file from the Biological Risks application and builds the cartographic representation.

Process step	Component / Communication Link	Functionalities
1	Companies / https	Online registration of CO projects at the Federal Coordination Center for Biotechnology for authorization, done by the applicants (industry, universities, private laboratories etc.).
2	Federal Administration / https Cantonal Administration / https	Online access to the ECOGEN data by federal and cantonal administrations.
3	Batch Import ECOGEN / ①	This batch periodically downloads an XML file to the dedicated file server, containing all the CO projects in Geneva that are new or have changed.
4	Batch ECOGEN Geneva / ②	This batch periodically (3 times a week) gets the CO projects file and updates the SI/GEI database.
5	CO Application (OUC)	This SI/GEI component provides the following capabilities under CO terms: - Inspection management, - Statistics and reporting - Filter CO projects with industrial risks falling under OMA and/or risk calculation.
6	Batch Export CO Inspection Geneva / ③	This batch periodically (one time a week) downloads an XML file to the dedicated file server, which contains all results of the inspections that have been performed during the precedent week.
7	Batch Import ECOGEN / ④	This batch periodically gets the inspections file from the dedicated file server and updates the ECOGEN database.
8	Biological Risk / ⑤	This CCR component provides the following capabilities under CO and OMA terms: - Get CO projects with industrial risks falling under OMA or/and risk calculation - Biological risks quantification - F/N diagram - Generation of export file for cartographic representation.
9	Cartographic Application / ⑦	The Cartographic Application gets the export file for the cartographic representation.
10	Cartographic Application / ⑧	The Cartographic Application generates cartographic representation.
	SI/GEI / ⑥ CCR / ⑨ SITG-REG/ ⑩	Gets data from the companies/organizations directory. (REG)

Table 7 : CO & OMA process flows and the components involved

The quality of the data was further enhanced by tapping into other cantonal databases; a wide range of cartographic standardized data were taken from the cantonal geographic database (SITG; www.sitg.ch) provided by Geomatic competence center (GCC) and Geneva liabilities data at the Geneva Companies Competence Center (REG; <http://www.reg.ge.ch>).

The software technologies used for the SI/GEI node is based on the standard 3 tiers Java framework of the Geneva Information Technology Center (CTI), which consists of:

- Java/Swing for the presentation (run on client workstation)
- Borland application server for the server tiers
- Oracle database for the persistence tiers

For historical reasons, the software technologies used for the CCR node is Oracle Forms. This technology will be replaced by the CTI standard Java Framework with Java/Swing and Borland Application Server next year. ArcGIS (ESRI) is the instrument of choice in the visualization of the results of the risk assessment.

As an example, we wish to describe the way that a given project will be followed through the system. We chose the example of the new Swiss National Reference Center for avian flu and hemorrhagic fever that will be built inside the Geneva Cantonal Hospital during the summer 2006. This project was first registered in December 2005 by the Federal Coordination Center for Biotechnology inside the ECOGEN information system and was therefore made available for the cantonal authorities for official statement about the safety measures for obtaining the authorization. The weekly regular batch with ECOGEN allows the import of this new project inside the SI/GEI which was added to the other existing projects of the Geneva cantonal hospital. This project with a risk class 4D (activity with high risks) and a diagnostic type of activity, was then automatically filtered to the CCR application for our cantonal risk register. Inside the CCR, the above described filtering criteria, allowed also the automatic choice of some parameters and the remaining were added by the user, allowing in that way the final risk calculations and also the export for cartographic representations for this project which became the highest risk classification in Switzerland for such kind of diagnostic activity.

3. Results

We succeeded in linking and integrating the above described information systems in order to reach the goals of the project. About 20 facilities representing 190 notified projects were subjected to these automatic selection procedures; further detailed risk calculations and GIS representation were possible. For the first time, a regional view of biological risks linked to activities involving contained pathogenic organisms was calculated and visualized using the Canton of Geneva as an example. Furthermore, the data management, risk calculation and visualization is, except for the selection of some model parameters and a quality assurance check, fully automatic, thus allowing us to represent the dynamic development of clinical, research and industrial facilities. The method – although simple and easy to apply, produces results that are comprehensible and reproducible.

All the calculations needed were made within the application, in order to generate interactive F/N-curves (Frequency of N or more fatalities, as a function of N) of plants and industrial facilities, and an export that is used to create visualization models. In the database, each project involving activities with pathogenic organisms in a plant, laboratory or an industrial facility was assigned with its precise topographic location that was used for the geographical localizations and calculations.

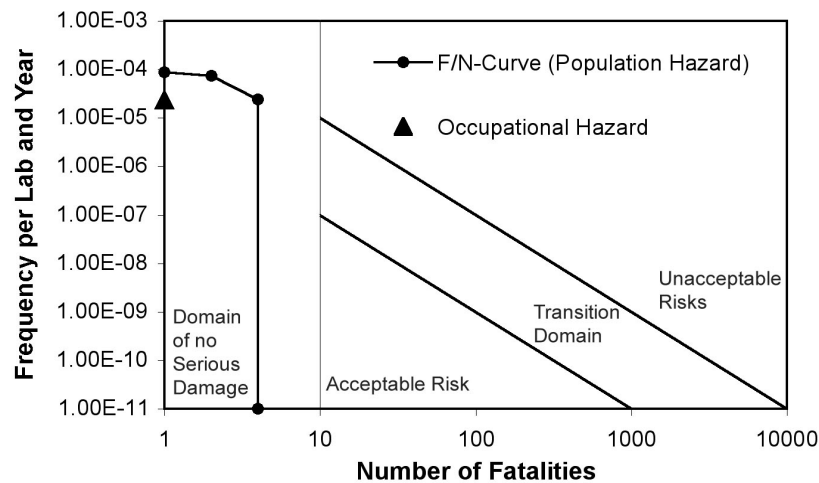


Fig. 2: Risk of a small clinical laboratory. A high reproduction factor (2), high morbidity (0.5) and high mortality (0.1) were chosen to calculate the occupational hazard to a lab worker (▲) and the risk to the population (●). In addition, low biosafety culture was assumed, i.e. the only safety measures implemented include Good Microbiological Technique, but neither biosafety policy, biosafety officer, nor biosafety cabinet.

Compared with industrial risks falling under the Ordinance on Major Accidents (e.g. facilities with relevant amounts of gaseous chlorine or ammonia or large petrol storage plants) like those shown in the Geneva risk project, the biological hazards seem to be less important. In essence, biological facilities dealing with pathogens seem to pose occupational hazards only (Figure 2, Gmünder and Susini, to be published). We also succeeded in producing 18 thematic GIS-maps, one for each kind of calculations, a global risk map and a map for information of the public. The cartographic representation of facilities with biological hazards is shown in Figure 3 (fictitious location of facilities).

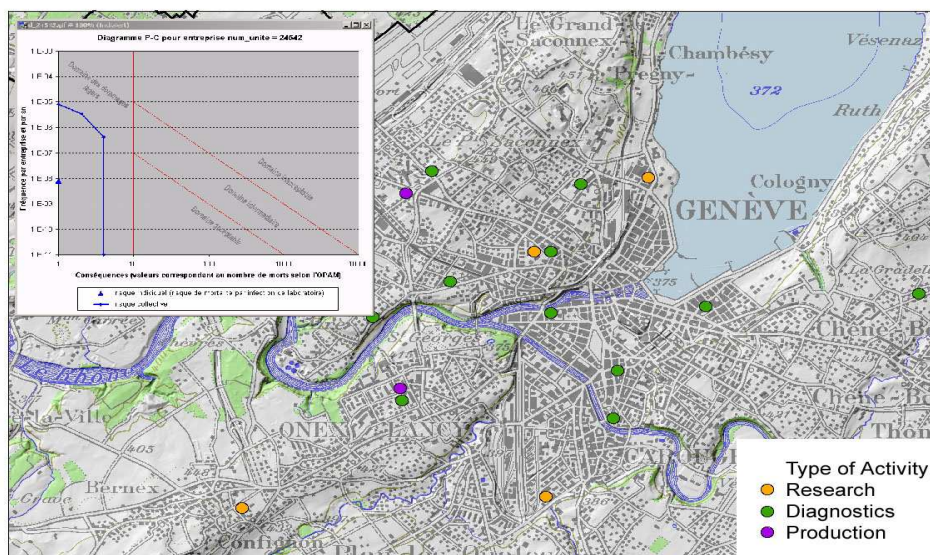


Fig. 3: Cartographic representation of biohazards in containment facilities (laboratories, industrial plants). When placing the cursor over a specific facility, the basic data becomes visible as well as the F/N diagram showing the occupational risk for personnel and for the population (F/N diagram s. Figure 2).

The quality and the completion of the projects data received from the ECOGEN Information System have great impact on the level of automation of the process. Currently information concerning the presence and type of pathogens is under construction and is planned for the next version of ECOGEN. The improvement of precision or coherence in the specification of the handled organisms implies less manual selection of the IAEA factors by a knowledgeable user and further automation possibilities of the process. The cartographic representation of biological hazards supplements the wide range of tools and projects of Geneva Risk, a project dealing with potential risks and damages caused dangerous chemical substances (Susini et al. 2004, Jesper et al. 2005).

4. Discussion

For the first time, a method to quantify biological hazards in the frame of the contained use of pathogens was developed and implemented as an integrated system to estimate and visualize the risks in the context of a regional risk management system, which is based on state-of-the-art risk modeling and GIS. The automated import, calculation and export of data are feasible and periodic automated updates are provided for. Risk visualization using GIS is used to identify risk clusters in the Canton of Geneva and to facilitate control and law enforcement, as well as prevention and mitigation of possible accidents in the future. This system will also promote good teamwork among state agencies, fire brigades and the industry by sharing the latest and validated data. The list of dangerous organisms with their properties will be part of the scientific support in the event of spills involving hazardous materials. This on-line service enhances the response and preparedness to civil and environmental emergencies in the Geneva Canton. The Federal Coordination Centre for Biotechnology gets important feedback about the results of inspections in the canton, improving in that manner its practice in delivering further notifications and permits. This system is evolutionary and allows the addition of new "layers" (for example for contamination by contained pathogens with effect on seedbeds, food crops, livestock and natural environment). It offers also potential for further developments like the use of the data available for analysis and cartographic representation on human and environmental safety. The system's possible role in accident prevention and mitigation will be discussed shortly with the different competent authorities. One next step will be to enhance the outputs of the ECOGEN data in terms of pathogens and organisms in order to raise the level of automation of the process and therefore limited manual entries and errors.

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