Sci Com Workshop 2007

Scientific exploitation of databases within the framework of food safety risk assessment
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Preface

The Scientific Committee of the Federal Agency for the Safety of the Food Chain organised the 23rd November 2007 a workshop for a broad audience. This was the third edition in a series of scientific communication events becoming a reference for scientists and stakeholders involved in risk assessment of the food chain in Belgium. The title of this third workshop was “Scientific Exploitation of Databases within the Framework of Food Safety Risk Assessment”.

As a scientific, independent advisory body, the Scientific Committee has as a major task to perform risk assessment studies for the Agency. As it is general practice there is a strict separation between independent risk assessment and risk management. It is however accepted, in broad circles, that some interaction is necessary between risk assessors, risk managers, risk communicators and other interested parties working in the food chain. The annual workshop was organized to fulfil, at least partially, this need.

Another important issue is that the workshop offers a unique opportunity for the Scientific Committee to reflect on its own work. Indeed speakers from external organisations have been invited to present their view and to share their experience. Several case studies worked out within the Scientific Secretariat of the Scientific Committee and the Agency have been presented and were thoroughly discussed.

Networking is also an important objective of a scientific workshop. There was indeed ample opportunity to discuss results with colleagues with a variable background and from different horizons.

From the first workshop on, it was decided to publish the contributions in a series of monographs. These publications are becoming an important source of scientific information and reference material for those interested in knowing more about the risk assessment in the food chain.

As chairman of the Scientific Committee I want to express my thanks to all parties that contributed to the success of this particular workshop:

• the executive officers of the Agency for their continuous support of the activities of the Scientific Committee,
• dr. L. Herman and dr. ir. L. Pussemier, both members of the Scientific Committee, who chaired the workshop in a very efficient way,
• the staff members of the Scientific Secretariat for their invaluable assistance.

Prof. Em. dr. ir. André Huyghebaert
Chairman of the Scientific Committee
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<tr>
<td>ADI</td>
<td>Acceptable Daily Intake</td>
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<td>ARfD</td>
<td>Acute Reference Dose</td>
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<td>BIP</td>
<td>Border Inspection Post</td>
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<td>BIRNH</td>
<td>Belgian Interuniversity Research on Nutrition and Health</td>
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<td>BNFCS</td>
<td>Belgian National Food Consumption Survey</td>
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<td>BO</td>
<td>Business Objects</td>
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<td>C</td>
<td>Number of sample units giving values over m or between m and M</td>
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<td>CCP</td>
<td>Critical Control Points</td>
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<td>Cd</td>
<td>Cadmium</td>
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<tr>
<td>CFU</td>
<td>Colony Forming Unit</td>
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<td>CIAA</td>
<td>Confédération des Industries Agro-Alimentaires de l'Union Européenne (Confederation of the Food and Drink Industries in the European Union)</td>
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<td>FASFC</td>
<td>Federal Agency for the Safety of the Food Chain</td>
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<td>FEVIA</td>
<td>Federatie Voedingsindustrie – Fédération de l'Industrie Alimentaire (Food Industry Federation)</td>
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<td>FFQ</td>
<td>Food Frequency Questionnaire</td>
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<td>FPS</td>
<td>Federal Public Service</td>
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<td>GAP</td>
<td>Good Agricultural Practices</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>HACCP</td>
<td>Hazard Analysis of Critical Control Points</td>
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<td>ILVO</td>
<td>Instituut voor Landbouw- en Visserijonderzoek (Institute for Agricultural and Fisheries Research)</td>
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<td>IPH</td>
<td>Scientific Institute of Public Health</td>
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<td>ITM</td>
<td>Institute of Tropical Medicine</td>
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<tr>
<td>ITX</td>
<td>Isopropyl Thioxanthone</td>
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<td>JECFA</td>
<td>Joint FAO/WHO Expert Committee on Food Additives</td>
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<td>JEMRA</td>
<td>Joint FAO/WHO Expert Committee on Microbiological Risk Assessments</td>
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<td>JRC</td>
<td>Joint Research Centre</td>
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<td>KULeuven</td>
<td>Catholic University of Leuven</td>
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</table>
**LIMS**: Laboratory Information Management System

**LOR**: Limit of Reporting

**M**: Limit of Acceptability

**m**: Limit of Satisfaction

**M(R)L**: Maximum (Residue) Level

**n**: Number of units comprising the Sample

**PCP**: Pentachlorophenol

**PCU**: Provincial Control Unit of the FASFC

**PTWI**: Provisional Tolerable Weekly Intake

**RASFF**: Rapid Alert System for Food and Feed

**RIKILT**: Rijksinstituut voor Voedselveiligheid (Institute of Food Safety) - the Netherlands

**SciCom**: Scientific Committee of the FASFC

**SHC**: Superior Health Council

**SQL**: Standard Query Language

**UGent**: University of Ghent

**UHasselt**: University of Hasselt

**ULg**: University of Liège

**VAR**: Veterinary and Agrochemical Research Centre

**WHO**: World Health Organization
Valorisation of monitoring programme databases by risk assessment studies: opportunities and constraints

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Official authorities in Europe and, more particularly in our country the Federal Agency for the Safety of the Food Chain (FASFC), have the mission to control the safety of the foodstuffs with special emphasis on biological and chemical contaminants that may have a negative impact on the health of the consumers. Therefore, monitoring programmes are developed either at the European level (as, for example, to determine pesticide residues in foodstuffs), or at the national level. Besides the official control programmes also private organisations are controlling safety parameters of the food sold to the consumer.

In Belgium, clear and transparent rules were set by the FASFC management, in close collaboration with the Scientific Committee (Sci Com), to design the monitoring programme. They were published in the open literature in order to ensure full transparency towards the general public¹. Those rules do take into consideration some important intrinsic properties of the contaminants as well as some important characteristics of the foodstuffs or groups of foodstuffs. Some examples of the most important features are:

- The harmful effect of the hazard
- The occurrence of the hazard in Belgium and elsewhere
- The importance of the contaminant and of the foodstuff (or group of foodstuffs) in the diet
- The number of analyses per foodstuff imposed by regulations
- The overall cost and the financial limitations

Each year the monitoring programme of the FASFC is designed using these rules and its application leads to thousands of analyses to be carried out for a large number of biological and chemical contaminants. The annual reports published by FASFC give, year after year, an overview of the results for the different parameters analysed.

Combining the results of different years, trends in the number and the nature of non compliant samples for a given parameter (or group of parameters) can be evaluated. These trends are offering qualitative indicators on food safety issues, useful to update and improve, where necessary, the monitoring programme of the food agency.
Besides the official control programme, private organisations and companies also collect data from food product analysis of different suppliers to the distribution. These results are collected in private databases, mainly used by internal decision makers.

However, the question arises how far the information available in these different databases could provide useful scientific data to determine the exposure of the consumer to some of the most relevant contaminants that can be found in our diet. These data constitute the basis of food safety risk assessment studies. These risk assessment studies can offer the risk manager valuable information concerning the importance of the different food safety risks for the consumer and, on top of this, an evaluation of the effect of different possible control measures to protect the consumer.

Such risk assessments can only be adequately realised when sufficient data are available for estimating the risks for the general population as well as for sensitive target groups (babies, infants, adolescents, elderly, pregnant women, vegetarians, …). Lack of quality data on the occurrence of contaminants in foodstuffs, on the level of contamination and on the consumption habits for specific foodstuffs is generally recognised as a major constraint to perform reliable risk assessments. The numerous analysis results collated by the food agency and by private bodies have the potential to substantially aid in the process of risk assessment, a potential which is worthwhile to be evaluated.

It was one of the main purposes of the 2007 workshop “Scientific exploitation of databases within the framework of food safety assessment“ to evaluate the opportunities offered by the available databases in order to increase the usefulness of these databases for risk assessment. It is obvious that the limitations of the available databases are numerous. Common drawbacks linked to the monitoring programme are for example the use of screening methods instead of confirmatory methods, the collection of qualitative data instead of quantitative data, the lack of information on the nature of the sample (geographical origin, mode of production, processing, …), and the analysis of a set of non representative test samples.

In this workshop the main features allowing a scientific exploitation of the databases were identified (Theme 1) and an overview was provided of existing databases available from official bodies (FASFC, for example) and private organisations (Theme 2). In addition, some concrete examples of the application of existing databases for risk assessment were presented by collaborators of the Scientific Secretariat of the FASFC (Theme 3).

This workshop, attended by numerous important stakeholders in the field of food safety, aimed to demonstrate the process of food safety risk assessment - its opportunities and constraints - in order to convince all actors in the food chain of the need to obtain quality data in order to perform reliable risk assessment, risk management and risk communication.
References

Sci Com Workshop 2007

Theme 1
Databases: characteristics and exploitability
Exploitation of data for risk assessment

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1. Introduction

In the narrow sense ‘database management’ can be understood as activities associated with storing and processing available information while in the broader sense it can be understood as all activities associated with collecting, storing, processing and validating the information. In this paper focus goes to the broader meaning and its relation to risk assessment. Risk assessment is often defined as ‘the scientific assessment of risks and potential risks that occur in a specific context’. To this aim, risk models describing the relationship among several entities and the risk are developed. A large caveat for the usability of a risk model is often the lack of (accurate) data and the lack of assessment of the associated variability. Next to summarizing the basic concepts of a database management system, it is shown how the statistical world answers to the inevitable complications that arise when collecting data and conducting surveys.

2. State of the art

Originally, databases were set up as rectangular, spreadsheet-like structures, closely followed by the development of hierarchical database structures and network structures. The associated inefficiency of storing data in this way resulted in the development of relational databases and finally objected-oriented databases. The latter database structure is for example used for SANITEL, the Belgian herd identification and registration database. In this way data are stored with minimal data redundancy, maximal data consistency, maximal integration and sharing of data, enforced standards, ease of application development, uniform security, privacy and integrity. In terms of software, the most popular and recent database management software packages include Oracle, Ingres, Informix, DB2, SQL Server and Microsoft Access.

3. Database management

A database management system (DBMS) consists of three different components: the design, the standard query language (SQL) and the programming component. It is emphasized that the excellence of a DBMS is a result of spending time on design and SQL rather than on programming (Figure 1).
The trade-off between design/SQL and programming.

**Figure 1.** The trade-off between design/SQL and programming.

**Design**

The design of a database is the first important step in the development of a DBMS. It is the essential core ingredient to construct an efficient and comprehensive DBMS and consists of six construction steps: 1) the identification of the exact goals of the system; 2) the identification of the basic data collection forms and reports; 3) the identification of the data items to be stored; 4) the design of the classes (tables) and relationships; 5) the identification of the so-called ‘business rules’, i.e. the context-specific rules; and 6) the verification of the design matching the ‘business rules’.

**Figure 2.** The Wilderness Risk Management Committee Incident Reporting database (© Outdoor Ed LLC (www.outdoored.com/safety/incidents/design/rationale.aspx)).
To this respect ‘data normalization’ has been developed as the method to efficiently store data coming from different sources. To ensure minimal data redundancy, a specific set of rules is followed when collecting and/or consulting data. In general, one distinguishes between 1st, 2nd, 3rd and 4th normal form. Once data have been normalized and thus minimal data redundancy is ensured, referential integrity is more easily verified and more easily validated. An example of a design is presented in Figure 2 for the Wilderness Risk Management Committee Incident Reporting database.

**Standard query language**

In a sense, normalizing databases leads to the construction of small datasets linked to each other by identifying relations between them (Figure 2). Information is thus spread over different sub-datasets. When interested in a specific scientific question, this information is collected from the database by merging different entities from these different sub-tables of the dataset using queries. To avoid the creation of ad hoc query languages, several proposals to construct a standard query language have been made among which SQL is the most commonly used one.

**Programming**

The final step in the development of a DBMS to achieve an easy-to-use application is the ‘programming’ step. This step essentially finalizes the development of the DBMS to answer user-defined needs. Depending on the time spent on design and SQL, the programming step ideally covers only a minor part of the DBMS (Figure 1). Programming cannot solve deficiencies created in the design stage of the DBMS development. It is therefore, that whenever user-specific needs change in time, a re-evaluation of the DBMS should take place and whenever necessary a new DBMS should be developed. To avoid creating new DBMS over and over again, developing a DBMS goes hand in hand with forecasting future needs, obviously a very difficult task in a rapidly changing information society.

### 4. On the use of different databases in risk assessment

Building up risk models often relies on constructing mathematical/stochastic models as for example compartmental models. In such compartmental models, different parameters are used to describe the rate of transition between compartments (Figure 3). These parameters are often determined using specific databases as for instance infection data, demographic data… There is often no link between these different datasets and thus consistency, especially with respect to space and time, should be checked.
Whenever a link is available, different databases can be merged to one. However, by doing so there is a likely occurrence of creating structural incompleteness in the non-common entities (Figure 4). While incompleteness often results in bias in terms of modelling results, this is not necessarily the case for structural incomplete data. A formal sensitivity analysis could show the effect of potential bias on the modelling results and provides a more honest analysis.

5. From databases to statistics

In any statistical package the optimal statistical database structure is of a rectangular format where the consensus is often made that entries in rows correspond to subjects while columns correspond to different factors measured on those subjects.

The export/import function often available in any DBMS or statistical program provides the link between both. However, the transition from a DBMS to a statistical program is often associated with writing the corresponding SQL code and limiting the information to the essential since statistical software often have limited storage capability (Figure 5).

Exporting/importing data is ideally done only once and as such the relevant information has to be identified and retained from the DBMS using queries. This is accompanied with the identification of potential risk factors, a potentially complex task in many applications.
Once data have been stored into a rectangular data format, statistical analyses are easy to conduct although different complex data structures require different statistical techniques to be employed. In the following section, a flavour of modern statistical techniques developed to handle specific complex data structures such as clustering and incomplete data, are briefly discussed.

6. Modern statistics for complex data

The development of new statistical methodology is mostly motivated from practical applications. In the past few decades, several new statistical techniques have been developed to deal with clustering, incomplete data and other complications that arise when collecting and analyzing data. Let us give an overview of a few of these domains that can help to ease the burden associated with collecting data and conducting surveys. Although these techniques can deal with a lot of these complications, they still inevitably rely on assumptions and the quality of data collection. The information loss associated with sloppy data can never be rectified.

Data mining

In terms of risk assessment it is important to identify risk factors. Data mining is the principle of sorting through large amounts of data and picking out relevant information. It is increasingly used in the sciences to extract information from the enormous data sets generated by modern experimental and observational methods. Often the information is scarce and the identification of a sole or a limited set of risk factors is the scope of mining the data. An excellent reference to this respect is the work of Hastie et al.2.

Incomplete data

Collecting survey data is inevitably associated with data loss, potentially due to several different causes. Analyzing incomplete data with inappropriate methods leads to serious bias and false results. There exists a whole taxonomy on different incomplete data mechanisms and techniques to handle them (see e.g. Little and Rubin; Schafer). In essence, two components are now modelled simultaneously, i.e. the measurement part and the missingness part, the latter referring to modelling the underlying mechanism generating the missingness, while the measurement part is modelled in the same way as if the data would have been completely observed. A sensitivity analyses with respect to the model describing the missingness mechanism is needed since often untestable assumptions need to be made.

Diagnostic uncertainty

In the risk assessment context, data are often collected using diagnostic tests. These test results are merely markers but are often treated as if they were the true result. This could lead to bias but more surely to overestimated precision. Complications as detection limits and diagnostic uncertainty need to be taken into account. Censoring techniques and mixture modelling are two approaches that have been proven worthwhile.

Whenever a test result is lower or higher than a certain detection limit, the observation is said to be censored. Appropriate
techniques to handle censoring exist. Mixture modelling deals with diagnostic uncertainty in that test-positives and test-negatives are classified as true positives and true negatives by directly using the marker of infection. Note that other techniques relying on for example receiver operator characteristic curves exist but are often considered to be outdated.

**Bayesian data analysis**

Next to the well known likelihood framework, the Bayesian paradigm exists. In a Bayesian analysis a postulated model is fitted to the data incorporating prior knowledge on the parameters of that model. In this way, information from several sources can be combined to produce a comprehensive model. Of course this is not without disadvantages. The dependency of the results on the prior distribution makes it necessary to perform sensitivity analysis with respect to their choice. If no prior knowledge is available, uninformative priors are used, implying that the data drives the model and as such the method is comparable to the likelihood approach. Often, the likelihood and the Bayesian paradigm are contrasted to one another instead of considering them to be complementary.

**7. Prospects**

Current practice in risk assessment should continue aiming at bringing researchers from different fields together. Interdisciplinary research between chemists, epidemiologists, data managers, microbiologists, statisticians, toxicologists and others is of utmost importance to achieve a high standard in risk assessment.

**8. Summary and Conclusion**

The process from data collection to the models that constitute risk assessment is not a straightforward process. It all starts with the collection of accurate data. To efficiently exploit data, database management systems need to be installed, maintained and made available to researchers. The quality of such a DBMS is determined by the time spent on its design. A specific set of normalization rules should be followed in order to avoid data redundancy and to store data in an efficient way. Future needs have to be foreseen and if necessary the DBMS has to be re-evaluated and re-constructed. Once the DBMS is fully operational with all control facilities (privacy law), it can be exploited by the risk assessor using the appropriate techniques.
9. Samenvatting

Het proces van het verzamelen van gegevens tot het ontwikkelen van modellen als basis voor risicoevaluatie is geen eenvoudig proces. Het begint allemaal met het verzamelen van accurate gegevens. Om data efficiënt te benutten, dienen database management systemen (DBMS) geïnstalleerd, onderhouden en ter beschikking van onderzoekers gesteld worden. De kwaliteit van dergelijke DBMS wordt bepaald door de tijd die besteed wordt aan het ontwerp. Een specifieke set van normalisatieregels dient gevolgd te worden opdat overtolligheid van gegevens voorkomen wordt en gegevens op een efficiënte manier opgeslagen worden. Toekomstige behoeften moeten worden voorzien en, indien nodig, dient de DBMS gereëvalueerd en opnieuw geconstrueerd te worden. Zoedra de DBMS, rekening houdend met alle beperkingen (privacy wet), volledig operationeel is, kan deze met behulp van de juiste technieken geëxploiteerd worden door de risicoevaluator.

10. Résumé

Le processus de la collecte des données jusqu'à l'élaboration des modèles comme base pour l'évaluation des risques n'est pas un processus simple. Tout commence avec la collecte de données correctes. Afin d'exploiter efficacement les données, des systèmes de gestion de bases de données (SGBD) doivent être installés, entretenus et mis à la disposition des chercheurs. La qualité d'un tel SGBD est déterminée par le temps consacré à son développement. Un ensemble spécifique de règles de normalisation doit être suivi afin d'éviter la redondance des données et d'enregistrer les données d'une manière efficace. Des besoins futurs doivent être prévus et, si nécessaire, le SGBD doit être ré-évalué et re-construit. Dès que le SGBD est pleinement opérationnel, en tenant compte de toutes les restrictions (loi relative à la protection de la vie privée), celui-ci peut être exploité par l'évaluateur du risque à l'aide des techniques appropriées.

11. References


European food safety databases: keystone role of the EFSA

Hubert Deluyker¹

¹EFSA, Parma

1. Introduction and context

Introductory statement 49 of Regulation (EC) No 178/2002 of the European Parliament and the Council reads as follows: “The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority [European Food Safety Authority (EFSA)] should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for”.

2. Data collection at an European level

In accordance with Article 12 of Regulation (EC) No 178/2002, the EFSA collects data related to its mission to allow the characterisation and monitoring of risks that have a direct or indirect impact on food and feed safety. The mission includes the human diet, matters concerning animal health and welfare as well as plant health and products other than food and feed relating to genetically modified organisms.

As stated in Article 22, data are required to enable the Authority to carry out risk assessments. A critical point in making risk assessments concerns the exposure assessment, i.e. estimating the probability that a consumer will be exposed to a hazardous substance. Typical for exposure assessments is that data on levels of a chemical or a biological agent in food are combined with data on the quantity of the food consumed in the European Union. The methodology can equally be applied to substances that are harmful or beneficial to health in case of food constituents that are naturally present (including macro- and micronutrients), food additives, dietary supplements and contaminants, pesticide residues included. It is therefore important that the probability of the presence of the substance or biological agent in a food is known and

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that, if present, the concentrations at which the substance or
the biological agent can be found as well as the consump-
tion of the particular food, in general, for high consumers and
for special high-risk groups, is known.

Article 33 of Regulation (EC) No 178/2002 deals therefore with
data collection and stipulates the following:

1. The EFSA searches for, collects, collates, and analyses
data on
   a) food consumption
   b) the prevalence of microorganisms
   c) contaminants and residues

Furthermore, Article 33 stipulates that all data within the
mission of the EFSA should be collected. It can therefore
be assumed that e.g. also the composition of foods has to
be taken into account.

2. The EFSA carries out these tasks in close cooperation with
the Member States, organizations in candidate Member
States and third countries, as well as with international
bodies.

3. The EFSA makes appropriate recommendations to the
Member States with which the comparability of data can
be improved and the data can be consolidated at the
community level.

4. The Commission publishes a compendium of data
collection systems existing at the community level. This
report is, where appropriate, accompanied by proposals
regarding the role of the EFSA and regarding changes
and improvements to correct deficiencies.

5. The EFSA forwards the results of its activities in the field
of data collection to the European Parliament, the Com-
mission and the Member States.

Besides Regulation (EC) No 178/2002, there is also a specific
Community legislation that allocates tasks associated with data
collection to the EFSA. Directive 2003/99/EC on zoonoses\textsuperscript{b} de-
termines that the EFSA should investigate the data transmitted
by the Member States on zoonoses, antimicrobial resistance
and outbreaks of food-borne zoonoses and publish an annual
summary report with the results. Regulation (EC) No 396/2005\textsuperscript{c}
stipulates that the EFSA should collect and analyse the results
of official controls on residues in food and feed.

Some of these activities are already routinely carried out
whereas others were only recently begun. It is very important
that the EFSA consolidates this cooperation with the Com-
mission and the Member States while taking into account
all the above-mentioned needs. Therefore the aim of the
present document was to present an overview of:

1. the needs of the EFSA for information that enable to
   perform risk assessments and the needs of the Commis-
   sion and the Member States regarding the support of
   executing monitoring activities;

\textsuperscript{b} Directive 2003/99/EC of 17 November 2003 on the monitoring of
zoonoses and zoonotic agents, amending Council Decision 90/424/

\textsuperscript{c} Regulation (EC) No 396/2005 of 23 February 2005 on maximum resi-
due levels of pesticides in or on food and feed of plant and animal
2. the already existing systems of data collection, including an assessment of the extent to which they meet the requirements listed in Article 22; and

3. the need for data, which is currently not being met, and the need to formulate proposals on how and with which priority this need can be met in the future.

Article 34 of the regulation establishing the Authority imposes the EFSA the duty to coordinate activities related to the identification of new risks. It is recognized that to carry out this task, the EFSA must be able to have access to other databases or to create new databases.

The Scientific Committee and the scientific panels of the EFSA are responsible to provide risk assessments in the form of scientific advices. Each panel does so within its own competence. The necessity for data for risk assessments can vary widely between the various panels and within a single panel. Similarly, depending on the nature of the data, differences exist between the networks through which data are collected.

The quality of data depends on several factors, such as the methods, the sampling plans, the collection and the reporting of data. Additionally, the aspect of the availability of data is important as well. This is determined by the right of ownership and the efficiency of access to the data.

3. Conclusions

EFSA is the keystone of European Union risk assessment regarding food and feed safety. Its mission is legally established by Regulation No 178/2002. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks in the areas of food and feed safety.

4. Samenvatting

De Europese voedselautoriteit (EFSA) vormt de hoeksteen voor risicoevaluatie met betrekking tot veiligheid van levensmiddelen en diervoeders binnen de Europese Unie. Haar missie is wettelijk vastgelegd in Verordening (EG) nr. 178/2002. In nauwe samenwerking met nationale overheden en in open overleg met de stakeholders, geeft de EFSA onafhankelijk wetenschappelijk advies en verzorgt de EFSA een duidelijke communicatie over bestaande en nieuwe risico’s op het gebied van de veiligheid van levensmiddelen en diervoeders.

Verordening (EG) nr. 178/2002 behandelt het aspect van het verzamelen van gegevens. Daarnaast is er ook een specifieke communautaire wetgeving die aan de EFSA taken toewijst die verband houden met gegevensverzameling. Zo bepaalt Richtlijn 2003/99/EG inzake zoönoses dat de EFSA de door de lidstaten toegezonden gegevens over zoönoses, antimicrobiële resistentie en uitbraken van door voedsel overgedragen zoönoses moet onderzoeken en per jaar hiervan een samenvattend verslag moet publiceren waarin de resultaten zijn opgenomen. Verordening (EG) nr. 396/2005 schrijft voor
dat het EFSA de resultaten van de officiële controles op residuen in levensmiddelen en diervoeders moet verzamelen en analyseren.

De kwaliteit van gegevens hangt af van meerdere elementen zoals methoden, bemonsteringsplannen, het verzamelen en rapporteren van gegevens.

Verder is ook het aspect gegevensbeschikbaarheid van belang. Dat wordt bepaald door het eigendomsrecht en de efficiëntie van de toegang tot de gegevens. Er wordt hierop niet nader ingegaan, al wordt er, waar reden tot bezorgdheid is, wel naar verwezen.

5. Résumé


La qualité des données est fonction de plusieurs éléments dont les méthodes de mesure, les plans d’échantillonnage, le rassemblement et le rapportage des données.

Un autre aspect important est la disponibilité des données. Celle-ci est fonction des droits de propriété et de l’efficacité de l’accès aux données. Ces points ne sont pas examinés en profondeur bien qu’il en soit fait mention dans les cas où des préoccupations existent à ce sujet.
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Theme 2

Availability of databases for risk assessment
Scientific exploitation of FASFC databases for risk assessment in a food safety context

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1. Introduction

Databases are a crucial instrument in order to perform risk assessment studies. The databases of the Belgian Federal Agency for the Safety of the Food Chain (FASFC) have been created in a historical context of a food chain risk management organisation under reconstruction. This article describes the structure of the FASFC databases, the regulation aspects and the characteristics of the databases in the light of extraction of data for reporting and for scientific purposes.

2. Regulations related to FASFC data use

The two most important laws regulating databases deal with the use of private data of individual persons (name, address, ...) and with the use of data for other intentions than specified by the objectives of the database. Databases using private data are strictly regulated. The objectives of the database have to be communicated to a special commission for personal life environment. This article describes the structure of the FASFC databases, the regulation aspects and the characteristics of the databases in the light of extraction of data for reporting and for scientific purposes.

Specific conditions of use of databases apply to the Federal Public Service for Finance which has full authorisation to use FASFC data and also to the Regions (Programme Law of 4 February 2000 + specific regulations) which are allowed to use FASFC data in relation to fulfil objectives of common interest.

In general, no private data are needed to perform scientific risk assessment studies and there is no limitation for the use of databases of the FASFC for purposes which are in accordance with the competences of the FASFC.

Data of the FASFC can therefore be used by third parties for performing risk assessment studies after having introduced a justified request specifying the objectives of the study. The conclusions made by third parties based on studies using FASFC data are the entire responsibility of the authors. The origin of the data has to be mentioned in each publication.
3. Structure and characteristics of the main FASFC databases

For a good understanding of the FASFC database system it is important to make a clear distinction between the databases and the application. Five main databases have been developed by the FASFC.

**BOOD**

BOOD is a database containing basic information (master data) about the operators (company or person) in the food chain and on the localisation of the facility. The BOOD database has an automatic link with the Belgian crossroads bank of enterprises. The BOOD database is an authentic source for all applications of FASFC. The database is permanently updated. Good knowledge of metadata is mandatory for a good understanding of the structure of the database. Additional attributes are in preparation in relationship to the auto-control system.

**FOODNET**

FOODNET is a database containing results of control activities undertaken at the facilities of the operators. It is a new database with data on missions (planning, changes, control, …), observations and actions (checklists, sampling, …), results of laboratory tests (LIMS, see below), allocated time and accounting data. The database uses master data (activities, parameters, matrices, …) and is under full development.

**LIMS**

LIMS (Laboratory Information Management System) is a new database containing laboratory management data about reception and treatment of the samples, procedures for testing, surveillance of laboratory processes, test results (including standards and action limits), … The database uses master data and has recently become operational.

**SANITRACE**

SANITRACE contains information related to living animals (identification, exploitation, owner, movement of animals, status of the exploitation (sanitary, residues, contaminants)) and related to slaughtering (inspection observations and decisions). SANITRACE originates from two databases: SANITEL (containing information related to living animals) and BELTRACE (containing information related to the meat sector).

The SANITRACE database is actually in a transition state (fusion of two sources). Not all data are transferred yet.

**TRACES**

TRACES is a European database about intra-communautary movements of animals and animal products. The TRACES databank is the successor of the former ANIMO and SHIFT databases. It contains data about persons and places, concerning trade traffic, concerning regions in Europe with trade limitations, health certificates for intra-communautary trade traffic and transit, control results for Border Inspection Post (BIP), …

The TRACES database is not up-to-date for all Member States. The EU is therefore increasing the pressure upon certain Member States in order to update the databank. An exchange of information between TRACES and the FASFC database will be worked out.
4. Practical aspects of consulting databases for scientific purposes

Most FASFC databases are consultable via the Business Objects (BO) program. This is an application which can be consulted by FASFC experts in order to make reports. The principle of BO is to transfer data and records in more understandable "objects", taking profit of a correct linking. No primary knowledge is required of the database structure. New queries can be developed at any time or existing queries can be used. The documents are exploited with metadata.

By way of illustration, Figure 1 represents the actual consultation process of the old SANITEL database. The latter was consultable for the FASFC’s Provincial Control Units (PCU), the professional associations, the Federal Public Service of Health, Food Chain Safety and Environment (FPS) and the Veterinary and Agrochemical Research Centre (VAR) through a BO application locally installed.

Figure 2 shows how the new SANITRACE database (after merging Sanitel and Beltrace) is currently consultable for the FASFC’s PCU’s, the FPS and the VAR through a BO application also locally installed.

Figure 1. Actual consultation process of FASFC Databases (Old Sanitel).

Figure 2. Consultation of FASFC Databases after reengineering SaniTrace.

PCU = FASFC’s Provincial Control Units; FPS = Federal Public Service of Health, Food Chain Safety and Environment; VAR = Veterinary and Agrochemical Research Centre.
In the future, it is foreseen that the SANITRACE database will be consultable for the FASFC’s PCU’s, the FASFC’s controllers, the FPS and the VAR through a BO web application (Figure 3).

Certain data need to be calculated (i.e. number of bovines in an exploitation). In regard to linking between tables and data the type of linking has to be taken into account (i.e. all operators of a sector with their auto-control system dependent on the type of link, the operators without an auto-control system will be included or not) as well as the linking of the correct fields (i.e. herd nr. in table RUND: beslnr (= current herd), vor_beslnr (= previous herd), vol_beslnr (= next herd), beslnr_geb (= herd of birth). Some fields contain classic conditions (<, >, =, in, and, or, …) which demand a further evaluation or interpretation by the examiner. It is also crucial to pay attention to the defined status of the operator in BOOD.

After having completed a data query it is very important to verify in a logic way if the obtained information (i.e. number of animals, …) is realistic to be sure that correct linking or correct conditions have been used in the query and to be able to draw correct conclusions afterwards.

5. Perspectives

Databases are under continuous development and updating. Linking between in house databases and external databases will further improve the quality of the database structure.
6. Conclusions

It is important to realize that the management of databases and the use of data is regulated. The scientific exploitation of FASFC databases is growing out of its infancy’s. The FASFC uses multiple big databases which are continuously updated. Extracting correct data out of complex databases is not always simple. Special attention has always to be paid to the formulation of the query in order to extract complete and informative data. The data mining tool used by FASFC is Business Objects.

7. Samenvatting

De twee voornaamste reglementaire bepalingen voor het gebruik van gegevens in databanken houden verband met het gebruik van privé gegevens (naam, adres, …) van natuurlijke personen en het gebruik van gegevens voor andere doeleinden dan waarvoor ze in de databank werden opgenomen. In de regel zijn geen persoonsgegevens nodig voor het uitvoeren van een risicoevaluatie en is er dus geen beperking voor het gebruik van de databanken van het Belgische Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV) voor doeleinden die behoren tot de opdrachten van het FAVV.

De voornaamste databanken van het FAVV zijn: BOOD (basisgegevens van de operatoren), FOODNET (gegevens aangaande de controles bij de operatoren), LIMS (gegevens in verband met laboratorium management en testen), SANITRACE (allerhande informatie over de levende dieren, over de slachting en over de slachtbevindingen) en TRACES (gegevens over de internationale handel van dieren en dierlijke producten).

De meeste databanken van het FAVV zijn consulteerbaar via Business Objects. Bij extractie van gegevens uit een databank wordt vaak vastgesteld dat de resultaten die men wenst te gebruiken als basis voor risicoevaluatie onvolledig zijn of onjuist zijn of zich niet in het goede formaat bevinden. De voornaamste oorzaken hiervan zijn het ontbreeken van metadata, onttrekende of niet bruikbare gegevens, verkeerde koppeling tussen tabellen en verkeerde interpretatie van gegevens. Het blijft dus belangrijk om geëxtraheerde gegevens kritisch te beoordelen vooraleer verdere verwerking toe te passen.

8. Résumé

Les deux principales dispositions réglementaires pour l'utilisation de données stockées dans des banques de données se rapportent à l'utilisation des données privées (nom, adresse, …) de personnes physiques et à l'utilisation de données pour d'autres finalités que celles pour lesquelles elles ont été enregistrées dans la banque de données. En général, aucune donnée personnelle n'est nécessaire pour la réalisation d'une évaluation des risques et il n'y a donc pas de restriction concernant l'utilisation des banques de données de l'Agence Fédérale belge pour la Sécurité de la Chaîne Alimentaire (AFSCA) pour des finalités qui font partie des missions de l'AFSCA.
Les principales banques de données de l'AFSCA sont: BOOD (données de base des opérateurs), FOODNET (données concernant les contrôles effectués chez les opérateurs), LIMS (données concernant la gestion des laboratoires et des tests effectués), SANITRACE (toutes sortes d'informations sur les animaux vivants, l'abattage et les observations dans les abattoirs), TRACES (données sur les échanges internationaux d'animaux et des produits animaux).

La plupart des banques de données de l'AFSCA sont consultables via Business Objects. Lors de l'extraction de données à partir d'une banque de données, il est souvent constaté que les résultats, que l'on souhaite utiliser comme données initiales pour une évaluation des risques, sont incomplets ou incorrects, ou ne se trouvent pas dans le format adéquat. Les principales causes de ce problème sont l'absence de méta-données, le fait que certaines données sont manquantes ou inutilisables, la présence d'un lien erroné entre des tableaux ou encore une interprétation erronée des données. Par conséquent, il reste important d'évaluer les données extraites de façon critique avant de leur appliquer un traitement ultérieur.

9. References


Font consumption databases

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1. Introduction

In 2004, at the request of the academic community and of the National Health Council, the Ministry of Social Affairs, Public Health and Environment initiated the Belgian National Food Consumption Survey (BNFCS). Belgium was one of the countries in Europe that lacked a systematic survey on dietary habits of their inhabitants. The last study including a dietary assessment at the population level, was the Belgian Interuniversity Research on Nutrition and Health (BIRNH study)¹ held from 1980-1985.

The main objective of the BNFCS was to monitor the adequacy of the food and nutrient consumption. Data of the survey can be used to develop evidence-based food and nutrition policy. In addition, the detailed quantitative consumption data will help to address food safety issues by performing exposure analyses for food chemicals and toxins. The survey was carried out in collaboration with the Department of Public Health, Ghent University and the Department of Epidemiology and Health Promotion, School of Public Health, Université libre de Bruxelles. The results have been described in Devriese et al.².

2. Description of database and characteristics

This study included a random sample of all inhabitants of Belgium, stratified per region, province and municipality, and constructed on the basis of the National Register using the household as sampling unit. Information on dietary intake was obtained for 3245 subjects of 15 years and older.

Participants were invited to participate in the study by a letter and leaflet. A trained dietitian visited the participants twice. At the first visit the participants completed a face-to-face questionnaire about general health, lifestyle and physical activity. This questionnaire included also self-reported weight and height. A 24-h recall assessed dietary intake of the previous day. During the second visit, two to eight week’s later (median of three weeks), a second 24-h dietary recall was performed. In the time between these two visits, participants were asked to complete a food frequency questionnaire. The person of the household, who was responsible for the food preparation most of the time, was asked to complete a questionnaire on food safety aspects. The dietitian checked the questionnaires for completeness. All dietitians followed a compulsory two and half day training session.
During this session the dietitians were trained in methods to approach the selected persons, to assess diets by 24-h recalls and to use the computer software EPIC SOFT in a standardized way. Data from the questionnaires are available through a web application on www.iph.fgov.be/nutria/.

3. Dietary assessment: main part of the survey

Information on food intake was collected using a repeated non-consecutive 24-h recall (face-to-face) in combination with a food frequency questionnaire (self-administered) covering 60 food items. The one-year survey was distributed equally over the seasons and days of the week. During a 24-h recall the participants reported the types and quantities of all foods and beverages that were consumed during the preceding day. To obtain a standardized 24-h recall interview, the validated software package EPIC-SOFT was used. EPIC-SOFT is designed for uniform data collection in the 10 countries participating in the EPIC study. The software allows obtaining a very detailed description and quantification of foods, recipes and supplements consumed. Quantification of the consumed foods is supported by a picture book that comprises photographs of foods in different portion sizes (Figure 1).

Figure 1. Portion size of tomato.
4. Examples of use

Food consumption survey data may be used either directly to know the (habitual)intake from a food group or specific foods in the population. Or after linking the data with data on nutrients/dietary substances or potential harmful substances and assessing intake of these substances in the population. Examples are given in this paragraph.

**Intake of foods**

With data of the food consumption survey, habitual food intake was assessed in the different groups of the Flemish food based dietary guidelines and compared with them. Food intakes deviate significantly from the recommendations (Figure 2). In particular fruit (118 g/day) and vegetable (138 g/day) consumption and intake of dairy and calcium-enriched soy products (159 g/day) are inadequate. Consumption of energy-dense, nutrient-poor foods (like soft drinks, alcohol and snacks), is excessive (481 g/day). There are important age and gender differences. Fruit, vegetable and spreadable fat consumption are lowest while consumption of dairy, starchy and energy-dense, nutrient-poor foods is highest among the youngest age group. Men consume more animal and starchy foods than women, who consume more fruits. There are only slight differences by education level. From these data it was concluded that improvement of the Belgian food pattern, in particular among the youngest age group, is necessary for a better prevention of diet-related diseases.

**Figure 2.** The Flemish food triangle and the extent to which the average food intake deviates from the recommendations. If the Belgian population attained all recommendations, all areas of the observed food triangle would have the same surface as the areas of the recommended food triangle. ©Vlaams Instituut voor Gezondheids promotie vzw.
Intake of nutrients

The database of consumed food items was linked to food composition data (Nutrient Belgium, NUBEL). Habitual macronutrient intake was estimated by the Nusser method. Mean energy percent (en%) of total fat (37.9 en%) and saturated fatty acids (16.0 en%) was higher than the dietary reference intakes (DRI). Mean en% of total carbohydrates (45.8 en%) was lower than the dietary reference intakes, while mono/disaccharides intake was 20.3 en%. Also in these data the influence of age was prominent. Total fat and saturated fatty acid intake was higher and total carbohydrates and sugar intake lower in the older compared with the younger age categories. The percent of energy from saturated fatty acid intake is lower and from carbohydrates is higher than in an earlier Belgian study. The dietary macronutrient intake in Belgium deviates from the National dietary guidelines. Further efforts are necessary to improve dietary macronutrient composition, taking into account differences in age categories.

Intake of additives/contaminants/residues

Food consumption data may be used for exposure assessments. Based on calculated intake of selected products such as beer or apple juice or by combining food consumption data with available data on additives/contaminants/residues.

The intake of nitrate was assessed. The nitrate contents of vegetables, cheese and processed meats were analyzed and completed by concentration data from literature. Concentration data for nitrate and nitrite were linked to food consumption data of the Belgian National Food Composition Survey 2004. For the intake assessment, average concentration data and individual consumption data were used.

The estimated average daily intake of nitrate is 1.38 mg/kg bodyweight/day, at the 97.5 percentile the intake is 2.76 mg/kg bw/day. Exposure to nitrate of Belgian adults at average intake is 38 % of the ADI (76 % at P97.5). For the average consumer half of the intake is derived from vegetables (especially lettuce) and 20 % of water and drinks based on water.
Daily intake of the food additives nitrate (0.2 % of ADI at average intake) and nitrite (6 % of ADI at average intake) from cheese and meat products is low. Within this group cooked ham sausages contribute most to nitrite intake. Exposure to nitrate of Belgian adults is below the ADI for all percentiles of the population.

5. Strengths/weaknesses and challenges

Food consumption surveys are a very valuable tool to assess the dietary intake in a population. Data can be linked to food composition data from different sources as has been showed in the examples above for either dietary as well as exposure assessments. The quality of available data - both on food consumption and on composition/occurrence levels - can have a major impact on the outcome of intake/risk assessment.

The current survey represents the general population of Belgium of 15 years and older. Other recent dietary intake studies in Belgium were mostly restricted to local areas. Great efforts have been made to select a representative sample of the Belgian population for this survey. This type of large-scale studies suffer more or less from non-response bias (the (un)willingness to participate). The participation rate, in this study, was below 50 %. We have no additional information on the non-responders. Non-responders were replaced by a beforehand selected reserve person of the same gender, age and living in a household of the same size and in the same municipality as the originally selected person. In the phase of statistical analyses, in addition, the sample was weighted to the age and sex distribution of the Belgian population in 2004. In addition, emphasis was put on standardizing methods of dietary assessment by using standardized software and by training the dietitians.

Under-reporting of food intake is another well-recognized phenomenon and common problem to dietary surveys worldwide. Methods to improve the quality of dietary data like adding external markers of intake must be further explored.

Overall, it is an intensive and expensive task to have and keep up-to-date food consumption data. Data need to be updated every few years to be able to track changes in food consumption, with the huge rapidly changing supply and variety of foods. Food consumption data nowadays are mainly derived from individual dietary surveys (record, recall, FFQ). Therefore, only periodic monitoring is possible in a limited number of subjects and with a limited number of intake days. It is a challenge to develop additional methods for dietary assessment. For example probabilistic methods may be developed that combine consumption (and composition) data from various sources (e.g. from individual consumption and household purchase data of specific foods). Another challenge is on the food composition site. Detailed and up-to-date food composition databases both in the field of nutrients/dietary components as in the field of harmful substances used in exposure assessment must be maintained.
6. Conclusions

Good quality food consumption data are crucial to support nutritional and food safety policy. It will be important to monitor changes in food consumption regularly for trend analyses. Challenges are ahead to develop detailed and continuous food consumption databases.

Voedselconsumptiedatabanken worden meer en meer gebruikt vanuit het beleidsperspectief (zowel nationaal als internationaal) om de inname van voedingsmiddelen te kennen en te toetsen aan richtlijnen voor gezonde voeding of schadelijke stoffen. Daarnaast kan de data gebruikt worden om de effectiviteit van beleidsmaatregelen, maar mogelijk ook de effectiviteit van productinnovaties, in kaart te brengen. Voorwaarden daarvoor zijn a) het regelmatig monitoren van voedingsgewoonten van de bevolking bijvoorbeeld ook door gebruik van aanvullende data (bijvoorbeeld aankoopdata), b) methodiekontwikkeling en c) een betere afstemming van consumptie- en compositiedata. Meer onderzoek is nodig om voedselconsumptiedatabanken ten volle te exploreren op het gebied van de volksgezondheid (voedsel veiligheid inbegrepen).

7. Samenvatting

In 2004 werd een nationale voedselconsumptiepeiling gehouden in een representatieve steekproef van de Belgische bevolking. De voedselconsumptiepeiling werd uitgevoerd in opdracht van de federale overheid in samenwerking met de Universiteit van Gent en de Université libre de Bruxelles. Via het Nationale bevolkingsregister werd een steekproef genomen van 3245 inwoners van 15 jaar en ouder, gelaagd per regio en provincie. De voedingsinname werd door getrainde diëtisten geschat met behulp van EPIC-soft (een gestandaardiseerd software model). Daarnaast werd de frequentie van gebruik van diverse voedingsmiddelen in het afgelopen jaar nagevraagd.

De voedselconsumptiedata werden gebruikt om de nutriënten- en voedingsmiddeleninname van de Belgische bevolking te beoordelen ten opzichte van richtlijnen voor een gezonde voeding. Voor het bepalen van de nutriënteninname werd een koppeling gemaakt tussen voedselconsumptiedata en voedselcompositiedata uit de NUBEL (merknamen) tabel. Daarnaast werden innamen berekend van enkele contaminanten en additieven door de voedselconsumptiedatabank te koppelen aan data over contaminanten/additieven.

8. Résumé

En 2004, une enquête nationale de consommation alimentaire a été menée auprès d’un échantillon représentatif de la population belge. L’enquête de consommation alimentaire a été réalisée pour le compte des autorités fédérales en collaboration avec l’Université de Gand et l’Université libre de Bruxelles. Via le registre national de la population, on a pris un échantillon de 3245 habitants âgés de 15 ans et plus, classés par région et par province. Des diététiciens expérimentés ont estimé l’ingestion alimentaire à l’aide d’un recall répété de 24h à l’aide d’EPIC-soft (un logiciel standardisé). En outre, on a vérifié la fréquence de consommation de diverses denrées alimentaires au cours de l’année écoulée.
Les données de consommation alimentaire ont été utilisées pour évaluer l’ingestion de nutriments et de denrées alimentaires par la population belge par rapport aux directives en vue d’une alimentation saine. Pour déterminer l’ingestion de nutriments, on a établi un lien entre les données de consommation alimentaire et les données de composition des aliments du tableau NUBEL (marques déposées). En outre, on a calculé les ingestions de quelques contaminants et additifs en reliant la banque de données de la consommation alimentaire aux données sur les contaminants/additifs.

Les banques de données de consommation alimentaire sont de plus en plus utilisées dans une perspective stratégique (que ce soit sur le plan national ou international) pour connaître l’ingestion de denrées alimentaires et la confronter aux directives pour une alimentation saine ou relatives aux substances nocives. En outre, les données peuvent être utilisées pour inventorier l’efficacité des mesures de politique, mais éventuellement aussi l’efficacité des innovations en termes de produits. Les conditions pour cela sont a) le monitoring régulier des habitudes alimentaires de la population, par exemple en utilisant aussi des données complémentaires (p.ex. données d’achat), b) un développement des méthodes et c) une meilleure harmonisation des données de consommation et de composition. Davantage d’études sont nécessaires pour explorer pleinement les banques de données sur la consommation alimentaire dans le domaine de la santé publique (y compris la sécurité alimentaire).

9. References


Databases used by the professional sectors

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1. Introduction and context

Most of the data generated by the operators in the food sector are not used for risk assessment purposes, but are situated in a context of risk management. The operators have indeed much information that is collected during the verification of compliance of foodstuffs with statutory requirements. At the company’s level, the implementation of HACCP (“Hazard Analysis of Critical Control Points”) leads to many “compliance data”. Thanks to the collection of such data at the level of the sectors (e.g. Monimilk, GMP for the feed sector, …), an interesting statistical scale effect is possible. The resulting data are constantly evaluated by the competent authorities.

In the context of risk assessment, data from the professional sectors can provide important information with respect to the identification of hazards or - more often – with respect to the assessment of the exposure. If companies identify new hazards, they will transfer the available information to the competent authority (e.g. the ITX issue, where ITX or isopropyl thioxanthone, a component of printing ink used on the exterior of food packaging, was found in infant milk due to migration from the packing).

Individual companies and/or sector associations have collected data that were transferred the competent authority at several occasions (e.g. acrylamide, coumarin or more recently, guar gum infected with pentachlorophenol (PCP) & dioxins, and the collection of data regarding the intake of additives). This gave the competent authority the opportunity to assess the exposure, before making a decision on the risk management measures to be taken.

2. Some case studies (acrylamide, coumarin, guar gum, intake of additives, …)

After the discovery in 2002 of acrylamide in food, the food industry quickly came to the conclusion that this is of concern to the entire food industry worldwide, involving different sectors. Food sectors gathered data to get an idea of the occurrence of acrylamide in food. These data were added to the JRC (EC Joint Research Centre) database. Meanwhile, the CIAA (Confederation of the food and drink industries of the EU) members continue to keep an eye on the presence of acrylamide. In the “CIAA Acrylamide Status Report” of 2004 the first results of the general approach of the acrylamide issue were published.
More recently, the food industry has gathered data concerning the presence of coumarin in certain foods. Based on this data collection the industry could clearly see that the exposure to coumarin is not comparable between the Member States.

Only a few months ago, CIAA members helped to identify the supplier of contaminated guar gum through a large collection of data, which was transferred to the Commission.

Presently, CIAA members help the Commission with the collection of data concerning the intake of additives ("tier approach").

Finally, the CIAA is also involved in the EU-funded programme FACET project (Flavourings, Additives and food Contact material Exposure Task), which aims to set harmonised methods for the collection of intake data and to create an EU-wide database of information.

3. Conclusion

Data collection is essential for the public risk evaluator and the risk manager as well as for the food industry. Ideally, data are collected in a harmonized way to guarantee the comparability of the data. This is of utmost importance in the European context.

4. Samenvatting

De meeste gegevens die door de operatoren van de voedingssector worden gegenereerd, hebben in de eerste fase geen betrekking op risicoevaluatie, maar wel op risicobeheer (verificatie van het naleven van de wettelijke voorschriften). Op bedrijfsniveau leidt de toepassing van HACCP ("Hazard Analysis of Critical Control Points") tot veel "compliance data". Dankzij de verzameling van die gegevens op sectorniveau is er een interessant statistisch schaaleffect mogelijk. De resulterende data worden voortdurend geëvalueerd door de bevoegde autoriteiten.

In de context van risicoevaluatie kunnen bedrijfsgegevens belangrijke informatie leveren met betrekking tot identificatie van gevaren of – vaker – tot een evaluatie van de blootstelling. Als bedrijven nieuwe gevaren identificeren, zullen zij de beschikbare informatie overmaken aan de overheid (bvb. de ITX-zaak).

Bij verscheidene gelegenheden (bvb. acrylamide, coumarine of meer recent guarpitmeel besmet met pentachlorofenol (PCP) & dioxines en het verzamelen van gegevens m.b.t. de inname van additieven) hebben individuele bedrijven en/of sectorverenigingen gegevens verzameld die overgemaakt werden aan de overheid. Hierdoor kon de overheid een evaluatie van de blootstelling uitvoeren, alvorens een beslissing te nemen op vlak van het risicobeheer.

Gegevensverzameling is van fundamenteel belang voor zowel de risicoevaluator en de risicobeheerder als voor de voedingsindustrie. Idealiter worden de gegevens verzameld op een geharmoniseerde wijze om de vergelijkbaarheid van de gegevens te garanderen. Dit is van het grootste belang in de Europese context.
5. Résumé
La plupart des données générées par les opérateurs du secteur alimentaire n'ont en premier lieu aucun rapport avec l'évaluation des risques, mais servent plutôt à la gestion des risques (la vérification du respect des prescriptions légales).

Au niveau de l'entreprise, l'application du concept HACCP ("Hazard Analysis of Critical Control Points") entraîne de nombreuses données d'observation (compliance data). Le rassemblement de ces données au niveau sectoriel rend possible un effet d'échelle statistique intéressant. Les banques de données qui en résultent sont continuellement évaluées par les autorités compétentes.

Dans le contexte de l'évaluation des risques, les données d'entreprises peuvent fournir des informations importantes concernant l'identification de dangers ou – plus souvent – l'évaluation de l'exposition. Si des entreprises identifient de nouveaux dangers, elles transmettront les informations disponibles aux autorités (par ex. l'affaire ITX).

Lors de diverses circonstances (par ex. l'acrylamide, la coumarine ou, plus récemment, la gomme de guar contaminée par du pentachlorophénol (PCP) et des dioxines, et la collecte de données relatives à l'ingestion d'additifs), des entreprises individuelles et/ou des associations sectorielles ont rassemblé des données qui ont été transmises aux autorités. Ces données ont permis aux autorités de réaliser une évaluation de l'exposition, avant de prendre une décision sur le plan de la gestion des risques.

La collecte de données est d'une importance fondamentale tant pour l'évaluateur des risques et le gestionnaire des risques que pour l'industrie alimentaire. Idéalement, les données sont rassemblées d'une manière harmonisée afin de garantir leur comparabilité, ce qui est essentiel dans le contexte européen.

6. References
1. CIAA, 2005. Technical Report “Acrylamide Status Report December 2004.” A summary of the efforts and progress achieved to date by the European Food and Drink Industry (CIAA) in lowering levels of acrylamide in food.
Sci Com Workshop 2007

Theme 3

Use of databases available in Belgium – Case studies
Listeria monocytogenes on smoked salmon: a case study to evaluate the suitability of available Belgian data for exposure assessment

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1. Localisation of the hazard in the food chain

Listeria monocytogenes is a Gram positive bacterium that is ubiquitous in the environment and may cause human listeriosis. Consumption of contaminated food is the most important cause of listeriosis. L. monocytogenes is one of the leading microbiological causes of food recalls as reported to the EU Rapid Alert System for Food and Feed, mainly associated with animal products. The foods that are most often involved with listeriosis are soft cheeses (based on raw milk), milk products, deli meats, smoked fish (salmon, halibut), salads and in a more general way refrigerated ready-to-eat products with an extended shelf life that are consumed without prior heat treatment.

Smoked salmon is made from raw fillets that are brined or injected with salt. Different routes for contamination of the smoked salmon are possible: it can already be contaminated during catch or aquaculture, but can also be contaminated during production steps like salting, slicing and packaging. Due to product characteristics, smoked salmon can support the growth of L. monocytogenes.

2. Reference terms

In the framework of the FASFC control programme, yearly a large number of analyses are performed. This concerns biological parameters like Salmonella spp., L. monocytogenes, Staphylococcus aureus, Bacillus cereus but also chemical parameters like dioxins, PCB’s, heavy metals, mycotoxins and animal diseases (e.g. tuberculosis). In 2004 a Belgian survey on the consumption habits of the Belgian population (age 15-99 years), was performed.
The current case study focuses on the microbiological hazard *L. monocytogenes* on smoked salmon. The motivation for the choice of the case study '*L. monocytogenes* on smoked salmon' was that several studies identified cold-smoked fish as a high risk product for listeriosis and also because a set of data was available from the FASFC control programme.

Data were used from the FASFC database containing information on the prevalence and contamination level of *L. monocytogenes* on smoked salmon, and from the Belgian National Food Consumption Survey with information on the consumption frequency and the serving size. The case study deals with the following key questions: 'How suitable are the above mentioned data to perform a probabilistic exposure assessment?' and 'What recommendations can be made in order to make similar (future) data more appropriate for future exposure assessments?' (Figure 1).

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### 3. Risk assessment

#### Hazard identification

*Listeria monocytogenes* is potentially pathogenic for humans and may cause listeriosis. This infection can be life-threatening for at risk populations like immuno-compromised persons, the elderly people and pregnant women. Most European countries have an annual incidence of human listeriosis between one and ten reported cases per million inhabitants. The number of reported listeriosis cases in Belgium (ca. 10 million inhabitants) during the years 2002 to 2006 was respectively 44, 76, 89, 62 and 67. Although the incidence of listeriosis in comparison with campylobacteriosis and salmonellosis (respectively 5571 and 3693 cases in 2006) is low, listeriosis is, seen its high mortality rate (20-30%), an important zoonotic pathogen. Several scientific publications suggest that the principal contamination in cases of listeriosis is foodborne.

The above mentioned information in combination with the ability of *L. monocytogenes* to multiply at refrigerator temperatures in certain foods like smoked salmon or cheese and its high persistence in food-processing environments necessitates a special attention for this pathogen.

#### Hazard characterisation

According to the Codex Alimentarius a hazard characterisation is “the qualitative and/or quantitative evaluation of the negative consequences that can be associated with the hazard.”
Several research groups developed dose/response models for establishing the relationship between the ingested dose of *L. monocytogenes* and the probability of illness. The probability of illness from consuming a specified number of *L. monocytogenes* depends mainly on the virulence of the strain and the susceptibility of the consumer.

The Joint Expert Committee on Microbiological Risk Assessments (JEMRA) compared a number of published dose/response models and concluded that the predictions in the dose region corresponding to levels commonly found in food differ widely.

Three of these models were used in the case study to estimate the number of Belgian listeriosis cases due to consumption of smoked salmon (see part risk characterisation).

**Exposure assessment**

The purpose of the exposure assessment is to make a quantitative estimation of the probable intake of *L. monocytogenes* per serving of smoked salmon by a Belgian consumer. An exposure assessment can be performed by a deterministic approach using point estimations of the input parameters e.g. the average or the worst case but also by a probabilistic approach, using distributions of the input parameters.

In the presented case study, a probabilistic approach for estimation of the exposure of *L. monocytogenes* per serving of smoked salmon was used by means of a model that was run with the software @RISK (version 4.5.5., Palissade Corp.) As input for the model, two probability distributions were required:

i) A probability distribution of the contamination level of *L. monocytogenes* on smoked salmon (number of colony forming units (cfu) per gram of smoked salmon);

ii) A probability distribution of the weight per serving (g smoked salmon/serving).

The output of the simulation was also a probability distribution representing the exposure of the consumer to *L. monocytogenes* per serving of smoked salmon.

**Elaboration of the probability distribution of the contamination level of *L. monocytogenes* on the smoked salmon**

To elaborate this distribution, the following test results from the database of the FASFC were used:

1. 576 results (2002-2006) of the test “detection of *L. monocytogenes* in 25 g smoked salmon”. For this qualitative test, the test result is either ‘absent’ (≈ ‘<0.04 cfu/g’) or ‘present’ (≈ ‘≥0.04 cfu/g’). The smoked salmon was sampled at the production sites and the analyses were performed immediately after sampling. The prevalence was 19.4 %.

2. 209 results (2002-2005) of the test “detection of *L. monocytogenes* in 0.01 g smoked salmon”. For this qualitative test, the test result is either ‘absent’ (≈ ‘<100 cfu/g’) or ‘present’ (≈ ‘≥100 cfu/g’). The smoked salmon was sampled at the production site and the tests were performed at the end of the shelf life of the smoked salmon (after cooled storage at 4 °C/7 °C). The prevalence was 4.8 % (≈ 4.8 % ≥100 cfu/g). On these 209 smoked salmon samples, the analysis ‘detection in 25 g’ was also performed immediately after sampling, representing 209 results of
the group of 576 results mentioned above. Thirty-seven of these 209 analyses (17.8%) were positive (= 17.8% >0.04 cfu/g).

The above mentioned data contain some shortcomings as input data for elaboration of a probability distribution describing the contamination level of *L. monocytogenes* on the smoked salmon:

i) It concerns qualitative data that, when combined (209 samples), allow to classify the samples in three categories corresponding with a different contamination level range: 82.2 % <0.04 cfu/g, 13.0 % between 0.04 and 100 cfu/g and 4.8 % ≥100 cfu/g. However for a quantitative exposure assessment this approach is not sufficient. To complete the assessment, it was assumed that the growth of *L. monocytogenes* on smoked salmon was limited to maximal 105 cfu/g smoked salmon. Further a quantitative distribution for the contaminated samples (≥0.04 cfu/g) was obtained after fitting the (three cumulative) data (points (0 %, 1 cfu/g; 73.0 %, 100 cfu/g; 100 %, 105 cfu/g) to an exponential curve. This choice was based on the following expert opinion (assumption) of the FASFC Scientific Committee Microbiology working group: the smoked salmon that have ≥0.04 cfu *L. monocytogenes*/g are more probably contaminated at a low level than at a high level and the curve of this probability (in function of the contamination level) follows an exponential decreasing shape.

ii) Another shortcoming of the data concerns the combining of qualitative data (‘detection in 25 g’ and ‘detection in 0.01 g’) obtained at two different points in time, respectively at the ‘end of production’ and at the ‘end of the shelf life’. Ideally only qualitative results obtained at one moment in time should be combined. For this, it was assumed that the results of the analyses ‘detection in 25 g’ determined at the point in time ‘end of production’ are equal to the results that hypothetically would have been obtained for the same analyses performed at the point in time ‘end of the shelf life’. It was also assumed that ‘the end of shelf life’ equaled the moment of consumption for the consumption of all the smoked salmons by the consumer.

This implicates that the potential growth of *L. monocytogenes* on the smoked salmon during refrigerated storage (doubling time between 40 and 49 h at 5 °C[14,15]) for one part of the data, (the analysis results ‘detection in 25 g’) was not taken into account. Also the growth due to possible temperature abuse during storage in the distribution or by the consumer was not taken into account in the case study. This can possibly lead to an underestimation of the risk. On the other hand, the assumption that ‘the end of shelf life’ equaled the moment of consumption for all smoked salmons may imply an overestimation of the risk. Indeed most foods are consumed on the day of purchase or shortly after it whereas likely only a limited part remain in the home refrigerator till the end of the shelf life before consumption.

Figure 2 presents the probability distribution of the contamination level of *L. monocytogenes* on smoked salmon after application of the above-mentioned assumptions on the FASFC data. It should be stressed that the application of these assumptions has a considerable impact on the uncertainty of the distribution[15].
Elaboration of the probability distribution of the weight per serving of smoked salmon

For the elaboration of the probability distribution of the weight of the servings of the smoked salmon, data were used from the Belgian National Food Consumption Survey executed in 2004 by the Scientific Institute for Public Health. The survey concerned 3245 consumers older than 15 years, who were interviewed twice (two nonconsecutive days) to determine what they consumed during the last 24 hours. The database contains information on 114 consumed servings of smoked salmon and also on the age of the consumers.

Quantitative data for a total of 114 servings of smoked salmon were available. A division was made representing two age groups: 15-59 years and 60-99 years. The average serving size for these two groups is respectively 38 g (n= 61) and 44 g (n= 53). The data are quantitative and it was evaluated that, although rather limited in number, these data were suitable as input for the elaboration of a quantitative distribution (Figure 3).

After performing Monte Carlo Simulations (100000 iterations), using the two above mentioned distributions for the contamination level and consumption size (Figure 2 and Figure 3) as input for the exposure model, a probability distribution for the exposure of *L. monocytogenes* per serving size of smoked salmon was obtained (Figure 4).
Table 1 represents the percentiles for this distribution for the age groups 15-59 years, 60-99 years and 15-99 years. Taking into account the uncertainty linked to the input data and the small difference between the exposures per serving for the different age groups, it can be concluded that the differences in exposure between the age groups are not significant. For the population 15-99 years, the output of the simulations shows that for 85% of the servings the exposure is less than about 75 cells of *L. monocytogenes*. Five percent of the servings implicate an exposure per serving more than 2500 cells of *L. monocytogenes* and 1% of the servings implicate an exposure of more than 170000 cells of *L. monocytogenes*.

The three models are single hit exponential models with the underlying assumption that one single *L. monocytogenes* can cause disease. The three models differ in the value for the parameter R (the probability that a single cell will cause invasive listeriosis), reflecting different assumptions for the virulence and host characteristics. It concerns three models for the high risk population. It was estimated that about 20% of the high risk population (2 million persons) belongs to the high risk population for listeriosis.

The number of yearly consumed smoked salmon servings was estimated from the Belgian Consumption Survey: 6.6 million consumed servings per million persons (age group 15-99 years). For this, the assumption was made that the numbers of servings of smoked salmon measured on two days could be extrapolated to the whole year and that the eaters of the smoked salmon on these two days represent the eaters of the smoked salmon over 365 days.

Monte Carlo Simulations with 100 000 iterations on the three models were applied. The output of the simulation indicated an estimated yearly number of listeriosis cases for the immuno-compromised persons (2 million), due to the consumption of smoked salmon, of 86, 13 and 1, using respectively the models of Lindqvist & Westöö, Buchanan et al. and WHO.

As mentioned above, smoked salmon is one of the ready-to-eat products in Belgium for which the prevalence of *L. monocytogenes* is high (19.4%). The output of the risk characterisation, based on Belgian data with the contamination level of *L. monocytogenes* and consumption data, suggests that it is likely that consumption of smoked salmon contributes to the disease burden caused by *L. monocytogenes*. 

<table>
<thead>
<tr>
<th>Percentiles (%)</th>
<th>15-59 years</th>
<th>60-99 years</th>
<th>15-99 years</th>
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<tbody>
<tr>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>80</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>85</td>
<td>68</td>
<td>83</td>
<td>75</td>
</tr>
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<td>90</td>
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</tr>
<tr>
<td>95</td>
<td>2.3 x 10³</td>
<td>2.7 x 10³</td>
<td>2.5 x 10³</td>
</tr>
<tr>
<td>97.5</td>
<td>1.7 x 10⁴</td>
<td>1.9 x 10⁴</td>
<td>1.8 x 10⁴</td>
</tr>
<tr>
<td>99</td>
<td>1.6 x 10⁵</td>
<td>1.8 x 10⁵</td>
<td>1.7 x 10⁵</td>
</tr>
</tbody>
</table>

### Risk characterisation

In order to estimate the number of Belgian listeriosis cases due to the consumption of smoked salmon, the output from the exposure assessment describing the exposure per serving of smoked salmon (population 15-99 years), was used as an input for 3 different published exponential dose/response models: Lindqvist & Westöö, Buchanan et al. and WHO.
However, it should be mentioned that smoked salmon is only one of the foods where *L. monocytogenes* can occur in a high prevalence: the prevalence in other foods such as minced meat (42 %), smoked halibut (33 %) and tuna salad can also be quite high. The estimated number of listeriosis cases varied about 100-fold according to the used dose/response model. This reflects the large uncertainty linked to these models. Despite this difference, and also taken into account the assumptions, it can be observed that the estimated numbers due to the consumption of smoked salmon are in the same order of magnitude as the total number of reported cases of listeriosis in Belgium: 67 reported cases of listeriosis in Belgium in 2006.

4. Obtained targets and recommendations

In the case study, data from the FASFC database and data from the Belgian National Food Consumption Survey were used and evaluated for their suitability as input data for the probabilistic exposure assessment “*Listeria monocytogenes* on smoked salmon”. Subsequently to this analysis also a risk characterisation was performed in order to estimate the number of listeriosis cases due to consumption of smoked salmon.

It was shown that after the application of a number of assumptions, data from the FASFC and data from the IPH Belgian National Food Consumption Survey can be used as input data for performing a probabilistic exposure assessment. No specific shortcomings of the consumption data of smoked salmon from the IPH consumption survey were identified for elaboration of a probability distribution of the serving size. For the contamination data corresponding with the level of *L. monocytogenes* on smoked salmon, it is recommended to dispose of quantitative data (enumerations) instead of qualitative data (presence/absence testing), obtained at one time moment e.g. production or retail.

In the framework of a food control agency, analyses are performed in order to check compliance with the legislation. The test results that were used in this case study were therefore not specifically obtained with the aim of performing a quantitative risk assessment. As mentioned above the shortcomings of the data concern the disposal of qualitative data instead of quantitative data and the different points in time for the analyses.

From 2006 on, the European Community Regulation (EC) No 2073/2005 on microbiological criteria came into force. This regulation requires for *L. monocytogenes* in ready-to-eat foods compliance with two food safety criteria: absence in 25 g at “the end of production” and contamination level <100 cfu/g “during the shelf life”. In the FASFC control programme for 2007, analyses were performed to check compliance with this regulation and this for different ready-to-eat foods like smoked salmon, sliced meat and cheese products.

Although still not ideal, these results are more suitable as input data for risk assessment than the data used in this case study. The analyses planned by FASFC for checking compliance with the criterion “<100 cfu/g” at the distribution concern enumerations and will thus result in quantitative results. The results of the analyses required to check compliance with the criterion “absence in 25 g” remain qualitative.
Also the disadvantage of disposing of data at two different points in time ('end of production' and 'during shelf life') remains.

For a food control agency, it would be useful to rank the different food products according to the risk (exposure) for the consumer. This information can then subsequently be used for adoption of the FASFC control programme, aiming to protect the consumer’s health in a maximal way. The study presented here forms the methodological basis for this more extended ranking.

5. Samenvatting

In het kader van het controleprogramma van het Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV), worden jaarlijks een groot aantal analyses uitgevoerd. Het betreft biologische parameters zoals *Salmonella spp.*, *Listeria monocytogenes* en *Bacillus cereus* maar ook chemische parameters zoals dioxines, PCB’s, zware metalen, mycotoxines en dierenziekten (bv. tuberculose). In 2004 werd een voedselconsumptiepeiling uitgevoerd voor de Belgische populatie (leeftijd 15-99 jaar) door het Wetenschappelijk Instituut voor Volksgezondheid (WIV).

De hierboven beschreven gevalsstudie focust op het microbiologische gevaar *L. monocytogenes* op gerookte zalm. Data werden gebruikt van de FAVV-databank die informatie bevat over de prevalentie en het contaminatieniveau van *L. monocytogenes* op gerookte zalm en van de databank voor de Belgische voedselconsumptie.

Er werd onderzocht hoe geschikt deze data zijn om een probabilistische blootstellingsschatting uit te voeren alsook welke aanbevelingen er kunnen gemaakt worden om gelijkaardige (toekomstige) data beter geschikt te maken voor toekomstige blootstellingsschattingen.

Geen specifieke tekortkomingen voor de consumptiedata werden geïdentificeerd voor het opstellen van een waarschijnlijkheidsdistributie van de portiegrootte. Voor het opstellen van een waarschijnlijkheidsdistributie overeenkomend met het niveau van *L. monocytogenes* op gerookte zalm, is de grootste tekortkoming dat er geen kwantitatieve data (tellingen) beschikbaar zijn. Enkel kwalitatieve data (aanwezigheid/afwezigheid) zijn momenteel beschikbaar. De nodige veronderstellingen die met deze tekortkoming gepaard gaan, brengen een aanzienlijke onzekerheid mee voor de blootstellingsschatting. Er wordt aangeraden om, indien het de bedoeling is de analyseresultaten te gebruiken voor een probabilistische blootstellingsschatting, kwantitatieve bepalingen uit te voeren (tellingen) i.p.v. kwalitatieve bepalingen (aanwezigheid/afwezigheid).

Sedert 2006 worden in het kader van het FAVV-controleprogramma volgens Verordening (EG) nr. 2073/2005 voor *L. monocytogenes* in bepaalde kant-en-klar levensmiddelen twee types analyses uitgevoerd: i) tijdstip productie, bepaling in 25 g (voedselveiligheidscriterium: afwezig), en ii) tijdstip distributie, telling (voedselveiligheidscriterium: <100 kve/g). De gevalsstudie toonde aan dat, mits bepaalde veronderstellingen, deze data, samen met de Belgische consumptiedata kunnen gebruikt worden voor een blootstellingsschatting aan *L. monocytogenes* en wanneer dit voor verschillende levensmiddelen wordt uitgevoerd, laat dit toe
deze levensmiddelen te rangschikken volgens het risico. Deze informatie kan dan vervolgens gebruikt worden voor de eventuele bijsturing van het controleprogramma teneinde de gezondheid van de consument maximaal te beschermen.

6. Résumé
Dans le cadre du programme de contrôle de l'Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA), un grand nombre d'analyses sont réalisées annuellement. Cela concerne des paramètres biologiques tels que Salmonella spp., Listeria monocytogenes et Bacillus cereus mais aussi des paramètres chimiques tels que les dioxines, les PCB's, les métaux lourds ou les mycotoxines, et les maladies animales (par exemple, la tuberculose). En 2004, une enquête de consommation alimentaire fut réalisée pour la population belge (âges de 15 à 99 ans) par l'Institut scientifique de Santé Publique (ISP).

L'étude de cas décrite ci-dessus s'intéresse au danger microbiologique L. monocytogenes dans le saumon fumé. Des données issues de la banque de données de l'AFSCA, qui contient des informations sur la prévalence et le niveau de contamination de L. monocytogenes dans le saumon fumé, et de la banque de données pour la consommation alimentaire belge ont été utilisées.

Il a été examiné dans quelle mesure ces données étaient appropriées pour réaliser une estimation probabiliste de l'exposition et aussi quelles étaient les recommandations qui pouvaient être faites afin de rendre des données similaires (futures) encore plus appropriées pour des estimations futures de l'exposition.

Aucun lacune spécifique au niveau des données de consommation n'a été identifiée pour l'élaboration d'une distribution de la probabilité des grandeurs de portion. Pour l'élaboration d'une distribution de la probabilité correspondant au niveau de L. monocytogenes dans le saumon fumé, la lacune la plus importante est qu'aucune donnée quantitative (dénombrement) n'est disponible. Seules des données qualitatives (présence/absence) sont actuellement disponibles. Les hypothèses qui vont de pair avec cette lacune entraînent une incertitude considérable pour l'estimation de l'exposition. Il est conseillé, si l'objectif est d'utiliser les résultats d'analyse pour une estimation probabiliste de l'exposition, de réaliser des déterminations quantitatives (dénombrements) au lieu de déterminations qualitatives (présence/absence).

Depuis 2006, dans le cadre du programme de contrôle de l'AFSCA, deux types d'analyses sont réalisées pour L. monocytogenes dans certaines denrées alimentaires prêtes à être consommées suivant le Règlement (CE) n° 2073/2005 : i) au moment de la production, une détermination dans 25 g (critère de sécurité alimentaire : absence) et ii) au moment de la distribution, un dénombrement (critère de sécurité alimentaire : <100 ufc/g). L'étude de cas a démontré, moyennant certaines hypothèses, que ces données peuvent être utilisées ensemble avec les données belges de consommation pour une estimation de l'exposition à L. monocytogenes et que, lorsque ceci est réalisé pour plusieurs denrées alimentaires, cela permet de classer ces denrées alimentaires selon le risque. Ces informations peuvent ensuite être utilisées pour l'adaptation éventuelle du programme de contrôle afin de protéger au maximum la santé du consommateur.
7. References


15. Uyttendaele et al., 2006. Quantitative risk assessment of Campylobacter spp. in poultry based meat preparations as one of the factors to support the development of risk-based microbiological criteria in Belgium. Int J Food Micr, 111: 149.

Exposure assessment of the Belgian population to pesticide residues in 2005a

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1. Localisation of the hazard in the food chain

Pesticides are used to protect crops from pests, such as rodents, insects, fungi, weeds and bacteria. They include insecticides (insect killers), fungicides, herbicides (weed killers), molluscicides (snail and slug poisons) and plant growth regulators. Some pesticides are used as wood preservatives, to protect food in storage and for many other domestic uses. Consumers are exposed to pesticide residues on a daily basis e.g. through the consumption of fruits and vegetables. Therefore, it is important that the application of pesticides is well controlled.

Regulatory authorities must approve all pesticides before they can be commercialised. Once approved, pesticide residues in the food chain are monitored through a surveillance or monitoring programme. Although such programmes are a useful tool to verify that consumers are not exposed to unacceptable pesticide residue levels, their outcome does not give information on the actual exposure of the population to pesticide residues.

2. Objectives

The aim of the present study was to evaluate whether the estimated daily intake of the Belgian adult population of pesticide residues through fruit and vegetable consumption is a reason for health concern. The study was based on the pesticide residue concentration data recorded in the monitoring programme 2005 of the Belgian Federal Agency for the Safety of the Food Chain¹ and food consumption data collected in the Belgian nation-wide food consumption survey performed in 2004 by the Belgian Institute for Public Health (IPH)².

3. Risk assessment

Hazard identification: selection of pesticides

The pesticide monitoring programme 2005 of the FASFC includes 1322 samples of fruit and vegetables (tea and cacao included). During the year 2005, no less than 134940 residue/food combinations were analysed. From this vast amount of data, a first selection of 25 pesticide residues out of the 200 residues analysed was made based on their frequency of detection (>2 % of analysed samples exceeded the limit of reporting, LOR). Next, only those pesticide residue/food combinations were selected that could be considered as being authorized in June 2005 according to Fytoweb, a Belgian website supported by the Federal Public Service Health, Food Chain Safety and Environment containing information on authorized pesticides (www.fytoweb.fgov.be/indexEn.asp).

Hazard characterisation

In surveillance or monitoring programmes, pesticide residue concentrations in products are checked against legally defined MRL values (maximum residue limit). The MRL is a product limit and is based on the application of pesticides on crops according to Good Agricultural Practices (GAP) in controlled field experiments. The MRL gives a good indication on residues and food commodities to prospect, but lacks information in terms of food safety. The residue concentration may be above the MRL without representing a risk to the consumer.

Health safety limits or toxicological endpoint values such as the ADI (acceptable daily intake) and the ARfD (acute reference dose) on the other hand, are based on toxicological data. Exposure or intake of a compound below its health safety limit is considered to be “safe”.

Exposure assessment

Before the exposure or intake could be calculated, a lot of preparatory work went to structuring and harmonising the databases. The pesticide monitoring data were in the form in which they were reported, not immediately applicable for an exposure assessment study. At first, data had to be sorted in structured tables, from which a selection of 25 pesticides and relevant foodstuffs was made (see “Hazard identification: selection of pesticides”). Subsequently, the pesticide residues and food consumption database were harmonised and rendered compatible with respect to food product categories.

To link both databases, pesticide residues as well as foodstuffs were encoded. During the coding process both national languages, spelling and/or terminology needed to be considered. Additional difficulties in this preliminary phase were amongst others the presence of contra-analyses, which were difficult to discriminate from the other results, and the absence of samples for which no residue was detected (“non-detects”). Because the actual residue concentration of such samples is situated between 0 and the LOR (i.e. the “limit of reporting”, the detection or quantification limit of the analytical method applied), they were assigned either 0, ½ LOR or LOR, corresponding to a lower, middle and upper bound (worst case) scenario in the exposure assessment. Doing so, attention had to be paid to the fact that analyses
were performed by different laboratories using sometimes
different analytical methods and different LOR.

With respect to the consumption data collected by the
IPH\(^2\), foodstuffs needed to be selected and grouped to be
in accordance with the pesticide residue database. In some
cases a larger degree of detail occurred in the consump-
tion survey compared to the residue monitoring campaign.
Moreover, the demarcation of food categories was not always
straightforward because a pesticide may be authorized for
one product but not for a “similar” product (e.g. iprodione is
authorized for cabbages, Chinese cabbage, white cabbage,
etc., but not for cauliflower).

Since the main interest of this study was to evaluate the
probability the ADI is exceeded and not so much to evaluate
the safety of eating a certain commodity, the total dataset,
including zero intakes (“zero consumption days”), was used as
part of producing an “average” diet for long-term consumer
exposure assessment\(^3\).\(^4\).

To assess the exposure or intake, two main approaches can
be distinguished: the deterministic and the probabilistic
approaches. The deterministic approach is based on single
point estimates that are used for each variable within the
model. In this study, the average residue concentration was
multiplied with the average consumption as well as with dif-
fferent percentiles of consumption for a given
residue/food combination. A rough estimate of the total
exposure to a given pesticide residue \(\alpha\) was obtained by
summing exposures from all residue \(\alpha\)/food combinations
considered. Advantages of the deterministic approach are
that there is less need for extensive databases to support the
input variables, that default standard assumptions can be
used, that it is relatively easy to carry out, and that the single-
risk estimate output is easy to understand and interpret. Due
to its simplicity and its worldwide use and acceptance, the
point estimate approach may be used as a first screening tool
to identify possible pesticides that may pose a problem.

In the probabilistic approach the variables are described
in terms of distributions. In this way, all possible values for
consumption and residue concentration are taken into ac-
count and each possible model outcome is weighted by the
probability of its occurrence. Different techniques are avail-
able to calculate the outcome distribution, such as the Monte
Carlo simulation\(^5\). The Monte Carlo technique involves the
random sampling of each probability distribution within the
model to produce hundreds or even thousands of scenarios
(also called iterations or trials). Advantages of probabilistic
modelling are that all available data and knowledge are used,
that the exposure estimate is presented as a distribution, with
each value having a probability attached to it, and that vari-
ability and uncertainty can be quantified.

**Risk characterisation**

As a first screening, the exposure to pesticide residues was
calculated by a deterministic approach. Figure 1 presents an
overview of the exposure to the 25 selected pesticides for
the average and the 97.5\(^{th}\) percentile (P97.5) of consumption
according to a scenario where the residue concentration
of “non-detects” is equal to half the LOR of the analytical
method used (middle bound scenario).
Generally, chronic intakes of the 25 selected pesticide residues were rather low compared to the ADI (mostly < 1 % of ADI). However, some residues needed to be considered more closely. For a high consumer (P97.5) and the middle bound scenario, relatively higher exposure values were observed for imazalil, chlorpropham, the dithiocarbamates, lambda-cyhalothrin, dimethoate and chlorpyriphos. Therefore, in a second phase of the study, the exposure to these pesticides was recalculated according to the probabilistic approach.

Results of the probabilistic assessment approach are given in Table 1. From this table it can be seen that there is no direct correlation between detection frequency and the exposure. In general, replacing “non-detects” by 0, the LOR or the LOR/2 did not seem to affect the outcome significantly. Except for chlorpropham, the probability to exceed the ADI appeared to be much lower than 0.1 %. Next to chlorpropham, a relatively high intake in terms of % ADI was also observed for imazalil and dimethoate. Figures 2 a, b and c give more specific information on the contribution of several food items to the exposure of these pesticide residues.
Table 1. Total exposure in terms of % ADI of selected pesticide residues based on a probabilistic exposure assessment approach.

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>ADI mg kg(^{-1}) bw day(^{-1})</th>
<th>ARfD mg kg(^{-1}) bw day(^{-1})</th>
<th>Det. freq. (%(^a))</th>
<th>Average</th>
<th>P97.5</th>
<th>P99.9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Chlorpropham</td>
<td>0.05</td>
<td>0.5</td>
<td>41.3 (104)</td>
<td>4.26</td>
<td>34.65</td>
<td>119.61</td>
</tr>
<tr>
<td>Imazalil</td>
<td>0.025</td>
<td>0.05</td>
<td>26 (323)</td>
<td>1.65</td>
<td>15.99</td>
<td>54.19</td>
</tr>
<tr>
<td>Dimethoate</td>
<td>0.001</td>
<td>0.01</td>
<td>9.6 (197)</td>
<td>0.25</td>
<td>0.68</td>
<td>3.62</td>
</tr>
<tr>
<td>Dithiocarbamates</td>
<td>0.05</td>
<td>0.2-0.6(^b)</td>
<td>16.4 (861)</td>
<td>0.26</td>
<td>2.22</td>
<td>11.66</td>
</tr>
<tr>
<td>Chlorpyriphos</td>
<td>0.01</td>
<td>0.1</td>
<td>5.3 (509)</td>
<td>0.05</td>
<td>0.68</td>
<td>3.62</td>
</tr>
<tr>
<td>Lambda-cyhalothrin</td>
<td>0.005</td>
<td>0.0075</td>
<td>1.9 (855)</td>
<td>0.01</td>
<td>0.00</td>
<td>1.63</td>
</tr>
</tbody>
</table>

\(^{a}\) Detection frequency; total number of samples is indicated between brackets
\(^{b}\) ARfD of Maneb and Mancozeb respectively

Figure 2. Contribution of different food items to the total exposure (in terms of % ADI, middle bound scenario) of (a) chlorpropham, (b) imazalil, and (c) dimethoate.
The relatively high exposure to chlorpropham is solely due to one crop, namely potatoes. The high exposure value for dimethoate is mainly due to a high or frequent consumption of cherries and lettuce. With respect to imazalil, citrus fruit, orange and mandarin in particular, contributed most to the intake.

Comparing e.g. Figure 2a with Figure 2b, different profiles can be distinguished between the high exposure levels. Exposure to imazalil is relatively high since the amount of commodities on which it was detected and its use is authorized, is high. For chlorpropham on the other hand, the high exposure was due to some high levels of pesticide residues detected on a single food item, potatoes, and the relatively high consumption of that food item.

Considering acute exposure to pesticide residues, interpretation of exposure levels determined in this study in terms of % of the ARfD indicates the absence of acute risks, even for high consumers, given that ADI values for pesticides are lower than ARfD values (Table 1).

### 4. Discussion and recommendations

In 2005, the FASFC controlled 1322 samples of fruit and vegetables. Pesticide residues were found in 56 % of the samples and standards were exceeded for 7.9 % of the samples⁵⁶.

These numbers could give unnecessary rise to consumers’ concern. A more refined and different picture is obtained when the actual exposure of consumers to pesticide residues is considered. Based on results of the present study, chronic exposure to pesticide residues due to the consumption of fruit and vegetables seems generally to be under control in Belgium, even for frequent consumers.

It has to be noted that the present study focused on fruits and vegetables only. Therefore, the total exposure of pesticides studied is underestimated. On the other hand, processing factors were ignored, whereas fruit and vegetables (potatoes, citrus fruit, ...) are often peeled, cooked or boiled before consumption, resulting in an overestimation of the actual exposure to pesticide residues. Other variables affecting the pesticide residue concentration include storage, transport, shelf life, use patterns, lab-to-lab variation and analytical methods used to measure chemicals⁶. Additionally, it has to be noted that the dietary consumption data provided by the IPH did not include data for children under 15 years old. A special attention to this sensitive group could be given in further research.

Further research could also deal with exposure assessment related to the presence of multiple residues on a single food or serving, i.e. cumulative dietary intake assessment. Cumulative exposure to various residues of pesticides in food is a potential area of concern and gaining more and more interest. This issue is especially relevant for pesticides with a common mechanism of toxicity (e.g. organophosphates, carbamates)⁷⁸.

Finally, the exposure could be calculated and compared for different years. Based on this information, certain trends or

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⁵ With respect to samples exceeding the MRL, it has to be noted that MRL values are not completely harmonised in the EU. As such, imported food could exceed the Belgian MRL but comply to the MRL of the country of origin.


⁶ With respect to samples exceeding the MRL, it has to be noted that MRL values are not completely harmonised in the EU. As such, imported food could exceed the Belgian MRL but comply to the MRL of the country of origin.


⁷ With respect to samples exceeding the MRL, it has to be noted that MRL values are not completely harmonised in the EU. As such, imported food could exceed the Belgian MRL but comply to the MRL of the country of origin.


⁸ With respect to samples exceeding the MRL, it has to be noted that MRL values are not completely harmonised in the EU. As such, imported food could exceed the Belgian MRL but comply to the MRL of the country of origin.

evolutions could be derived. Although this seems theoretically feasible in theory, in practice some obstacles remain. For example, neither the same foodstuff nor the same amount of foodstuffs are analysed each year. Moreover, the authorisation and the MRL values of pesticides as well as toxicological values are dynamic.

5. Samenvatting

In 2005 controleerde het Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV) 1322 stalen van groenten en fruit. In 56% van de stalen werden pesticidenresidu’s gedetecteerd en in 7.9% van de gevallen werden de normen overschreden. Deze cijfers kunnen aanleiding geven tot ongerustheid bij de consument. Een verschillend of beter nuances beeld wordt verkregen wanneer de blootstelling aan pesticidenresidu’s wordt beschouwd.

In deze studie werd de blootstelling van de Belgische consument aan pesticidenresidu’s via de consumptie van groenten en fruit geëvalueerd op basis van de gegevens van de voedselconsumptiepeiling 2004 van het Wetenschappelijk Instituut Volksgezondheid en pesticide monitoring data 2005 van het FAVV. Echter, vooraleer de blootstelling berekend kon worden, ging heel wat voorbereidend werk naar het structureren en harmoniseren van de databanken (sorteren, coderen, selecteren, … van data).

Op basis van de resultaten bleek de chronische blootstelling van de Belgische consument aan pesticidenresidu’s t.g.v. de consumptie van groenten en fruit in het algemeen onder controle te zijn, zelfs bij hoge of frequente consumptie.

6. Résumé

En 2005, l’Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA) a contrôlé 1322 échantillons de fruits et légumes. Dans 56 % des échantillons, des résidus de pesticides ont été détectés, et dans 7.9 % des cas, les normes étaient dépassées. Ces chiffres peuvent entraîner une inquiétude chez le consommateur. Un tableau différent ou mieux nuancé s’obtient lorsqu’on considère l’exposition aux résidus de pesticides.

Dans la présente étude, l’exposition du consommateur belge aux résidus de pesticides via la consommation de fruits et légumes a été évaluée sur base des données de l’enquête nationale de consommation alimentaire 2004 de l’Institut Scientifique de Santé Publique et des données de monitoring des pesticides pour l’année 2005 de l’AFSCA. Néanmoins, avant que l’exposition ne puisse être calculée, beaucoup de travail préparatif a été consacré à la structuration et à l’harmonisation des banques de données (trier, encoder, sélectionner, … les données).

Sur base des résultats, l’exposition chronique du consommateur belge aux résidus de pesticides suite à la consommation de fruits et légumes semble, en général, être sous contrôle et ce, même en cas de consommation importante ou frequente.
7. References


Microbiological surveillance of carcasses and meat in Belgium: scientific exploitation of databases

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1FASFC, Brussels

1. Introduction

In industrialized countries Campylobacter and Salmonella represent the most frequent causes of acute bacterial enteritis. Contaminated food of animal origin is often involved in these infections.

Since 1997, the Belgian Federal Agency for the Safety of the Food Chain (FASFC) performs a surveillance of the prevalence of bacterial zoonotic agents (Salmonella, Campylobacter, Listeria monocytogenes, enterohemorrhagic E. coli O157) in poultry, in pork and in beef meat. An introductory study took place from 1997 to 1999, which allowed to determine the number of samples to be taken and the number of sample dilutions to be tested. Between 2000 and 2003, a new sampling plan was implemented to allow for representative sampling of the entire Belgian meat production process. In the sampling plan the number and the capacity of meat producing plants were taken into account. The samples were taken by well-trained veterinarians during 10 to 11 months each year. The laboratories performing the analysis were accredited according to the ISO 17.025 standard and all laboratories used the same analytical method. The sampling method used was the wet and dry swabbing technique for cattle and pig carcasses and the neck skin excision for broiler and layer chicken carcasses.

This study included also the surveillance of several bacterial indicators (E. coli, Enterobacteriaceae and aerobic colony counts) in order to evaluate the meat slaughtering process hygiene and the relationship between the indicators and zoonotic agents to establish hygiene indicator criteria for cattle, pig and chicken carcasses and for meat.

2. Examples of use

The results of this surveillance have been used for several purposes at the Belgian and European level. Several examples were given in the presentation.

**Determination of process hygiene criteria for indicator bacteria on beef and pig carcasses**

In 2002, the results of E. coli and aerobic colony counts have been used for the determination of hygiene criteria on beef and pig carcasses for the adaptation of the royal decree of 4 July 1996. E. coli was chosen as indicator of faecal contamination and indicator of a possible presence of pathogenic...
microorganisms of faecal origin (as *Salmonella, Campylobacter*). Aerobic colony counts have been chosen as indicator for general hygiene. The results were recorded as log cfu/cm² of sample. The 75th percentile has been considered as the m limit or limit of satisfaction, and the 95th percentile has been considered as the M limit or limit of acceptability.

The establishment of the criterion values on the 75th and 95th percentiles obtained in Belgium after official national surveillance plans takes into account the national situation in the slaughterhouses.

The European Community Regulation (EC) No 2073/2005 has replaced the royal decree. This regulation defines an official sampling method for the enumeration of indicator bacteria on beef and pig carcasses (the destructive method), but also allows the use of the swabbing technique. The results of the Belgian surveillance plans and the same approach have been used by the Scientific committee of the Federal Agency for the Safety of the Food Chain for the establishment of hygiene process criteria to be used for the Belgian swabbing sampling technique (Figure 1).
Determination of process hygiene criteria for pathogenic agents on beef and pig carcasses

The same approach may be used for the pathogenic agents, using the prevalence of Salmonella e.g. (proportion of samples with no detection of Salmonella) (Table 1).

Table 1. Criteria from the surveillance plan in comparison with the criteria of the European Community Regulation (EC) No 2073/2005.

\[ n = \text{number of units comprising the sample}; \quad c = \text{number of sample units giving values over } m \text{ or between } m \text{ and } M. \]

<table>
<thead>
<tr>
<th>Pig carcasses (swabbed area)</th>
<th>Poultry carcasses</th>
</tr>
</thead>
<tbody>
<tr>
<td>n 50</td>
<td>50</td>
</tr>
<tr>
<td>c 5</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Semi-quantitative estimation of Campylobacter prevalence in poultry meat preparation

Between 1997 and 1999, different dilutions of the same samples have been analysed: 10, 1 and 0.1 ml corresponding to 1, 0.1 or 0.01 g of sample. Figure 2 shows the results for Campylobacter.

Figure 2. Semi-quantitative evaluation of Campylobacter contamination in poultry meat according to prevalence results obtained from 1997 to 1999.
The same approach has been used by the Belgian Superior Health Council for a risk evaluation of poultry meat preparation (Figure 3)\(^7\).

### 3. Conclusions

In conclusion, the surveillance system and data collection are very important and are very useful for the determination of criteria and limits. Their use allow to take into account the Belgian situation. More quantitative data are needed for a quantitative risk assessment of pathogenic agents in food from animal origin.

### 4. Samenvatting

Sinds 1997 werd een plan voor de bewaking van micro-organismen ingevoerd voor levensmiddelen van dierlijke oorsprong. Dit werd voorafgegaan door een inleidend onderzoek dat geleid heeft tot de bepaling van de parameters, de matrices en de verdunningen die geanalyseerd moeten worden. Vanaf 2000 werd dan de nadruk gelegd op de representativiteit van de bemonstering om aldus de nationale situatie te bepalen. Deze bewaking werd uitgevoerd door het Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV).

Verschillende elementen hebben het mogelijk gemaakt om de representativiteit van de bemonsteringen te garanderen: de periode van de bemonsteringen, de verschillende categorieën van bemonsterde bedrijven, de afgenomen monsters (karkassen en rundvlees, vlees van varkens en pluimvee), de pathogene agentia en de geanalyseerde indicatoren (Salmonella, Campylobacter, Listeria monocytogenes, enterohemorrhagische E. coli O157, E. coli, totale aërobe kiemgetallen en enterobacteriën), de bemonsteringsmethode, de opleiding van de monsternemers, de laboratoriumanalysen.
Deze databank werd meermaals gebruikt op Belgisch en Europees vlak, zoals weergeven in de hieronder vermelde voorbeelden:

- De resultaten van de tellingen van de indicatorkiemen (percentiel 75 en 98 van de telling E. coli, totale kiemgetallen) op de karkassen van runderen en varkens werden in 2002 gebruikt als basis voor de bepaling van de criteria in het kader van het koninklijk besluit van 4 juli 1996 betreffende de algemene en bijzondere exploitatievoorwaarden van slachthuizen en andere inrichtingen.


- In een advies van de Hoge Gezondheidsraad, werden de semi-kwantitatieve onderzoeken, uitgevoerd ter gelegenheid van deze bewakingsplannen (voor de opsporing van Campylobacter) gebruikt als basis voor de bepaling van voorlopige criteria voor de bereidingen op basis van gehakt vlees van pluimvee.

5. Résumé


Différents éléments ont permis d’assurer la représentativité de l’échantillonnage : la période des prélèvements, les différentes catégories d’entreprises échantillonnées, les échantillons prélevés (carcasses et les viandes de bœuf, porc et volaille), les agents pathogènes et indicateurs analysés (Salmonella, Campylobacter, Listeria monocytogenes, E. coli O157 entérohémorragiques, E. coli, germes aérobies totaux et entérobactéries), la méthode d’échantillonnage, la formation des préleveurs, les analyses de laboratoire.

Cette base de données a été utilisée à plusieurs reprises au niveau belge et européen, comme les exemples ci-dessous le montrent :


Dans un avis du Conseil Supérieur de la Santé, les études semi-quantitatives réalisées lors de ces plans de surveillance (pour la recherche de *Campylobacter*) ont servi de base à la détermination de critères provisoires dans les préparations de viande à base de viande hachée de volaille.

6. References


Estimation of the dietary exposure to Cadmium

Valérie Vromman\textsuperscript{1} and Luc Pussemier\textsuperscript{2,3}

\textsuperscript{1}FASFC, Brussels; \textsuperscript{2}Sci Com FASFC, Brussels; \textsuperscript{3}VAR, Tervuren

1. Localisation of the hazard in the food chain

Cadmium is present in ambient air, in the smoke of cigarettes. Other sources of exposure to cadmium are ingestion of dust, drinking water and diet. It is estimated that the diet contributes for 99\% to the cadmium exposure of non smokers\textsuperscript{1}.

The major routes of cadmium (Cd) transfer to humans via the food chain are illustrated in Figure 1. Soils are contaminated by Cd through wet and dry deposition of Cd emissions. Contaminated soil, in turn, can be the origin of groundwater pollution and of contamination of locally grown crops (fodder crops, such as maize and grass, as well as vegetables, such as potatoes, carrots and cabbages). The fodder crops are fed to cattle, which accumulate Cd in specific organs, such as kidneys and liver\textsuperscript{2}. At the top of the food chain, the consumer of locally produced foodstuffs in particular will be exposed principally via the consumption of animal products (especially the organs) and vegetables (mostly broad-leaf and root vegetables)\textsuperscript{3}.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Main routes for entry of cadmium into the food chain and uptake by humans. (---: Contamination of cattle from the environment; ---: Contamination of humans through food consumption.)}
\end{figure}

2. Objective of the study

The objective of this study was to estimate human Cd exposure through the food chain in areas of northern Belgium close to non-ferrous metal plants. Cd concentrations were recorded in vegetables and animal products from these areas and other regions in Belgium. Dietary Cd intake was calculated for consumers of these locally produced food items and compared to the dietary intake of the general adult population in Belgium.

3. Risk assessment

Hazard identification

Cadmium is a heavy metal found in the earth crust. It can occur naturally in the environment from the gradual erosion and abrasion of rocks and soils or from singular events, such as forest fires and volcanic eruptions. It is, therefore, naturally present in air, water, soils and foodstuffs. Cadmium can be formed as a by-product from the production of non-ferrous metals zinc, lead, copper.

In Belgium, many industrial sites were developed for the production and treatment of non-ferrous metals, with several zinc and copper foundries being built in the northern part of the country (Campine region). An adverse consequence of these activities is the mainly historical, local emission into air, water and soil of large amounts of contaminants, such as cadmium (Cd), of which Belgium was one of the principal producers in Europe1.

Hazard characterisation

Cadmium is a cumulative contaminant. The kidney is the main target organ for chronic Cd toxicity. Environmental exposure to cadmium is associated with renal tubular dysfunction4. Cadmium and cadmium compounds are carcinogenic to human5. Exposure to cadmium may increase risk of lung cancer6. Chronic exposure to cadmium may promote urinary calcium loss and increase risk of bone fracture7.

A provisional tolerable weekly intake (PTWI) of 7 µg kg⁻¹ bw per week has been established by the FAO/WHO Joint Expert Committee of Food Additives and Contaminants8.

Exposure assessment

Average Cd intake was calculated both for adults living in contaminated areas (local adult population in a contaminated area) and those in areas of ambient environmental Cd levels (general adult population). Differences in Cd intake between adults from both areas are based on differences in measured Cd concentrations in locally produced food items. Food products were classified in 13 major food groups (Table 1). Daily consumption of each of the major food groups and subgroups was estimated for adults between the ages of 19 and 59 years.
<table>
<thead>
<tr>
<th>Commodity</th>
<th>Average</th>
<th>P97.5</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit (all)</td>
<td>0.111</td>
<td>0.288</td>
<td>IPH*</td>
</tr>
<tr>
<td>berries</td>
<td>0.006</td>
<td>0.015</td>
<td>PSD*</td>
</tr>
<tr>
<td>other fruit</td>
<td>0.106</td>
<td>0.273</td>
<td>calculated from IPH* and PSD*</td>
</tr>
<tr>
<td>Vegetables (all)</td>
<td>0.141</td>
<td>0.257</td>
<td>IPH*</td>
</tr>
<tr>
<td>vegetables</td>
<td>0.102</td>
<td>0.186</td>
<td>calculated from IPH* and PSD*</td>
</tr>
<tr>
<td>(standard* 0.05 mg kg⁻¹)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td>0.023</td>
<td>0.042</td>
<td>calculated from IPH* and PSD*</td>
</tr>
<tr>
<td>(standard 0.1 mg kg⁻¹)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td>0.016</td>
<td>0.030</td>
<td>calculated from IPH* and PSD*</td>
</tr>
<tr>
<td>(standard 0.2 mg kg⁻¹)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes</td>
<td>0.281</td>
<td>0.466</td>
<td>IPH*</td>
</tr>
<tr>
<td>Meat (all)</td>
<td>0.143</td>
<td>0.285</td>
<td>IPH*</td>
</tr>
<tr>
<td>poultry meat</td>
<td>0.019</td>
<td>0.053</td>
<td>IPH*</td>
</tr>
<tr>
<td>cattle meat</td>
<td>0.068</td>
<td>0.128</td>
<td>calculated from WHO¹ and IPH*</td>
</tr>
<tr>
<td>pig meat</td>
<td>0.056</td>
<td>0.104</td>
<td>calculated from WHO¹ and IPH*</td>
</tr>
<tr>
<td>Offal (all)</td>
<td>3.0 10⁻⁴</td>
<td>0.003</td>
<td>IPH* and PSD*</td>
</tr>
<tr>
<td>cattle offal</td>
<td>1.2 10⁻⁴</td>
<td>0.001</td>
<td>calculated from WHO¹ and IPH*</td>
</tr>
<tr>
<td>kidney</td>
<td>2.0 10⁻⁵</td>
<td>1.7 10⁻⁴</td>
<td>PSD*</td>
</tr>
<tr>
<td>liver</td>
<td>9.7 10⁻⁵</td>
<td>8.4 10⁻⁴</td>
<td>PSD*</td>
</tr>
<tr>
<td>other offal</td>
<td>1.8 10⁻⁴</td>
<td>0.002</td>
<td>calculated from WHO¹ and IPH*</td>
</tr>
<tr>
<td>Cereals</td>
<td>0.194</td>
<td>0.402</td>
<td>IPH*</td>
</tr>
<tr>
<td>Eggs</td>
<td>0.010</td>
<td>0.028</td>
<td>IPH*</td>
</tr>
<tr>
<td>Milk &amp; milk products (excluding cheese)</td>
<td>0.164</td>
<td>0.483</td>
<td>IPH*</td>
</tr>
<tr>
<td>Cheese</td>
<td>0.032</td>
<td>0.075</td>
<td>IPH*</td>
</tr>
<tr>
<td>Fish</td>
<td>0.017</td>
<td>0.050</td>
<td>IPH*</td>
</tr>
<tr>
<td>Seafood</td>
<td>0.006</td>
<td>0.025</td>
<td>IPH*</td>
</tr>
<tr>
<td>Oils and fats</td>
<td>0.021</td>
<td>0.073</td>
<td>IPH*</td>
</tr>
<tr>
<td>Other (e.g. sweets, sugar)</td>
<td>0.295</td>
<td>0.987</td>
<td>IPH*</td>
</tr>
<tr>
<td>Total</td>
<td>1.417</td>
<td>3.421</td>
<td></td>
</tr>
</tbody>
</table>

*Standard refers to food or food group according to the European maximum limit.
Vegetables and animal food products were sampled in the period 2004–2005 by the Belgian Federal Agency for the Safety of the Food Chain (FASFC), both in contaminated and “uncontaminated” areas of Belgium, i.e. areas at ambient environmental Cd levels. Samples, in contaminated areas, were taken close to the emission sources and at increasing distances (within a radius from 4 up to 10 km). Animal food products (kidney, liver and meat) were sampled at random in slaughterhouses by the FASFC in 2005. Tissues were sampled from animals that had resided more than 18 months in the contaminated areas and animals from areas of ambient environmental Cd levels. The Cd content of food groups not sampled within the framework of this study (e.g. cereals, fish, milk) were collected from literature^{12,13} or from the FASFC (unpublished results).

**Cadmium in vegetables and animal food products**

Mean Cd concentrations in fruits, vegetables and potatoes from the contaminated area were significantly greater (1.1- to 9-fold) than samples from other regions in Belgium with ambient environmental Cd concentrations (Table 2). The greatest increase in Cd content was found for stem, root and leafy vegetables. The mean Cd concentrations in meat, liver and kidney from the contaminated area were significantly greater (2-fold) than from other regions in Belgium with ambient environmental Cd concentrations. The average Cd concentration in bovine kidneys, both from contaminated and uncontaminated areas, exceeds the European maximum level of 1.0 mg kg\(^{-1}\) fresh weight\(^{14}\). About 75 % of the kidneys from the contaminated area were above the maximum level and were unsuitable to enter the food chain. Also, 50 % of the kidneys from other regions in Belgium surpassed the limit value. The average Cd concentration in liver from the contaminated area was close to the European maximum level of 0.5 mg kg\(^{-1}\) fresh weight\(^{14}\). Cadmium concentrations were, however, below the European maximum level of 0.05 mg kg\(^{-1}\) fresh weight in all meat samples from Belgian cattle\(^{3}\).
Table 2. Average cadmium concentration (mg kg\(^{-1}\) fresh weight) in fruits, vegetables, bovine muscle, liver and kidney sampled in the polluted area versus other regions in Belgium at ambient environmental Cd levels. The number of samples from which the mean is calculated, is indicated between brackets.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Polluted area</th>
<th>Regions at ambient Cd levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (Number)</td>
<td>S.D.</td>
</tr>
<tr>
<td>Berries</td>
<td>0.012 (n=35)</td>
<td>0.0106</td>
</tr>
<tr>
<td></td>
<td>0.012</td>
<td></td>
</tr>
<tr>
<td>Strawberries</td>
<td>(n=28)</td>
<td>0.011</td>
</tr>
<tr>
<td>Other berries</td>
<td>(n=7)</td>
<td>0.01</td>
</tr>
<tr>
<td>Vegetables</td>
<td>0.008 (n=25)</td>
<td>0.0054</td>
</tr>
<tr>
<td></td>
<td>0.009 (n=21)</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>0.007 (n=4)</td>
<td>0.004</td>
</tr>
<tr>
<td>Vegetables</td>
<td>0.085 (n=41)</td>
<td>0.0767</td>
</tr>
<tr>
<td></td>
<td>0.009 (n=11)</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>0.065 (n=5)</td>
<td>0.043</td>
</tr>
<tr>
<td></td>
<td>0.124 (n=15)</td>
<td>0.073</td>
</tr>
<tr>
<td></td>
<td>0.12 (n=10)</td>
<td>0.073</td>
</tr>
<tr>
<td>Vegetables</td>
<td>0.277 (n=31)</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Potatoes</td>
<td>0.051 (n=98)</td>
<td>0.0297</td>
</tr>
<tr>
<td>Meat</td>
<td>0.004 (n=53)</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>0.446 (n=53)</td>
<td>0.473</td>
</tr>
<tr>
<td></td>
<td>2.862 (n=53)</td>
<td>2.655</td>
</tr>
</tbody>
</table>

*Standard refers to food or food group according to the European maximum limit.

sNA: not available. The Cd content of this food has not been determined in the framework of this study but is derived from unpublished data of the Federal Agency for the Safety of the Food Chain.
Mean Cd concentrations were calculated for the major food groups or their subgroups. All measured Cd concentrations of individual food samples were averaged per (sub)group. Average dietary Cd intake (mg day\(^{-1}\)) was calculated by multiplying the average Cd concentration in each food (sub)group (mg kg\(^{-1}\)) by the average daily consumed weight of that food (sub)group (kg day\(^{-1}\)). Daily dietary Cd intake was compared with the provisional tolerable weekly intake (PTWI) of 7 µg kg\(^{-1}\) bw per week\(^8\) for a 60-kg adult.

**Risk characterisation**

Dietary Cd intake was calculated for adult populations (19–59 years; assumed mean weight 60 kg) living in the Cd-contaminated area or elsewhere in Belgium, i.e. at ambient environmental Cd levels. It was assumed that the vegetables, potatoes and small fruit (berries) consumed by adults living in the contaminated area were locally produced. As a large number of cattle farms are situated in the contaminated area, it was also assumed that the consumed cattle meat and offal was locally produced. In general, this meat is nationally distributed, but farmers might have slaughtered some of their cattle for private consumption (e.g. Saegerman et al.\(^{15}\)).

At average food consumption levels (Table 1), adults living in the Cd-contaminated area had an estimated daily Cd intake of 31 mg day\(^{-1}\) (Table 3), which is almost double the estimated intake of the general adult population (17 mg day\(^{-1}\); Table 3). Potato consumption was responsible for 46 % of the daily Cd intake in the contaminated area and accounted for 24 % of the PTWI (Table 3). The Cd content of potatoes was lower at ambient environmental Cd levels; only contributing to 10 % of the PTWI in those areas. Other major contributors to the average daily Cd intake were vegetables and cereals. Despite the large Cd concentrations found in cattle offal, their contribution to the daily Cd intake was negligible (Table 3). The percentage of the PTWI due to cattle offal consumption was less than 0.1 %, regardless of environmental Cd levels\(^3\).

**Table 3.** Daily Cd intake (µg day\(^{-1}\)) by a 60-kg adult living in a Cd polluted area or living in a region at ambient Cd levels with an average consumption pattern, and percentage of the PTWI attained for each food group.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Local adult population in a polluted area</th>
<th>General adult population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Daily Cd intake µg day(^{-1})</td>
<td>% PTWI</td>
</tr>
<tr>
<td>Fruit (all)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>berries</td>
<td>0.07</td>
<td>0.11</td>
</tr>
<tr>
<td>other fruit</td>
<td>0.42</td>
<td>0.70</td>
</tr>
<tr>
<td>Vegetables (all)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td>0.82</td>
<td>1.36</td>
</tr>
<tr>
<td>(standard* 0.05 mg kg(^{-1}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td>1.95</td>
<td>3.24</td>
</tr>
<tr>
<td>(standard 0.1 mg kg(^{-1}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td>4.55</td>
<td>7.57</td>
</tr>
<tr>
<td>(standard 0.2 mg kg(^{-1}))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes</td>
<td>14.3</td>
<td>23.9</td>
</tr>
<tr>
<td>Meat (all)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>poultry meat</td>
<td>0.09</td>
<td>0.16</td>
</tr>
<tr>
<td>cattle meat</td>
<td>0.27</td>
<td>0.45</td>
</tr>
<tr>
<td>pig meat</td>
<td>0.39</td>
<td>0.65</td>
</tr>
<tr>
<td>Offal (all)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cattle offal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>kidney</td>
<td>0.06</td>
<td>0.09</td>
</tr>
<tr>
<td>liver</td>
<td>0.04</td>
<td>0.07</td>
</tr>
<tr>
<td>other offal</td>
<td>0.01</td>
<td>0.02</td>
</tr>
<tr>
<td>Cereals</td>
<td>4.47</td>
<td>7.45</td>
</tr>
</tbody>
</table>
### Local adult population in a polluted area

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Daily Cd intake µg day^{-1}</th>
<th>% PTWI</th>
<th>General adult population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eggs</td>
<td>0.03</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>Milk &amp; milk products</td>
<td>0.07</td>
<td>0.11</td>
<td>0.07</td>
</tr>
<tr>
<td>Cheese</td>
<td>0.03</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>Fish</td>
<td>0.12</td>
<td>0.20</td>
<td>0.12</td>
</tr>
<tr>
<td>Seafood</td>
<td>0.86</td>
<td>1.43</td>
<td>0.86</td>
</tr>
<tr>
<td>Oils and fats</td>
<td>0.07</td>
<td>0.12</td>
<td>0.07</td>
</tr>
<tr>
<td>Other (e.g. sweets, sugar)</td>
<td>2.66</td>
<td>4.43</td>
<td>2.66</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>31.3</strong></td>
<td><strong>52.2</strong></td>
<td><strong>17.0</strong></td>
</tr>
</tbody>
</table>

*Standard refers to food or food group according to the European maximum limit.

The high Cd concentrations in cattle offal are relatively unimportant in terms of Cd intake due to its low consumption. However, consumption data are based on the general population. Assuming that offal is eaten as a replacement for meat, i.e. 143 g meat is replaced by an equal amount of liver or kidney, it can be calculated that the high figures for cattle liver and kidney consumption presented in Table 1 correspond to two portions of cattle liver per year and one portion of cattle kidneys every 2 years. These figures are realistic for average Belgian adults between the ages of 19 and 59 years. It is possible, however, that some people, especially cattle farmers, consume liver or kidneys more regularly. Where cattle liver originating from the contaminated area is eaten at a portion of once per month, this would increase the average weekly intake of Cd to 14.9 mg or 3.5 % of the PTWI. One portion of cattle kidneys per month would increase the average weekly Cd intake to 95.5 mg or 22.7 % of the PTWI. Thus, the high Cd concentrations in cattle offal are significant.

### 4. Conclusions and perspectives

A deterministic approach was used to estimate Cd intake for an adult population living in a Cd-contaminated area close to non-ferrous metal plants. The study revealed the possible intake of almost twice as much Cd as the general adult population in Belgium (consumption scenario assuming the local population consumes foodstuffs exclusively produced in the contaminated area). Potatoes and vegetables are the highest contributors to cadmium exposure.

A probabilistic approach is recommended to improve Cd intake estimation, taking into account (i) the distribution of individual consumption data for the sub-population living within the contaminated vicinity of non-ferrous metal plants and for the general Belgian population, and (ii) geographic distribution of Cd concentrations in an extended array of food items.
5. Samenvatting

Er werden in België een aantal industriële vestigingen uitgebouwd waar non-ferrometalen werden geproduceerd en behandeld. In het noorden van het land (de Kempen) werden in het bijzonder zink- en kopergieterijen opgericht. Een nadelig gevolg van deze activiteiten is de uitstoot van grote hoeveelheden cadmium in de onmiddellijke omgeving (lucht, water en bodem). In deze gebieden zijn er risico’s voor verontreiniging van de voedselketen en van de mens als gevolg van de overdracht en de accumulatie van verontreinigingen.

De blootstelling aan cadmium via levensmiddelen werd geschat voor volwassenen die wonen in een gebied dichtbij de fabrieken van non-ferrometalen in de Kempen, en vergeleken met de blootstelling via levensmiddelen van de volwassen bevolking van België. Er werden monsters genomen van levensmiddelen om het niveau van de cadmiumverontreiniging te kunnen schatten. De cadmiumconcentraties in groenten en fruit waren 1.1 tot 9 maal groter in de monsters die in de omgeving van de non-ferrometaalfabrieken werden genomen. De gemiddelde concentraties in rundvlees waren tweemaal zo groot.

Er werd een deterministische benadering toegepast om de gemiddelde inname van cadmium en het 97,5 percentiel van inname te bepalen.

De dagelijkse cadmiuminname werd geschat op 31,3 en 63,3 µg dag⁻¹ voor gemiddelde consumenten en grote consumenten in de verontreinigde zone tegenover 17 en 38,3 µg dag⁻¹ voor de volwassen bevolking in het algemeen.

Buitenmatige consumptie van levensmiddelen die zijn geteeld op plaatsen in de nabijheid van de non-ferrometaalfabrieken kan aanleiding geven tot innameniveaus die de ‘Provisonal Tolerated Weekly Intake’ (PTWI) overschrijden.

6. Résumé

Plusieurs sites industriels belges ont été développés pour la production et le traitement des métaux non-ferreux. En particulier, des fonderies de zinc et de cuivre ont été construites dans le nord du pays (Campine). Une conséquence néfaste de ces activités est l’émission dans l’environnement local (air, eau et sol) de grandes quantités de cadmium. Dans ces zones, des risques de contamination de la chaîne alimentaire et de l’homme existent en raison des phénomènes de transfert et d’accumulation des contaminants.

L’exposition alimentaire au cadmium a été estimée pour les adultes vivant dans une zone proche des usines de métaux non-ferreux en Campine et comparée à l’exposition alimentaire de la population adulte en Belgique. Des échantillons de denrées alimentaires ont été prélevés pour évaluer le niveau de contamination au cadmium. Les concentrations en cadmium dans les fruits et les légumes étaient 1,1 à 9 fois plus élevées dans les échantillons prélevés aux alentours des usines de métaux non ferreux. Les concentrations moyennes dans la viande bovine étaient, quant à elles, deux fois plus élevées.

Une approche déterministe a été utilisée pour déterminer l’ingestion moyenne de cadmium ainsi que l’ingestion au 97,5 percentile.
L’ingestion journalière de cadmium a été estimée à 31.3 et 63.3 µg jour⁻¹ pour les consommateurs moyens et les grands consommateurs dans la zone contaminée comparée à 17 et 38.3 µg jour⁻¹ pour la population générale adulte. La consommation excessive de certaines denrées produites localement dans des zones proches des usines de métaux non-ferreux peut résulter en des niveaux d’ingestion dépassant la dose hebdomadaire tolérable provisoire (Provisional Tolerated Weekly Intake, PTWI).

7. References


Conclusions

Xavier Van Huffel

FASFC, Brussels

The subject treated at the 3rd workshop of the Scientific Committee of the FASFC went back to the roots of risk assessment and dealt with food chain related databases in general and with the scientific exploitation of data for risk assessment purposes in particular.

Collecting data is an essential activity for a food control agency for many reasons: databases are a valuable business tool and source of information helping to develop and plan the control programmes and evaluate the necessary actions. Data are essential to make up reports and communicate about the results of the control programmes, to study trends in food safety of commodities and to assess risks.

The programme of this year’s workshop treated 3 principal themes:

1. Databases in general:
   a. the “state of the art” on the development of databases and their analysis;
   b. the EFSA vision on the development and use of European databases.

2. Available databases to perform food safety risk assessment studies applicable to the Belgian situation.

3. Presentation of case studies worked out by risk assessors of the Belgian Food Agency.

Prof. Niel Hens (UHasselt, Diepenbeek) gave a general presentation on the process going from data collection and development of database management systems to the treatment of data and the application of adequate statistical methodology for the analysis of data. The three basic components of database management systems were discussed: the design of the database, the standard query language and the programming component. The importance of functional linking between multiple databases was also accentuated. Once data are stored in an adequate format they can be used for multiple purposes such as for scientific risk assessment using appropriate techniques and methodology.

Dr. Hubert Deluyker (EFSA, Parma) explained the EFSA vision on the development of European databases. EFSA has the legal obligation to identify available databases and to develop new databases where needed in different domains of the food chain as there are food consumption and composition, chemical contaminants, zoonotic agents, pesticide residues and animal and plant pathogens. This task is accomplished in narrow collaboration with the Member States with the aim of obtaining harmonised databases.
At the Belgian level risk assessors can use different databases in order to perform risk assessment studies applicable to the national situation. Three presentations treated the characteristics of the available data.

Dr. Jean-Marie Robijns (FASFC, Brussels) gave insight into the historical background, the structure, the content and the complexity of the five main databases related to the food chain and which were developed by the FASFC. Most of them are consultable via the Business Objects program. Dr. Robijns discussed some examples of problems (missing data, incorrect linking between different tables, lack of precision in defining the queries, …) which may be encountered when extracting specific data. He accentuated that risk assessors and researchers should always maintain a critical attitude when analysing the data.

Dr. Liesbeth Temme (ex-IPH, Brussels) presented the Belgian National Food Consumption Survey and database which was developed at the Institute of Public Health. It has become a valuable instrument, not only to measure the food and nutrient intake of the population, but also to be used in risk assessment studies of contaminants and residues.

Ir. Johan Hallaert (FEVIA, Brussels) and Mrs. Beate Kettlitz (CIAA, Brussels) addressed the significant role of the professional sector in collecting data on (chemical) contaminants in the food chain. Data generated by the food sector operators most frequently relate to a risk management context (compliance data). However, the sector also may play an important role in hazard identification and in its communication to the public authorities.

In the last session, different case studies were presented by FASFC experts of the scientific secretariat of the Scientific Committee. The purpose was to show how the data of the FASFC can be used for risk assessment or at least to prepare the first stages of it.

Ir. Sigrid Van Boxstael (FASFC, Brussels) discussed the suitability of data originating from the FASFC and from the Belgian National Food Consumption Survey as input for the probabilistic exposure assessment “Listeria monocytogenes on smoked salmon”. It was the purpose of the study to perform a quantitative estimation of the probable intake of L. monocytogenes per serving of smoked salmon by the Belgian consumer. After the application of a number of assumptions, data from FASFC and from the Belgian National Food Consumption Survey were used as input values. Although only limited consumption data of smoked salmon were available it was felt that the data were valid enough for the elaboration of a quantitative distribution. The FASFC contamination data of L. monocytogenes on smoked salmon were of qualitative nature and represented analysis taken at different points in time. Different assumptions had to be made in order to convert these data to quantitative data. Subsequently a risk characterisation was performed in order to estimate the number of listeriosis cases due to consumption of smoked salmon. It was finally shown that the relatively scarce data from the FASFC and the Belgian National Food Consumption Survey on smoked salmon contamination and consumption could be used to work out a probabilistic exposure assessment.

Ir. Olivier Wilmart (FASFC, Brussels) showed the results of an exposure assessment study worked out by Ir. Wendie Claeyts (FASFC, Brussels). This study was aimed at evaluating whether
the estimated daily intake of pesticide residues by the Belgian adult population through fruit and vegetable consumption should be a cause for health concern. The study used the pesticide residue concentrations recorded in 2005 by the FASFC monitoring programme and the national food consumption data. Both a deterministic and a probabilistic quantitative approach were used. The study showed that chronic exposure to pesticide residues due to the consumption of fruit and vegetables seems generally to be under control in Belgium, even for frequent fruit and vegetables consumers.

Dr. Yasmine Ghafir (FASFC, Brussels) presented data obtained in different studies on the microbiological surveillance of pig and beef carcasses and of meat. Process hygiene criteria for indicator microorganisms and for pathogens were assessed and the data have been used for the determination of hygiene limits for slaughterhouses, for the preparation of a scientific advice and for negotiation purposes at the European level.

Ir. Valérie Vromman (FASFC, Brussels) presented the exposure of consumers to cadmium in a contaminated region in the north of the country and compared this situation with this of the general adult population in Belgium. This study was based on the cadmium contamination data in samples from vegetable and animal food products originating from the contaminated area and on data from the Belgian National Food Consumption Survey. A deterministic approach showed a risk of increased dietary cadmium intake in consumers living in a cadmium-contaminated area close to non-ferrous metal plants. In the consumption scenario it was assumed that exclusively foodstuffs were consumed which were produced in the contaminated area. Potatoes and vegetables were the highest contributors to the cadmium exposure.

The following conclusions were taken at the end of this workshop:

1. In the framework of a food control agency, analyses are performed in order to check compliance with the legislation. The data are therefore not specifically obtained with the aim of performing a quantitative risk assessment which has practical consequences in regard to data treatment for risk assessors.

2. The availability of sufficient sound quantitative data remains of crucial concern in risk assessment studies. This was not only observed in the case studies presented by FASFC experts but it is also of great general concern to scientific advisory committees and to EFSA.

3. Quantitative data are a condition sine qua non to work out deterministic or probabilistic quantitative risk assessment studies.

4. During risk assessment studies risk assessors are confronted with many pitfalls such as:
   - missing data,
   - data reported in a non-conform format,
   - limited reporting such as the mentioning “conform” or “not conform”, “presence” or “absence” of microbial contamination,…
   - values below the limit of detection or the limit of quantification,
   - unknown origin of the data,
   - the composition of the foodgroups in food con-
sumption databases which does not correspond with the own study set-up,
- limited availability of food consumption data on certain foodstuffs or of certain subpopulations, ...

5. It is crucial for the risk assessor to be familiar with the origin of the data. Are they obtained by a randomized sampling or do they originate from a targeted risk based sampling programme? This information is important in order to decide if the data are valid to be used in prevalence or exposure assessment studies.

6. It is crucial to have a good understanding of the analytical method by which the data are obtained in order to decide if they can be used for exposure assessment studies. In this context the Scientific Committee of the FASFC is examining if dioxin contamination data, obtained by the CALUX screening method, can be used for quantitative risk assessment studies. An advice on this subject will be emitted in 2008.

7. It is felt important to develop a harmonised risk assessment methodology. The intentions of EFSA in this matter are fully appreciated and the scientific secretariat of the FASFC participates in an EFSA workgroup dedicated to this subject.

8. Risk assessment is a method to upgrade “data” towards “information”. This has been shown in the presented case studies, worked out by highly qualified experts from the scientific secretariat and “peer reviewed” by the Scientific Committee. The publication of the results in scientific literature is considered to be important.

9. Collaboration with academic scientists and scientific institutions has to be encouraged in order to maximally valorise the existing data and knowledge.
ADI – Acceptable Daily Intake
The amount of a substance, expressed on a body mass basis (usually mg/kg body weight), which can be ingested daily over a lifetime without appreciable health risk; typically applied for food additives and pesticide residues (contrary to the tolerable daily dose that is used for contaminants).

ARfD – Acute Reference Dose
The ARfD is an estimate of the amount of a substance, normally expressed on a body weight basis, that can be ingested during a short period (usually a period of 24 h or less), without appreciable health risks (e.g. typically used for fruit and vegetables where a certain piece of fruit or vegetable has an excessive amount of a pesticide residue with a high acute toxicity). The concept was developed as a result of the observation that some substances caused health problems at occasional exposure levels above the ADI.

Chronic toxicity
Chronic toxicity is a property of a substance that has toxic effects on a living organism, when that organism is exposed to the substance continuously or repeatedly.

Crossroads bank
National register with all basic facts of ventures and their entities.

Data normalization
The process of creating a well-behaved set of tables to efficiently store data, minimize redundancy and ensure data integrity.

DBMS - Database management system
Software that defines a database, stores the data, supports a query language, produces reports and creates data entry screens.

Deterministic risk assessment
Risk assessment based on a deterministic method. For each variable of the model a punctual estimation (e.g. mean) is used to determine the output of the model.

GAP – Good Agricultural Practices
Broadly defined, GAP applies available knowledge to addressing environmental, economic and social sustainability for on-farm production and post-production processes resulting in safe and healthy food and non-food agricultural products.

HACCP – Hazard Analysis of Critical Control Points
HACCP is a systematic preventive approach used at all stages of food production and preparation processes, by which potential physical, chemical, and biological food safety hazards are identified so that key actions, known as Critical Control Points (CCP’s), can be taken to reduce or eliminate the risk of the hazards.
M limit
Limit of acceptability: limit beyond which the results are considered unacceptable. This is the maximum acceptable level.

m limit
Limit of satisfaction: limit below which all results are considered satisfactory. This level is the target normally achieved using HACCP and good hygienic practice.

M(R)L - Maximum (Residue) Level
M(R)L is the legal threshold limit of a hazardous substance that is allowed in a commodity (typical for residues of phytosanitary products or of veterinary medicines).

Maximum likelihood estimation
The maximum likelihood estimation is a popular statistical method used to calculate the best way of fitting a mathematical model to some data. Modelling real world data by estimating maximum likelihood offers a way of tuning the free parameters of the model to provide an optimum fit.

Meta-data
Data describing the characteristics of particular data.

Microbiological criterion
A criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

Percentile
One of 100 equal parts of a series of measurements, each group being of equal size, and arranged in order of their magnitude; the 20th percentile is the value in the series below which 20% of the values fall.

Probabilistic risk assessment
Risk assessment based on a probabilistic method. The variables of the model are represented as distributions.

Process hygiene criterion
A criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with the food law.

PTWI - Provisional Tolerable Weekly Intake
PTWI is the quantity of a given substance (expressed in kg body weight) which may weekly be ingested during the entire lifespan without adverse health effects. PTWI is typically used for contaminants with accumulating characteristics. This intake may be considered as a temporary value which may be adapted if new scientific knowledge becomes available.
**Relational database**

The most popular type of database management system. All data are stored in tables (sometimes called relations). Tables are logically connected by the data they hold (e.g. through key values). Relational databases should be designed through data normalization.

**Risk assessment**

Scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

**Risk analysis**

Process consisting of three interconnected components: risk assessment, risk management and risk communication.

**SQL - Standard Query Language**

A standardized data language, used for data retrieval (queries), data definition, and data manipulation.