CHEMICAL RISKS IN THE FOOD CHAIN:

CHALLENGES FOR THE RISK ASSESSOR AND THE RISK MANAGER

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the Safety of the Food Chain

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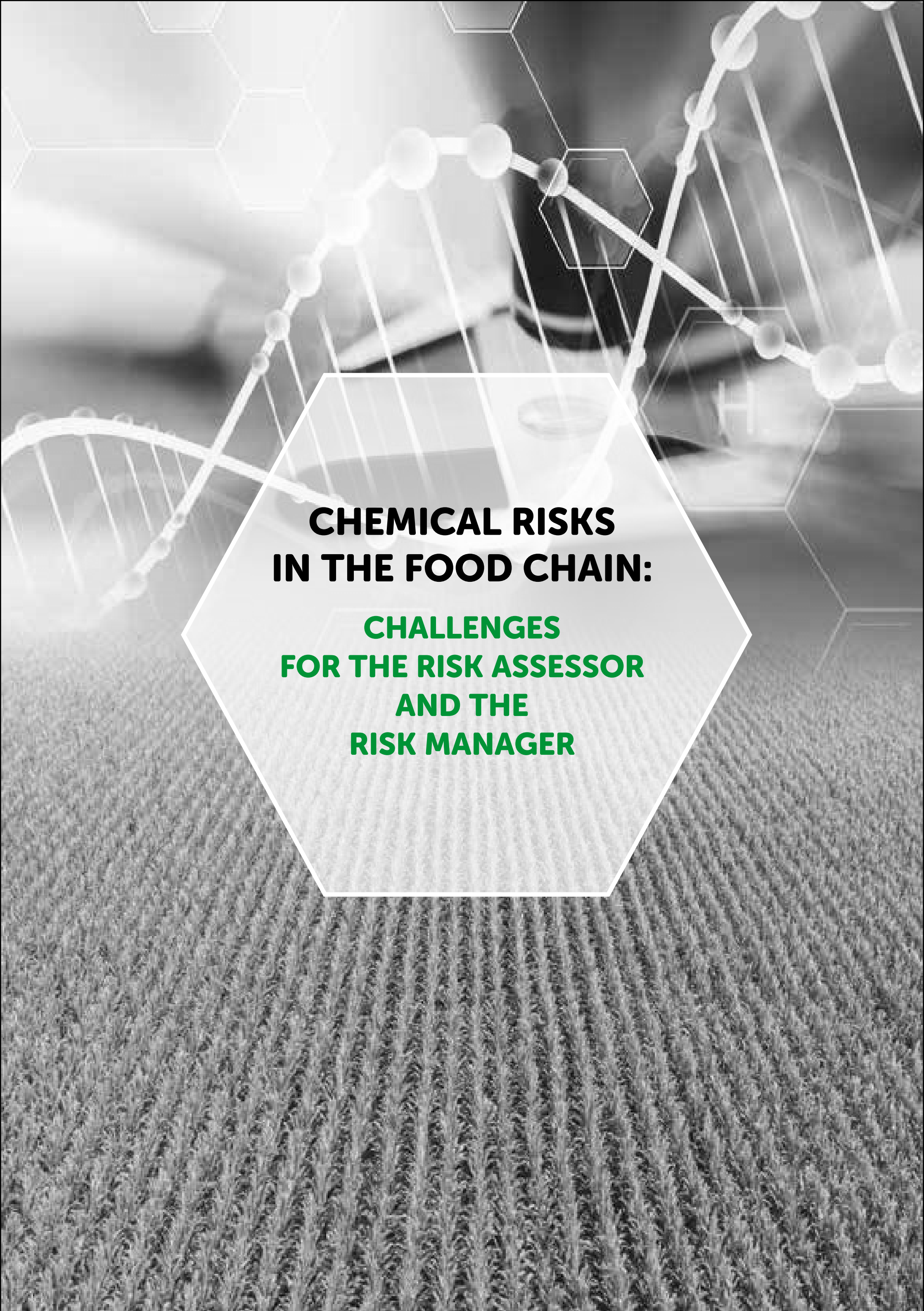


CHEMICAL RISKS IN THE FOOD CHAIN:

CHALLENGES FOR THE RISK ASSESSOR AND THE RISK MANAGER

“Chemical risks in the food chain: challenges for the risk assessor and the risk manager” is the topic of this 13th annual symposium of the Scientific Committee of the Belgian Food Safety Agency.

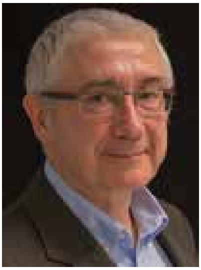
Chemical hazards are largely present in the food chain. Their detection and quantification are of upmost importance. However, a real challenge is their huge diversity. It is essential to assist the risk manager with sound scientific opinions, especially for newly identified contaminants.
The objective of this symposium is to discuss the most important challenges for the risk assessor and risk manager confronted with chemical risks in the food chain. Issues such as consumer exposure, risk characterization, risk assessment, control measures and risk communication are addressed. Specific challenging cases like microplastics, nanomaterials and mineral oil are developed. The trends on chemical food safety in the EU by 2050 is also presented.

The recent fipronil crisis puts food safety back into the focal attention of our society and showed the vulnerability of the food chain. Preserving the safety of the food chain is precisely the task of our Food Safety Agency and the Scientific Committee has the mandate to assist the Agency scientifically with this task. Our Scientific Committee is a board of experts who give independent scientific advice to the Agency and the Minister in all matters related to the competencies of the Agency, especially with respect to risk assessment regarding food safety, but including also animal and plant health. The Committee enforces a policy of impartial and independent scientific consultation and transparent communication, including an open management of conflicts of interest. The Committee acknowledges the strong support of the Agency through its Chief Executive Officer, the General Director of the Directorate General Control Policy and the Staff Direction for Risk Assessment.

I express very special thanks to my fellow members of the Scientific Committee, Prof. Bruno De Meulenaer, Prof. Sarah De Saeger, Dr. Philippe Delahaut, Prof. Mia Eeckhout, Prof. Peter Hoet and Prof. Marie-Louise Scippo, and Dr. Xavier Van Huffel and Wendie Claeys from the Staff Direction for Risk Assessment, for their invaluable contributions to the scientific organization of this symposium. These acknowledgements are extended to the Agency for providing the needed human and financial resources.

The very high scientific quality of the symposium is supported by prominent speakers coming from Belgium, Switzerland, the European Commission, the European Food Safety Authority and the Université Laval of Canada. They are warmly acknowledged.
Your presence as participants reveals that the selection of this topic by the Scientific Committee was more than appropriate and meets the concerns of scientists, risk assessors, risk managers and stakeholders involved in the analysis of risks in the food chain. Indeed, we all pursue the same objective: to provide safe food to our society.

I wish you a very fruitful symposium.



Prof. Etienne Thiry,
Chair of the Scientific Committee
of the Belgian Food Safety Agency.

Etienne Thiry graduated from the University of Liège as doctor in veterinary medicine in 1980 and obtained a Ph.D. in veterinary sciences in 1985. He was recognized in 2001 as diplomate of the European College for Veterinary Public Health. He is full professor and head of veterinary virology and animal viral diseases laboratory, at the University of Liège. His research interests cover several aspects of animal virology, especially the study of animal virus-host interactions and the evolution of viral populations through genetic recombination and reassortment in viruses. E. Thiry is member of several scientific committees and is also chairman of the Scientific Committee of the Belgian Food Safety Agency and of the Expert Committee for animal health and well-being (ANSES).

13th Symposium of the Scientific Committee of the Belgian Food Safety Agency

Chemical risks in the food chain: challenges for the risk assessor and the risk manager

Friday, 24th November 2017 - Pacheco auditory - Finance Tower
1000 Brussels, Belgium

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& M.-L. Scippo (ULiège, SciCom member)

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Samy GODEFROY (Université Laval, Canada)

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Vicky LEFEVRE (FASFC, Brussels)

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Etienne THIRY (ULiège, Chair SciCom)

Introduction – Objectives of the symposium

Chemical risks keep presenting challenges for all stakeholders within the agri-food chain and this on the level of both assessing and managing these risks. Knowledge gaps are still being identified with respect to for instance, short and long term toxicological effects or combined (cumulative) exposure to a variety of chemicals. New risks are being identified and introduced in the chain due to for instance, a shift to a more circular economy, changes in dietary patterns or climatological conditions, … The agri-food chain also becomes ever more complex, given the globalized market, the increase of different types of market operators and the multi-dimensional organization of production, manufacturing and distribution stages of the chain.

This should not lead to distrust of the consumer given that the level of food safety in our country and in the Western world is very high, but it should sharpen the vigilance of stakeholders within the chain, in order to maintain and further improve its current status and increase awareness with respect to chemical risks.

In a first part of the symposium the current state of the art, challenges and new developments of risk management and risk assessment are given from four different perspectives. The European Commission's viewpoint on the risk management approach to be followed within Europe is presented and confronted within an international context to the approach followed in Canada. A third perspective is the industrial one: how does the food industry assess and controls (new) chemical risks? Of course also the scientific perspective is addressed, more particularly EFSA's work with respect to harmonization and guidelines of risk assessment approaches used within Europe.

In a second session, some specific chemical risks are addressed in more detail. Results of a Belgian human biomonitoring study shows which metabolites of chemical contaminants are most frequently encountered in the human body. Although they can be considered as physical contaminants, microplastics, especially present in aquatic systems, represent a particular challenge for both the assessor and the manager because of major knowledge gaps. Similarly, the knowledge on nanomaterials, present already in various foods and other consumer goods, is quite limited, but growing. Finally, to illustrate the complexity of managing risks within a global food chain and a circular economy, the case of mineral oil is presented.

In a third session, a perspective of the future is presented from two different angles: the EU policy on the long term and the national policy on the shorter term. Using various scenarios of how the world and the position of the EU within it will evolve till 2050, different options for EU food safety policy and their impact are presented. As the robustness of food safety management systems are unfortunately best challenged when a crisis occurs, lessons can be learned from them in order to further improve these systems for the future. Considering the recent fipronil crisis as a good example, a reflection from the Belgian FASFC is therefore made.

Bruno DE MEULENAER
Ghent University, Belgium – SciCom member

Session 1:
State of the art, challenges and new developments

CONTROL OF CHEMICAL HAZARDS IN THE FOOD CHAIN: CHALLENGES FOR THE RISK MANAGERS

Frans VERSTRAETE

European Commission, Brussels (Belgium)

Frans Verstraete graduated in 1985 as agricultural engineer at the University of Ghent (Belgium). After his studies he held positions at the University of Ghent and thereafter at the Belgian Ministry of Agriculture and he was for a period technical adviser of the Belgian Minister of Agriculture. He is working for the European Commission since 1997. In the European Commission he has had various functions but since 2000 he is working at the Directorate General Health and Food Safety. He is responsible for the elaboration, development and management of the EU-legislation concerning certain contaminants in feed and food.

CHALLENGES AND NEW DEVELOPMENTS IN CHEMICAL RISK ASSESSMENT: A VIEW ON CHEMICAL CONTAMINANTS

Katleen BAERT

European Food Safety Authority - EFSA, Parma (Italy)

Katleen Baert graduated in 2001 as bio-engineer in chemistry from Ghent University. She obtained her Ph.D. at Ghent University in the field of probabilistic exposure assessment. During that period, she worked on biological and chemical hazards such as mycotoxins, *Campylobacter* and *Salmonella*. After that she joined the Belgian Food Safety Agency as a risk assessor for biological and chemical hazards. She joined EFSA in 2010, where she currently works as scientific officer for the BIOCONTAM unit.

ABSTRACT

The way in which risk assessments are performed in Europe has evolved during the last decades. There is a continuous process of refining existing risk assessment approaches and developing new, innovative approaches. A continuous process, since implementation of the approaches typically triggers further refinements. By publishing guidance documents, EFSA contributes to the harmonisation of the way in which risk assessment methodologies are applied. Examples of recent guidance documents in relation to chemical risk assessment are given. Besides a methodology, a risk assessment also needs data. Dealing with a lack of data, and knowledge in general, is a hurdle that every risk assessor has to take. Examples of efforts made in this field are outlined in this text.

INTRODUCTION

In 1975, the first reports of the Scientific Committee for Food, including opinions on mercury in food and erucic acid in rapeseed oil, were published. Since then, the way in which risk assessments are performed in Europe has evolved. The risk assessment community is continuously looking for new and better ways to deal with the challenges of today and tomorrow, and to elaborate innovative risk assessment approaches.

INNOVATION

Innovation is a prerequisite to develop new risk assessment approaches. From its start, the European Food Safety Agency (EFSA) has invested in innovative risk assessment methodologies by developing them in-house or by assessing innovative methods originally designed by others. By publishing guidance documents, EFSA contributes to the harmonisation of the way in which these innovative risk assessment methodologies are applied. Below, some examples are given of guidance documents on innovative risk assessment methodologies relevant for chemical risk assessment. During the presentation, some of these guidance documents will be discussed in detail and illustrated with examples.

BENCHMARK DOSE (BMD) APPROACH IN RISK ASSESSMENT

Recently, EFSA published an update of its guidance on the use of the benchmark dose (BMD) approach in risk assessment (EFSA Scientific Committee et al., 2017a). The BMD approach is the preferred approach to define a reference point (i.e. the dose that can be used as a starting point for the risk assessment). In the recent update, main revisions were made regarding the application of the BMD approach. A flowchart has been included that guides the assessor through the different steps when performing a BMD analysis.

WEIGHT OF EVIDENCE AND BIOLOGICAL RELEVANCE

In the context of harmonisation and development of new methodologies for risk assessment, EFSA's Scientific Committee adopted in July 2017 two guidance documents on key topics: weight of evidence and biological relevance.

The guidance document on biological relevance provides a general framework for establishing the biological relevance of observations at different stages of the risk assessment, namely the development of the strategy, collection and extraction of data, and appraisal and integration of the relevance of each data set (EFSA Scientific Committee et al., 2017b).

Weight of evidence is defined in the guidance as a process in which evidence is integrated to determine the relative support for possible answers to a question. The guidance does not prescribe a specific method but lists a set of criteria for comparing weight of evidence methods to assist in the evaluation of relative strengths and weaknesses of the different methods (EFSA Scientific Committee et al., 2017c).

RISK ASSESSMENT OF SUBSTANCES THAT ARE GENOTOXIC AND CARCINOGENIC

In 2005, EFSA published a harmonised approach for the risk assessment of substances that are genotoxic and carcinogenic. These substances have the potential to directly interact with DNA and to cause cancer. It is generally assumed that there may be a risk associated with exposure to low amounts, especially when the exposure takes place on a regular basis. There was a clear need for such guidance since there was no international scientific consensus regarding the risk assessment approach for such substances. Within the European Union, the advice was given to reduce the exposure to a level that is as low as reasonably achievable (ALARA). However, this approach does not allow risk managers to set priorities. EFSA's Scientific Committee advises to use the margin of exposure (MOE) approach for the assessment of these substances (EFSA, 2005).

THRESHOLD OF TOXICOLOGICAL CONCERN (TTC) AS A SCREENING TOOL FOR PROVIDING SCIENTIFIC ADVICE

In 2012, EFSA's Scientific Committee published an opinion on the TTC approach and concluded that "the TTC approach can be recommended as a useful screening tool either for priority setting or for deciding whether exposure to a substance is so low that the probability of adverse health effects is low and that no further data are necessary" (EFSA Scientific Committee, 2012c).

In 2014, EFSA and WHO (World Health Organisation) organised a scientific workshop to consider whether the current TTC approach is still fit for purpose, or whether an update or review is needed (EFSA & WHO, 2016). It was concluded that the TTC approach is fit for purpose as a screening tool, to assess low dose chemical exposures and to identify those substances for which further data are necessary to assess the human health risk. Recommendations were made to improve and expand the TTC concept. As a follow-up, EFSA will update the 2012 Scientific Opinion on TTC (foreseen deadline: 31/12/2018).

RISK/BENEFIT ASSESSMENT OF FOOD

In some particular cases it is important for the risk manager to weigh the risks against the benefits on the basis of a risk-benefit assessment. In 2006, EFSA organised a Scientific Colloquium on Risk-benefit analysis of foods (EFSA, 2006b). As a follow-up, EFSA's Scientific Committee developed a guidance document on the methodology, approaches, tools and potential limitations in risk-benefit assessment (EFSA Scientific Committee, 2010).

GENOTOXICITY TESTING STRATEGIES

The Scientific Opinion on genotoxicity testing strategies recommends a step-wise approach for the generation and evaluation of data on genotoxic potential (EFSA Scientific Committee, 2011).

DIETARY EXPOSURE ASSESSMENT

Besides major effort in data collection for dietary exposure assessment, EFSA has also worked on the methodology for dietary exposure assessment such as dealing with left-censored data and probabilistic modelling (EFSA, 2010a; EFSA PPR Panel, 2012).

… A NEVER-ENDING STORY

Implementation of new approaches typically triggers further refinements, resulting in a continuous process of change. In addition, other interesting topics are waiting to be addressed. For example, EFSA is currently working on the development of harmonised methods for the risk assessment of combined exposure to multiple chemicals.

LACK OF KNOWLEDGE; A RISKY ISSUE

How can we reply to the risk manager's questions and prepare a high-quality output, given that we have no or limited data on specific areas? A re-occurring question that risk assessors are facing, particularly in the area of chemical contaminants where no dossier is prepared by an applicant.

The guidance on selected default values of the EFSA's Scientific Committee provides a set of default values, and their rationale, that can be used in the absence of actual measured data. This includes default values for food intake and human body weight, conversion factors to calculate doses from concentrations in feed or drinking water in experimental animal studies and uncertainty factors when using animal data for the risk assessment (EFSA Scientific Committee, 2012a).

Large efforts have also been made in the collection of occurrence and consumption data for dietary exposure assessment. These are shared efforts between EFSA and all data providers. EFSA's Comprehensive European Food Consumption Database is the most complete and detailed dataset currently available in the EU. It was built in 2010 from existing detailed national information on food consumption provided by EU Member

States and food consumption data for children obtained through an EFSA Article 36 project. Details on how the Comprehensive Database is build and used are published in a Guidance (EFSA, 2011). EFSA has also received a mandate to collect on a continuous basis the available data on the occurrence of chemical contaminants in food and feed. This collection follows EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010b).

Despite major efforts to gather evidence, we must realise that we can never be completely certain and an uncertainty chapter has (or should) become a standard item in every risk assessment. One of the key questions in risk assessment is how to take the uncertainties into account in a way that allows a clear and transparent conclusion regarding the risk. For many years, EFSA is active in this field:

- EFSA's Scientific Committee published a scientific opinion related to uncertainties in dietary exposure assessment in 2006 (EFSA, 2006a) and a scientific opinion on general principles to ensure the transparency of risk assessment, including the need to identify and characterise uncertainties in 2009 (EFSA, 2009).
- In 2013, EFSA's Scientific Committee started to work on a self-task mandate to develop Guidance on Uncertainty in Scientific Assessment to increase robustness, transparency and openness of scientific assessments. Following this self-task mandate, EFSA organised a workshop in 2015 and launched in the same year a public consultation of the draft guidance. The draft guidance has been piloted in several scientific opinions by different EFSA Panels, and the outcome of this piloting phase is taken into account for the finalisation of the guidance document.

CONCLUSIONS

The aim of chemical risk assessment is protecting consumers' health by preparing high-quality scientific advice. In this context, efforts have been made to collect evidence and develop innovative and refined risk assessment approaches. However, in a continuous process of improvement, further developments are expected.

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ADDRESSING FOOD CHEMICAL SAFETY RISKS THROUGH RISK-BASED REGULATORY MEASURES – DOMESTIC AND INTERNATIONAL PERSPECTIVES

Samuel GODEFROY

Université Laval, Québec (Canada), Queens University, Belfast (UK)

Samuel Godefroy graduated from the University of Pierre et Marie Curie (Paris) as (bio)chemical engineer where he obtained his Ph.D. in analytical chemistry. He assumed senior food regulatory positions at the executive level with Health Canada for over 10 years. In addition, he worked with the World Bank's Global Food Safety Partnership where a Strategic Framework was developed and adopted under his leadership to guide actions in food safety capacity building globally. From 2011 to 2014, he served as Vice Chair of the Codex Alimentarius Commission for development and adoption of the 2014-2019 strategic plan. Currently he serves as a senior food science and regulatory expert on a number of advisory bodies, including the United Nations Industrial Development Organization (UNIDO) and to the International Advisory Committee of the China Centre for Food Safety Risk Assessment (CFSA). Since 2015, he is a Full Professor of Food Risk Analysis and Regulatory Policies at University Laval (Canada). He is also professor at the Global Institute for Food Security (GIFS) at Queen's University of Belfast (UK).

ABSTRACT

By 2050, 2 billion more people will require access to food. Our planet is already experiencing food shortages, with over a billion people going hungry on a regular basis. How can we embark on feeding 9 billion people without exhausting our planet's resources, already under pressure? Reducing food waste, producing more efficiently and innovating drastically are part of the solutions being explored. Novel sources of protein, new methods of production, recycling, the reliance on new additives and novel process are all being explored. All these approaches will no doubt require regulatory oversight. In particular, the management of chemicals in food, whether as result of deliberate use or as a result of contamination (natural or intentional) will require to be revisited.

This presentation will review the drivers of change for food chemical management, with the emergence of new challenges related to the use and presence of chemicals in food and the development of new risk assessment methodologies. The review of risk management strategies and the need for more reliance on common approaches pursued through international standard development, with the underlying scientific foundation will also be discussed.

ASSESSMENT AND CONTROL OF (NEW) CHEMICAL RISKS: A FOOD INDUSTRY APPROACH

Walburga SEEFELDER

Nestlé, Vevey (Switzerland)

Walburga Seefelder is holding a university degree in Food Chemistry and attained a PhD in 2003 from the University of Würzburg in Germany. After a 2 year post doc focusing on MCPD-esters at the Nestlé Research Centre (NRC) in Lausanne, she joined Nestlé as an Analytical Scientist in the area of mycotoxins. In 2007 she was appointed as an Early Warning System Manager dealing with the detection and management of emerging food safety issues. In 2012 , she was assigned as Crisis Manager and later as Issue & Food Safety Manager for Chemical Contaminants at Nestlé Nutrition Business. Currently she holds the position of Group Expert for Chemical Food Safety, within Corporate Nestlé Quality Management. She is active member of several industry expert groups.

ABSTRACT

In order to manage food safety risks, food industry needs to react proactively to (new) chemical hazards that might potentially contaminate foods and beverages along the process chain, from raw materials to final products. To detect potential food safety threats beforehand, Nestlé applies an Early Warning (EW) system complementary to Quality Management. Being a preventive approach, the EW system provides mitigation and appropriate control options as a guidance to Quality Management.

Nevertheless, managing potential food safety threats is accompanied with a number of constraints and challenges requiring joint efforts of the food industry and regulatory bodies. This is illustrated by recent food safety issues, including the occurrence of chlorate in fruits and vegetables, the presence of 4-methylimidazone in processed food and ingredients and of monochloropropanediol- and glycidyl-esters in infant formula, and contamination of food with mineral oil hydrocarbons.

INTRODUCTION

Protecting consumers from harmful contaminants in food is essential if food industries are to retain consumers' trust and confidence. This requires a thorough understanding of potential contaminant hazards from raw materials and ingredients, as well as an understanding of potential toxins that might form during food processing, such as for example acrylamide and 3-MCPD esters. The Early Warning (EW) system in place at Nestlé can be described as a complementary tool to support Quality Management in managing potentially harmful contaminants.

THE EARLY WARNING (EW) SYSTEM

The Early Warning (EW) system is a proactive and scientific approach to detect - in advance - potential food safety threats. EW enables preparedness and focus, providing avenues to mitigate issues, implement appropriate controls, before such issues seriously impact operations (examples: semicarbazide migrating into foods from jar lids; mepiquat – a plant growth regulator - formed naturally in roasted coffee and cereals). Such discoveries are in most cases not associated with a food safety hazard but may lead to a risk of "non-compliance" in some countries and consequently costly withdrawals / recalls of food products. Within the EW program, new and emerging issues are fully assessed following a defined process using available scientific data and knowledge. Tools for issue detection include among others cross-functional communication technical networks, web scouting, and analytical data mining. The gathered information is assessed using available scientific knowledge in order to provide guidance to Quality Management for further issue control (see **Figure 1**).

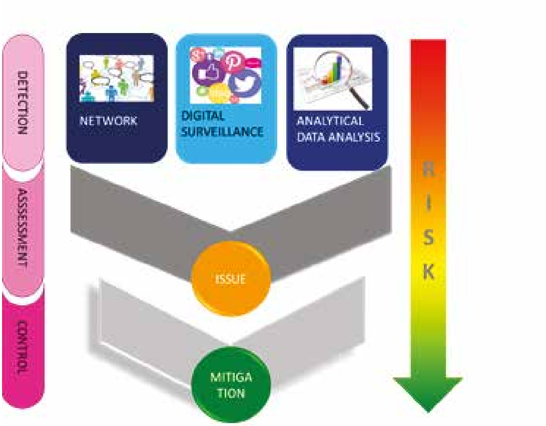


Figure 1. Principles of the Early Warning System

CASE STUDIES

The food industry has an important role to play in being transparent with new emerging findings, but also highlighting certain constraints and challenges. Following topics are providing examples where joint efforts of the food industry and regulatory bodies are required to address emerging risks.

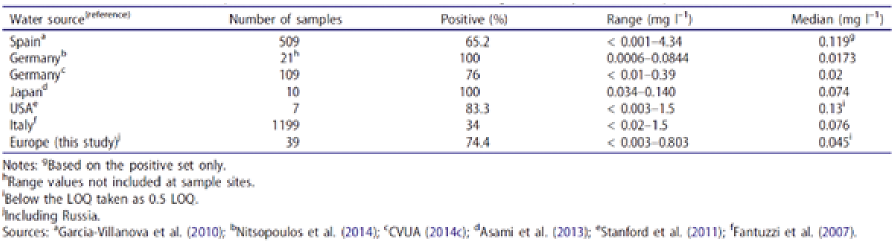
CHLORATE RESIDUES IN FRUITS AND VEGETABLES

Recently, reports have been published on the occurrence of chlorate mainly in fruits and vegetables. Chlorate is a by-product of chlorinating agents used to disinfect water, and can be expected to be found in varying concentrations in drinking water. Chlorate, however, can also be used as a pesticide, but authorisation was withdrawn in the European Union (EU), resulting in a default maximum residue limit (MRL) for foods of 0.01 mg kg^{-1}. This default MRL has now led to significant problems in the EU, where routinely disinfected water, used in the preparation of food products such as vegetables or fruits, leaves chlorate residues in excess of the default MRL, and in strict legal terms renders the food unmarketable.

Recent published data (Kettlitz et al., 2016) indicate that residues of chlorate do not originate from the use of chlorate as a pesticide but mainly come from the occurrence of chlorate as an unavoidable disinfectant by-product. A further entry point of chlorate into foods may be via additives/ingredients that may contain chlorate as a by-product of the manufacturing process (e.g. electrolysis). Disinfectants for water treatment play an essential role in the control of microbial, viral or parasitic pathogens and thereby limit the occurrence of food-borne diseases. One commonly and widely used approach by many municipal drinking water suppliers is the use of chlorine as a disinfectant.

Table 1 illustrates the occurrence of chlorate in potable water, reported in selected published studies conducted across different countries, as well as a limited sampling conducted during our surveillance program across Europe (including Russia).
Chlorination is legitimately applied in the EU by some member states to disinfect water to render it potable; in the case of chlorine dioxide or hypochlorite treatment, chlorate residues are expected to be present at low amounts in potable water. However, no maximum levels for chlorate in drinking water have been set in the EU.
In the absence of EU levels for chlorate in water, any future EU regulations must consider the already available WHO guideline, and the continued importance of the usage of oxyhalides for disinfection purposes.

Table 1. Chlorate occurrence in potable water (different studies including this study across Europe) (Kettlitz et al., 2016)



Water source$^{(reference)}$	Number of samples	Positive (%)	Range (mg l^{-1})	Median (mg l^{-1})
Spain^{a}	509	65.2	< 0.001–4.34	0.119^{g}
Germany^{b}	21^{h}	100	0.0006–0.0844	0.0173
Germany^{c}	109	76	< 0.01–0.39	0.02
Japan^{d}	10	100	0.034–0.140	0.074
USA^{e}	7	83.3	< 0.003–1.5	0.13^{i}
Italy^{f}	1199	34	< 0.02–1.5	0.076
Europe (this study)^{j}	39	74.4	< 0.003–0.803	0.045^{i}

Notes: [g] Based on the positive set only.
[h] Range values not included at sample sites.
[i] Below the LOQ taken as 0.5 LOQ.
[j] Including Russia.
Sources: [a] Garcia-Villanova et al. (2010); [b] Nitsopoulos et al. (2014); [c] CVUA (2014c); [d] Asami et al. (2013); [e] Stanford et al. (2011); [f] Fantuzzi et al. (2007).

4-METHYLIMIDAZOLE IN PROCESSED FOOD AND INGREDIENTS

The chemical 4-methylimidazole (4-MEI) is a well-known by-product present in certain types of caramel colorants, i.e. E150c (Class III) and E150d (Class IV). 4-MEI is also formed adventitiously during cooking processes such as toasting, roasting and grilling. As a result, it is present in very small amounts in a wide range of foods and beverages, including those prepared in the home (e.g. toasted bread). Current scientific evidence does not indicate that the levels of 4-MEI commonly found in colorants or in foods and beverages are a health concern. Through the Nestlé Research Program it has been demonstrated that 4-MEI can be "naturally" formed during cooking and processing practices (Mottier et al., 2017).

Figure 2 depictures as an example the content of 4-MEI in roasted malt samples (for beer production) that were obtained from a malting company in Belgium. Color measurements of the roasted malts revealed a positive correlation between color (correlated to intensity of thermal load) and 4-MEI content.

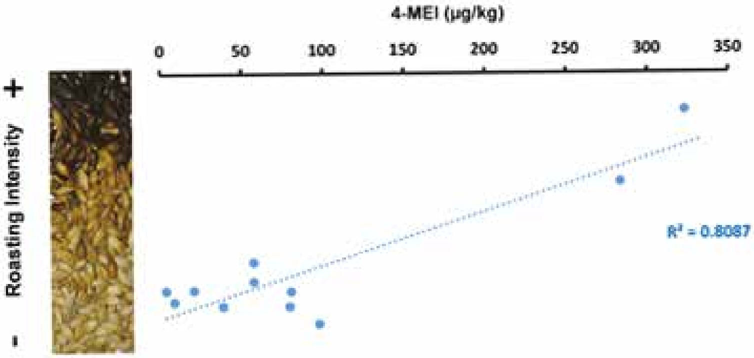
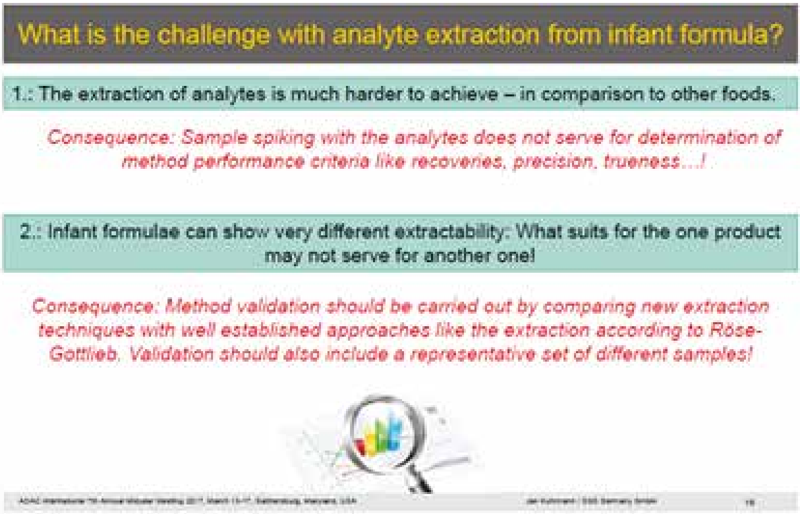


Figure 2. Correlation between 4-MEI levels and malt roasting intensity (color measurement CbL, n = 11).

This shows that 4-MEI is not a reliable indicator of the addition of caramel colorants to certain processed foods and beverages.

MONOCHLOROPROPANEDIOL- AND GLYCIDYL-ESTERS IN INFANT FORMULA

Scientific and regulatory bodies in Europe and elsewhere are currently studying finished infant formula products and moving towards regulatory steps to address the possible presence for monochloropropanediol(MCPD)-esters and glycidyl-esters (GE) in these products. While limits are on the way to be established, there is currently no validated method of analysis for the determination of these compounds in infant formula. Potential false compliance issues could be expected. **Figure 3** is highlighting challenges specifically related to the matrix of infant formulas. An AOAC Working Group supported by the industry trade association of global infant formula manufacturers has been established aiming to establish a reliable testing procedure (Kuhlmann, 2017).



What is the challenge with analyte extraction from infant formula?

1.: The extraction of analytes is much harder to achieve – in comparison to other foods.

Consequence: Sample spiking with the analytes does not serve for determination of method performance criteria like recoveries, precision, trueness…!

2.: Infant formulae can show very different extractability: What suits for the one product may not serve for another one!

Consequence: Method validation should be carried out by comparing new extraction techniques with well established approaches like the extraction according to Röse-Gottlieb. Validation should also include a representative set of different samples!

Figure 3. Analytical challenges and gaps in existing extraction methodologies for 2- and 3-MCPD and GE in finished infant formula products

CONTAMINATION WITH MINERAL OIL HYDROCARBONS

Mineral oil hydrocarbons (MOH) are chemical compounds that can enter food through environmental contamination, food processing equipment, food additives and food contact materials. As a follow up of the 2012 EFSA conclusions for MOH, the European Commission has organized a monitoring of MOH (Commission Recommendation (EU) 2017/84) to better understand the relative presence of MOH fractions in food commodities that are major contributors to dietary exposure. The availability of reliable analytical methods for data collection are crucial in this context as they guarantee that correct data for risk assessment purposes are obtained but also that root cause analysis activities are efficient.

The conventional liquid chromatography-one-dimensional GC coupled to a flame ionisation detector (LC-GC-FID) is a useful screening method, but in cases of positive samples any 'humps' of MOH require confirmation by a selective detector to avoid false positives (**Figure 4**) (Spack et al., 2017).

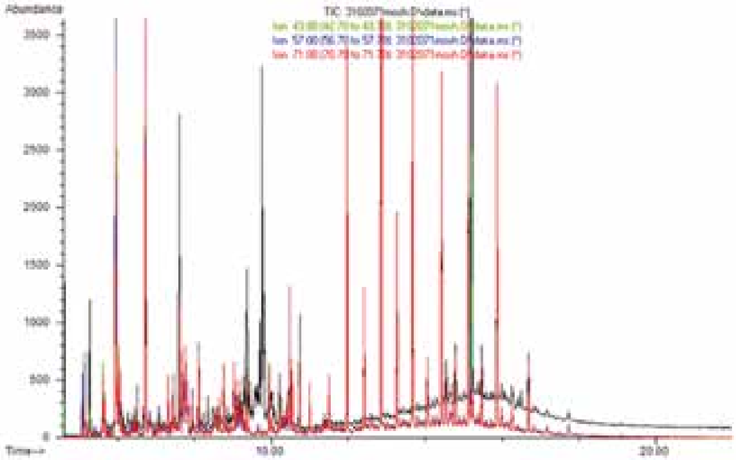


Figure 4. Chromatograms depicting a false-positive MOH sample (chocolate) (Spack et al., 2017)

Further knowledge has to be created to better characterize and profile the MOH "humps". To support root cause analysis further knowledge on the identification of marker substances needs to be acquired to allow a more specific conclusion on the source of contamination. In fact, the identification of chemical markers should be part of the mineral oil analysis in food, as proposed in the flow chart depicted in Figure 5.

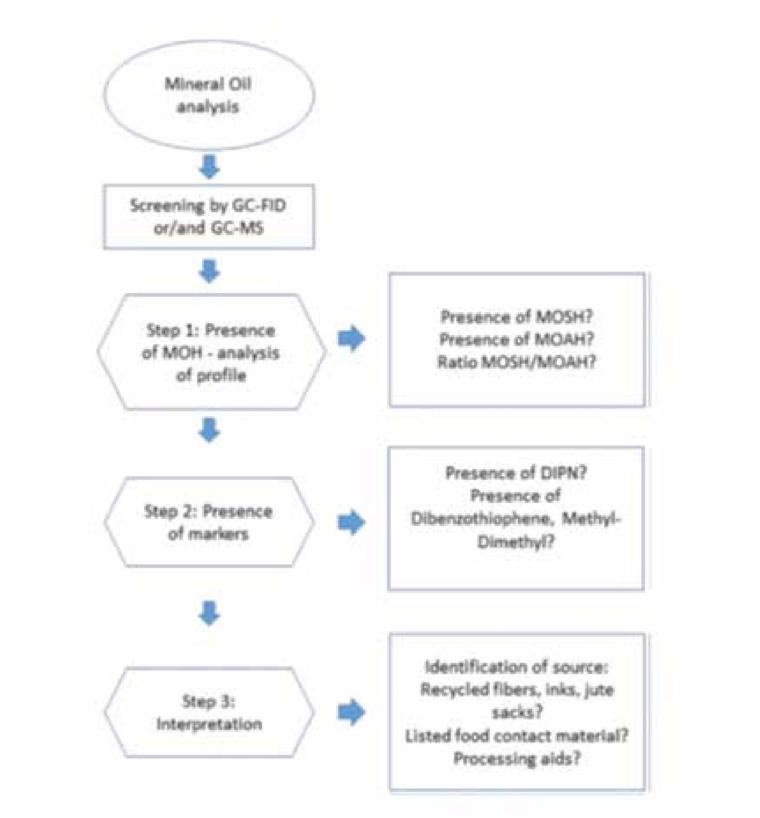


Figure 5: Proposed work flow to identify the source of mineral oils in food products (Spack et al., 2017)

The overall approach used entails: profile analysis, marker identification, and interpretation and final quantification. This process is fully aligned with the recently issued Commission Recommendation (EU) No. 2017/84 that stipulates identification of the origin of mineral oil contamination.

In the case of chemical markers, several substances can lead to a more specific conclusion on the source of the oils. For example, methyl-dibenzothiophene or dimethyl dibenzothiophene can be detected in cocoa products originating from the mineral oils used to manufacture jute sacks.

Further work in this area is highly encouraged, and will assist in identifying the sources of mineral oil hydrocarbons in foods.

CONCLUSIONS

The hurdles encountered when assessing and handling (new) chemical hazards, are illustrated by means of four recent food safety cases, including chlorate, 4-methylimidazole, monochloropropanediol- and glycidyl-esters, and mineral oil hydrocarbons. Main hurdles relate to knowledge gaps, the identification of contamination routes and analytics, but also to the regulatory framework. Managing (new) chemical hazards therefore entails joint efforts of food industry and regulatory bodies.

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Session 2:
Exposure and emerging issues

EXPOSURE OF THE BELGIAN CONSUMER TO CHEMICAL CONTAMINANTS AND HEALTH CONSEQUENCES

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ABSTRACT

Human biomonitoring (HBM) measures the levels of substances in body fluids and tissues. There is increasing interest in European countries to use human biomonitoring to support chemical risk assessment. In Flanders, a human biomonitoring programme of the general population has run for more than 15 years. Individual data that are collected allow to evaluate internal exposure in relation to personal characteristics, including dietary habits, hence providing opportunities to improve chemical risk assessment also in relation to food safety.

INTRODUCTION

Chemicals may enter the body by various routes: inhalation, ingestion, dermal exposure. As an example, consumers can be exposed to bisphenol A by eating canned food as well as by skin contact with thermal paper. At the end, it is the total concentration of the chemical which enters the body that is important for potential health effects. Human biomonitoring measures directly the concentration of chemicals or their metabolites in the body, hence aggregating exposure by various routes. Measuring chemical exposure biomarkers demonstrates at which levels a chemical is effectively taken up by the body. It is not the presence of chemicals in our environment that poses concern for health effects, but rather the levels that may reach some sensitive target organs and tissues in the body. These internal exposure concentrations can be associated with effect biomarkers such as DNA damage, hormone or cytokine levels, that are known to be mechanistically linked to the chemical exposures and to certain diseases. These exposure biomarkers can also be linked to health outcomes such as asthma occurrence or neurobehavioural changes by following the study population over time. Linking exposure biomarkers with effects and health outcomes strengthens the evidence for the causal pathway between exposure and health. In addition, the exposure biomarkers can also be linked with personal information of the participants on their age, sex, the place where they live and work, but also with their life style and behaviour such as smoking, hobbies and dietary intake. This requires an interdisciplinary collaboration and thorough knowledge on potential factors that determine the internal exposure levels, on potential sources and exposure pathways.

Since 2002 the Flemish authorities have funded the Flemish Environmental Health Surveillance Programme in which the general population of Flanders is biomonitored in 4 successive campaigns. In total 5825 participants have been recruited with emphasis on newborns and their mothers, adolescents of 14 and 15 years old and the older population. Urine, blood and sometimes hair samples were taken and up to 50 different biomarkers have been measured, including many substances that are potentially associated with food intake. We will focus on how these data have informed us on food related chemical exposure risks. In addition in Europe a new initiative, HBM4EU, has been initiated as an European Joint Project, co-financed by Horizon 2020 and the consortium partners (Ganzleben et al., 2017). The programme builds on existing programmes and has as main aim to coordinate and advance human biomonitoring in Europe in order to provide better evidence of the actual exposure of citizens to chemicals and the possible health effects to support policy making.

LINKING DIETARY INFORMATION WITH INTERNAL EXPOSURE

Diet is a known source of human contaminant intake. This may relate to the presence of residues from pesticides in food, food grown in polluted areas, food packaging materials that migrate in food, food preparation techniques. Human biomonitoring programs often obtain individual information on dietary habits by e.g. food frequency questionnaires or 24 hr food recall diaries. This information can be used in univariate and multivariate statistical regression techniques to explain the variability of the internal exposure levels (exposure biomarkers) in the study population. This offers the unique possibility to shed some light on the association between dietary intake and exposure biomarkers.
Table 1 illustrates the associations that have been observed in the Flemish Environmental Health Surveillance programme (FLEHS). We have results of three cycles of the programme: FLEHS I: 2002-2006, FLEHS II: 2007-2011, FLEHS III: 2012-2015. In all campaigns we recruited mother-newborn pairs to monitor exposure of a sensitive population at the beginning of life, adolescents of 14-15 years which are considered as sentinels of the environment where they grew up without yet commuting and being occupationally exposed, and adults between 20 and 40 or between 50 and 65 years to monitor exposures that are more specific for adult life style. We aimed for 1600 participants for each age group in FLEHS I (though only 1200 newborn-mothers were recruited). In FLEHS II and FLEHS III, between 200 and 300 study participants per age group were recruited by a randomised sampling strategy to obtain a representative sample of the general population for the selected age group. In addition about 400 adolescents were recruited in industrialised so-called "hot spot areas" of Genk Zuid and Menen (FLEHS II). The recruitment procedure, techniques for biomarker analysis and statistics can be consulted (Schoeters et al., 2017 & 2012).

The associations between the exposure biomarker concentrations and dietary intake were studied in each of the study populations separately. In line with other literature findings, we confirmed that arsenic and mercury were associated with fish intake, nickel with chocolate, nuts and seeds (Castaño et al., 2015; Molin et al., 2015; Wilhelm et al., 2013). In the oldest study (FLEHS I), cadmium and lead were associated with canned food and with vegetables, fruit, rice , intake of grain products (cadmium) and with leafy vegetables (lead). The use of local vegetables was positively associated with higher internal exposure levels of cadmium, lead and nickel in adolescents from hot spot areas. The biomarker levels of persistent halogenated pollutants **(Table 2**) that are known to be lipophilic, were associated with intake of fish (PCBs, oxychlordane, trans-nonachlore, lindane), animal fat (PCBs, pp'-DDE, HCB), eggs (pp'-DDE, HCB, oxychlordane, trans-nonachlore, perfluorononanoic acid (PFNA)), milk and milk products (oxychlordane), and offal (PCBs, pp'-DDE, lindane, perfluorooctanoic acid(PFOA). Consumption of locally grown vegetables was associated with increases of pp'-DDE, HCB, oxychlordane and of perfluorooctane sulfonate (PFOS). Consumption of locally produced eggs was associated with PCBs, pp'-DDE, HCB en PFOS, self-caught fish with PCBs, pp'-DDE and HCB, lindane with the use of well water. The increases were seen in the general population and were not restricted to hot spot areas. Significant associations ($p<0.05$) showed always a positive correlation, but they did not always occur in the same age group or in each study area. This may relate to specific characteristics of the study population e.g. in hot spot areas and to the size of the study populations which influences the statistical power to identify significant differences. Although human exposure levels can be predicted based on measurements of contaminants in food and subsequent exposure modelling, human biomonitoring allows to validate the model predictions and adds to the information by taking into account differences in personal habits and characteristics. Increases in exposure levels related to consumption of locally produced food supported policy campaigns in Flanders to advice home farming (consumption of eggs, disposal of persistent pesticides) (Reynders et al., 2017).

Table 1. Overview of associations between increasing levels/grades of exposure determinants and exposure biomarkers of heavy metals, measured in different Flemish biomonitoring campaigns.

Exposures	Cadmium				Lead		Manganese	Copper	Thallium		Nickel		Arsenic						Mercury	
	Newborns*	Adolescents**	Adolescents*	Adults*	Adolescents*	Adults*	Adults*	Newborns*	Adolescents*	Adolescents**	Adolescents**	Adults**	Adolescents**	Adolescents**	Adolescents**	Adolescents**	Adolescents*	Adults**	Adolescents$	Adolescents$
Food: specific sources: fish													🟧 ↑e, f	🟨 ↑ e, f	🟦 ↑ f	🟩 ↑d, e	🟩 ↑f	🟦 ↑e, f	🟨 ↑	🟧 ↑
Food: specific sources: vegetables, fruit, rice, grain	⬜ ↑			⬜ ↑				🟩 ↑a				⬜ ↑b								
Food: leafy vegetables						⬜ ↑														
Food: specific sources: local vegetables		🟧 ↑	🟨 ↑						🟨 ↑	🟧 ↑	🟧 ↑									
Food: Specific sources: crustaceans																		🟩 ↑f		
Food: Specific sources: chocolat											🟧 ↑									
Food: Canned food				⬜ ↑	⬜ ↑															

*: measurement in blood
**: measurement in urine
$: measured in hair
a: legumes; b: nuts and seeds; c: MMA; d:DMA; e:Toxicologically relevant arsenic (TRA); f: total arsenic

⬜ Tested in Flemish Environment and Health Study FLEHS I (2002-2006)

🟦 Tested in Flemish Environment and Health Study FLEHS II (2007-2011);

🟩 Tested in Flemish Environment and Health Study FLEHS III (2012-2015);

🟧 Tested in Flemish biomonitoring study in Genk-Zuid (2007-2011);

🟨 Tested in Flemish biomonitoring study in Menen (2007-2011);

Table 2. Overview of significantly positive ↑(p<0.05) associations between increasing levels/grades of exposure determinants and exposure biomarkers of persistent organic compounds measured in blood samples of participants of different Flemish biomonitoring campaigns.

Exposure	Sum PCBs					P,p’-DDE					HCB					Oxychlordane		Trans-nonachlore			Lindane		PFAS			
	Newborns	Newborns	Adolescents	Adolescents	Adults	Newborns	Newbirns	Adolescents	Adolescents	Adults	Newborns	Adolescents	Adolescents	Adolescents	Adults	Newborns	Adolescents	Newborns	Adolescents	Adults	Newborns	Adolescents	Newborns	Adolescents	Adults	Adults
Food: specific sources: fish		↑	↑														↑	↑	↑	↑		↑				
Food: specific sources : animal fat			↑		↑					↑		↑			↑											
Food: specific sources: vegetables, fruit, rice, grain															↑											
Food: specific sources: eggs						↑		↑				↑					↑		↑						↑i	
Food: specific sources : milk and milk products																↑										
Food: specific sources: offal	↑		↑					↑													↑	↑	↑h i			
Food: self caught fish			↑				↑		↑			↑	↑	↑												
Food: specific sources: local food				↑	↑				↑	↑		↑														
Food: specific sources: local vegetables							↑	↑	↑	↑	↑	↑			↑	↑							↑g	↑g		
Food: specific sources: local eggs		↑	↑				↑	↑	↑			↑											↑g	↑g	↑g	↑g
Food: specific sources: well water																					↑					
Food: specific sources: potatoes																							↑j			
Food: Mediterranean diet																									↑	
Food: Specific sources: crustaceans																									↑i	

PCBs: polychlorinated biphenyls; P,p’-DDE: dichlorodiphenyldichloroethylene ; HCB: hexachlorobenzene ; PFAS: Per/polyfluorinated alkylated substances, g: PFOS: perfluorooctane sulfonate ; h: PFOA: perfluorooctanoic acid ; i:PFNA: perfluorononanoic acid ; j:PFHxS: Perfluorohexanesulfonicacid

EXPOSURE AND EFFECTS

Human biomonitoring allows to link individual exposure data to individual health outcomes. Most powerful are prospective studies in which exposure is measured and the health of the study participants is followed over time. FLEHS studies have reported associations of measured exposure biomarkers at birth with postnatal health outcomes (birth weight, neurobehaviour) suggesting that actual exposure levels in Flanders are still of health concern (Govarts et al., 2016; Sioen et al., 2013). Often data of different studies need to be pooled to obtain enough statistical power to evaluate exposure response associations. European collaborative projects have shown increasing prenatal PCB exposure related to reduced birth weight (Casas et al., 2015) and increasing prenatal p,p'-DDE exposure to increased postnatal weight gain (Iszatt et al., 2015). Prenatal PFAS exposures are associated with reduced vaccination responses (Grandjean et al., 2017). These studies are costly and require long time follow up. Most studies address well known compounds such as the persistent halogenated compounds or heavy metals. There are fewer long term follow-up studies of newer compounds, such as the phthalates, newer pesticides or bisphenols. These compounds are not persistent, do not accumulate in the body and are rapidly excreted. As such, the characterization of the exposure is less accurate and requires repeated sampling or large study populations. The observational nature of the population studies hampers their interpretation. Humans are exposed to combinations of chemicals. Most studies measure only one or a few chemicals. Health effects may be related to the combination of chemicals and not to a single chemical that is taken as a proxy for the mixture that is present in the body. It is important that findings are confirmed in different study populations and that mechanistic evidence of causality supports the human exposure studies either by experimental work or by introducing molecular mechanistically based markers in the epidemiological studies.

CONCLUSIONS

In the food safety area, human biomonitoring offers the unique possibility to validate predicted exposures to environmental contaminants that are based on monitoring of contaminants in food and exposure modelling. Collecting information at the level of the individual allows to introduce personal exposure levels and to study exposure variability that relates to dietary habits, but also to age, sex, socio-demographic characteristics and spatial characteristics, such as living in contaminated sites. However, one should be aware that many factors influence environmental exposures and it remains a challenge to explain the high interindividual variability in exposure. As exposure biomonitoring may be a better predictor of dose compared to dose calculations based on environmental monitoring, further challenges like dealing with combined exposures and accurate exposure measurements of non-persistent chemicals, need to be tackled to further support dose response studies in humans.

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MICROPLASTICS IN THE FOOD CHAIN: RISK CHARACTERIZATION FOR HUMAN HEALTH AND PREVALENCE

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ABSTRACT

The presence of microplastics in the marine and terrestrial environment has gained a lot of attention over the past decade. Especially the continuously increasing litter contamination has led to an increased concern about plastics and more specifically, microplastics in the marine environment. However, it remains unclear to what extent microplastics in the whole food basket affect human health.

Research on microplastics in seafood already led to several publications. Only recently, the presence of microplastics in a few other food items, such as salt, honey, beer and drinking water, has gained some attention. On the other hand, the analytical methods and the associated quality assessments to quantify microplastics in different food products are still evolving and not readily comparable. Therefore, total exposure of the consumer to microplastics via food is still unknown.

The main contamination routes of microplastics in food are either environmental, i.e. through contamination by the surrounding water or air, or through food processing and packaging. The relative importance of both contamination routes of food remains unclear. Also, the risks associated with microplastic exposure, being related to either chemical, biological or physical hazards, still needs to be investigated. Toxicity tests already revealed different effects on marine animals. Still, little is known on human health effects.

The current state of the worldwide research does not yet allow a sound risk characterization of microplastic exposure through food, as essential information on the daily intake of humans as well as the associated toxicity are still lacking. It is a work in progress, in which ILVO wants to play a key role, both at national and international levels.

INTRODUCTION

Plastic production increased worldwide from 1.5 million ton in 1950 to 230 million ton in 2009 (Hammer et al., 2012). Since plastics are strong, durable and buoyant, they are persistent in the environment and may be transported over long distances (Derraik, 2002). One major aspect of plastic pollution is the occurrence of microplastics. Microplastics are defined as particles <5 mm (Van Der Meulen et al., 2015). They may originate from primary as well as from secondary sources. Primary sources include particles which are produced either for direct use, such as industrial abrasives, exfoliants and cosmetics, or as precursors (resin pellets) for the production of consumer products. Secondary sources are the formation of microplastics due to the degradation of larger plastic material (Piha Henna et al., 2011).

Because of their small size, microplastics are potentially bioavailable to a wide range of organisms. They can be ingested by low trophic feeders and can be transferred through the food web to higher trophic levels (Setälä et al., 2014). As accumulation of microplastics in the marine environment became of high concern, several scientific publications focused on the presence of microplastics in seafood (e.g. Devriese et al., 2015; De Witte et al., 2014; Van Cauwenberghe et al., 2015; Van Cauwenberghe & Janssen, 2014; Vandermeersch et al., 2015). However, awareness is growing that other food matrices may also be highly contaminated. Recent years, research has extended to other food matrices such as sea salt, beer, honey, sugar, drinking water, …

Figure 1. Sources and effects of plastic exposure (© L. Devriese – ILVO, 2012)

ANALYTICAL METHODOLOGY

The analytical methodology for microplastic determination in food has strongly evolved over the last decade. However, many different methods exist, and although the analytical methods are slowly converting towards each other and standardization of quality assurance is increasing, this process is still ongoing. Therefore, the methodology should be carefully checked when interpreting public data on microplastic contamination.

The research on microplastics in food generally consists of an appropriate sampling, followed by a digestion of the matrix, filtering the digested sample, and counting and determining the microplastics. Diversification between microplastics can be made based on color, shape or size and based on polymer type (**Figure 2**). An appropriate digestion agent is capable of efficiently digesting the food matrix without degrading plastics. Acid digestion was frequently performed in previous research, but high concentrations of nitric, hydrofluoric, perchloric and sulphuric acid may damage or destroy certain polymers, particularly at high temperatures. Therefore, alkaline and enzymatic digestions are becoming the preferred methods (Dehaut et al., 2017; Lusher et al., 2017).

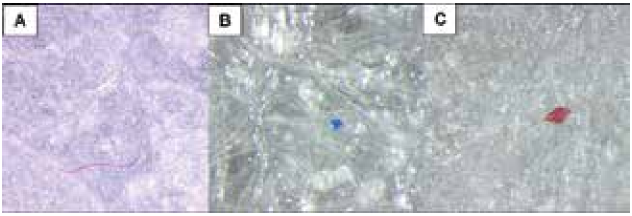

Figure 2. Example of different microplastic shapes in salt: (A) fibre, (B) granule and (C) sheet (Devriese et al., 2017a)

Microplastic analysis is subject to background contamination. Contact with plastic materials, use of non-filtered solvents or water, use of non-rinsed glassware or exposure to laboratory air may lead to highly overestimated concentrations of microplastic contamination. The use of appropriate measures against background contamination and the analysis of multiple procedure blanks are minimum requirements for high quality microplastic assessments in different food products. Also, the use of validated methods for microplastics determination is gaining importance. At the moment, this is hampered by the lack of appropriate reference material and the lack of proficiency testing schemes, although progress in this field is expected in the near future.

MICROPLASTIC EXPOSURE ROUTES

Food products may be contaminated by microplastics either through environmental contamination or through food processing and packaging materials.

The occurrence of microplastics in marine waters, lakes or river waters all can lead to microplastic contamination of seafood. However, fish filets are normally not affected by this contamination route, as the potentially ingested microplastics are too big to pass the intestinal wall towards the blood or muscles. On the other hand, seafood from which the gut is not removed before consumption, such as mussels and shrimps, may be of higher risk to human health, once contaminated with microplastics (Devriese et al., 2015; De Witte et al., 2014; Van Cauwenberghe et al., 2015; Van Cauwenberghe & Janssen, 2014; Vandermeersch et al., 2015). In a recent study, the presence of microplastics in sea salt revealed higher microplastic contamination when the salt was harvested at the water surface (Devriese et al., 2017a).

Atmospheric fallout may also be a significant source of microplastic contamination (Dris et al., 2016). Fibres originate from clothes, households, degradation of macroplastics, landfills and waste incineration. Liebezeit & Liebezeit (2013) suggested that the transport of particles by bees into the hive is a major contamination route for microplastics in honey. Also in beer, airborne particles are seen as a main source of microplastics (Liebezeit & Liebezeit, 2014).

Also the food processing and packaging contamination route may be an important source of microplastics. In many cases, food comes in contact with plastic food contact materials during transport, processing, storage or serving. During processing, food products may be rinsed with water containing microplastics, or they can be exposed to indoor air within an industrial environment. All those steps may affect the microplastic concentrations in food. Whereas most of these steps will increase microplastic contamination, the inverse may also happen. For instance, rinsing sea salt with brine seems to reduce the microplastic contamination of industrial salts (Devriese et al., 2017a). The use of plastic packaging material, on the other hand, was suggested to slightly increase the microplastic concentration in salt (Devriese et al., 2017a).

RISKS ASSOCIATED WITH MICROPLASTIC EXPOSURE

Up till now, it remains unclear to which extent microplastic exposure through food is a health risk for the consumer. Risks associated with microplastic exposure involve chemical, biological and physical hazards.

Many chemical compounds have been identified when extracting microplastics with organic solvents followed by GC-MS analysis (Gauquie et al., 2015). Numerous plastic additives incorporated during manufacturing as well as accumulated environmental pollutants can be detected. This may potentially lead to an additional contaminant exposure route (Teuten et al., 2009), although this seems to be highly dependent on the bioavailability of the contaminants. Bioavailability depends of the chemical compound as well as of the polymer type. Devriese et al. (2017b) showed that the relative uptake of polychlorinated biphenyls in Norwegian lobster is much higher when these contaminants where attached to polyethylene compared to polystyrene microplastics. Due to the strong binding capabilities of microplastics, the presence of such microplastic particles may even reduce toxicity (Koelmans et al., 2013). It is questionable if exposure to chemicals sorbed onto microplastics is really relevant compared to other exposure routes. For example, Koelmans et al. (2013) stated that water and food are more important for chemical contaminant exposure of aquatic organisms than microplastics. A similar argumentation sounds plausible for human exposure risks.

Also, the biological impact of microplastic contamination needs to be further investigated. The bacterial flora on microplastics found in marine waters is clearly distinct from the surrounding marine environment (De Tender et al., 2015). Microorganisms, including pathogens, may rapidly colonize microplastics (Zettler et al., 2013). Still, it remains unclear to which extent this can influence human health (EFSA, 2016).

The physical effects of microplastic ingestion are related to the translocation potential of such small particles. The epithelium of the gut wall represents an important barrier to microplastics. However, translocation from the gut into the lymphatic system is possible, and may cause systemic exposure (EFSA, 2016). Moreover, such translocation routes may be even more profound for the smaller fraction of plastics, i.e. the nanoplastics, causing a much bigger problem to animal and human health. For a number of marine invertebrates, a physical impact of microplastics has been reported, related to an influence on growth, reproduction, stress and hormonal functioning (Horton et al., 2017). Still, the toxicity of microplastics to human consumers has not yet been studied in detail. As such, it remains unclear to which extent microplastics are a real threat to human health. This poses a major challenge for future research at ILVO and collaborating institutes.

CONCLUSIONS

Microplastics can contaminate food via the environment, but also via food processing and packaging materials. The total extent of human exposure to microplastics is however, still unclear. Although the analysis of microplastics in food has evolved over the last decade, further standardization and validation of the methods is needed.
Microplastic contamination not only poses a risk in physical terms, but also in chemical and biological terms. Therefore many challenges remain for the risk evaluation, including the assessment of potential health effects posed by the exposure to microplastics (and also to possible substances released from or absorbed on microplastics).

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NANOMATERIALS IN THE FOOD CHAIN (DETECTION AND RECENT TOXICOLOGICAL ISSUES)

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ABSTRACT

Nanotechnology and - more precisely - manufactured nanomaterials (MNM) are highly promising and rapidly emerging areas for industrial innovation. Evaluation of exposure to MNM is not an easy task because there are no standardized measurement methods and protocols. Moreover, toxicological exposure parameters for MNM that are most relevant for further risk and toxicity analysis need to be determined. In this respect, the influence of aggregation / agglomeration (AA) and size distribution of primary particles on MNM toxicity will be discussed in addition to analytical challenges.

INTRODUCTION

Nanotechnology is one of the fastest growing technologies. Currently, over a thousand consumer products worldwide with very diverse applications contain Manufactured Nanomaterials (MNM). MNM are therefore present in many aspects of our daily live, e.g. in cosmetics and skin care products, clothing, food additives, waste water treatment, specific drug delivery in the body, etc. (Nel et al., 2006).

Despite the bright outlooks for the future of nanotechnology, there also exist concerns that intentional or unintentional human exposure to some types of MNM may lead to significant adverse health effects (Drobne, 2007).

CHARACTERISTICS OF MANUFACTURED NANOMATERIALS

MNMs may consist of unbound (colloidal) primary particles, aggregates and/or agglomerates of primary particles with one or more external dimensions in the size range of 1 to 100 nm (EC, 2011). The physical properties of MNM can deviate from the corresponding bulk material properties, due to their reduced size and dimensionality (Auffan et al., 2009; Luyts et al., 2013).

The unique physico-chemical characteristics of MNM provide technological advances, but their small size implicates an increased reactivity at the surface, which determines their biological behavior (Hoet et al., 2004; Oberdorster et al., 2005). Such different behavior can often be attributed to the increased surface-to-volume ratio. For example, the surface-to-volume ratio scales with the inverse of primary particle size, and therefore numerous properties, such as phase transition temperatures, obey the same scaling law (Roduner, 2006). The surface-to-volume ratio is generally expressed by the volume specific surface area (VSSA, [m2/cm3]), which is defined as the specific surface area (SSA, [m2/g]) multiplied by the particle density ([g/cm3]). The nanoscale size of these particles also implies that they can distribute to the smallest biological structures, to access and interact with fine cellular and molecular structures, indicating the need for a careful toxicological evaluation and a thorough risk assessment.

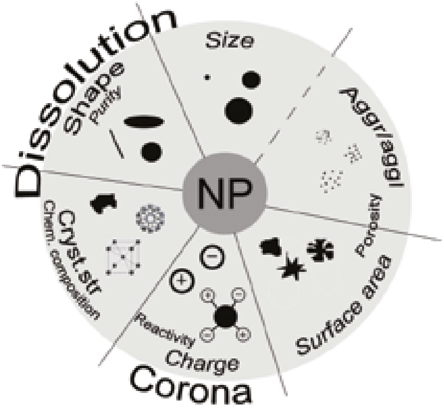

Figure 1. Important physico-chemical properties for NP characterization and their interrelations (source: Luyts et al., 2013)

TOXICITY OF MANUFACTURED NANOMATERIALS

Generally, researchers assume that the smaller the size, the more toxic the particle (Luyts et al., 2006; Napierska et al.,2009), while other particle properties, like shape and surface coating are also important. The importance of MNM characterization has been largely highlighted and efforts are being made to understand the behavior of MNM in the used preparations (Bouwmeester et al., 2011; Lison et al., 2014; Warheit et al.,2008). There is a great need for protocols that are benchmarked, validated and cost-efficient to screen the potential hazards (Maynard , 2007) and for physico-chemical characterisation.

Several investigations have shown that the biological consequences of exposure to insoluble manufactured nanoparticles (MNP) scale with surface area rather than with mass (Hoet et al., 2004; Lison et al., 2008; Oberdorster et al., 1992; Rabolli et al. 2010). For example, ultrafine particles cause a greater lung inflammatory response because of the greater surface area they possess (Brown et al., 2001; Obersorster et al., 2005), although it has also been shown that increasing the surface area of a MNM can have a moderating effect on the hazard (Rabolli et al., 2010). Notwithstanding the major efforts done during the last decades, it is not yet possible to reliably link the physico-chemical characteristics of MNM to their toxicity (Luyts et al., 2013).

AGGREGATES AND AGGLOMERATES

A complicating factor is the tendency of primary particles to agglomerate or aggregate into larger sized assemblages/clusters due to their enormous surface energies (Kreyling et al., 2010). According to the ISO definition (International Organization for Standardization, 2008), the surface area of agglomerates is similar to the sum of the individual primary particulate structures, whereas the external surface area of aggregates may be significantly smaller than the sum of the areas of the individual primary particulate structures. How aggregation can be related to biological effects has not been explored in detail (Rabolli et al., 2011; Thomassen et al., 2011). It is worth to note that agglomerates can still offer nano-related properties because of the primary particle surface areas held together, albeit with a reduced ability to penetrate biological barriers due to larger secondary sizes (Kreyling et al., 2010).

In this respect, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) proposed to use VSSA as a proxy to identify nanomaterials, complementing the available definition of a nanomaterial (NM) based on size (SCENIHR, 2010). This definition considers a particulate material as a NM if it has a VSSA equal to or greater than 60 m^2/cm^3 for spherical particles (EC, 2011).

It is of major importance to precisely define MNM for the correct assessment of human exposure and possible health risks. The current EU definition, as stated higher, includes size (1-100 nm), aggregation and agglomeration (AA) and poly-dispersity (50 % or more) as important parameters. From a toxicological perspective, next to size, two additional issues about particle dispersion stand out from this definition. It is remarkable that it remains unclear whether particles with similar mean size, but with a significantly different size distribution, also differ significantly in toxic activity. Secondly, the AA raises a lot of debate as it is currently not known how this exactly affects the toxic activity of NM. Consequently, it remains unclear whether it is toxicologically relevant to consider unbound and AA MNM equally for regulatory purposes, while it is known that larger aggregates may behave differently in the body.

ANALYTICAL CHALLENGES

In order to evaluate the importance of the size distribution and AA aspects on biological characteristics, physical characteristics of NM need to be measured and quantified. In this perspective, Jan Mast will present the approach to develop and validate analytical methodologies to define and characterize the physico-chemical properties of nanomaterials in a regulatory context based on specific examples. The possibilities and limitations of methods, including dynamic light scattering, particle tracking analysis and electron microscopy, will be evaluated. In addition, the analytical aspects to identify and characterize nanomaterials in complex matrices such as food will be illustrated.

TOXICOLOGICAL ISSUES

In the second part of the presentation, Peter Hoet will discuss (briefly) some health-related aspects of nanomaterials in food, and biological pertinent NM characteristics.

CONCLUSIONS

Although a definition of nanomaterials is available in the European legislation already for a number of years, risk assessors and risk managers still face several challenges related to analytical protocols to follow and suitable toxicological exposure parameters to measure.

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MINERAL OIL HYDROCARBONS IN THE FOOD CHAIN

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ABSTRACT

Mineral oils are complex mixtures of saturated (MOSH, mineral oil saturated hydrocarbons) and aromatic (MOAH, mineral oil aromatic hydrocarbons) hydrocarbons with a strongly varying composition. They can be present in foods due to their use in the agro-food chain, their presence in the environment or via migration from food contact materials. Because of their complex composition and the additional presence in foods of other hydrophobic substances which may interfere during analytics, the quantitative analysis of mineral oil components is challenging. MOSH causes granulomas in specific rats and seem to accumulate in organs within the human body. A toxicological threshold value (NOAEL) could be derived, which is not the case for MOAH. MOAH may contain carcinogenic and mutagenic substances. Risk characterization allowed to conclude that especially the chronic exposure to MOAH is a public health concern, while for MOSH, only

at the highest exposure levels health effects are likely to occur. Some EU member states currently take individual measures to manage the risk. It is considered essential that the awareness with respect to mineral oil at all levels of the agro-food chain is increased and that in all steps of this chain, steps are taken to reduce the mineral oil contamination in general and in particular the MOAH contamination.

INTRODUCTION

The presence of mineral oil hydrocarbons in foods has already been described since the early 90's in the pioneering work of Grob et al. (1991). Remarkably, it became only a hot food safety issue in 2008-9 (Biedermann & Grob, 2012). Today, "MOSH" and "MOAH" are almost buzz words in the food and related industries.

MOSH stands for mineral oil saturated hydrocarbons, while MOAH stands for mineral oil aromatic hydrocarbons, indicating that they are mineral oil derived substances. They are obtained via the cracking process of mineral oil and subsequent distillation. During the distillation process, the complex mixture of hydrocarbons is separated in different fractions according to their boiling point, which is related to their molecular weight. Given their origin, it is not surprising that their composition is very complex (>100 000 compounds) and may vary strongly.

The most straightforward differentiation between the various compounds within a mineral oil is made using the presence of unsaturated C=C bonds, which are typically present in aromatic ring structures, similar to the ring structure of benzene or the cyclic molecules present in the well-known polyaromatic hydrocarbons (PAH). Hence the differentiation made above between MOSH, consisting of saturated aliphatic and napthenic hydrocarbons and MOAH, containing substances with at least one aromatic ring. This differentiation is not only supported by the well-established analytical separation between these fractions, but is also of prime importance with respect to the toxicological properties of both classes of compounds.

ANALYTICS OF MINERAL OIL HYDROCARBONS

Given their hydrophobic nature, mineral oil hydrocarbons are often present in food in combination with other hydrophobic substances from a different origin and nature. This fact is important because unfortunately, it makes the analytics of mineral oil hydrocarbons in food - and especially the interpretation of the analytical data - in some cases troublesome. Consequently, the presence of mineral oil hydrocarbons can be overestimated due to the presence of other, interfering substances. Some of these potentially interfering substances include naturally present waxes (i.e. carnuba wax) and hydrocarbon waxes, which can both be used as food additives. Others include the oligomeric hydrocarbons present in widely-used polyolefinic food contact materials such as polyethylene and –propylene, or in particular adhesives used in food contact materials. Finally, various foods contain also a number of naturally occurring hydrocarbons such as squalene, steradienes, etc. (Biedermann et al., 2009; Biedermann-Brem et al., 2012; Gómez-Coca et al., 2016).

Given the rather large variety of compounds potentially interfering with the quantitative analysis of mineral oil hydrocarbons and the differentiation which should be made between the MOSH and MOAH fraction, a dedicated and complex analytical approach is necessary in order to quantify both mineral oil fractions in food. Nevertheless, considerable progress with respect to the analytics has been made the last years, resulting in a performant, sensitive and reliable standardized CEN/ISO method for the determination of MOSH and MOAH in vegetable oils (ISO 17780; prEN 16995), which is considered as reference method (Lacoste, 2017). Given that the amount of oil which can be analysed is the restrictive element in the analysis, expanding the scope of this method to other food matrices containing less fat, is feasible.

The method requires a dedicated analytical infrastructure as it is based upon an on-line-HPLC-GC-FID hyphenated analysis. Before the introduction of the lipid sample, unsaturated interfering hydrocarbons need to be epoxidized in order to decrease interference with the MOAH fraction (Biedermann et al., 2009). Next, the MOSH and MOAH fractions are separated in the liquid chromatography (LC) part by means of Ag+-based separation of saturated and unsaturated hydrocarbons. Each fraction is then analysed via a large volume injection using capillary gaschromatography (GC). Quantification is usually done with a flame ionization detector (FID) although the use of mass spectrometry (MS) is also claimed to allow reliable quantification. Moreover, MS has the advantage of allowing identification of specific peaks in the chromatogram (Spack et al., 2017). This is useful for identifying potential interferences (and not accounting them in the final result). In addition, more information with respect to the specific source of mineral oil contamination can be obtained. Additional purification steps (Biedermann et al., 2009) are recommended for reaching a higher analytical sensitivity and reducing further potential interferences (Lacoste, 2017). The analytical limit depends to a great extent of the fat content of the sample, but is certainly in the 1 ppm range.

A key element of the analytics is the correct interpretation of the chromatograms, and this with respect to both the integration and the correction for interfering substances of the detected signals. This is illustrated in **Figure 1**. Due to the high number of related compounds present in both the MOSH and MOAH fraction, chromatograms show a 'hump' instead of nicely separated peaks. The peaks present on top of the hump are regarded as interfering substances and need to be subtracted from the total peak area. This approach can be considered as quite particular, albeit pragmatically necessary. Moreover, due to the typical elution behaviour of mineral oil hydrocarbons as a chromatographic hump a sensitive quantification is rather challenging. As shown in **Figures 1B** and **1C**, a dedicated enrichment of the MOAH fraction is necessary in order to distinguish the observed hump from the baseline and to increase the sensitivity of quantification.

Given these analytical challenges, it is obvious that stakeholders are often confronted with a substantial lack in reproducibility of analytical results.

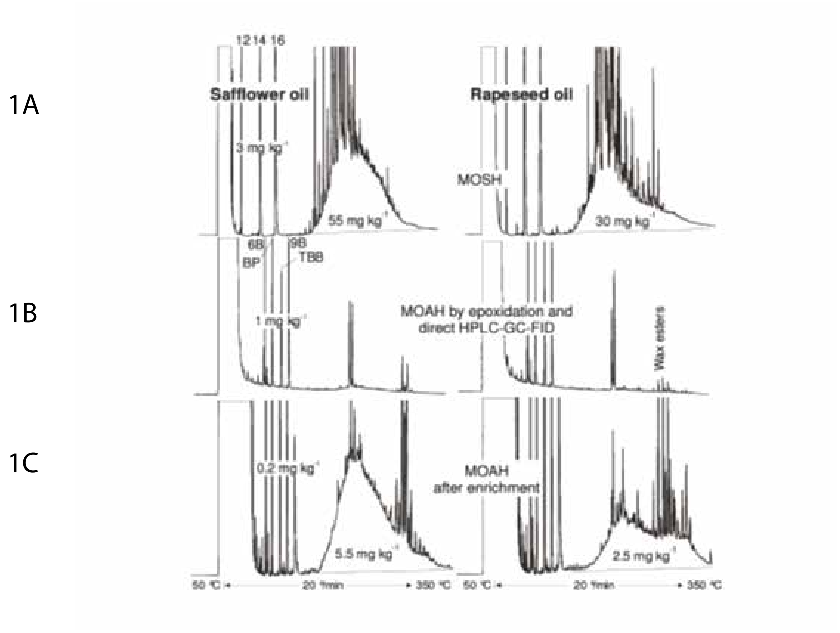

Figure 1. Determination of MOSH and MOAH in safflower and rapeseed oil 1A represents the MOSH fraction; 1B and C the MOAH fraction after respectively a pre-treatment consisting of epoxidation or an additional enrichment on silicagel and subsequent epoxidation (Biedermann et al., 2009). The peaks eluting before the chromatographic 'hump' are standard compounds added to the samples for quality assurance. Resolved peaks eluting within the chromatographic hump are not considered as mineral oil components

POTENTIAL SOURCES OF MINERAL OIL HYDROCARBONS IN FOOD

The Association of the German Confectionary Industry (BDSI) and the Foundation of the German Cocoa and Chocolate Industry have studied in a joint research project the various sources of mineral oil hydrocarbons in the food chain (Matissek et al., 2016). This study resulted in a toolbox which is useful for the industry in order to identify potential mineral oil sources and to mitigate the presence of mineral oil hydrocarbons in their products. A comprehensive overview of the various sources is given in **Figure 2**.

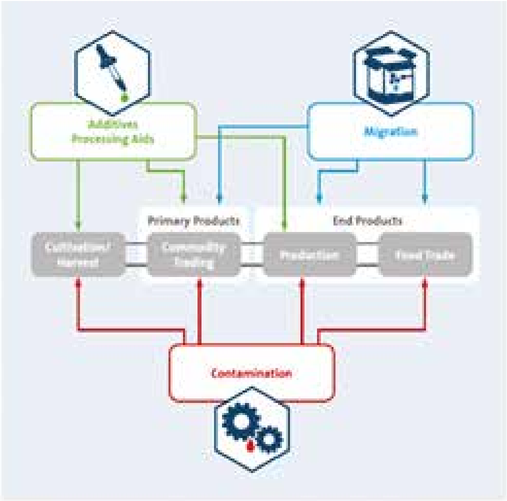

Figure 2. Various sources of mineral oil hydrocarbons in the food chain (source: Matissek et al., 2016)

A first potential source is the use of particular food additives and processing aids. Food additives such as waxes and paraffinic oils, should be accounted for when considering potential analytical interference with mineral oil components. Mineral oil hydrocarbons as such, are used as technical aids in the oilseed industry to prevent dust explosions and as adjuvants in particular crop protection formulations. A second important source is contamination. Due to the presence of mineral oil components in engine exhausts for example, deposition from the environment occurs. Similarly, accidental contamination of food, but also of raw materials can occur via lubrication and thermal oils used in agronomic, processing or other equipment. Particular attention should be given to the application of good manufacturing practices in e.g. drying operations. Finally the presence of mineral oil hydrocarbons in food contact materials - particularly in recycled board, printing inks and sisal or jute bags for bulk storage - and their migration to foods should be considered as a third potential source.

CHALLENGES FOR THE RISK ASSESSMENT

HAZARD CHARCTERIZATION

Hazard characterization of mineral oil components is complicated because of their complex and variable composition. The MOAH fraction can be mutagenic and may contain also carcinogenic components, although no direct link could be established between the MOAH content of mineral oils and their carcinogenic potency (Hellwig, 2017). Exposure to MOAH via food is considered as a potential concern, but no health based safety values are available, making quantitative risk assessment difficult (EFSA, 2012). MOSH are neither carcinogenic or mutagenic. The most relevant critical effect is the formation of granuloma in various organs, but particularly in the liver. This phenomenon is however observed in Fisher rats, a rat species that seems to have a particular pharmacokinetic profile (Hellwig, 2017). In addition, it has recently been shown that a substantial accumulation of MOSH occurs in human tissue, including the liver (Barp et al., 2014). Although this effect is considered to be undesirable, clear evidence of clinical significance is lacking (Hellwig, 2017). Based on the critical effect of microgranuloma formation in the liver, a health based safety value was derived for MOSH which can support quantitative risk assessment and risk management (no-observed-adverse-effect level or NOAEL of 19 mg/kg bodyweight per day) (EFSA, 2012).

RISK CHARACTERIZATION

EFSA (2012) reported highest mean MOSH concentrations to occur in confectionary (excluding chocolate), vegetable oils, canned fish and seeds (values ranging between 38 and 46 mg MOSH/kg). MOAH concentrations are typically 15 to 35% of the MOSH concentrations. In a more recent study, similar values were reported, but most critical commodities were: spices, vegetable fats (particularly coco's fat), butter, egg powder, cocoa and coffee beans (Matissek et al., 2016). In addition, bulk cereals, especially rice, should be considered to be at higher risk for contamination (Biedermann et al., 2013). In summary, foods produced in circumstances were Good Manufacturing Practices (GMP) are not commonly applied, bulk commodities and matrices which are likely to absorb hydrophobic compounds (i.e. fatty or starch containing commodities) can be considered to be particularly vulnerable for mineral oil contamination. With respect to the risk characterization, EFSA concluded that the margins of exposure (MOE) for MOSH ranged in average between 110-663, while for the most frequent consumers (P95) MOE values varied between 59 and 330. Considering for non-genotoxic compounds a MOE of 100, it can be concluded that some consumers are exposed to too high MOSH levels (EFSA, 2012). However, particularly the exposure to MOAH, for which no health based safety value could be derived, can be considered of concern given the possible mutagenic and carcinogenic properties of this fraction (EFSA, 2012; Hellwig, 2017).

CHALLENGES FOR THE RISK MANAGEMENT

It is clear from the various potential sources of mineral oil hydrocarbons in food (**Figure 2**) that managing the risk of mineral oil hydrocarbons involves the whole agro-food chain. Hereto, awareness should be increased in the whole chain.

Currently no specific legal restrictions are in place within the EU, although some horizontal legislation with respect to, for example, general food safety or food contact materials should be considered. In view of the absence of legal limits on the EU level, some individual member states took initiative to manage the risk of these compounds. In Germany for instance, the last draft 'mineral oil ordinance' specifies that no migration of MOAH from recycled cardboard or paper might occur (i.e. undetectable or < LOD (limit of detection), considered to be 0.5 mg/kg) (Helling, 2017). In Belgium, the Scientific Committee of the Federal Agency for the Safety of the Food Chain proposed action thresholds in order to provide the agency with a scientific basis for preserving safety of the food chain (SciCom, 2017). In parallel it was suggested to limit the levels of MOAH to the LOD.

It is however expected that for a number of food commodities, additional measures within the agro-food chain are necessary in order to meet such requirements. In this respect, some food sectors published already guidance documents. Care should be taken that risk management options taken are realistic, feasible and sensible. An example of a too strict measure is the complete ban by default of recycled cardboard as a food packaging material. These materials are suitable to pack foods which are not receptive for mineral oil hydrocarbons or when an adequate functional barrier is present between the food and the cardboard. In this respect it is interesting to observe that the mineral oil issue creates potential conflicts between the cradle-to-cradle policy which should increase the sustainability at one hand and food safety at the other hand.

CONCLUSIONS

Mineral oil hydrocarbon contamination of foods is a challenging issue given the various potential sources and complex composition, difficulties encountered regarding analytics and knowledge gaps with respect to toxicity. It is considered essential that the awareness with respect to mineral oil at all levels of the agro-food chain is increased and that in all parts of this chain, steps are taken to reduce the mineral oil contamination in general and in particular the MOAH contamination.

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Session 3:
Long term perspectives and lessons learned

LONG TERM PERSPECTIVES (2050) ON CHEMICAL FOOD SAFETY IN THE FOOD CHAIN

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ABSTRACT

By analysing four scenarios based on different developments of specific drivers that can significantly impact and bring change to the food system, long term perspectives and future challenges for the 2050 EU food chain were identified to ensure that EU citizens continue to enjoy high standards of safe, nutritious and affordable food.

The four scenarios analysed in this foresight study are: "Global Food", "Regional Food", "Partnership Food" and "Pharma Food". Drivers considered are global trade, EU economic

growth, agro-food chain structure, technology uptake, social cohesion, food values, climate change, depletion of natural resources and world population growth. For each scenario, several food safety and nutrition challenges were identified and prioritised based on their importance and likelihood to occur. On this basis, scenario-specific policy options were developed as suggestions to policy-makers on how to address these challenges to ensure the resilience of the future EU food safety and nutrition regulatory framework. Research needs were also identified to complement the proposed policy options, as well as a set of food-chain related indicators that could inform in advance if the EU is headed towards one of the study's scenarios.

INTRODUCTION

The foresight study 'Delivering on EU food safety and nutrition in 2050 - future challenges and policy preparedness' was carried out by the Directorate General Joint Research Centre (JRC) in cooperation with the Directorate General for Health and Food Safety (DG SANTE) to aid policy makers in their assessment of the resilience of the current food policy and regulatory framework with a time horizon to 2050, contributing to ensuring that EU citizens continue to enjoy high standards of safe, nutritious and affordable food.

The main elements of the study include:

- the development of scenarios for the EU in 2050 that systematically illustrate possible combinations of future developments;
- the identification of critical challenges to food safety and nutrition in each of the scenarios and their potential implications;
- a set of indicators that can flag particular scenario-related developments and the potential for the critical challenges to take place;
- proposals for possible policy options and related research needs for the development of a more resilient EU food safety and nutrition policy and legislative framework.

Foresight is a process aimed at providing the necessary anticipatory intelligence to shape medium- to long-term policies. It enhances innovative thinking by involving a broad range of stakeholders and knowledge sources and by systematically exploring alternative perspectives for the future.

THE JRC – DG SANTE FORESIGHT STUDY

The foresight study employed scenario development as a research approach. Scenarios are tools to illustrate possible combinations of developments from the present to the future and to explore their potential impacts. The scenarios were constructed based on drivers, i.e. forces that can significantly impact and bring change to the food system.

The drivers of change in the study were: Global trade, EU economic growth, Agro-food chain structure, Technology uptake, Social cohesion, Food values, Climate change, Depletion of natural resources and World population growth.

Various meaningful driver development combinations were used to create the backbone of four study scenarios, taking into account their plausibility, consistency, diversity and decision-making utility. The four scenarios were further developed, describing the evolution towards, as well as the situation in the EU in 2050, mainly focussing on the European food system and its actors. The four study scenarios are: "Global Food", "Regional Food", "Partnership Food" and "Pharma Food".

From each scenario, a number of food safety and nutrition challenges were identified, further describing their potential impacts on the EU food system. Some of these challenges were prioritised, based on their importance and likelihood to occur, and were further discussed in a scenario specific context. Based on these prioritised challenges, a number of policy options were identified. These policy options are suggestions to the policy maker, framed in the current legislative and policy structure on how to address the prioritised challenges to ensure the resilience of the future EU food system. For each scenario, research needs were identified to complement the proposed policy options, as well as a set of food-chain related indicators to notify in advance if the EU is headed towards one of the study's scenarios. A summary of the main study outputs, i.e. scenarios, prioritised challenges and related policy responses are given below.

1. “GLOBAL FOOD” SCENARIO

“Global Food” is in some way a 2050 magnification of the situation in which the EU finds itself in 2015; i.e. an even more interconnected global food chain with increased global trade and a more concentrated food industry; however, facing enhanced challenges from climate change and depletion of natural resources that impact on primary production and sourcing of raw materials. Global trade, technologies and innovation are, therefore, employed to overcome the barriers these factors pose to the food system. However, the mainly urban population in Europe, with its increased sedentary behaviour, decreased physical activity and over consumption of highly processed foods rich in energy, fats, sugar and salt, faces significant health challenges, such as increased prevalence of obesity and non-communicable diseases.

As the challenges faced in “Global Food” are in essence a magnification of issues already encountered today, many of the policy options do not introduce new measures, but rather aim to improve existing policies and provisions, and enhance their implementation. Harmonisation of food safety standards at the global level, improved risk assessment based on global cooperation, vulnerability analysis followed by enhanced implementation, inspection and controls along the entire food chain, would allow a smoother functioning of global trade. Sharing of some regulatory tasks with the food industry in a certain form of appropriately designed, monitored and controlled “co-regulation”, would allow for better use of the available state resources, while giving more flexibility to the food industry and enhancing innovation. Urgent action would need to be taken in relation to nutrition and the diet-related public health issues anticipated in this scenario. Implementation of nutrient profiles, combined with food industry incentives for reformulation and more harmonised approaches in the provision of information and education, as well as potential fiscal measures, may all have to be considered to avoid the impacts of poor diets in public health, state finances and workforce productivity.

2. "REGIONAL FOOD" SCENARIO

In "Regional Food", the 2050 EU food chain looks quite different from the current one. Under the impacts of climate change and the depleting natural resources, and led by an increasingly aware and concerned population, the EU focuses on self-sufficiency and a circular economy model, abandoning international trade agreements. In this scenario, food has an important value and is produced locally or regionally using advanced technologies. Citizens are involved in food production, even in urban settings, and peer-to-peer trade becomes increasingly common in this society. Food waste reduction and re-use are of particular importance, while diets are more sustainable with reduced animal protein consumption, although occasionally subject to reduced availability of fresh produce.

In the local and fragmented food system of "Regional Food", the extensive presence of individuals producing food - and potentially lacking the food safety know-how of the organised food industry - could cause food safety challenges such as, frequent, but localised, animal disease and food poisoning outbreaks. Such challenges would require adaptation of the present framework to include individuals producing food, who are currently not considered food business operators. Proactive education initiatives to ensure a minimum level of food safety awareness and technology understanding for anyone engaging in food production should also be considered. At the same time, monitoring, enforcement and traceability systems would need to be re-organised to control the local and fragmented food production and distribution channels effectively. Action may also be required to ensure that all consumers receive information on safety and nutrition aspects of their food, even if obtained directly from the producer without any packaging. The use of ICTs and social networks could be further exploited for this purpose. Finally, to ensure fresh produce availability and a varied diet when temporary disruptions of local production occur, appropriate mechanisms will need to be designed for food re-distribution within and between the Member States, e.g. introduction of production quotas. These mechanisms can also be combined with consumer education on the seasonal availability of foods and their nutrition values.

3. "PARTNERSHIP FOOD" SCENARIO

"Partnership Food" is characterised by an EU with strong trade and food policy ties with the US and Canada and little global trade with the rest of the planet. The European economy is stagnating, however, and the EU has lost importance in geopolitics and trade, especially in agriculture and food. EU citizens embrace technological innovation in the agro-food sector, which is mostly developed in the US, since food technology innovation and R&D investments are at the minimum in the EU. The European society in 2050 does not value food highly. Food choice is driven by price and convenience and characterised by a transatlantic food culture focused on consumption of highly processed foods and out of home eating. The agro-food chain activities concentrate on efficiency, mass production and climate change resilience.

In "Partnership Food", the loss of scientific and technological expertise in the EU can have serious repercussions for the food system, including increased vulnerability to food fraud and inappropriate use of novel technologies leading to food safety hazards, as well as impacts on the EU economy due to the central role the food sector has in it. This loss of technological know-how is expected to stem from reduced investment in R&D and barriers to innovation, such as consumer scepticism and resistance to new technologies or a cumbersome legal framework. The suggested policy options discuss how to lift barriers to innovation, e.g. by reducing the cost of regulatory compliance, increasing co-operation between authorities and food business operators and further improving consumer perception of new technologies. The notion of trade-offs is also being discussed, highlighting that the EU society may in the future need to select where to focus its efforts and investments, and to prioritise between equally important aspects in the food system. In "Partnership Food", food safety and nutrition literacy will deteriorate, impacting on basic hygienic food preparation and the capacity to make informed and healthy dietary choices. Policy options to address this include mandatory food safety and nutrition courses in schools and continuous education via life-long learning ICT-based programs. Strengthening the Transatlantic Consumer Dialog has also been proposed as a means of exchanging information and practices among EU and US consumers. "Partnership Food" faces nutrition challenges and public-health issues similar to those encountered in "Global Food", and, therefore, the measures suggested to tackle them include implementation of nutrient profiles, food industry incentives for re-formulation, provision of nutrition information and education, as well as potential fiscal measures and creating environments where certain food items must not be offered to vulnerable population groups (‘zoning’).

4. “PHARMA FOOD” SCENARIO

“Pharma Food” foresees a globalised world trade with a strong EU economy, which emphasises the need to maintain a healthy and active workforce population. To achieve this in a context where fresh produce is not abundant due to climate change effects, people turn to functional, processed foods and even foods with added pharmaceutical substances (“phoods”), in a personalised diet regimen aimed at optimising their health status. Multinationals control most of the food chain as the investments needed to research and place such foods on the market are too high for small and medium sized enterprises. Decades of careful attention to food safety as well as inspiration from the tight pharmaceutical quality and safety controls result in a highly controlled, transparent and traceable EU food chain, and this ensures trust and technology acceptance by the consumers.

The challenges faced by this scenario mainly arise from the global liberalised trade system and the predominance of personalised nutrition and “phoods” in EU diets. Difficulties to perform official food-related controls in this scenario stem from the globalised sourcing of food and pharmaceutical ingredients that are present in “phoods”, from the individual home or small-scale production of foods and “phoods” using novel technologies, or by the difficulty of regulatory authorities to keep up with fast-paced development of such new products and technologies. To address these, policy options include, respectively, expanding third-country point of origin controls, introducing a certification scheme for home “phood” manufacture and implementing post-market monitoring of new products and technologies. The need to provide a legal framework that could cover the nature of health claims and “phoods” in this scenario, has also been identified. Additionally, the high complexity and number of active compounds, including pharmaceuticals, present in foodstuffs, bear a high risk of adverse health effects due to cocktail effects. To address the challenge of performing risk assessment related to cumulative and mixture effects, the improvement and expansion of existing *in silico* computational tools will therefore be beneficial.

CONCLUSIONS

Within the boundaries of this study, the EU legislative framework governing food safety appears robust, effective and efficient. However, certain elements would need to be strengthened to better prepare for the challenges ahead, including harmonisation and streamlining of risk assessment approaches and inclusion of risk-benefit assessment, need for a benchmarking system to monitor food safety and nutrition performance, an effective early-warning system for emerging hazards, adaptation of official controls and inspections for future needs, providing clear food information to the public and investment in food and nutrition education. The latter has also been identified as a cornerstone of a society able to tackle current and future challenges in nutrition and health, along with crucial backing by governance that collaborates with all relevant stakeholders and maintains nutrition and health high on the agenda. Should this approach fail, stronger legislative measures could be adopted in nutrition policies. Their efficiency, however, remains uncertain.

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MANAGING CHEMICAL HAZARDS IN THE FOOD CHAIN: LESSONS LEARNED FROM THE FIPRONIL INCIDENT

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ABSTRACT

Food safety is the responsibility of various players in the food chain: from legislator and the food safety authority up to food business operator, the retailer and distributor to the consumer. Zero risk for the consumer is impossible to achieve. The authorities are confronted with an ongoing objective for more efficiency at a reduced cost for society. Food safety control programs remain a priority. They are risk-based and target the key hazards in the food chain. A scientifically based methodology to control chemical as well as microbiological hazards is applied by the FASFC. This results in an annual control and inspection program which is regularly updated. The cornerstones of the Belgian system for safeguarding food safety are: self-checking, mandatory notification, traceability and monitoring the food chain via official controls and inspections. However, tackling food

fraud remains a continues challenge. The recent fipronil incident showed the impact of illegal use of biocides and lessons were learned from the resulting food scare.

INTRODUCTION

The main competent authorities for food safety in Belgium are the Federal Agency for the Safety of the Food Chain (FASFC), the Federal Public Service for Health, Safety of the Food Chain and Environment (FPS-HSFCE) and the Federal Agency for Medicines and Health Products (FAMHP).

The FASFC sets out the operational regulations (process standards for business operators), and prepares and implements a multi-annual control plan. The FPS-HSFCE is in charge of regulatory policy on products and contaminants and policy in the field of animal and plant health. The FAMHP is responsible for human and veterinary medicines: research and development, registration, vigilance, manufacturing and distribution and proper use.

The mission of the FASFC is to preserve safety of the food chain and food quality in order to protect the health of humans, animals and plants. Control of the food chain is its core business. To accomplish this mission, FASFC integrates all control services that are related to the entire food chain (from farm to fork). An integrated, end-to-end approach ensures optimal monitoring of all activities in the food chain.

In addition, the FASFC ensures that its enforcement policy, aimed at changing behaviour, addresses non-conformities in a timely manner. The FASFC provides all relevant information as fully and as appropriately as possible. It also supports and stimulates further expansion of the application of self-checking systems (auto-control) by operators of the Belgian food chain.

CORNERSTONES OF THE FOOD SAFETY CONTROL POLICY IN BELGIUM

The Belgian food safety control system is based on the European Food Law (EC 178/2002) which provides assurance of a high level of protection of public health and consumers' interest in relation to food and feed. The cornerstones of the Belgian system for safeguarding food safety are: self-checking, mandatory notification, traceability and monitoring of the food chain by official controls and inspections.

SELF-CHECKING

Self-checking has to do with operator accountability in the food chain. This principle is included in the Food Law (EC Regulation No 178/2002) and was further developed in Belgium in the royal decree of 14 November 2003 regarding mandatory notification and traceability in the food chain.

Self-checking includes all measures taken by operators to ensure that the products at all stages of production, processing and distribution under their control :

- meet the legal requirements with regard to food safety;
- meet the legal requirements with regard to quality of products falling within the competence of the FASFC;
- meet the requirements laid down with regard to traceability.

It also includes the supervision of effective compliance with these requirements. To ensure the safety of food and feed, the self-checking system has to be based on the HACCP principles (Hazard Analysis and Critical Control Points). In the primary production sector, self-checking pertains to compliance with hygiene requirements and keeping the necessary registers.

NOTIFICATION REQUIREMENT

Every notification should be the result of a prior risk assessment. Any operator shall promptly inform the Agency when he is of the opinion or has reason to believe that an imported, produced, reared, grown, processed, manufactured or distributed product may be injurious to the health of humans, animals or plants. The operator is also obliged to inform the Agency about the measures taken to prevent and eliminate the risk. In case a non-compliant product has been placed on the market the operator should either withdraw it from the market or recall it. In Belgium the notification requirement also applies to laboratories.

TRACEABILITY

Referring to the EU General Food Law (EC Regulation 178/2002) traceability means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be, incorporated into a food or feed, through all stages of production, processing and distribution. This regulation has promoted the transfer of information through the food chain from primary producer to the consumer, to help identify the cause of an event of major non-compliance related to product safety and to limit the expansion of negative consequences.

Food and feed business operators should be able to identify any person by whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators should have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

Food or feed which is placed on the market or is likely to be placed on the market should be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

MONITORING THE FOOD CHAIN BY OFFICIAL CONTROLS AND INSPECTIONS

Monitoring the food chain is a core task of the FASFC. The applied control methodology of the FASFC provides a systematic and harmonized approach aimed at targeted and transparent controls and inspections. The methodology is based on a scientifically substantiated, risk based sampling and inspection program that evolves in line with new needs and risks.

The control program consists of two parts: the analysis program and the inspection program. The analysis program is based on a systematic yearly assessment of the risks by in-house experts from the Directorate General Control Policy. The experts take into account updated information on the safety of the food chain originating from multiple sources such as the results of the analysis program of the Agency of the previous year, RASFF (Rapid Alert System for Food and Feed) reports, scientific opinions published by national or European scientific bodies, stakeholder information, etc. The analysis program is translated into a sampling plan. The inspection program is aimed at inspecting all food business operators at a predefined frequency.

The control program is complemented by specific actions on certain activities and products.

THE CONTROL OF CHEMICAL CONTAMINANTS IN THE FOOD CHAIN: PROGRAMMING OFFICIAL ANALYSIS

FASFC has adopted a general approach that allows objective programming of official controls (Maudoux et al, 2006). In general terms the approach is based on risk assessment in order to select a combination of hazards (parameters), products (matrices) and premises and on a statistical method to determine the number of samples to be taken in the food chain. The whole process is prepared by in-house experts from the FASFC and validated by the Scientific Committee. The control program is readjusted annually, based on new information from different sources (results of previous year, RASFF alerts, scientific opinions, scientific literature, etc.). In future, the multi-annual national control program will evolve towards a standard routine program combined with a more flexible and adjustable program.

The number of analyses programmed for selected matrix-parameter combinations is based on a statistical approach with the purpose either (i) of detecting a contamination above a certain confidence level or (ii) of estimating the true prevalence. The confidence level (90%, 95%, 99%) to be achieved in the former case is dependent on three parameters: the degree of harmful effect of the hazard, presence of the hazard in the population of food products and the contribution of the food product to overall food chain contamination.

THE FIPRONIL CONTAMINATION OF THE FOOD CHAIN

In June/July 2017 thanks to the self-checking system of a food business operator and to the notification requirement, the FASFC discovered fipronil in the poultry product chain. The contamination resulted from an illegal, fraudulent use of fipronil for the treatment of red lice (Dermanyssus gallinae) in laying hens. Assessment of the risk associated with the consumption of contaminated eggs showed a very low public health risk. When it became clear that the fraudulent contamination involved multiple operators in different countries and that a different risk communication and risk management approach was followed by these countries, the incident became a full-grown media crisis and had a major impact on the sector (massive withdrawal of eggs, poultry meat and egg products from the market) and on the image of national food safety agencies, especially in Belgium and the Netherlands.

LESSONS LEARNED FROM THE FIPRONIL INCIDENT

100 % control (zero risk) of the food chain is impossible. The fipronil incident demonstrated the vulnerability of the food chain. This chemical contaminant entered the food chain fraudulently via an adulterated by-product used for the cleaning and disinfection of poultry houses by a service provider. Better control of biocides and service providers in the food chain is therefore necessary.

Pro-active, adequate and transparent risk communication is crucial. Although there was no risk to public health, the fipronil incident developed into a food scare, especially in Belgium and the Netherlands, because the media perceived the communication by the authorities unsatisfactory.

There is a need for enforced and harmonized European collaboration (information exchange, risk assessment, risk management, risk communication) between member states and a stronger role for the European Commission and EFSA in case of cross-border incidents.

Closer interaction and cooperation should be promoted between criminal investigators and national food safety authorities in matters related to food fraud. Criminal investigation should not prevent food safety authorities from communicating.

CONCLUSIONS

Various chemical hazards may threaten food chain safety. By rigorously applying good practices on the part of operators and national authorities, most chemical hazards are under control. Food and feed safety has never been higher than today. It remains a challenge, however, to prevent illegal products from entering the food chain. The recent fipronil contamination of the food chain provided an example. Lessons were learned from this incident and a set of measures have been agreed upon at EU level.

REFERENCES

EC Regulation No 178/2002 of the European Parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

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