Risk assessment by the Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain (FASFC)

V. Vromman[1], E. Thiry[2,3], L. Herman[2,4] and X. Van Huffel[1]

[1]Federal Agency for the Safety of the Food Chain, Directorate General Control Policy, Staff Direction for Risk Assessment, Brussels, Belgium.

[2]Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain, Brussels, Belgium.

[3]University of Liège, Liege, Belgium-Chair of the Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain.

[4]Institute for Agricultural and Fisheries Research (ILVO), Merelbeke, Belgium-Vice-chair of the Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain.

Correspondence: Vromman V.

e-mail: valerie.vromman@afsca.be

Abstract

The Scientific Committee (SciCom) is a consultative body of the Belgian Federal Agency for the Safety of the Food Chain (FASFC) providing independent scientific opinions in relation to risk assessment and risk management in the food chain. The Scientific Committee is composed of 22 external members with complementary expertise in scientific domains related to the food chain. They are nominated by royal decree for a mandate of 4 years. The Scientific Committee is scientifically and administratively supported by a scientific secretariat (the Staff Direction for Risk assessment of the FASFC) consisting of one director, seven scientific experts in risk assessment and two administrative collaborators. The Scientific Committee and the Staff Direction for Risk assessment are responsible for the scientific risk assessment with respect to hazards related to food safety, animal health and plant health.

The legal basis of the Scientific Committee is laid down in the law of 4/02/2000 on the creation of the Belgian Federal Agency for the Safety of the Food Chain and in specific royal and ministerial decrees regulating the functioning and composition of the Committee. House rules, an ethical code and work procedures further assure its daily independent functioning, its transparency and the quality of its work.

Each year the Scientific Committee issues between 20 to 30 opinions, which are published on the FASFC website in Dutch, French and in English (abstracts). Opinions can be either formal opinions (given within 3 to 6 months), rapid opinions (within 1 month) or urgent opinions (in case of a crisis situation, issued within 24 to 48 hours). Opinions are given either on request of the Chief Executive Officer of the Belgian Food Safety Agency or the Federal Minister who has food safety within its competencies or may also result from self-tasking activities. Opinions are given on all projects of legislation issued by the FASFC and the Federal Public Service of Public Health,

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Food Safety and Environment (the former Ministery) and related to the control of the food chain, on sectorial self-control guides and sectorial sampling plans, on control and inspection plans of the FASFC, on disease monitoring plans, on emerging risks, on incidents in the food chain, etc.

Examples of risk assessment issued by the Scientific Committee in the field of chemical risks, microbiological risks, animal health and plant health are given in this article.

Key words

Scientific Committee, FASFC, food safety, risk assessment, opinion.

1. Organizational structure of the Belgian Federal Agency for the Safety of the Food Chain

The Belgian Federal Agency for the Safety of the Food Chain (FASFC) is a federal executive agency with authority over the whole Belgian territory. The FASFC was founded in 2000 as a response of the government to the 1999 PCB/dioxin crisis (a mixture of polychlorinated biphenyls was inadvertently mixed with recycled fats used in the production of animal feeds. Dioxins were present as secondary contaminants arising from the thermal degradation of the PCBs) which had revealed lack of coordination between different inspection services of the food chain.

The mission of the FASFC is to preserve the safety of the food chain and the quality of the food in order to protect the health of humans, animals and plants.

The FASFC is responsible for laying down, implementing and enforcing measures related to food safety, animal health and plant protection.

The Chief Executive Officer (CEO) is responsible for the Agency. He reports back to the Federal Minister who has food safety within his competencies. The Agency is organized into four Directorates General (Figure 1).

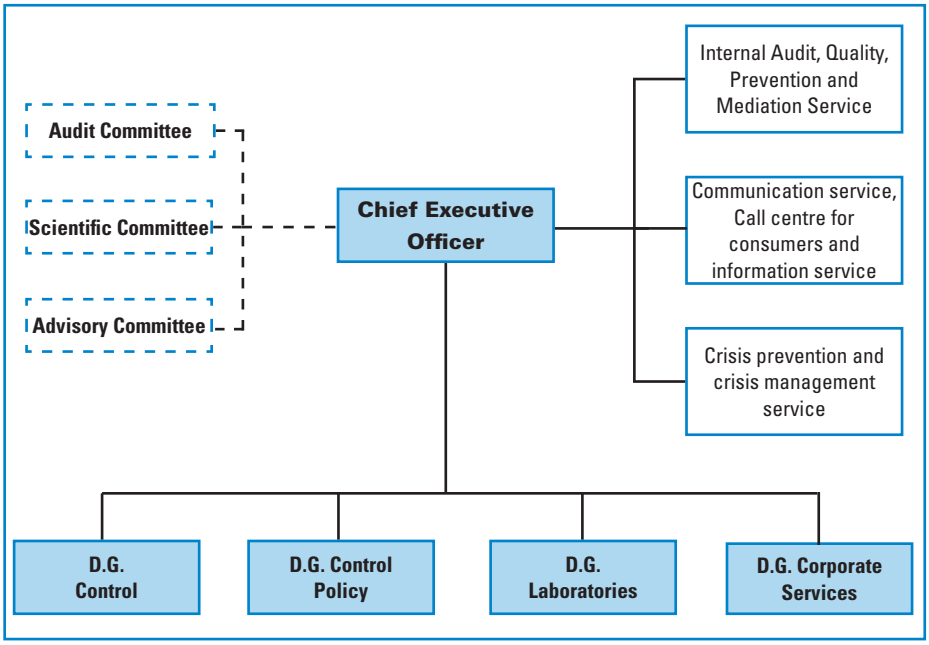

Figure 1. Organizational chart of the FASFC.

The Directorate General Control performs the core task of the Agency namely the control and inspection of the food chain in the field, the managing of the RASFF messages (Rapid Alert System for Food and Feed), the granting of approvals and authorizations, the delivery of certificates, the execution of import controls and the coordination of investigations to fight fraud in the food chain.

The Directorate General Control Policy is responsible for policy making, for preparing the operational legislation in regard to the control of food, feed, animal and plant health at all stages in the food chain and for the development of a risk based multi-annual control plan.

The Directorate General Control Policy contains three sectorial Directions (Direction for Plant Protection and Safety of Plant Production, Direction for Animal Health and Safety of Animal Products and Direction for Transformation and Distribution of food) and three Staff Directions (Staff Direction for International Relations, Staff Direction for Risk Assessment and Staff Direction for Integration of Business Information). The Staff Direction for Risk assessment (DirRisk) is responsible for the scientific support of the Scientific Committee and also of the Agency for matters related to risk assessment.

The Directorate General Laboratories co-ordinates the analyses provided in the control program. It has five own ISO 17025 accredited laboratories and a network of fifty external laboratories. The laboratory network is scientifically and technically supported by the National Reference Laboratories (NRL) which are specialized in specific fields.

The Directorate General Corporate Services has a transversal supportive role for the Agency.

The FASFC holds three advisory bodies (the Scientific Committee, the Advisory Committee and the Audit Committee).

The Scientific Committee (SciCom) is a consultative body of the FASFC. It occupies a central position in the risk assessment of the food safety policy of the Agency. The main task of the SciCom is to provide independent scientific opinions on the matters related to the competencies of the FASFC namely on:

- all projects of laws and royal decrees in relation to risk assessment and risk management of the food chain, animal health and plant protection;
- the control and inspection program of the food chain;
- the self-checking sectorial guides and sectorial control plans;
- (emerging) risks in the entire food chain.

The composition and functioning of the SciCom are described in the royal decree of 19 May 2000. The Committee is composed of 22 scientists with complementary expertise in the food chain: animal health, zoonoses, epidemiology and statistics, veterinary public health, disease monitoring and control, food safety, livestock production systems, phytosanitary plant health, plant protection, pest control, food and feed quality and hygiene, food microbiology, food contaminants, food allergens, food technology, residues, toxicology, etc.

The members are nominated by royal decree for a mandate of 4 years (renewable). Members of the SciCom elect a Chair and a Vice-Chair during the first plenary session after their nomination.

The members of the SciCom are proposed to the Federal Minister who has food safety within its competencies after being evaluated by an ad hoc selection committee based on their *curriculum vitae* and expertise. They have to declare not to belong to an establishment controlled by the Agency and to be able to give independent and impartial advice.

Besides the Scientific Committee two other consultation committees exist within the FASFC: the Advisory Committee and the Audit Committee. The Advisory Committee brings together all stakeholders, from producers to consumers, involved in the safety of the food chain through their associations. They give advice to the Chief Executive Officer in regard to the control policy of the Agency. The Audit Committee coordinates and evaluates the internal audits performed in the Agency.

2. The functioning of the Scientific Committee

The Scientific Committee receives formal requests for scientific advice from the Chief Executive Officer of the Agency or from the Federal Minister who has food safety within his competencies. In case of crisis situations in the food chain the crisis manager may also consult the SciCom. The SciCom can also initiate its own activities (self tasking activities'). In particular dossiers SciCom works together with the Belgian Superior Health Council and publishes common opinions.

The SciCom meets monthly in plenary session. New requests for opinions are presented, the progress of ongoing dossiers is discussed and draft opinions are approved. The *quorum* (50 % of the members present) must be reached for the approval of draft opinions.

The secretariat of the Scientific Committee is executed by the Staff Direction for Risk Assessment (DirRisk) consisting of a team of two administrative assistants, seven experts in risk assessment with respect to biological and chemical hazards in the food chain, animal health and plant health and one director. DirRisk supports scientifically and administratively the functioning of the SciCom. This represents 60 % of its work load. The remaining 40 % consist of the initiation and follow-up of research projects and the synthesis of scientific literature, the scientific valorization and operational follow-up of the opinions of the Scientific Committee and the scientific support of risk management decisions.

Opinions are prepared in working groups composed of SciCom members, external scientific experts and a file manager from the Staff Direction for Risk Assessment. External experts are chosen for their personal technical or scientific expertise related to specific dossiers. SciCom members and external experts are senior scientists from universities, high schools, scientific institutions, research centers or laboratories. They have a proven track record of expertise in specific domains related to the safety of the food chain and are able to provide independent opinions. For particular dossiers international experts are consulted. About 60 working group meetings are organized each year. SciCom members and external experts are reimbursed for their work.

A reporter, member of the Scientific Committee, is responsible for the progression of the activities of the working group. He regularly gives state of the art of the activities of the working group and presents the draft opinion to the SciCom during plenary sessions.

House rules

House rules describe the functioning of the SciCom, the tasks and responsibilities of the Chair, the declaration and management of conflict of interests, the rights and obligations of the members, the procedure for the resignation of a member and the tasks and responsibilities of the scientific secretariat executed by the Staff Direction for Risk Assessment.

Code of ethics

A code of ethics stipulates specific provisions to assure that the independence of the opinions and the transparency of the functioning of the SciCom is respected by all members and participating external experts.

Independence and impartiality

At the start of their mandate SciCom members sign a general declaration stipulating that they do not belong to the Board, management or staff of an enterprise subject to the supervision of the Agency and that they commit to promptly notify the Chair of the Scientific Committee in case a change in their situation occurs. They declare to respect the clauses of the house rules and code of ethics.

Per dossier, members of the SciCom verify if they have an interest in the dossier. In that case they inform the Chair via a declaration of interests. Interests can be of financial or familial nature, may be related to intellectual property or professional activities performed for a company, a laboratory, an interest group or a sector. Declarations of interests are examined by the Bureau of the SciCom (Chair, Vice-Chair and the Director of the Staff Direction for Risk Assessment) which decides upon the appropriate measures to be taken in function of the nature of the conflict of interest. In case of a conflict of interest, the concerned member of the SciCom is not allowed to take part in the deliberations of the dossier.

The same conditions of independency and impartiality apply to external experts, invited to participate in a working group. For these reasons they have to sign at the start of the working group a declaration of independence and impartiality and a declaration of interest, if applicable. External experts are therefore subject to the same house rules as the members of the SciCom in regard to independency and impartiality. In case of conflict of interest, external experts may not participate in the activities of the working group. They can only be audited.

Procedures for requesting and preparing opinions

The SciCom can be consulted according to three procedures: a formal request (including a rapid procedure), a request for a scientific opinion on a sector guide or a sector monitoring program and a request for urgent consultation in crisis situations.

The procedures are published on the website of the FASFC. Requests for scientific opinions undergo first a preliminary investigation by the scientific secretariat (DirRisk) in order to verify compliance to administrative and scientific quality criteria. The dossier is then transmitted electronically to the SciCom members and discussed for the first time at the next plenary

session of the SciCom during which is decided upon the composition of the working group. A reporter, member of the SciCom, and a file manager, member of DirRisk, are designated. They are responsible for the management of the dossier, the organization of working group meetings and the drafting of the opinion. Draft opinions are discussed and approved by the SciCom during the monthly plenary sessions. The approval of the opinion is mostly done on the basis of an unanimous decision although minority opinions can also be given. The throughput time for preparing opinions varies between 24-48 hours for urgent consultations in crisis situations, 1 month for rapid opinions and 3 months for formal opinions on legislation or sector guides. In case of complex questions an acceptable and realistic throughput time is discussed with the applicant of the opinions. Each opinion is published on the website of the FASFC within 15 days after transmission to the CEO. Stakeholders are informed about the publication of new opinions by electronic newsletter. Opinions with a major societal impact are announced via press communications. Members of the Advisory Committee (stakeholders of the food chain) may get the opinion and press communication under embargo five working days before the official publication.

The SciCom can also self-initiate dossiers. To identify interesting topics a yearly survey is organized amongst SciCom members. New dossiers are initiated taking into account the work load and annual planning. A working group determines the reference terms and prepares a draft opinion. The throughput time of self-tasking activities may reach up to 2 years or longer. Self-tasking activities may contain recommendations for control policy. These recommendations are followed-up by DirRisk to give SciCom an idea about the impact of their opinions. In general, approximately 75 % of the recommendations are followed-up by risk management measures within one year.

As all core processes of the Agency the functioning of SciCom is ISO 9001 certified.

3. General risk assessment approaches performed by the Scientific Committee

Opinions by the Scientific Committee can be classified into different types: opinions on projects of legislation in regard to the control of the food chain, opinions on sectorial guides or sectorial monitoring programs, opinions on strategic documents such as the control and inspection program, opinions on specific questions or issues (emerging risks for example Avian Influenza H5N8, *Aethina tumida* in bees or emerging issues such as the consumption of insects,…). The used risk assessment approaches are fit-for-purpose meaning that the type of the question will determine the approach to be followed.

In general the risk assessment methodology applied by the SciCom is based on a multidisciplinary and structured international accepted approach as put forward by the European Commission (EC 2000) (EU, 2002), EFSA (European Food Safety Authority), the *Codex Alimentarius* (CAC, 1999, 2003) and the Food and Agriculture Organization of the United Nations (FAO, 2005, 2007). It consists mainly of developing the four different steps in the risk assessment process: hazard identification, hazard characterization, exposure assessment and risk characterization whether or not supplemented with a description of uncertainties and the proposal of recommendations.

Risk assessments are used in a flexible and pragmatic way taking account of data-, knowledge- and time constraints. Depending on the nature of the question not all aspects of the complete risk assessment process can be covered with the same thoroughness. In exceptional cases risk-benefit assessments are performed (i.e. on the consumption of raw milk).

The risk assessment applied to animal diseases may contain an additional step, entry assessment, and may follow further an adapted flow: exposure assessment, consequence assessment and risk estimation, as recommended by OIE (World Organisation for Animal Health) (OIE, 2013). For an animal disease, it is often not possible to describe a dose-effect relationship. Opinions concerning animal health risks are often rapid opinions because urgent measures have to be taken to limit the spread of a disease. Other opinions concern antibacterial resistance, risk factors of emerging diseases, monitoring and surveillance programs, etc.

The risk assessment applied to phytosanitary hazards includes pest categorization, assessment of probability of entry, establishment and spread (EFSA, 2010). Risk assessment in regard to plant health by SciCom is mostly related to specific questions involving the legislation or the control program. A simplified procedure for rapid pest risk assessment (quick scans) has been developed and is used in case of risk of introduction of harmful organisms on the Belgian territory. Risk assessment includes gathering of information on the localization of the pest, its harmful properties, the host plants and the risk of introduction, establishment and spread. These rapid pest risk assessments (quick scans) are performed by DirRisk experts and validated by a member of the SciCom-expert in plant pathology and plant pests or by an external expert. Until now quick scans have been performed for the following organisms: *Thaumatotibia leucotreta, Phytophthora lateralis, Scirtothrips dorsalis, Anthonomus eugenii, Xiphinema bricolensis, Meloidogyne ethiopica, Drosophila suzukii, Leucinodes orbonalis, Callidiellum rufipenne, Meloidogyne enterolobii, Sinibotys butleri.*

Whatever the hazard being considered and the risk assessment approach used, the identification and evaluation of risk management options is a common feature and is very helpful to guide the risk managers for taking decisions.

Depending on the available data and time, exposure assessments may be either qualitative, semi-quantitative or quantitative (deterministic or probabilistic). Data are collected from different databases such as the FASFC food safety control database, Sanitel, national or international food consumption databases and external databases from the EU (TRACES), from OIE or from universities or scientific institutions. Data are further processed and analyzed with suitable methods and software tools such as predictive growth models, statistics, R, @Risk. For non-genotoxic substances, the exposure is compared to the acceptable/tolerable daily intake. For genotoxic substances, the margin of exposure (MOE) approach is applied according to EFSA (2005).

Scientific sources of information are consulted such as PubMed, Web of Science, Toxnet, IPCS, IARC, ChemIDplus, Sciencedirect, Google Scholar, websites of international organizations such as WHO, FAO, OIE, website of other food safety authorities/agencies EFSA, nVWA, ANSES, DEFRA, BFR, etc.

Expert opinions are obtained through knowledge elicitation of experts in working groups or through hearings or in case of thorough studies through electronic questionnaires or Delphi survey's (Wentholt et al., 2012) (Cardoen et al., 2014).

Hazard/risk ranking has also been applied by the SciCom i.e. in the field of food borne zoonoses (FASFC, 2008a) (Cardoen et al., 2009), animal diseases to be monitored by the Agency (FASFC, 2009a,b, 2010a,b) and carcinogenics and genotoxic contaminants (FASFC, 2008b, 2010c, 2013a) (Vromman et al., 2014). In these opinions recommendations are made for the implementation of hazard/risk ranking into control policy.

For the ranking of zoonoses in foodstuffs an evidence-based semi-quantitative methodology has been applied in order to prioritize an extended list of food- and water-borne zoonoses. This prioritization was based on scores given by 35 scientific experts to five criteria in an exhaustive list of 51 zoonotic agents (FASFC, 2008a) (Cardoen et al., 2009).

The SciCom is regularly mandated to issue opinions on the risk-based methodology of the FASFC control program. These opinions deal with different aspects of the methodology such as:

- the inventory of hazards in the food chain and their severity of heath effect level;
- the relevance of the selected matrix-hazard combinations and the determination of the number of analyzes;
- the relevance of the selected sampling sites;
- the scope of inspections and their frequency.

Some examples are given below to illustrate the risk assessments performed in the field of chemical contaminants, (micro)biological contaminants, animal health, plant health and particular topics.

4. Examples of risk assessments performed by the Scientific Committee

4.1 Examples of chemical risk assessments

Acrylamide (AA) intake of the Belgian population (FASFC, 2014a)

Based on FASFC control results during 2 time periods (respectively 2002-2007 and 2008-2013) it was evaluated if the various initiatives that have been taken to reduce the acrylamide content in food have had an impact on the exposure level of the consumer. The results of the acrylamide content varied per food item. A significant decrease was observed for crisps and gingerbread. Also a significant decrease, but less important, was seen for the mean AA levels of cereals, bread & rolls, chocolate and baby biscuits. In contrast, the AA content of coffee and paprika powder increased significantly, and the AA level of coffee substitute and fries seems to show a rising, although not significant, trend. Since 2008, the AA intake appears to have declined a little, but not significantly. For neoplastic effects ($BMDL_{10}$= 0.17 mg/kg b.w. per day), the mean intake of children, adolescents and adults corresponds to a margin of exposure (MOE) varying between 515 and 236 and the P97.5 intake corresponds to an MOE between 113 and 53. Such low MOE values for a genotoxic carcinogen, the level of which should in principle be as low as reasonably achievable (i.e. the ALARA principle), indicate that additional measures are essential for reducing the AA content in food.

A first evaluation of AA intake by the Belgian population can be found in the SciCom opinion (25-2008) (FASFC, 2008c) (Claeys et al., 2010).

Risks of carcinogenic and/or genotoxic environmental contaminants in food (FASFC, 2013a) (Vromman et al., 2014)

In 2008 the SciCom gave an introduction on relevant carcinogenic and/or genotoxic compounds in the diet (FASFC, 2008b). In a second opinion, the SciCom handled contaminants associated with the transformation processes (FASFC, 2010c). This third opinion focused on the risks of environmental carcinogenic and/or genotoxic contaminants in food. It described, for each contaminant studied, carcinogenicity and genotoxicity data, toxicological reference values, exposure and risk characterization. The compounds studied were classified into three categories based on risk (FASFC, 2013a). Other effects than carcinogenicity and/or genotoxicity (e.g. endocrine disruptors) were also taken into account for the classification.

Given the low MOE values for arsenic and lead, the SciCom considered these two compounds of high concern for food safety and as first priority to take action to reduce exposure.

Benzene, cadmium, methylmercury, dioxins & dioxins like polychlorinated biphenyls (PCB), non dioxins like PCB, polycyclic aromatic hydrocarbons (PAHs) and toxaphene are classified as priority 2 (medium concern). Nitro-PAH, 2-nitroanisole, polybrominated biphenyls, chlordane, heptachlor, dichlorodiphenyltrichloroethane (DDT) and metabolites, hexachlorobenzene, hexachlorocyclohexane (lindane included), polychlorophenols and their salts are classified as priority 3 (low concern).

Risk assessment of migration from food contact materials: explorative case studies (FASFC, 2014b)

The risk of migrating components from food contact materials (FCM; packaging, but also e.g. ustensils, pipes, storage tanks) is discussed by means of a number of exploratory case studies.
As explorative case studies, the risk of the daily (chronic) exposure to ESBO (Epoxidized soya bean oil) and to the phthalates DEHP (di(2-ethylhexyl) phthalate), DiNP (di-isononyl phthalate) and DiDP (di-isodecyl phthalate), plasticizers used amongst others in the seals of lids of glass jars, was evaluated based on the results of the FASFC monitoring program 2008-2012. Given that DiNP and DiDP were hardly detected, an estimation of the exposure to these phthalates appeared to make little sense.

For adults, the exposure to ESBO and the evaluated phthalates seems to hold no significant health risk, even for the most pessimistic scenario where a high consumption and contamination of the food were assumed. For infants (<1 year), however, the exposure to ESBO may exceed the tolerable daily intake (TDI) in case of a frequent or of a large consumption of baby food packed in glass jars. On the other hand, since (i) ESBO is neither carcinogenic nor genotoxic and has no detrimental effect on development, and since (ii) the consumption of baby food in jars significantly decreases after the first year of life, as a result of which such potentially large exposure shall only occur for a limited time, a limited risk can be assumed. The exposure of infants to DEHP is below

50 % of the TDI, even when baby food in jars is frequently consumed. In addition to FCM, however, other sources of contamination (e.g. the environment) and other sources of exposure (e.g. plastic toys and dust which are taken into the mouth) are possible. Furthermore, DEHP has endocrine disrupting properties (for which a classical toxicological approach, such as for example based on the TDI, is inadequate).

4.2 Examples of (micro)biological risk assessments

Exposure assessment to cephalosporin resistant *E. coli* through consumption of broiler meat (FASFC, 2011a) (Depoorter et al., 2012)

In Belgium, about 36 % of the *E. coli* strains isolated from live poultry are resistant to cephalosporin antimicrobial drugs while 60 % of the broilers are carrier of these cephalosporin resistant *E. coli*. The risk of consuming chicken meat contaminated with cephalosporin resistant *E. coli* consists mainly of the possible transfer of resistance genes to other, potential pathogenic bacteria present in the human intestinal tract. Indeed, cephalosporin resistant *E. coli* strains from poultry only exceptionally cause infections in humans.

Therefore, from a food safety point of view, the SciCom wanted to gain insight into the degree of exposure of people to cephalosporin resistant *E. coli* through consumption of chicken meat. For this purpose a quantitative model aimed at estimating the exposure of the consumer to cephalosporin resistant *E. coli* by consumption of Belgian chicken meat was elaborated. The model consists of different modules that simulate the farm to fork chain starting from primary production, over slaughter, processing and distribution to storage, preparation and consumption of chicken meat.

The results indicated that about 1.5 % of the meals with chicken meat contain more than 1 000 colony forming units (cfu) of cephalosporin resistant *E. coli*. The risk of this exposure to human health cannot be estimated at this stage given a lack of understanding and quantitative data on the minimal infectious dose and on the factors influencing the transfer of cephalosporin antimicrobial resistance genes from *E. coli* to the intestinal bacterial flora of men.

The model shows that the majority of exposure is caused by cross contamination in the kitchen, which is again an argument to respect good hygiene measures during preparation of chicken meat. Furthermore the proportion of cephalosporin resistant *E. coli* (within the total number of *E. coli*) in primary production and the overall contamination of chicken carcasses or chicken parts with E. coli are of significant influence on the risk of consumer exposure to cephalosporin resistant *E. coli*. This means that a sound antibiotic drug policy in primary production and respect of good hygiene practices in the slaughterhouse and cutting plant could reduce significantly the risk of exposure to cephalosporin resistant *E. coli* during consumption of chicken meat.

Antibiotical resistance has been studied by the SciCom in feed (FASFC, 2013b) and in the food chain (FASFC, 2012). Related articles have been published by Van Boxstael et al. (2012) and Verraes et al. (2013).

Risk-benefit evaluation of raw cow milk consumption and the effect of heat treatment on these risks and benefits (FASFC, 2011b) (Claeys et al., 2013)

Many human pathogens including *Salmonella* spp., *Campylobacter* spp., human pathogenic verocytotoxin-producing *E. coli, Listeria monocytogenes, Yersinia*, enterotoxin producing *Staphylococcus aureus*, *Bacillus cereus, Cryptosporidium parvum*, etc. as well as *Clostridium botulinum* toxins, can be isolated from raw cow milk. The prevalence of food-borne pathogens in raw cow milk varies, but their presence has been demonstrated in many surveys. In industrialized countries, milk-borne and milk product-borne outbreaks represent 2 to 6 % of the bacterial food-borne outbreaks.

The aim of this study was to evaluate the risks and benefits related to the consumption of raw cow milk in Belgium, and to evaluate the effect of heat treatments of milk on these risks and benefits, considering the microbiological as well as the (bio)chemical and the nutritional aspects.

The majority of reported raw cow milk-borne outbreaks are attributable to *Campylobacter* spp., human pathogenic O157 and non-O157 *E. coli, Salmonella* spp., and in some rare cases to *Listeria monocytogenes*. Human pathogenic verocytotoxin-producing *E. coli* and *Listeria monocytogenes* can cause severe illness, followed by *Campylobacter* spp. and *Salmonella* spp. These four pathogens can be present in cattle or in the farm environment, and in raw cow milk in Belgium. From a microbiological point of view, the consumption of raw milk is considered as a risk product for a human food-borne infection. The availability of raw milk vending machines for direct sale encourages the sale of raw milk amongst the population. The exposure and as such the risk is raised, especially for at risk populations (YOPIs, i.e. the very young, elderly persons, pregnant women, those already suffering from illness, and immune-compromised persons), if the consumer is not well informed about the necessity of boiling the raw milk before consumption. Such vending machines must be well managed and clear information should be provided to the groups at risk.

The risk of raw milk consumption is considerably reduced and even eliminated by heat treatment. Pasteurization (min. 71 °C/15 s or 63 °C/30 min or equivalent) reduces the vegetative pathogens in milk to a level considered safe for public health. Pasteurization is however, inadequate to destroy spores of *Clostridium botulinum* and *Bacillus cereus* and the heat shock may induce their germination. Sterilization and UHT treatment destroy both vegetative microorganisms and spores and produce a commercially sterile product.

Several microbiological benefits are assigned to raw cow milk consumption, namely pathogen growth inhibition by antimicrobial (mainly enzymatic) systems and by lactic acid producing bacteria, increased immunity, reduced allergies, and health effects of probiotic bacteria. Nevertheless, the activity of most antimicrobial enzymes is limited at the refrigeration temperature used to store raw milk, and many of the antimicrobial systems retain almost all their antimicrobial activity after pasteurization. After sterilization (including UHT treatment), most endogenous antimicrobial activities are obliterated, but their activity is no longer needed since the milk is commercially sterile. The growth of lactic acid producing bacteria and the subsequent acidification and coagulation of the milk limit the outgrowth of pathogens but also the shelf-life

of raw milk. Consequently, pathogens requiring an outgrowth in the raw milk before reaching their infectious dose represent a low risk for raw milk consumers. The current evidence for the assumed relation between drinking raw milk and an increased immunity at one hand and a reduction of allergies on the other hand, is controversial and the underlying mechanisms are unknown. It is therefore difficult to conclude about a possible effect of heating milk on these parameters. The growth of probiotic bacteria is too limited in raw milk to have beneficial effects for the consumer.

The nutritional benefits associated with raw milk consumption generally remain after pasteurization, UHT treatment and/or homogenization of the milk (changes of a technical nature were not considered). Milk is an important source of calcium, phosphor, proteins and essential amino acids (especially lysine), and the vitamins B_2 and B_{12}. The effect of a heat treatment on the deliverance of these nutrients is negligible. Other nutrients present in milk that could be (partly) destroyed by heating, contribute less to the daily requirement. Reduced levels of these nutrients are easily compensated by a balanced diet.

In addition, heating (and/or homogenization) is, most probably wrongfully, associated with a reduced milk digestibility, inactivation of beneficial enzymes, reduction of lactose with the formation of lactulose, and an increased risk of various conditions (e.g. milk allergy, lactose intolerance, diabetes, osteoporosis, arthritis). These allegations are refuted and/or put into a scientific perspective in this advice. The main negative effect of biochemical nature of heating milk is the modified organoleptic profile, although this is rather a matter of perception.

In this advice it was demonstrated that when consuming raw milk the exposure to microbiological hazards is real and that this has resulted several times in food-borne infections. Heat treatment (pasteurization, boiling, but UHT treatment in particular) is a historically and scientifically proven, efficient method for guaranteeing the microbiological safety of milk without affecting significantly the nutritional value of milk.

When purchasing raw milk, the SciCom recommends that the raw milk is heated just at boiling point before consumption.

A similar evaluation has recently been performed for the consumption of raw milk from animal species other than cows (FASFC, 2013c) (Verraes et al., 2014) and for the consumption of raw milk products (FASFC, 2015a).

4.3 Examples of risk assessment related to animal health

The risk of introduction of the highly pathogenic avian influenza virus in Belgium,particularly the H5N8 strain via wild birds, taking into account the current epidemiological context (FASFC, 2015b)

Several outbreaks of avian influenza caused by highly pathogenic avian influenza (HPAI) H5N8 were recorded in the EU since early November 2014. The SciCom is asked to give an opinion, via an accelerated procedure, on the length of the period of increased risk for introduction of the highly pathogenic avian influenza H5N8 virus and to justify this period by scientific arguments. As periods of increased risk are combined with specific preventive biosecurity measures, the SciCom gives also an opinion on these preventive measures.

The SciCom is of the opinion that the period of increased risk can be stopped in March 2015 and that the measures have no longer to be prolonged because the risk of introduction of highly pathogenic avian influenza virus is lower during spring migration than during autumn migration of wild birds. The Committee recommends to encourage private holders of birds and poultry to (continue to) notify mortality cases in order to reinforce the passive surveillance for avian influenza in our country.

In order to provide a sustainable response to the question, the SciCom proposes a warning system with three risk levels based on scientific parameters established according to signal capture outside Belgium. The three risk levels are basic vigilance, increased vigilance and increased risk. This warning system will be published in a subsequent opinion of the SciCom.

The risk of introduction of Bluetongue virus serotype 4 in Belgium (FASFC, 2014c)

Recently, Bluetongue virus (BTV) emerged in South-East Europe in sheep, goats and cattle during which serotype 4 (BTV4) was isolated. Given these circumstances, the SciCom was asked to give a rapid advice on the possible introduction of BTV4 in Belgium. More specifically, it was asked to identify the risks for the introduction of BTV4 and to investigate the need for additional measures in order to prevent the introduction of the virus in Belgium and to detect a potential introduction at an early stage.

The SciCom has listed all possible ways of introduction of BTV4 and has assigned them a score according to their risk for the introduction of BTV4 in Belgium. The main risks lie in the intra-community trade of ruminants and the natural inflow of infected vectors from infected regions.

Although depended on many factors, the spread of infected vectors is believed to be the most likely way of introduction of BTV4. This way of introduction is difficult to prevent. In general, the introduction of BTV4 in Belgium or in its neighboring countries, in the absence of vaccination, is deemed realistic at the end of the vector season 2015 or during the vector season 2016.

The SciCom is of the opinion that the passive and active surveillance, as it is currently organized in Belgium, are sufficient to detect an introduction of BTV4. However, it is recommended to include farms that are located near important introduction spots (e.g. airports, ports, highways) in the active surveillance and to perform this active surveillance not only during winter but during the entire year.

The experiences with the past BTV8 epidemic (2006-2010) have shown that vaccination is a very effective measure to prevent and control a BTV epidemic. To prevent a possible spread of BTV4 in Belgium, it is important to have a sufficiently high vaccination coverage in sheep, goats and cattle. If during the 2015 vector season the virus is further spreading towards North-Western Europe then the installation of a generalized vaccination campaign will strongly reduce the risk of a BTV4 epidemic in Belgium. The SciCom recommends to consider such a vaccination campaign once a BTV4 outbreak is notified within a 700 km zone around Brussels.

Risk factors of (re)-emerging infectious animal diseases (FASFC, 2013d) (Cardoen et al., 2014)

The objective of this advice is to identify the risk factors of emergence of infectious animal diseases in Belgium to allow the risk managers to undertake control measures in time.

For that purpose, 34 examples of (re)-emerging or at risk of (re)-emergence infectious animal diseases and 33 risk (or protection) factors of emergence were selected aiming for the most complete representativeness as possible. The effect of these factors on the risk of emergence of the 34 animal diseases was analyzed via a Delphi survey by 50 experts.

The study allowed to rank the risk factors according to their relevance to the emergence of separate groups of infectious animal diseases (for example, exotic, zoonotic, foodborne diseases, etc.), as well as for all the diseases, taken together in one global group. The six most important risk factors, when considering (re)-emerging animal diseases as one global group, are the following: presence of an animal reservoir, detection problems of emergence of disease, difficulties to control the disease by vaccination, geographical extension of the disease, asymptomatic carriage and increase in the incidence of the disease in other countries.

This ranking of risk factors allowed to make recommendations, namely in regard to "early warning", vigilance, surveillance, and control of animal diseases. Concerning the "early warning", it is recommended to monitor the measurable risk factors of emergence. The appearance of the increase in incidence of risk factors can alert the risk manager early of the increased risk of emergence of infectious animal diseases.

4.4 Examples of risk assessment related to plant health

Risk assessment of the presence of harmful nematodes in soil or growing medium stuck on topiary trees and tropical plants imported from third countries (FASFC, 2011c)

The SciCom has assessed the risk associated with the presence of non-quarantine harmful nematodes in the soil or growing medium stuck on topiary trees and tropical plants imported from third countries in Belgium.

The SciCom considers that ideally a Pest Risk Assessment (PRA) should be performed for each species of detected harmful nematodes. This requires notably to specifically know the ability of the harmful nematode to be introduced, to expand and to establish on the Belgian territory. However, such specific data are little or not available currently and their determination would require extensive research.

In general, the SciCom considers that the risk posed by the presence of non-quarantine harmful nematodes in soil or growing medium stuck on topiary trees and tropical plants imported from third countries is a priori quite limited for cultivated plants and wild flora in Belgium. However, this risk could be significant to the infested plant, for some producers of plants and plant products in greenhouses and cultivated plants and wild flora of the southern countries of Europe to which the plants imported into Belgium would then re-exported.

The SciCom proposes to allow importation into the Belgian territory of batches of plants infested with harmful nematodes whose presence in Belgium is proven, provided that these nematodes are neither virus vectors nor quarantine pests and are not mentioned on the EPPO Alert and

Action List. Imported plants which are infested with harmful nematodes that are on the quarantine list should be destroyed in accordance with the legislation. Imported plants which are infested with nematodes on the lists of EPPO should be treated to significantly reduce the infestation. Imported plants which are infested with harmful nematodes whose presence in Belgium is not confirmed and which are not vectors of viruses, or of quarantine, nor listed on the EPPO lists can be placed on the market provided that the detection of these harmful nematodes is notified to the FASFC. Imported plants which are infested with virus vectors harmful nematodes (*Longidoridae* and *Trichodoridae*) should be analyzed to detect the presence of viruses. If a quarantine virus is detected, the infested plants should be destroyed in accordance with the legislation. If a non-quarantine virus is detected that is included on the EPPO lists, or if a non-quarantine virus is detected that is not on the EPPO lists and which is not present on the Belgian territory, the plants should be treated to significantly reduce the infestation. If a non-quarantine virus is detected, which is not on the EPPO lists and which is present on the Belgian territory, or if no virus is detected, plants could be placed on the market.

Different control methods are proposed but their respective efficiency in relation to the different detected harmful nematodes should be evaluated in detail.

4.5 Examples of opinions related to a specific topic

Food safety aspects of insects intended for human consumption (FASFC, 2014d)

In the search for alternative dietary protein sources, insects appear to offer great potential. Currently there are no specific regulations neither in Belgium, nor in Europe, on the breeding and marketing of insects destined for human consumption. The trade of a number of insect species destined for human consumption is however tolerated in Belgium. In this context, the SciCom and the Superior Health Council (SHC) were asked to give advice on the potential risks (hazards) associated with the consumption of these insects (entomophagy).

Worldwide there are about 2 000 edible insect species known and, in certain regions, insects are already eaten for ages by humans. Nevertheless, there is only little scientific literature available on the food safety of insects. To guarantee the food safety of entomophagy on a large scale, more research on the microbial and chemical safety of insects destined for human consumption is needed.

In this opinion, the potential microbial, chemical (including allergens) and physical hazards specifically related to the consumption of insects are discussed. These hazards depend on the insect species, the cultivation conditions (feed and environment) and the subsequent processing, and can largely be controlled by the adequate application of the prevailing good hygiene and manufacturing practices during breeding and marketing of insects. Contamination with yeasts and fungi that can produce harmful secondary metabolites (mycotoxins) is also to be avoided. Since it cannot be excluded that pathogenic bacteria (and spores) from the production environment may infect the insects and its consumers, a heating step (minimally blanching, cooking, frying or stir frying) is indispensable before the products are put on to market or consumed as well as the mentioning of appropriate storage and preparation conditions on the label. As far as chemical

hazards are concerned, composition and possible defensive secretions need to be assessed for each insect species separately. There are however no indications that the 10 insect species tolerated in Belgium contain or secrete such natural toxins in the stage of consumption. Allergic reactions after consuming *Arthropoda* or arthropods are possible, although information on this is scarce. The label should contain a warning for a possible allergic reaction of persons allergic to seafood and/or dust mites.

Development of measuring instruments (barometers) of food safety, animal health and plant health

The Scientific Committee developed a concept for measuring the safety of the whole food chain (from farm to fork) based on the annual evolution of measurable and weighted indicators: a food safety barometer (FASFC, 2010d), an animal health barometer (FASFC, 2011d) and a plant health (phytosanitary situation) barometer (FASFC, 2011e).

The barometers are meant to be a practical measuring instrument that allows to monitor annually the safety of the food chain in a simple way and to communicate in clear terms on this subject (http://www.favv-afsca.fgov.be/scientificcommittee/barometer/).

5. Output by the SciCom

Each year the SciCom issues between 20-30 opinions, which are published on the FASFC website (http://www.favv-afsca.fgov.be/scientificcommittee/) in Dutch, French and English (abstracts). Figure 2 shows the evolution of the number of SciCom opinions since 2002. Up till 2006 SciCom was mandated to give opinions on every project of legislation in regard to the activities of the Agency. After 2006 this has been limited to questions in regard to risk assessment and risk management in the food chain which represents the core business of the SciCom.

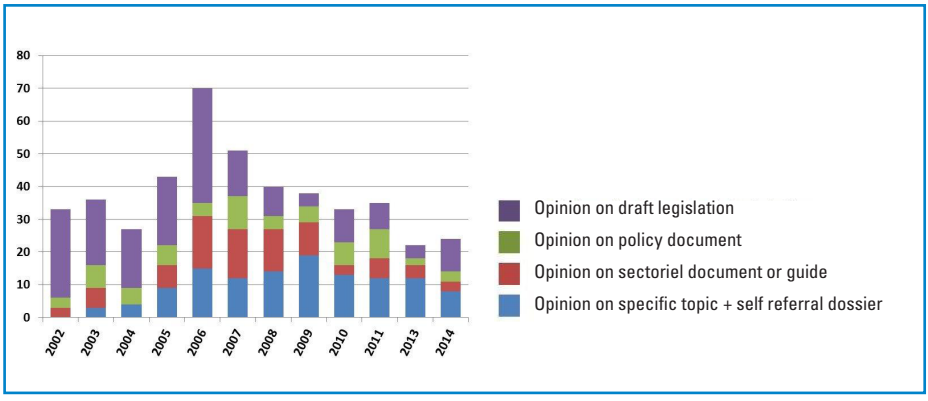

Figure 2. Number of SciCom opinions issued between 2002 and 2014.

In order to valorize the work by SciCom members and to better visualize their work internationally an effort is made by DirRisk to transform SciCom opinions into scientific articles. A list can be consulted at http://www.favv-afsca.fgov.be/comitescientifique/publications/default.asp.

The SciCom has, since many years, the tradition to organize annually a scientific symposium to present the state of knowledge in regard to an actual theme related to risk assessment in the food chain. This offers the opportunity for interaction and exchange of ideas with stakeholders and peers. Themes of the last symposia are "Improving the safety of the food chain through risk prevention in plant and animal production" (2014),"Risk ranking in the food chain" (2013), "Food Safety of the Short Supply Chain" (2012), "Applications of Microbiological Risk Assessment in the Food Chain" (2011), "Nanotechnology in the Food Chain" (2010).

6. Conclusion

In the Belgian model an independent Scientific Committee is positioned within the organization of a national control agency of the food chain.

The Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain has proven, since its creation, that it is a very efficient advisory body. Despite the application of pragmatic approaches in risk assessment it has been able to issue opinions of international quality and reputation and respecting short throughput times. The scientific and administrative support of the Scientific Committee by a highly qualified dynamic team of in-house experts in risk assessment of the food chain is one of the key factors of its success.

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