

Summary

Ris2 - Session Risk Management and Regulatory Aspects

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In the Session Risk Management and Regulatory aspects, several lectures and posters are presented highlighting findings of possible sources of contamination of environment, feed and food by dioxins and other harmful substances and possible management measures to limit human exposure to dioxins are presented.

A presentation concerns the environmental risk management for pharmaceutical compounds. Pharmaceuticals are a highly variable group of organic compounds with the potential to cause harm to aquatic ecosystems and human health. Regulatory approaches based on risk assessment have seriously failed to anticipate some of the deleterious effects of chemicals. In environmental policy, the precautionary principle has emerged as a driving force behind new legislative mandates aimed at reducing public health risks from exposure to harmful environmental contaminants, even before the scientific community has reached consensus on the exact mechanism that may cause adverse effects in humans. The key element is the justification for acting in the face of uncertainty. The precautionary principle can be however controversial, and critics support the need to wait for "sound science" before taking "costly" regulatory action. However, risks associated with human and ecological health as a result of exposure to environmental pollutants are difficult to assess and accurately quantify.

The new approach to risk management to reduce the presence of pharmaceuticals in the environment presented is through an integrated framework, where there is a better balance between precaution and reality. The proposed scientific framework for the management of chemicals is based on an environmental risk-benefit analysis tool, which uses the conceptual model of 'sources - pathways – impacts' for the presence of chemicals in the environment. According to this model, sources, pathways and impacts can be managed in order for risks to be reduced.

Humans are exposed to dioxins not only through food, but also eg. through intake of dust. The paper "Surface dust criteria for dioxins and dioxin-like compounds for re-entry to buildings describes recommended re-entry "building surface" criteria for four different exposure scenarios (adult occupational, adult residential, childhood occupational and childhood residential. Re-entry criteria considering a wide range of exposure scenarios, exposure pathways, bioavailability and behavioural parameters would be very useful to risk managers in order to address multiple diverse situations. It can be concluded that it is reasonable to calculate different re-entry criteria based on age and activity, that the calculated re-entry criteria result in exposure of 1/100 to 1/1000 of the 70 pg/kg bw a month tolerable intake level established by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA). The calculation of the re-entry criteria is driven by the dissipation constant for the amount.

Another paper provides a summary of the key findings from a comprehensive survey of dioxin levels undertaken in Australia through the National Dioxins Program (NDP). The program aims to determine levels, assess the risks to Australians and the environment and consider appropriate management actions.

With regard to emission sources, bushfires are estimated to be around 20-30 % of all emissions to air while motor vehicle emission account only for 2 % of all emissions to air.

Uncontrolled combustion, including bushfires, waste burning and accidental fires is estimated to contribute nearly 70% of total emissions to air and over 80% of total emissions to land. Disposal and landfill is estimated to be the largest source of dioxin emissions to water, contributing over 75% of the total.

In the programme also background levels were measured in the environment (air, soils, aquatic environment and fauna). Dioxins levels found were generally low and the risks to the environment are considered to be generally low. The study identified a potential risk to birds of prey from exposure to dioxins.

Also dioxin levels in a range of foods were monitored and low levels of dioxins were found. This resulted in a monthly intake of dioxins between 3.9 – 15.8 pg TEQ/kg bw/month or between 6-23% of the Tolerable Monthly intake established by JECFA.

Also comparatively low levels of dioxins in blood serum and breast milk were found in the Australian population. The levels in breast milk collected in 2003 were almost halved in comparison with the levels found in 1993.

Another presentation focuses on case study in Belgium whereby dioxins levels were determined in environment and food produced in a city in the neighbourhood of two waste incinerators. Although the waste incinerators complied with the EU dioxin emission standard of 0.1 ng TEQ per m³, deposition measurements and analysis in the region indicate a high burden of the local environment of dioxin-like PCBs and dioxins and furans. Analyses were performed on soil, vegetables, eggs and milk produced in the region. For some soil samples an unexpectedly relatively high contribution of the dioxin-like PCBs (more than 50%) could be observed compared to PCDD/Fs. This relatively high contribution of the concentration of dioxin-like PCBs was also found in the vegetables, free range eggs and milk produced on the same locations from where the soil samples with high dioxin-like PCB levels originated.

These measurements were a clear indication that in the vicinity of the monitored area there is a considerable but not widespread contamination by a local PCB source. Close to a metal recycling plant high deposition levels of dioxin-like PCBs were observed. The potential contribution to the overall contamination of shredder activities and blown up dust particles is currently investigated. Several exposure scenarios have been calculated. In particular the consumption of locally produced free range eggs increases the human exposure to dioxins and dioxin-like PCBs, resulting in exposures to what has been assessed as tolerable.

A final presentation in this session of Risk Management and Regulatory Aspects concern comments on the performed risk assessments of dioxins and dioxin-like PCBs in food. An overview is provided of the risk assessments performed by the German Federal Environment Agency (UBA) in 1985, the World Health Organisation (WHO) in 1997, the EU Scientific Committee on Food (SCF) in 2000 and updated in 2001 and the JECFA in 2001. Detailed comments are given on the SCF opinion. It is recognised that any recommendation of a precise number for a tolerable intake is flawed by uncertainties and the possibility of different weighing being given to the studies of relevance. The authors therefore suggest, in order to have a high level of protection for humans, to use the lower end of the WHO TDI range of 1 pg/kg per day, for all standard settings and reduction measures and that the goal set by the WHO “to reduce human intake levels below 1 pg TEQ/kg bw day” should be maintained. Finally it is proposed that the TDI be reassessed in a process transparent to the public and on the basis of all relevant toxicological endpoints from animal and human epidemiology, including the assessment of cancer risks.

Several interesting posters are presented in relation to this Session.

The Ministry of the Environment in Japan has been conducting environmental monitoring of various pollutants including major POPs in Japan for more than two decades. Since 2002, the POPs are analysed by using more sensitive method of analysis. Dioxin levels have been monitored in air, water and sediments and showed a clear decreasing trend. PCB levels in fish did not show a clear temporal trend. Other POPs such as HCB, aldrin, endrin, mirex and toxaphene were not detected while dieldrin and heptachlor were detected in only limited number of samples. DDT and chlordane were detected in many biological samples and, certainly in the case of chlordane, a clear decreasing trend in recent years could be observed.

Another poster present a review of the different approaches that have been used to identify sediment benchmarks for PCDD/Fs in US and elsewhere. Three approaches for deriving benchmark concentrations of PCDD/Fs in sediment are commented and their current limitations are highlighted: the background approach, equilibrium partitioning (EqP) and the tissue residue-based (TRB) method. Among the three approaches, the TRB method, which relies on acceptable tissue concentrations and BSAFs (biota-sediment accumulation factors) to calculate sediment concentrations, appears to be one of the more promising approaches for developing SQGs (sediment quality guidelines). The TRB approach, together with information derived using other assessment tools, may provide the best means for establishing a scientifically defensible foundation for developing benchmarks to screen effect and no-effect concentrations in sediment.

Another poster reports on the risks to human health for the people involved in the clean-up operation of leftovers of 2,4,5-T with TCDD as dioxin trace. This clean-up operation was necessary as one of the runaways of the Hua Hin airport in Thailand was being expanded. No specific correlation or any significant biomarker of toxicity has been observed. Some correlation could be observed between the level of some dioxin/furan/PCB congeners in the serum and the frequency of fish consumption, age and the duration of time near the site.

Another poster presents CASCADE. CASCADE was established in the spring of 2004 to provide Europe with a durable, comprehensive and independent network of excellence in research, risk assessment, and education concerning endocrine disrupting chemicals in food. Activities include state-of-the-art research from the best European research centres in the field, innovative training programmes, relevant information to consumers and reliable assessments to risk managers concerning risks of chemicals in food. The focus on nuclear receptors is highly relevant not only since these transcription factors span all aspects of human disease from growth and development to reproduction, but also because many food contaminants interfere with the nuclear receptor signalling pathway. The CASCADE network of excellence is not static. It is to be continuously enriched with valuable activities that can add strength and competitiveness. Research centres, organisations, policy makers, and the public are always welcome to discuss collaboration.

A quantitative data analysis of chemical contamination in the Venice lagoon is presented in another poster. The data show that biota contamination levels seem to reflect local environmental pollutant levels. The quantitative and qualitative influence of Porto Maghera and the city of Venice on the pollution in the central basin of the Venice lagoon is an relevant issue when considering a management strategy to ensure that marine biota originating from that location are safe for human consumption.

The risk assessment and risk management activities undertaken in Canada under the Canadian Environmental Protection Act (CEPA) are presented in a poster as well the main results. Since 1990, dioxin and furan releases in Canada decreased by more than 60 % since 1990, releases to air by 61 % during the last decade and releases to water by 99%, thereby in this latter case achieving the goal of virtual elimination from the pulp and paper sector. Average Canadian intake from food is estimated to be approximately 5.6 pg/kg bw/week. Levels of dioxin in Canadian serum and breast milk declined by 50 % from the 1980s (breast milk: 40,7 pg TEQ/g lipid) to the 1990s (breast milk: 19,9 pg TEQ/g lipid). Canadian human tissue levels is approximately 2-fold lower than those of most European countries.