TRENDS IN THE RISK ASSESSMENT STRATEGY OF PERSISTENT ORGANIC POLLUTANTS. THE EUROPEAN PERSPECTIVE

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Introduction

Risk assessment protocols are considered nowadays the best available tool for developing scientifically sound decision-making processes. A "risk assessment" is required in an increasing number of human activities, which according to the EU Scientific Steering Committee, range from prognoses for mental health patients, through industrial plant safety to sensitive ecological sites and consumer protection. In the chemicals' arena, risk assessment is the key tool for setting acceptable practices and uses, as well as to set restrictions and risk reduction needs. Currently, different requirements and protocols are established for several groups of chemicals. Industrial chemicals are covered by two categories: "existing" and "notified" (new) substances (see Hart et al[1] for details), which risk assessment protocol is covered by a common Technical Guidance Document (TGD)[2], while other regulations and technical notes for guidance cover the risk assessment of pesticides, biocides, pharmaceuticals, feed additives, etc.

Although the risk assessment is just one of the elements for the regulatory decision, the scientific basis of this assessment is considered a critical element. The European Commission reorganised their advisory body in 1997, establishing under DG SANCO a set of Scientific Committees, under the umbrella of a Scientific Steering Committee, for getting an independent view of the scientific basis of the proposals prior to the adoption of a final decision. Although the structure of these committees will be adapted to the needs of the new European Food Authority, the role of a scientifically solid risk assessment is getting even more importance in the regulation of chemicals.

A revolution in the European chemicals' policy is on-going, focused on the discussions for the implementation of the Commission's White Paper presented in February 2001[3]. Two basic ideas are centring the discussion. First, the use scientifically sound risk assessment methodologies in the decision process whenever possible. Second, the application of the Precautionary Principle, based for example on the intrinsic hazards of the chemicals, when a scientifically sound risk assessment cannot be conducted. Therefore, the basic question is: Can the scientific community offer regulators a sound risk assessment for POPs and related chemicals?

The risk assessment paradigm for POP

The TGD covers different exposure scenarios and presents guidance for assessing the risk on aquatic organisms, soil organisms and secondary poisoning in mammals and birds. Although the TGD has been recognised as a sound tool in most cases, there are serious doubts on its suitability for covering POP-like chemicals. In fact, the Scientific Committee on Toxicology, Ecotoxicology and the Environment expressed in their opinion on phthalates that the TGD should not be directly applied to these kind of chemicals[4]. There are several assumptions in the TGD considered unsuitable for POP-like chemicals, for example, the assessment of a local scenario based exclusively on dilution, the acceptance of short-term tests for predicting long-term effects, or the consideration of bioconcentration potential but not biomagnification through the food chain.

RISK ASSESSMENT

An additional source of information comes from the brominated flame-retardants. Their presence in the environment has become of increasing concern[5]. The EU has included several congeners in their priority list and risk assessment reports following the TGD principles are available[2]. Basically, the reports confirm the high toxicity and bioaccumulation potential of some of these chemicals, which apparently disappears for the highly brominated substitutes. This effect is explained by the high Kow and particularly the molecular mass of the octo and deca derivatives well above 700. However, these high molecular weight chemicals, assumed to be non bioavailable, have been recently found in top predators[6] suggesting that in-depth conceptual changes are required. Some alternatives have been already offered[7].

The basic difference when assessing the risk of highly persistent chemicals is to consider the lack of temporal and spatial homogeneity, and the lack of synchrony between the emission and the expected effects. As already observed for persistent organochlorines, these chemicals have potential for concentrating in certain areas/compartments. If the chemical has some "preferences" for sub-compartments, such as the cold artic regions, sediments of particular characteristics, or the lipid tissue of top predators, it is just a question of time for achieving significant levels in these sub-compartments, and time is not a problem for a highly persistent pollutant. Simplistic approaches, assuming averaged concentrations as the ratio of the total emission level versus the total compartment volume, or concentration in biota expressed as the concentration in the compartment multiplied by the bioconcentration factor, are not suitable. Additional aspects, as those presented in Figure 1 should be considered.

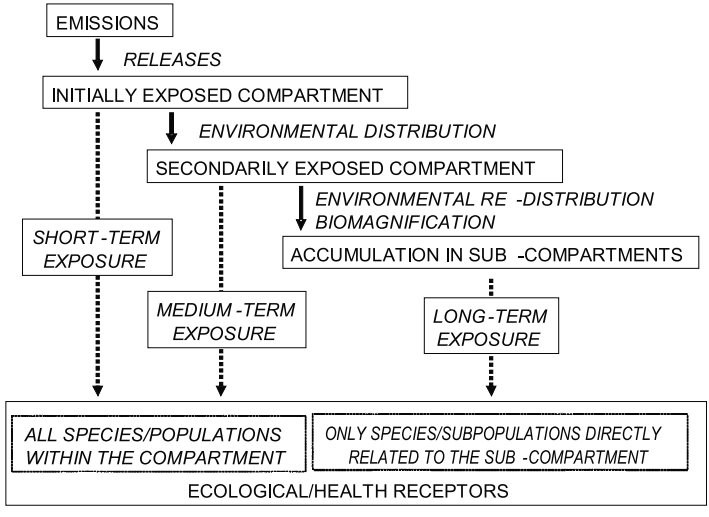

Figure 1. Proposed risk assessment model for highly persistent chemicals. The third level, accumulation in sub-compartments and long-term exposure becomes critical for these chemicals.

The initial difference is the need for considering a long-term risk assessment focusing on specific sub-compartments affecting exclusively to selected receptors. The key receptors are limited to a few species, i.e. top predators in the environmental risk assessment of biomagnificable chemicals, or specific sub-populations in the case of human health assessment, i.e. infants exposed via breast milk for persistent lipophilic substances.

The second difference appears in the timeframe for exposure and effects, as shown in Figure 2.

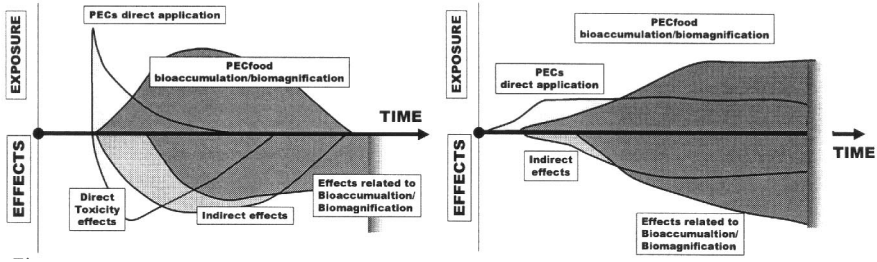

Figure 2. Comparisons of exposure *versus* effect timeframes for highly persistent bioaccumulable chemicals. Left, single-emissions. Right, accumulation of continuous single emissions.

In both cases, the effects only appear some time after reaching significant exposure levels. The timescale can be years or even centuries, and effects can still increase after reaching plateau exposure levels, as a consequence of concentration in specific sub-compartments. It is not easy, but the papers presented to this congress demonstrate that proper risk assessments can be conducted for POP-like chemicals if enough information is available. Alternatives for targeted risk assessment selecting the key exposure route-receptor combinations have been proposed[8].

Risk Assessment versus Precautionary Approaches

Due to the evident complexity for conducting a sound risk assessment for these chemicals there is a regulatory tendency to consider alternatives based on hazard identification. Very persistent and very bioaccumulable chemicals are identified and specific limitations and controls are imposed. The need for identifying these substances is very clear but the key question is to determine the next step. The White Paper on Chemicals Policy[3] indicates a mandatory authorisation process for these chemicals based on specific risk assessments for each intended use. However, there is a regulatory tendency for considering that a risk assessment is either not possible or not suitable for these substances, and that regulatory decisions should be based on the Precautionary Principle, and measures to avoid environmental releases are imposed. The assessment of Priority Hazardous Chemicals under the Water Framework Directive or the recently adopted proposal for the marine risk assessment in the new TGD revision, following the OSPAR convention, are good examples for this regulatory tendency.

In theory, the use of the Precautionary Principle should provide a higher level of protection for human health and the environment. In reality, this is not necessarily the case. In the 70s, this approach was applied to pesticides in drinking water. The initial intention "*the presence of pesticides in drinking water should not be allowed*" was transformed into a regulatory measure "*the concentration of pesticides should be below 0.1*mg/l" which was considered the limit of detection of analytical methods in those days. Nowadays, this limit has also been extrapolated to other areas, such as groundwater, and new pesticides, which can be toxic for some organisms at concentrations below this level, have been produced. In summary, the initial decision "NO PRESENCE" was interpreted as "NO DETECTION", a fixed limit of detection was established, and the final outcome is "PRESENCE ALLOWED BELOW A LIMIT" without considering the risk associated to that particular limit. The concern on regulatory measures on POP-like chemicals comes from the application of the regulatory measures. The initial decision "AVOID EMISSIONS" will become in "ACCEPTING EMISSIONS ASSUMED TO BE

NEGLIGIBLE OR NON DETECTABLE", but from a scientific perspective, how can we determine if an emission is negligible without a risk assessment?

In risk assessment, negligible should mean a level of exposure so low, compared to the level of effect, that the obtained margin of safety, accounting for the associated uncertainty, is large enough for considering a very low likelihood for resulting in adverse effects. If there is not sufficient information for identifying the concentrations expected to be safe for humans and the environment, or the long-term concentrations expected in biota, how can the emission be considered negligible or the proposed level of detection assumed to be acceptable?

Conclusions

From a scientific perspective, risk assessment is the only possibility for developing sound decision-making protocols. Precautionary decisions should be put on top of the risk results, but never substitute the risk assessment (unless a total ban is proposed). Opposite to the feeling of some regulatory bodies, it is possible to conduct sound risk assessment for these chemicals if the required information becomes available. Risks associated to releases assumed as negligible could be very high for particularly dangerous chemicals.

References

1. Hart JW, Hansen BG and Karcher W (1998) Hazard Assessment and Risk Assessment of Chemical Substances in the EU In D.M. Pugh and J.V. Tarazona (ed) Regulation for Chemical Safety in Europe: Analysis, comment and criticism. Kluwer Academic Publishers. Dordrecht.
2. Documents available from the web page of the European Chemicals Bureau, www.ecb.jrc.it
3. EC (2001) White Paper on the future of a chemicals' strategy. European Commission. Brussels.
4. CSTEE (2001) Opinion on the results of the Risk Assessment of di-"isodecyl"phthalate. Brussels, 5 pp.
5. Wit C.A (2002) An overview of brominated flame retardants in the environment. Chemosphere 46: 583-624.
6. Sellström U, Lindberg P, Hägglund L, de Wit, C. (2001). Higher brominated PBDEs found in eggs of Peregrine Falcons (*Falco peregrinus*) breeding in Sweden. Abstracts, II International Workshop on Brominated Flame Retardants, BFR 2001, May 14-16, Stockholm pp 159-162.
7. Wenning RJ (2002) Uncertainties and data needs in risk assessment of three commercial polybrominated diphenyl ethers: probabilistic exposure analysis and comparison with European Commission results. Chemosphere 46:779-96
8. Tarazona JV, Hund K, Jager, T., S-Salonen M., Soares AMVM, Skaare JU, and Vigui M. (2002) Standardizing chemical risk assessment, at last. Nature, 415, 14.