16 May 2006

Deca-BDE – Summary status report on additional information requirements

Environmental monitoring programme

Scope

At the 26 May 2004 Competent Authorities meeting, it was agreed that there should be a study "monitoring the environment to establish the trends in levels of contamination for both the substance and its more toxic and bio-accumulative degradation products over a suitable period of time".
A 10-year environmental monitoring programme of Deca-BDE is being carried out, after consultation with the rapporteur. It involves monitoring sediment in the UK, the Netherlands, Germany, France and Ireland and sludge in the UK and the Netherlands. Bird eggs are to be monitored in the UK and the Norwegian Arctic. These results will allow establishing trends over time on the presence of Deca-BDE in the environment.

In addition, at the request of the rapporteur, a pilot study on monitoring air samples in the UK was carried out to investigate the feasibility of reliably monitoring Deca-BDE in air.

Status

The environmental monitoring programme was started in April 2005. The first sampling round was completed in the fourth quarter of 2005 by the institutes involved in the program (Vrije Universiteit Amsterdam - IVM, the UK Centre for Environment, Fisheries and Aquaculture Sciences – CEFAS, the UK Centre for Ecology and Hydrology – CEH, and the Norwegian Polar Institute) and the laboratories are analyzing the samples. An update report has been provided to the UK rapporteur in early May and a full first interim report on the environmental monitoring results will be sent to the UK rapporteur by the end of May 2006. This will be the first of the bi-annual reports planned in the framework of the 10-year environmental monitoring programme of Deca-BDE aimed at establishing a temporal trend of levels of Deca-BDE in the environment.

It should be noted that after consultation with the rapporteur, the analysis of specific "marker congeners" was added to the scope of the programme. The amended protocol for this programme was circulated to the TC-NES in December 2005. This will allow specifically to analyse for the potential degradation of Deca-BDE to lower BDE congeners. From past studies, there has been no correlation between findings of breakdown products in laboratories and findings in the environment.

As a final point, it should be noted that the scientist leading the program, Prof. Jacob de Boer, and his research team have changed laboratories. Since 1 May 2006 the programme has moved to the Vrije Universiteit Amsterdam (IVM), from The Netherlands Institute for Fisheries Research (RIVO) in IJmuiden. This change will not impact the program since it is only a change in location for the original team. The other laboratories involved in the project since its initiation remain the same. While this change will have no substantial impact on the project, due to relocation and the practicalities involved (setting up instruments, transfer of contracts, etc.) a minor delay of a few weeks was incurred. The same considerations also apply to the analytical part of the biomonitoring programme described below, which is also carried out by IVM.

The pilot study on air monitoring was completed in February 2006 and the final report and results were communicated on 10 March 2006 to the UK rapporteur. The study showed a high variation of the levels found (the range was between 5 and 45 pg/m3) with a standard deviation of 69%. Industry and the research laboratory (University of Lancaster) met on 21 February to discuss these results, in particular how the variation of data could be reduced, and investigate the need for further steps. The researchers are currently preparing a revised proposal aimed at reducing this variability.

Bio-monitoring programme

Scope

At the 26 May 2004 Competent Authorities meeting, it was agreed that it would be necessary to initiate "a suitable human bio-monitoring programme, including breast milk, and the need for a trend analysis over a certain time period".

A 10-year bio-monitoring programme has been started by industry to monitor Deca-BDE levels in the blood of the European population. In a first phase, a pilot study will monitor blood levels in 4 different European countries – the Netherlands, Norway, the UK and Spain - to find out if there are regional differences in the levels found. Based on the data obtained in this pilot study, one country will be selected for further long-term monitoring of levels of DecaBDE over the full 10 year period.

Status

After the approval by the TC-NES meeting in November 2005 of the scope and protocol, the 10-year blood bio-monitoring programme started in December 2005. The research laboratories involved in the programme are the Institute for Risk Assessment Sciences (IRAS), Utrecht, the Vrije Universiteit Amsterdam (IVM), both in The Netherlands and the Norwegian Institute of Public Health. As requested by the Member States expert group that agreed on the study protocol and scope, a method development-study is currently being carried out to verify the analytical methods, carry out an interlaboratory comparison and to determine the most appropriate blood fractions to sample. The results of the pre-study are scheduled to be reported in June 2006. Such a biomonitoring programme as requested needs the approval of the relevant national Medical Ethical

Committees. The applications to the Medical Ethical Committees in the 4 countries have been filed in January 2006 in the four countries selected for the study and are currently being processed. Approval is expected in May/June 2006. On that basis, a first interim report is expected to be presented end-May 2007.
As already discussed in the environmental monitoring section, due to the move from Prof de Boer from RIVO to IVM a slight delay in the analytical work occurred. The results of the pre-study may therefore be delayed by a few weeks.

Following consultation and discussion the Member States expert group has agreed with the industry proposal to include Deca-BDE in the World Health Organisation (WHO) programme on breast milk monitoring in the framework of the WHO International Program on Chemical Safety. This WHO program is a standard working program with a well established protocol already agreed by the participating countries and which has been running since 1987. The WHO study has already been initiated (calls for interest have been sent to Member States, etc.) and is due to be started in 2006.

Developmental neurotoxicity study

Scope
The 26 May 2004 Competent Authorities' minutes defined one of the "outstanding questions" needed to be addressed as "neurotoxic effects and uptake of the substance by mammals in laboratory studies". To this end, it was agreed that there should be initiated "a further developmental neurotoxicity study in mice".

Status
In 2005, several meetings took place with the rapporteur as well as discussions with the EU expert group in order to define the most appropriate testing protocol for this study. It has been difficult to reach an agreement on the scope and details of the study given the differing views among the members of the EU expert group and the non-standard study design they have requested. It took significant time and effort to identify a competent laboratory able to lead the study. Moreover, since none of the contract research organizations (CROs) has experience with the non-standard dosing vehicle requested by the EU experts (there are no historical control data on this vehicle), the laboratory insisted to carry out a pre-study establishing important parameters that are crucial for carrying out the definitive study.

A general agreement has been reached in the TC-NES meeting in March 2006 on the scope and outline of the study and on 31 March the rapporteur was informed about the detailed study plan. In April 2006, a laboratory has been contracted to carry out the study. There are remaining technical questions, including the decision on how to best pre-dose the animals in the first part of the study, which are currently being addressed together with the rapporteur. However, this has not prevented the initiation of the study since in the first phase of the study the CRO is currently preparing a final, detailed, study protocol and any comments received in the coming weeks can still be integrated. On the basis of the general agreement reached on the general scope of the study, the study has officially

started at the end of April 2006 with results due in 2008. The experimental works are scheduled to start in late May 2006.

Conclusion

The different programmes covering the additional information requirements as agreed jointly with the EU Competent Authorities in May 2004 are all progressing. The developmental neurotoxicity study has been subject to a wide range of detailed technical discussions with the rapporteur and Member State experts so as to reach agreement on the testing protocol and scope for the study, which is now up and running. Both the environmental monitoring and the bio-monitoring programmes have been initiated, are proceeding according to schedule and will produce their initial interim reports for review by the rapporteurs and TC-NES as previously agreed.