

## SWEDISH CHEMICALS INSPECTORATE

### Work to reduce the environmental impact of PVC

#### Summary of Report No 2/01

#### **SUMMARY**

In its appropriation warrant for 1999, the Government has commissioned the National Chemicals Inspectorate to:

- observe the development of harmful and allegedly harmful plasticisers in PVC, in keeping with the phase-out plans set forth in Government Bill Prop. 1997/98:145,
- observe continuing efforts by manufacturers and importers to reduce the environmental impact of PVC, to develop better PVC and replace PVC with other materials where the use of PVC is suspected of harming the environment and human health,
- propose measures to be taken in the event of a phase-out not being accomplished on a voluntary basis.

A progress report on the phase-out is to be presented by the National Chemicals Inspectorate not later than 31st December 2000.

In the current remit, attention is being made to focus on the harmful additives contained by the PVC product. The account is dominated by the substances indicated by the Government in its Bill Prop. 1997/98:145. The substances/groups of substances concerned are phthalates, lead compounds, chloroparaffins and nonylphenoethoxylates. Lack of supportive data has made it impossible to confirm any occurrence of these substances in imported products. Conclusions regarding hazards and risks of phthalates have to a great extent been based on the documentation compiled within the EU programme for existing substances.

The remit has been conducted in collaboration with PVC Forum and a number of trade organisations. During 1999 PVC Forum drew up an environmental programme.

Measures against the most harmful tin stabilisers were reported by the National Chemicals Inspectorate on 31st May 2000.

#### **Risks associated with phthalates**

The National Chemicals Inspectorate's assessment of hazards and risks associated with phthalates are principally based on the documentation compiled within the framework of risk evaluations under the EU programme on the evaluation and control of the risks of existing substances. That work is based on Council Regulation (EEC) No. 793/93 of 23 March 1993. The programme includes toxicological and ecotoxicological assessments on selected chemical substances.

Five phthalates used among other things in PVC are currently being investigated under the programme. Where four of them – DEHP, DIDP, DINP and DBP – are concerned, the evaluation of risk has made considerable headway. For BBP there exists a draft

ecotoxicological risk evaluation from November 2000. DEHP, DIDP and DINP are the three phthalates most used as plasticisers in PVC.

### **Evaluation of hazard to man**

DEHP, DIDP, DINP and DBP have been discussed within the EU working group on classification and labelling. A formal decision is expected at the beginning of 2001. The effects judged to be critical in connection with exposure to DEHP are above all testicular injuries and foetal injuries, but they also include effects on the kidneys and impaired fertility.

It is proposed that DEHP be classified as toxic for both reproduction and embryonic development in category 2. This proposal is stricter than the classification hitherto applied by the manufacturers, namely category 3, and DEHP product information will accordingly be made to include the skull and crossbones.

Category 2 classification as reprotoxic is also proposed for DBP. Concerning BBP, additional studies have been requested before a decision can be taken on classification, but the BBP rapporteur has proposed classification as reprotoxic.

DIDP is assessed capable of causing harm to the unborn child but not testicular injury. DINP is judged to have a weak testicular impact. Both DIDP and DINP can also cause liver injury at lower dosage levels than those at which embryonic/testicular injury is established.

One difference in the supportive data for DEHP and that for DIDP and DINP is that for DEHP there exist studies of young, sexually immature rats indicating that they are more sensitive than older animals to testicular effects. Similar studies are lacking for DIDP and DINP. The National Chemicals Inspectorate has judged this to be a significant deficiency in the evaluations of risk for the phthalates in question and has therefore proposed that studies of this kind should be carried out by industry, but this proposal has not gained the support of the other Member States.

The National Chemicals Inspectorate has further stated that, owing to the lack of the above mentioned studies, a full comparison of DIDP and DINP with DEHP is impossible. The Inspectorate finds that data exist which justify classification as reprotoxic in category 3. However, the Inspectorate has not been supported by the other Member States in this assessment, and the working group has found that the supportive data do not provide cause for classification.

### **Evaluation of risk to man**

Where DEHP is concerned, the EU's risk assessment leads to the conclusion that risk reduction measures of risk limitation are needed above all as regards exposure of the following groups:

- Infants via breast milk.
- Infants via infant formulae
- Children via food.
- Children as consumers (mainly via toys).
- Patients regularly subjected to certain medical treatments (children and adults).
- Workers in a large number of branches of production.

In the EU risk assessment of DBP, a conclusion concerning the need for risk reduction measures of risk limitation has been agreed on for occupational exposure in activities giving rise to the formation of aerosols.

For DIDP and DINP, the EU risk assessment has led to the conclusion that with present-day use there is an adequate margin of safety. In the case of DIDP, however, concern is identified regarding effects on infants and children up to the age of 3 years if all plasticisers in toys were to have been replaced with DIDP. The same applies to these groups if all DEHP in materials coming into contact with foodstuffs were to be replaced with DIDP. For DINP the margin of safety is adequate even with alternative scenarios like these.

Evaluation of the danger and risk to the environment

For DBP the EU working group's proposal on classification and labelling is that the substance be classified as dangerous for the environment. The rapporteur within the existing substance programme for BBP has proposed classification as dangerous for the environment, but the EU working group for classification and labelling has not yet defined its standpoint on this proposal.

The other phthalates have not been proposed for classification as dangerous for the environment. The fact of DEHP, DBP and eventually also BBP being classified as reprotoxic, based on laboratory studies of mammals, naturally implies that these substances can be expected to have similar effects on mammals in the wild state. The ecotoxicity classification, however, does not contain any criteria of reprotoxicity, and there are no studies indicating such effects as are taken into account for classification purposes.

### **Deliberations concerning phthalates**

The rapid phase-out by 2001 of outdoor products indicated in the Government's Environmental Policy Bill, Prop. 1997/98:145, will not be fully implemented. In the case of other product groups, the phase-out rate will depend on the acceptance by foreign suppliers of a replacement of DEHP by 2005. In several cases DEHP quantities are indistinguishable from total phthalate quantities. A rough estimate can still be made, however, of the amount of DEHP possibly remaining after 2000. This estimate is of the order of 400-1,000 tonnes in outdoor products and 3,600 tonnes in other products, implying a total reduction of almost 10,000 tonnes compared with 1994.

Instead of phase-out targets in keeping with the Government's guidelines, the PVC Forum environmental programme defines emission requirements for plasticisers in products manufactured after 31st December 2001.

The conclusion drawn by the National Chemicals Inspectorate concerning DEHP, on the basis of the risk assessment within the EU programme on Existing Substances, is that concern for harmful effects on health has grown. It has been proposed that DEHP be classified as reprotoxic in category 2. In animal experiments, young growing individuals have proved particularly sensitive.

Generally speaking, the hazards and risks identified for DEHP within the EU programme for existing substances are of such a kind that measures should be proposed at EU level. Those measures should be based on the risks potentially entailed by both the known and the diffuse migration of DEHP. In view of the time it can take to implement measures at EU level, and given the serious risks involved, it is urgently necessary to continue with the national

activities which have already started. There should also be scope for faster action where the most sensitive groups are concerned.

One sensitive group of this kind is tube-fed premature babies. For this group, the National Chemicals Inspectorate's evaluation is that exposure to DEHP should cease at once.

Concern regarding harmful effects on the unborn child remains where DIDP and DINP are concerned, even though they will not be classified as reprotoxic. Here the Inspectorate finds that there are gaps in our knowledge as regards both data concerning the effects of the substances as such and data concerning effects of multiple exposure to phthalates.

### **Deliberations concerning other additives**

The Government's phase-out targets for lead and chloroparaffins have been included by PVC Forum in its environmental programme. For organotin compounds it is indicated that the guidelines in the Inspectorate's report to the Government on organotin stabilisers are to be complied with.

The voluntary national work done to replace lead, above all in stabilisers, has been successful. It is estimated that in 2002 approximately 30 tonnes of lead will remain in high-temperature cables and up to 20 tonnes in imported foils, profiles and products of coated fabric.

The voluntary work undertaken by European industry is insufficient and is not keeping step with the development in Sweden of alternatives to lead. Common EU rules are necessary in order for imported PVC products to be made free from lead. In its statement concerning the EU green paper on PVC, Sweden has highlighted the need to consider an EU prohibition of lead stabilisers in PVC.

The use of cadmium as a stabiliser and colouring agent has been prohibited for several years now. The corresponding prohibition at EU level is less far-reaching and does not, for example, include PVC window profiles.

Only a minor quantity, corresponding to 3 tonnes, of medium chain chloroparaffins is supplied to the Swedish market annually in imported safety flooring.

Nonylphenolethoxylates are no longer being used in flooring. No reports have been received of other PVC products containing nonylphenolethoxylates.

The National Chemicals Inspectorate judges the phase-out of dibutyl tin compounds in the flooring and coil-coated sheet metal trades to be proceeding at a rate in keeping with the Government's target.

The absence of phase-out measures concerning the use of octyltin compounds in packaging foil and shelf-edge strips, however, is judged incompatible with the Government's target.

In addition to the measures previously proposed with regard to organotin stabilisers, the National Chemicals Inspectorate regards continuing work on the common EU strategy for PVC and the work to which this may lead as a suitable forum for further investigations.

## **Systematic risk reduction work**

The National Chemicals Inspectorate's remit includes reporting on the work done by manufactures and importers to reduce the environmental impact of PVC and to develop a better PVC.

The prospects of developing a better PVC, sustainable in the long term in a life-cycle perspective, depend on systematic risk reduction work characterised by transparency and co-operation between manufactures/importers and users.

Systematic risk reduction implies a continuous process aimed at successively reducing the danger level until, eventually, the constituent substances of the product do not entail any risk of harm to health or the environment. The systematic approach means companies working in a life-cycle perspective, i.e. investigating and showing consideration for what happens to the products/goods throughout their life cycle, from production to waste, with evaluation of the effects on health and the environment at every stage.

Application of the precautionary principle and the substitution principle is a minimum level for meeting the requirements of the Environmental Code. But the targets defined for a non-toxic environment have a wider approach and set a high level of achievement for the period ending in 2020. The guidelines point out inherent properties instead of individual substances. Systematic risk reduction work of this kind, focusing on inherent properties, has not yet achieved any impact.

In its report, entitled "Non-Hazardous Products" (SOU 2000:53), the Chemicals Commission proposes phase-out targets for certain metals and for substances which are persistent, bioaccumulative, carcinogenic, mutagenic and harmful to reproduction. The report also proposes criteria for these properties.

The fact of no other additives having been specified by companies as being in urgent need of replacement indicates an absence of systematic risk reduction work on their part with a view to identifying and replacing dangerous additives.

The PVC Forum's environmental programme is a good initiative. It refers in general terms to the general phase-out requirements of Government Bill Prop. 1997/98:145. In view of the deficiency which has been indicated concerning systematic risk reduction work by undertakings, it should be possible to add to this programme a specific commitment to systematically counteracting the inclusion in production processes or goods of, in the first instance, substances which have especially dangerous properties or which entail risks in connection with exposure.

Users of PVC products can hasten the accumulation of knowledge and the transition to less hazardous additives by making demands in connection with purchasing.

## **Conclusions and recommendations**

### *Phthalates*

The Swedish PVC industry should continue its work to phase out DEHP and should broaden that work so as also to include DBP and BBP, insofar as these phthalates are used.

As part of the EU programme for existing substances, the National Chemicals Inspectorate intends to devise a risk management strategy for DEHP. Continuing work should be aimed most immediately at trying to identify sources making a significant contribution to the exposure of children via breast milk and food. Sources of this kind, if identifiable, should be dealt with first. If individual sources cannot be indicated, more general measures will need to be considered.

*DBP and BBP* have been proposed for classification as reprotoxic in category 2. Further risk reduction measures will be needed, but for the time being the National Chemicals Inspectorate awaits any proposals for action which may be formulated in the EU programme for Existing Substances.

Where DIDP and DINP are concerned, the National Chemicals Inspectorate is of the opinion that the existing documentation justifies classification as reprotoxic in category 3. This in turn argues in favour of a continuing ban on the use of DIDP and DINP in toys. Owing, however, to the lack of supportive data, it is impossible at present to draw any conclusions regarding the need for more general risk reduction measures.

The persistent concern regarding the reprotoxic effects of individual phthalates should prompt the suppliers responsible to ascertain more facts.

Lack of knowledge concerning possible effects of multiple exposure, e.g. to phthalates, should justify research in this field. The National Chemicals Inspectorate intends giving special consideration to this need in connection with its membership of various research committees.

Sweden should ensure that the current national ban on phthalates in toys is not emasculated but can be retained at EU level.

Sweden should act within relevant EU fora to bring about a rapid phase-out of DEHP and other fertility-impairing phthalates in feed tubes for premature babies.

National suppliers of feed tubes for premature/sick children should ensure that DEHP- free alternatives can quickly be made available to all relevant branches of medical care.

### **Other additives**

The preliminary evaluation in the fresh water environment of TBT as a contaminant in organotin stabilisers has lent further support to the conclusion that risk reduction measures should be taken from a precautionary viewpoint. Work to phase out the use of organotin compounds should continue in accordance with the proposals put forward previously by the National Chemicals Inspectorate.

During 2001 the National Chemicals Inspectorate will be working for the inclusion of butyltin and octyltin compounds on the agenda for classification as dangerous to health and environment within the scope of Council Directive 67/548/EEC on the classification and labelling of dangerous substances.

In the development of the common EU strategy for PVC and the work thus entailed, Sweden should continue to press for the dangers and risks associated with organotin compounds to be taken into account. As part of this work, an investigation should be made into the impact of PVC plastic on health and the environment compared with other packaging materials.

Sweden should work to secure the introduction at EU level by 31st December 2002 of a ban on cadmium corresponding to the ban applying in Sweden.

Work on possible risk reduction measures for the remaining use of intermediate chain chloroparaffins should be conducted within the EU programme for Existing Substances.

There is no need for any further risk reduction measures at national level concerning use of nonylphenoxyethoxylates in PVC, use of these substances having been discontinued.

### **Systematic risk reduction work**

The PVC Forum environmental programme should, as regards systematic risk reduction work, be supplemented by a commitment to the effect that not only specified substances but also other substances with especially dangerous properties\* or substances entailing risks in connection with exposure are to be identified and substituted. This work should also include contaminants in the additives.

The result of the systematic risk reduction work should be made available to the parties concerned by continuously publishing the targets defined for substances with especially hazardous properties and the extent to which the predefined targets have been achieved.

For PVC products as for other products, users should insist more on the health-related and environmental properties of the constituent substances being thoroughly investigated and should avoid products containing substances with particularly hazardous properties.

Major users/purchasers in the construction business should continuously present their systematic risk reduction work by publishing the targets defined for substances with particularly hazardous properties and the extent to which the predefined targets have been achieved.

\* In the report "Non-hazardous Products" (SOU 2000:53), the National Chemicals Inspectorate has proposed phase-out targets for certain metals and for substances which are persistent, bioaccumulative, carcinogenic, mutagenic and harmful to reproduction. The report also proposes criteria for these properties.