Response on European Community White Paper 'Strategy for a Future Chemicals Policy' to: The House of Lords - EUROPEAN UNION COMMITTEE Sub-Committee D (Environment, Agriculture, Public Health and Consumer Protection)

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PREAMBLE

I am grateful for the opportunity to respond to the Sub-Committee D of the House of Lords European Union Committee in relation to the '*Strategy for a Future Chemicals Policy'*. My response presents, first, a number of general comments in relation to the White Paper, followed by a section which addresses the fifteen questions posed in the call for evidence. I hope that this response helps the Sub-Committee's deliberation in this most difficult area.

GENERAL COMMENTS

(a) The White Paper appears to be encompass a new strategic approach to address the acknowledged and existing shortcomings of current European Commission (EC) legislation on the safe use of manufactured chemicals within the European Union (EU).

(b) Unfortunately, no attempt has been made to discuss or address how existing EU legislation could have been improved to achieve the same overall objectives. Thus, no comparison in terms of either feasibility or cost can be made.

(c) The main philosophical basis of the White Paper seems to be predicated on two main tenets. Firstly, that the new approach should be the same for existing (EINECS) substances as for new chemicals. Secondly, and more drastically, that the manufacture and use of many chemical substances should move to an 'approval system'. This is the authorisation component within the proposed Registration, Evaluation and Authorisation of Chemicals (REACH) scheme.

(d) Another change, but more a shift of emphasis within the White Paper, is that there is a move towards risk management based on hazard rather than risk; in other words, basing risk management options upon the inherent toxic properties of substances rather than a combined appreciation of toxicity ***and***

* Document based on a response by Dr LS Levy submitted to House of Lords European Union Committee Sub-Committee D

exposure. This approach, although apparently speeding up the risk management process by minimising or even eliminating the need to take exposure into account, may lead to inappropriate and detrimental policy outcomes.

(e) One particular concern within the White Paper is the question of liability involved in the authorisation procedure within the proposed REACH system. If, as proposed, authorisation (specific permission) needs to be given by a Competent Authority on behalf of the EU for the use of a substance, who then takes responsibility if later it is found that harm ensues to human health? At present, responsibility is firmly with the manufacturer, importer or supplier and it might well be that such a proposed authorisation procedure may alter the balance of responsibilities in spite of the 'polluter pays' principle.

(f) Overall, I found the White Paper a little disappointing in that although it attempts to address existing shortcomings with a solution that is both comprehensive (dealing with all chemicals) and speedier, the proposed new approach is not very innovative, not well targeted towards chemicals where the greatest risk might exist, not very supportive of novel scientific approaches and methodology, and poorly justified on the basis of the presented scientific arguments. Overall, the White Paper appears to be an amalgamation of existing and previous approaches without introducing any novel or targeted thinking. As an illustration of the poor use of scientific justification, it gives, as the one example of the benefits of the policy on human health, a reduction in chemically-induced allergy using asthma as the case in point; yet, in the White Paper itself, no mention is made of any targeted way of tackling allergens. Instead they talk about targeting CMR substances (carcinogens, mutagens and reproductive toxicants).

(g) On the question of animal toxicity testing for some 30 000 chemicals, the authors have underestimated the resources required to undertake such a mammoth task in the timescale set out and the cost. This requires a very detailed evaluation. Although they state that, for substances produced/imported in quantities between 1-10t, 'testing should be generally limited to *in vitro* methods', in the area of toxicology I am not aware that there are sufficiently validated *in vitro* tests that are available or likely to be available within the stated timescales.

(h) A number of general points need addressing regarding the White Paper, should it proceed. One is that the final document should avoid the use of fairly meaningless words such as 'safe' and 'non-toxic', as this perpetuates unachievable goals and continues to promote the ideas of unrealistic absolute expectations in the minds of the public. Should the scheme proceed, it is crucial that it should undergo a pilot trial followed by a critical evaluation.

SPECIFIC QUESTIONS IN *CALL FOR EVIDENCE*

1. What are the main differences between Commission's proposals and the approach of the UK Government's Chemicals Strategy (1999)?

On the face of it, both documents would appear to be attempting to achieve the same overall objectives of trying to provide sensible risk assessment and risk management for a large number of chemicals, speeding up the process, making the whole process more transparent and open to public scrutiny and phasing out those chemicals that appear to carry a significant and/or unacceptable risk to human health or the environment. However, the systems are quite far apart in both philosophical strategy and the detailed approaches.

The White Paper intends to require industry to undertake a vast amount of testing of some 30 000 substances in an unrealistic timescale utilising a vast number of animals. I would examine quite carefully the costing in the White Paper. In the case of the UK Government's Chemicals Strategy (1999), much hope (perhaps too much) is placed on industry to provide hazard assessments on a more modest number of substances, but with a more realistic timescale. The UK system, although sharing many of the broad objectives addressing the same issues, and basing many of its priorities on the same scientific end-points (e.g. persistent organic pollutants), appears far less ambitious and less confrontational than the measures proposed in the White Paper. It could be argued that the UK approach places too much reliance on industry 'coming up with the goods.' Only if targets are not met will the UK seek to develop an EU-based regulatory approach. The UK system takes cognisance of the views of stakeholders, but this does not seem to be the case for the EU White Paper position.

2. *How strong is the case for having a single regime for dealing with new and existing chemicals?*

There is a case for attempting to deal with existing and new chemicals within one framework. Only 2700 new chemicals have been introduced and evaluated in nearly twenty years; i.e. 135 chemicals per annum between fifteen Member States. Clearly, this has not overstretched the regulatory process. However, in order to achieve a single approach, the EU White Paper proposes a relaxation of the requirements for the testing of new substances by raising the production threshold from 10kg to 1 tonne. At the same time, if toxicological testing is to 'generally be limited to *in vitro* methods' for both new and existing substances without specifying the nature of these tests, it is difficult to comment on the quality of the data that will be available for either hazard or risk assessment. I assume all tests including any new *in vitro* tests will require validation and approval by the Organisation for Economic Cooperation and Development (OECD) - and this will take some time.

3. *Are the proposed procedures for testing of chemicals justified and proportionate?*

The testing procedures as outlined in the White Paper may present problems and need to be carefully spelled out before one can evaluate whether they are justified and proportionate. My main concern is that the testing procedures will be applied to a very large number (30 000 substances) on a checklist approach without any clear prioritisation. Simply building up a vast amount of toxicological data on many thousands of chemicals in itself will protect neither people nor the environment. There needs to be an intelligent selection of substances based on physicochemical and biological activity and related to true, likely exposure – not just tonnage. The

physicochemical and ecotoxicological testing procedures are fairly standard and should present no difficulties. My other concern regarding the testing strategy is that, under Action 3B, it is stated that 'Guidelines for testing strategies will be developed . . . . according to the uses and exposure of the substance.' In my experience, obtaining meaningful exposure data is not quite so simple as implied here. Much more thought needs to be applied to how exposure will be measured, modelled and used to trigger priorities/testing.

4. Are the overall timescale and deadlines for registration of chemicals realistic?

To some extent, the question of whether or not the timescales are realistic will depend on the resources allocated by industry and Member States to obtain the necessary data. However, I would have thought that the timescales are completely unachievable, partly based on the availability of contract toxicology laboratory facilities and also the number of skilled toxicologists able to undertake risk assessments for all the supposed uses of a substance that the scheme requires. Also, I do not believe that it would be possible to obtain reliable exposure assessments to feed into the risk assessments.

5. What are the implications for animal testing?

I believe that the implications of testing some 30 000 chemicals for animal toxicology are alarming and will raise major questions related to animal welfare issues. Validated alternative *in vitro* (non-animal) methods are simply not available for many endpoints and are unlikely to be so in the near future. Also, the use of derogation for substances in those tests where professional experience would suggest that the results would almost certainly be negative does not seem readily available within the proposed system. If animals are to be used in investigations, they should be used only with good reason and not simply to fill in a blank space on a data sheet.

6. Should a requirement to conduct life-cycle risk assessment of the use of chemicals form part of the strategy, or should it be addressed separately?

In principle, life-cycle risk assessment should be included as an element within any overall contemporary and comprehensive chemicals policy. Indeed, the White Paper, in its call for the involvement of downstream users in the risk assessment process and request for exposure monitoring at all stages, has set the scene for such life-cycle risk assessment. My concerns are the feasibility of obtaining such data and thus undertaking such assessments for substances with a wide variety of applications and many types of downstream users. This, coupled with the envisaged timescales, leads me to conclude that the suggestion is unrealistic.

7. How effectively will the proposed authorisation procedures meet the objectives of the strategy?

The proposed authorisation scheme seems to be directed at efforts which are already underway for certain classes of substances (POPs, CMR substances categories 1 & 2, and endocrine disruptors), but is hardly very innovative or imaginative. It seems to ignore allergens and neurotoxins, which are suggested elsewhere as being of great concern. My major anxiety regarding authorisation and its effectiveness is that, without care, it will change the White Paper's stated balance of responsibility (which

it wishes to fall upon the industry) from industry towards the authorising body. We may then end up in the situation of Government departments having to defend the uses of substances should harmful consequences ensue, or are thought to ensue (cf Ministry of Agriculture, Fisheries and Food (MAFF) and organophosphorous pesticide us in sheep dip).

8. What balance of effort and responsibilities should be struck between the Commission and Member States under the proposed Registration, Evaluation and Authorisation (REACH) regime?

Ultimately, Member States will, one assumes, share out the effort for REACH activities and I would think the best estimate of how this will be shared out will be found by examining what has happened for past and current chemical control schemes. I am somewhat nervous about the enlargement of the European Chemicals Bureau at Ispra, partly as I do not know where they will find the huge number of toxicological experts they aspire to recruit, but also because of uncertainties in the relationship and division of roles between them and the Competent Authorities of Member States.

9. Where will the costs of implementation principally fall? Has there been a realistic assessment of the likely costs to industry and regulatory authorities in the Member States?

Clearly, heavy costs for implementation will fall on industry and regulatory authorities in the Member States. Data, particularly on downstream users and exposure, will have to be sought and a vast amount of testing undertaken. Moreover, careful validation and checks will have to be made by Member States' experts to enable the public to have confidence in the process. My feelings are that both effort and cost have been markedly underestimated.

10. Have the responsibilities of downstream users been adequately addressed?

No: downstream users of chemical substances include many thousands of small and medium-sized enterprises (SMEs; including many one-man businesses) and the scheme seems totally unrealistic if the authors of the White Paper expect to gain a comprehensive understanding of all uses and exposures of many common substances that fall within the proposed scheme. It would have been more sensible for the authors of the White Paper to have engaged with the major chemical producers to develop a workable scheme to tackle this difficult and long-standing problem.

11. Do the proposals meet the needs for transparency and public access to information?

The proposals certainly appear to be both open and transparent. However, unlike the UK Chemicals Strategy, there does not seem the facility for stakeholder involvement on an ongoing basis.

12. How far should the strategy be concerned with providing safeguards in relation to chemicals (especially imported chemicals) as constituents of

finished products, or are these requirements dealt with adequately in other Community legislation?

Ideally, an EU chemicals policy should be as comprehensive as possible, including risk assessment and risk reduction measures for all chemicals that are likely to be used and enter the environment in EU Member States. However, there needs to be a balance between legislation that is so unwieldy that it becomes too complicated to manage and that which will be too limited in scope to achieve its stated objectives. Imported chemicals, many of which are more toxic than EU-produced substances (due to a process of 'social dumping' into Asia and the Far East from Europe), need equivalent controls, which should be no less protective than any general EU chemicals policy.

13. What are the implications for enforcement?

The proposed enforcement procedures in the White Paper, in particular action under the REACH proposals, will lead to an enormous amount of regulatory and enforcement activity. It is unclear from the White Paper whether 'authorisation' for a particular use of a chemical in one Member State will automatically mean authorisation in all Member States for that purpose. Until all details are spelled out, it is not possible to determine the true level of enforcement implications.

14. What criteria, methodology and administrative systems are appropriate for identifying chemicals, particularly existing chemicals, of highest concern and for setting priorities for action?

I find it generally disappointing that there has been so little advance in the thinking revealed in this (the White Paper) and other similar recent documents on chemical risk assessment priorities. This has resulted in little progress over the last decade in methodology for selecting chemicals for priority risk assessment. Potential human exposure based on tonnage can be entirely misleading, and simply identifying, as a reflex action, substances with certain hazardous characteristics as those requiring immediate action for risk reduction negates the use of intelligent judgement. It would have been better if the White Paper had dealt with this issue as a prelude to developing a sustainable policy. As an example, a number of schemes for prioritising chemicals, including the scheme produced by the European Chemicals Bureau, would have found an ideal basis for an EU workshop to produce an EU consensus priority approach using the very best science.