A new EU chemicals policy - some key arguments

1. Summary

Europe now has a chance to ensure that a new and effective chemicals policy is created, which will truly provide a high level of protection for both human health and the environment. This short paper highlights some of the arguments with respect to a number of key concerns regarding the implementation of such a policy:

- **Ensuring the long-term competitiveness of the European chemical industry.**
- **Helping small and medium sized enterprises.**
- **The vital importance of an effective, precautionary, authorisation procedure to ensure safe use of chemicals.**
- **The need to ensure that only the safest chemicals are used, and to phase out those chemicals that accumulate in our bodies, or in the environment, or disrupt hormone systems.**
- **A new chemicals policy must apply to all chemicals produced, not just those placed on the market.**
- **The importance of minimising animal testing, through tightening regulation and developing and validating alternative testing techniques.**

The current system for regulating the use of chemicals is ineffective and cumbersome. Very little is known about most of the chemicals in use today. Yet we are exposed not only to hormone disrupting chemicals, but also to a vast array of man-made chemicals that have accumulated in our bodies and the environment. The EU now has a chance to change things for the better, to finally bring in a coherent system for regulating chemicals and to stop producing or using hazardous chemicals.

It is undoubtedly a challenge, not least because there is a backlog of tens of thousands of unassessed and uncontrolled chemicals, which must be dealt with. The chemical industry has prevented effective control of chemicals over the last 50 years, for example by failing to deliver safety data on the vast majority of their chemicals [1], in spite of all their 'Responsible Care' and 'Product Stewardship'. The backlog is large, but it only has to be dealt with once.

The chemical industry may complain in the short term, but a world-leading European regulatory system will ensure that the EU industry innovates towards providing sustainable products via sustainable jobs in a sustainable industry.

Now is our chance - we must take it.

1. Allanou, R., B.G. Hansen, and Y. van der Bilt, *Public availability of data on EU High Production Volume chemicals*, 1999, European Chemicals Bureau, Ispra, Italy. http://ecb.ei.jrc.it/Data-Availability-Documents/datavail.pdf

2. Key arguments in more detail

a) Ensuring the long-term competitiveness of the European chemical industry

(i) **Consumers in the EU and across the world want safe products and are becoming more demanding.** The White Paper will give the EU industry a huge competitive advantage and a head start in global competition. A strong technology- and innovation-forcing regulatory system will ensure that the European chemical industry leads the world in the production of safer and greener chemicals.

(ii) **A properly regulated chemical industry will regain public confidence, and be able to recruit higher quality employees.** The public has little confidence in the chemical industry - rightly so, in our view. This is causing the industry to have problems with recruitment, and is even affecting the number of students studying chemistry. A truly sustainable chemical industry will be able to win back public confidence, and will become an attractive place to work.

(iii) **A move to safer chemicals will help protect the EU industry against future liability claims.** The chemical industry will become increasingly vulnerable to liability claims as the biomedical revolution provides better methods of linking exposure to harm. A regulatory system which forces industry away from risky chemicals will help reduce the vulnerability of EU companies to such legal cases.

(iv) **The EU must work to ensure safe production and use of chemicals across the world**. Ensuring that all imports of chemicals, including those in products, are controlled will assist in pressurising chemical industries across the world to produce the safest chemicals. However, this is not sufficient, the EU must also work within UNEP to bring in a global system for controlling chemical production and use. In the meantime, the EU and Member States should put pressure on multinationals to apply the best environmental and health standards in their plants across the world - environmental NGOs are already starting this pressure.

(v) **We do not consider that our proposals for a regulatory system would put an undue burden on the chemical industry.** It must be remembered that the EU provides industry with access to the largest single market in the world, which is soon to grow even bigger. Industry must accept that the EU is also committed to a high level of protection of human health and the environment. The EU also has a responsibility to governments and populations in the rest of the world to ensure that the chemical industry faces up to its global responsibilities.

Therefore we reject any industry suggestions that the White Paper will damage the competitiveness of the European chemical industry.

b) Helping small and medium sized enterprises

(i) **Small and medium sized enterprises (SMEs) must be subject to the same regulatory system as larger companies.** There is no excuse for a weakening of regulation, as chemicals from an SME are no different from those from multinationals.

(ii) **The main challenge to the chemical industry as a whole, and not just SMEs, is coming from global competition, not environmental or health legislation.** According to the OECD's recent report [2] on the environmental outlook for the chemical industry, the trend of companies consolidating into ever-larger multinationals is likely to continue.

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2. OECD, *OECD Environmental Outlook for the Chemicals Industry*, 2001, OECD, Paris, France. http://www.oecd.org/ehs

(iii) **SMEs need assistance to help them move to greener chemistry.** Numerous studies of waste minimisation in SMEs have shown that many are wasting large amounts of money because of poor management and selection of chemicals. Government-funded projects to advise SMEs have been very effective in saving large amounts of money. Such schemes should be encouraged to facilitate the changeover to the new chemicals regime.

(iv) **A move from chemical products to services provides opportunities for innovative SMEs.** Chemical 'service' companies focus on providing a function for their customers rather than a product, and they have more opportunities to reduce risks at the production, use and waste disposal stage. SMEs are perfectly placed to develop such services.

(v) **Being smaller in size means that some SMEs are able to be more flexible and innovative than larger companies**. Some SMEs will therefore be well placed to capitalise on the development of safer alternatives.

(vii) **Multinational companies should be implementing extended producer responsibility, assisting SME customers in implementing pollution prevention, resource efficiency and safety policies**.

Therefore we totally refute any suggestion from industry that small and medium sized businesses will be wiped out by the White Paper's proposals.

c) The vital importance of an effective, precautionary, authorisation procedure to ensure safe use of chemicals.

(i) **The current system under Directive 76/769/EEC (Marketing and Use Restriction) is bureaucratic and has failed to deliver sufficient control of chemicals.** Prior to the Marketing and Use Restriction, the burden on authorities to prove an unacceptable risk is very high and allows industry to delay or block the process. This system has contributed very little to the reduction of pollution by most dangerous substances.

(ii) **Authorisation must be the exceptional case not the general procedure.** Substances of very high concern (including persistent or bioaccumulative substances, hormone disrupters and sensitisers) should be phased out as a matter of principle. Industry will be able to apply for temporary derogations for specific uses where it can show that there is an overwhelming societal need and no safer alternative. Industry claims that the authorisation process will be bureaucratic and slow. However, in our view authorisation should be the exception, so will not create an undue burden. Industry should only apply where there is an overwhelming societal need and no safer alternative. Such a measure is necessary in order to create a safer way of doing business, moving away from the use of chemicals of very high concern.

Therefore we totally disagree with any suggestions from industry that the authorisation is bureaucratic, unnecessary, or leads to legal uncertainty

d) The need to ensure that only the safest chemicals are used, and the need to phase out those chemicals that accumulate in our bodies or in the environment, and those which disrupt hormone systems.

(i) **The current risk assessment procedure would assume that a man made chemical contaminating breast milk was safe until there was proof of its toxicity.** We consider it is unacceptable to expose the developing child to such chemicals, whether we currently know them to be toxic or not. The lesson of the past is that chemicals tend to be found to be more toxic (or dangerous to the environment) over time, for example PCBs and CFCs.

(ii) **Risk assessment is a limited tool to manage scientific ignorance on substance properties and exposure**, though industry (and regulators) frequently portray it as a 'sound, scientific' way to determine what level of risk society should accept. This disregards our ignorance of the toxic effects of chemicals, and the fact that little is known about the impacts of continuous

exposure to complex chemical cocktails. We are not even able to properly measure toxic effects on our complex immune or nervous systems, yet risk assessments assume that our current knowledge is perfect.

(iii) **Risk Assessments have proven to be cumbersome and ineffective.** Case by case risk assessments of all chemicals would take centuries, lead to inaction, and allow irreversible damage to continue, with even the most dangerous chemicals continuing to be released into the environment.

(iv) **Regulation must ensure that chemicals of very high concern are phased out.** The EU has already recognised the need to eliminate certain uses of chemicals without risk assessment, like CMRs, which are simply forbidden for use in consumer products. This has to be expanded now to all chemicals of very high concern, including persistent or bioaccumulative substances, hormone disrupters and sensitisers. This is a precautionary approach, controlling chemicals, which pose a threat of serious or irreversible damage because of their intrinsic properties.

(v) **The authorisation procedure should be available as a control mechanism for other substances which are assessed as being of high concern.** The authorisation system will be able to block all unauthorised uses, thus providing a higher level of protection than the current Marketing and Use Directive (76/769), which can only restrict specified uses.

(vi) **Where risk assessments are used they must be produced independently.** Such assessments should be done by, or on behalf of, public authorities, though using money collected from industry. We believe that the European Chemicals Bureau should collect a fee for assessing a chemical from the industry concerned. If the chemical is of lower concern, then this fee should be used by a Member State authority to commission a risk assessment from an independent consultant. If the chemical is of higher concern, then its safety should be assessed by Member States, using a system similar to the current one, but with more resources and support from an expanded European Chemicals Bureau.

(vii) **There must be a general duty on all industries to use the safest available chemicals or techniques.** Substitution is a crucial part of a precautionary regulatory approach, whereby chemicals with more hazardous properties are replaced by those with low hazard. The publication of a list of more hazardous chemicals, such as the Swedish 'Observation List' [3] is an effective way of providing industry with information to assist substitution. When decisions on substitution are particularly problematic, a provision for comparative assessment should be introduced.

(viii) **A comprehensive right to know is an important part of an open and precautionary regulatory system.** This should incorporate a right to know all the safety data about the chemical - there is no justification for commercial confidentiality - and the right to know what chemicals are used in the products we buy. Such a right to know will ensure that the supply chain is open and transparent, and allow individuals and companies to make decisions on which chemicals they use or are exposed to. We are not calling for products to be labelled with all the chemicals they contain, but rather for the information to be available on request.

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3. The Swedish Observation list is available in English from the KEMI web site: http://www.kemi.se/publikationer/obs_eng/defaulte.htm

We therefore do not accept any industry suggestion that chemicals regulation must be based on risk assessments or that the regulator must prove each use of a chemical to be unsafe before it can be taken off the market.

e) A new chemicals policy must apply to all chemicals produced, not just those placed on the market.

(i) **It would be irresponsible and unacceptable if we allow the production and export of chemicals that are not allowed to be placed on the EU market.** All manufactured chemicals present risks to workers, the environment and the public; they must have their safety properly assessed and they must be properly regulated. Even if chemicals never leave a factory, workers within the factory may be exposed to them, as will the environment and the public should there be a leak or accident. In addition, if they are exported outside the EU they may still return to the EU via food, consumer products, air pollution or marine currents. Furthermore, they may also present health and environmental risks in other areas of the world.

Therefore we do not accept any industry suggestion that the new chemicals policy must only apply to chemicals placed on the market in the EU, rather than all those produced here.

f) The importance of minimising animal testing, through tightening regulation and developing and validating alternative testing techniques.

(i) **The continued use of chemicals that have had little or no safety testing is a threat to humans and to wildlife.** However, unnecessary suffering of laboratory animals is unacceptable. The chemical industry refuses to move away from a policy where chemicals must be proven dangerous - through animal testing - before they are banned. This must change through the implementation of a precautionary chemicals policy based on the Copenhagen Charter.

(ii) **Implementation of the Copenhagen Charter (see Annex 1), combined with increased funding of research into alternative testing methods, will lead to a minimisation of animal testing.** This will make the regulatory system open and precautionary - so protecting both wildlife and people from unsafe chemicals. Complete openness, tighter regulation, and increased research into alternative, non-animal, testing methods will result in a minimisation of animal experimentation. It’s worth noting that not all animal tests are as reliable as they may be perceived to be in terms of their ability to predict health effects in humans; many have not been validated.

(iii) **We also consider that application of our policies will ensure that industry can easily meet the 'no data, no market' deadlines on delivering safety data.** The chemical industry's repeated claims that these deadlines are excessively burdensome do not stand up, and are indeed inconsistent with their other repeated claim that they have plenty of safety data on their chemicals.

(iv) **It is in the hands of industry to minimise animal testing and reduce the costs of testing.** The Commission’s White Paper has put forward various measures that will have an impact on costs and number of animals used. The industry should support these measures through making all existing safety data available and supporting a new safety–testing strategy based on in-vitro, physicochemical and computer based (e.g. QSAR) procedures.

(v) **It is essential that there is a substantial increase in funding of both research and validation of alternative methods.** This is not just the responsibility of European-level research bodies, but should be urgently pursued by Member States. The current resourcing of such work is grossly inadequate. In addition, measures should be taken to speed up the acceptance procedure for alternative methods and the international harmonisation of chemical testing guidelines.

(vi) **Non-animal tests are faster and cheaper than animal testing**. Though non-animal tests take time to research and validate, once in place they are almost invariably much faster and cheaper than animal tests. Using current techniques the Danish EPA has used QSAR to examine approximately 47,000 chemical substances, identifying 20,624 substances which are deemed to require classification for one or more of the following dangerous properties: Acute oral toxicity, sensitisation by skin contact, mutagenicity, carcinogenicity, and danger to the aquatic environment. The accuracy is approximately 70-85 per cent. Nevertheless, it is recognised that test methods are needed to identify chemicals that can affect the immune system, neurodevelopmental processes and chemicals that can act as endocrine disrupters.

(vii) **Much of the debate in this area has been based on a fundamentally flawed UK (IEH) report [4] examining the cost of the White Paper.** This IEH report, prepared for the UK Department of the Environment, Food and Rural Affairs, suggests that the timetable put forward by the Commission is unachievable. It suggests that 30,000 chemicals will need to be tested on animals, and that base set testing will take until 2048. However, once the assumptions of the IEH report are examined (below), it can be seen that it actually provides evidence to support the deadlines in the White Paper, even without considering our proposals:

- **The IEH report works on the basis that 30,000 chemicals will need to be tested on animals, whilst the White Paper states that it will only be 10,000, as those under 10 tpa will be tested in vitro.** Although the report also does a calculation on 10,000 chemicals, this calculation assumes that there will be no existing data available, although an assumption of 25% data available is made for 30,000 chemicals. In reality, there may even be more data available - it depends on how much information the chemical industry is sitting on. **We consider that all safety data must be publicly available** , and the data collection system must ensure that there is no unnecessary duplication of testing either between companies or between countries. It is up to governments and the chemical industry to work out how to deal with property rights to this data, to ensure that the new chemicals regulatory regime includes complete transparency for all safety testing.
- **The IEH report also assumes that there will be no testing in the rest of the world**, whilst in reality the US, Canada, Japan all have their own programmes.
- **The IEH report also assumes that no chemicals will be withdrawn from the market because of concerns about their safety profile**. This is happening with pesticides, where the Commission predicts that up to 500 of the 834 active ingredients will be withdrawn from the market [5].
- The calculation in the IEH report assumes that a very rare test will be done, and that no efforts will be made to reduce the number of animals used by combining tests.
- *Given that the IEH report itself calculates that testing on 10,000 chemicals could be completed by 2017, once the above 'real world' elements are introduced it can be seen that the White Paper's targets (e.g. 2012 for registration) are achievable.*

(viii) **However, we want to go further, and we believe that our proposals for a more precautionary regulatory system would make the targets even more achievable, and improve protection of our health and that of the environment:**

- All safety testing should be tiered, rather than 'tick box', initially focusing on the non-animal methods: persistence and bioaccumulation, all existing data, computer-based (QSAR) and *in vitro* techniques.

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4. IEH, Testing requirements for proposals under the EC White Paper 'Strategy for a future chemicals policy', 2001, Institute for Environment and Health, Leicester, UK.

5. European Commission, Report from the Commission to the European Parliament and the Council: Evaluation of the active substances of plant protection products, 2001, Commission of the European Communities, Brussels, Belgium. http://europa.eu.int/comm/food/fs/ph_ps/pro/ppp01_en.pdf

- It is crucial that safety testing is not considered as an end in itself, but is coupled with a precautionary regulatory system, as proposed in the Copenhagen Charter (see Annex 1), and tiered to fit into this regulatory system.
- We want a phase-out of all persistent or bioaccumulative chemicals. Persistence can be established without animal experiments; bioaccumulation can be determined by simple chemical tests. Such chemicals will then not have to go through toxicity testing on animals.
- There should be a requirement for all uses of a chemical to be 'safe beyond reasonable doubt', which reduces the amount of evidence required to phase-out a chemical. This should prevent more and more animal experiments being done by industry to rescue a chemical from a ban, and could allow 'reasonable doubt' to be created by *in vitro* or QSAR tests. This reduction in the burden of proof for the phase-out of a chemical is a crucial step in enabling these techniques to displace animal testing.
- A requirement to substitute less safe chemicals with safer alternatives will lead to the phase-out of a less tested chemical if either low-toxicity alternatives are available or it can be replaced by a non-chemical technique, without any further toxicity testing.

Therefore we totally refute any suggestion from industry that a new, more precautionary chemicals regime will necessarily involve a very large, unmanageable, increase in animal testing at prohibitive expense.

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4. Annex 1: The Copenhagen Charter

We demand from the EU review of chemicals policy:

1) A full right to know, including what chemicals are present in products.

2) A deadline by which all chemicals on the market must have had their safety independently assessed. All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.

3) A phase out of persistent or bioaccumulative chemicals.

4) A requirement to substitute less safe chemicals with safer alternatives.

5) A commitment to stop all releases to the environment of hazardous substances by 2020.

These principles are supported by more than 60 environment and consumer groups across Europe, including Friends of the Earth Europe, WWF Europe, the European Environmental Bureau, BEUC (the European Consumers Organisation), and Svend Auken, Danish Environment Minister.

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