



**ENVIRONMENT AND RURAL DEVELOPMENT COMMITTEE**

**AGENDA**

**2<sup>nd</sup> Meeting, 2004 (Session 2)**

**Wednesday 14 January 2004**

The Committee will meet at 11.00 am in Committee Room 1.

1. **Subordinate legislation:** The Committee will consider the following negative instrument—

the End-of-Life Vehicles (Storage and Treatment) (Scotland) Regulations 2003, (SSI 2003/593).

2. **Subordinate legislation:** Allan Wilson MSP (Deputy Minister for Environment and Rural Development) to move S2M-751 in the name of Ross Finnie MSP— That the Environment and Rural Development Committee recommends that the draft Solvent Emissions (Scotland) Regulations 2004 be approved.
3. **Work Programme:** The Committee will consider its forward work programme.

*Not before 12.00 noon*

4. **European issues:** The Committee will take evidence from Ross Finnie MSP (Minister for Environment and Rural Development) and Allan Wilson MSP (Deputy Minister for Environment and Rural Development) on a number of European issues.

**Tracey Hawe**  
Clerk to the Committee  
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The following papers are attached:

<p><u>Agenda Item 1</u></p> <p><a href="#">End-of-Life Vehicles (Storage and Treatment) (Scotland) Regulations 2003, (SSI 2003/593)</a></p> <p>Extract from the Subordinate Legislation Committee's 17th Report</p>	<p>ERD/S2/04/02/1a</p> <p><a href="#">ERD/S2/04/02/1b</a></p>
<p><u>Agenda Item 2</u></p> <p>The Solvent Emissions (Scotland) Regulations 2004, (draft)</p>	<p>ERD/S2/04/02/2a</p>
<p><u>Agenda Item 3</u></p> <p>A paper from the Convener is attached (<i>for members only</i>)</p>	<p>ERD/S2/04/02/3a</p>
<p><u>Agenda Item 4</u></p> <p>A letter from the Minister for Environment and Rural Development is attached.</p> <p>A paper from SPICe is attached (<i>for members only</i>)</p>	<p>ERD/S2/04/02/4a</p> <p>ERD/S2/04/02/4b</p>

**Subordinate Legislation Committee  
Extract of 17<sup>th</sup> Report, 2003**

1. At its meeting on 16<sup>th</sup> December the Committee determined that it did not need to draw the attention of the Parliament to the instruments listed in the Annexe to this report on any of the grounds in its remit.
2. The report is also addressed to the following committees as the lead committees for the instruments specified:

Environment and Rural Development

SSI 2003/593

**Instruments subject to annulment**

The End-of-Life Vehicles (Storage and Treatment) (Scotland) Regulations 2003 (**SSI 2003/593**)

*Background*

1. The Committee noted that regulation 7(4)(e)(i)(bb) omits “400 vehicles” from paragraph 45 of Table 4B of Schedule 3 to the Waste Management Licensing Regulations 1994. In the version of Table 4B available to the Committee, there is no reference to “400 vehicles”, only to “100 vehicles” and “1000 vehicles”.
2. The Executive has confirmed that the reference should have been to the removal of the reference to 100 rather than 400 vehicles and has undertaken to bring forward an amendment to the Regulations at an early date. The Executive’s response is reproduced at the Appendix to this report.

*Report*

3. **The Committee therefore reports the Regulations to the lead committee and the Parliament on the grounds of defective drafting acknowledged by the Executive, drawing attention to the Executive’s undertaking to correct the error.**

## **Appendix**

### **THE END-OF-LIFE VEHICLES (STORAGE AND TREATMENT) (SCOTLAND) REGULATIONS 2003 (SSI 2003/593)**

In its letter of 9th December 2003 to Catherine Hodgson, the Committee commented as follows-

“Regulation 7(4)(e)(i)(bb) omits “400 vehicles” from paragraph 45 of Table 4B. In the version of Table 4B available to the Committee there is no reference to “400 vehicles”, only to “100 vehicles” and “1000 vehicles”. The Committee seeks clarification on this point.”

#### **The Scottish Executive responds as follows:**

The Executive is grateful to the Committee for pointing out this typographical error. The amendment ought to have referred to the removal of the reference to “100 vehicles” from Table 4B of paragraph 45 of Schedule 3 to the Waste Management Licensing Regulations 1994 rather than “400 vehicles”. There is a legislative opportunity to correct this error at the beginning of next year which the Executive intends to take up.

#### **Scottish Executive**

11<sup>th</sup> December 2003

Minister for Environment & Rural Development  
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January 2004

You wrote to me on 8 December on a number of points arising from the Committee's discussion of European Union issues on 3 December, and inviting me to give evidence at your meeting on 14 January.

Taking the latter point first, I can confirm that I will be happy to attend on 14 January and if you are content will be accompanied by Allan Wilson, Deputy Minister for Environment and Rural Development who has responsibility for the chemicals issue.

On the specific issues raised in your letter:

(1) I attach as requested a briefing paper on the Commission's proposals for a new regulatory regime for chemicals (the REACH system – Registration, Evaluation and Authorisation of Chemicals), and a short note on the Waste Electrical and Electronic Equipment (WEEE) Directive and the proposed Batteries Directive.

(2) I welcome the Committee's support for the Executive's position on the Commission's proposals on sheep and goats. Our hard work has recently delivered the essential changes needed to make the Commission proposal workable in Scotland. These changes will allow us to retain the current Scottish system until 2008, subject to its receiving Commission approval. The role industry bodies played in our lobbying and negotiating tactics has been key to achieving this welcome outcome.

The Scottish industry will now not be facing the manual recording of individual 12 digit numbers or double tagging of lambs within one month of birth. It is important that the industry recognises that compliance with the current system is essential as this will form the basis of the Commission decision on whether or not to approve our system.

In addition, the date for the introduction of electronic identification (EID) has been postponed until January 2008. While EID certainly has the potential to benefit livestock traceability, it has to be workable across the whole of the production chain, affordable to industry and practical. The EID project already under way in Scotland will inform future discussions with the EU on this issue.

(3) I am happy to address at the meeting the outcome of the December Council, on which your Committee and the European and External Relations Committee will receive a written report shortly in accordance with the agreed procedures. The item on the Welfare of Animals During Transport did not make much progress, but the Council took note of the limited progress achieved and of the issues still outstanding, particularly the transport stages by road, which will still need to be worked on intensively under the Irish Presidency. The Council called on the Irish Presidency to pursue its discussions on the draft Regulation and, in particular, find a solution to the issues still pending, including loading densities and duration of journeys and rest periods. The next meeting of the Council Working Group has been provisionally arranged for 22<sup>nd</sup> and 23<sup>rd</sup> January and this issue will be further considered by the Council when more progress has been made.

**ROSS FINNIE**

## **Information for Environment and Rural Development Committee**

### **BACKGROUND**

In February 2001 the Commission published a White Paper proposing a single system to gather hazard information, assess risks, classify, label, and restrict the marketing and use of individual chemicals and mixtures. (This is known as the **REACH** system – **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals). In May 2003, the Commission published draft legislative proposals which were recently the subject of a public internet consultation. The Commission published the final legislative proposal on 29 October 2003. The dossier is expected to go through Competitiveness Council with Defra retaining its role as the lead policy Department.

The policy would cover both new and existing substances. All chemicals produced or imported into the European Union in quantities above 1 tonne per year would be registered in a central database. Chemicals deemed to be of most concern would be banned unless they were granted an authorisation for particular uses which have been demonstrated to be safe.

Most chemicals will be subject to registration only but those with properties suggesting they are of concern – substances which are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent organic pollutants (PDPs) and chemicals which are persistent, bioaccumulative and toxic (PBTs) or very persistent and very bioaccumulative (vPvB) – will be subject to evaluation and authorisation.

The Executive, in co-ordination with the UK Government and other Devolved Administrations is scrutinising the detailed proposals from the Commission and will be discussing with stakeholders and regulators to see how they might work in practice.

Given the inherent complexity of REACH and the vast number of substances involved, the most appropriate way forward for Scotland is to have a common approach with the rest of the UK. In addition, the problem of persistent, bioaccumulative and toxic chemicals (PBTs) is a Europe wide issue and in terms of negotiation it makes sense for a single UK position to be taken as the best way of getting a deal which is best for Scotland's people and its industries.

### **EXPECTED PROGRESS & TIMETABLE**

There will be a full UK consultation early in 2004, with an estimated adoption date for the Directive around the end of 2005 at the earliest.

## **PRIORITIES OF THE SCOTTISH EXECUTIVE AND UK GOVERNMENT**

The Scottish Executive fully supports the overall objective of the EU's Chemicals Strategy (REACH) to protect human health and the environment by taking steps to phase out chemicals of concern.

It is important that the system is transparent in its operation and provides users of chemicals with the information they require about the substances with which they come into contact.

It is hoped that the new regulatory regime will be a marked shift forward in terms of speeding up the regulation and authorisation process for both existing and new chemicals

Our objectives are to achieve a rapid, efficient system for collecting the necessary information on chemicals and for tackling those of most concern, whilst maintaining the competitiveness of the chemical industry.

Our priority is to focus on workable solutions that ensure adequate protection for human health and the environment. The main aim must be to ensure that action is taken quickly on chemicals of concern.

We recognise the particular concerns of industry and downstream users that the proposals may lead to increased costs. We need to design the REACH system so that it is workable for them and does not impose disproportionate financial burdens.

Concerns have been expressed by the animal welfare lobby about a potential increase in the need for animal testing. We believe that animal testing should be kept to the absolute minimum necessary to ensure that sufficient information is available for decision-making on health and environmental protection.

## **INFORMATION ON IMPLEMENTATION**

The Scottish Executive is at present in the early stages of discussion with Defra, SEPA, the Environment Agency and the Department of the Environment Northern Ireland with regards to setting up an appropriate regulatory regime.

## **FURTHER INFORMATION**

More detailed information can be found in the following annexes:

ANNEX A: Summary of the Commission's Legislative Proposal for a New EU Chemicals Strategy.

ANNEX B: Preliminary timeline for developments on EU Chemicals Legislation

ANNEX C: Objectives of the Scottish Executive and UK Government.

## Summary of the Commission's Legislative Proposal for a New EU Chemicals Strategy

### Background

1. In February 2001 the Commission published a White Paper proposing a single system to gather hazard information, assess risks, classify, label, and restrict the marketing and use of individual chemicals and mixtures. (This is known as the **REACH** system – **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals). The policy would cover both new and existing substances. All chemicals produced or imported into the European Union in quantities above 1 tonne per year would be registered in a central database. Chemicals deemed to be of most concern would be banned unless they were granted an authorisation for particular uses which have been demonstrated to be safe.
2. In May 2003, the Commission issued a consultation on the legislative proposal. More than 6000 distinct contributions were received (42% of which from industry). Six MS Governments responded (A, D, IRL, F, NL, UK).
3. In September 2003, the Commission's draft for inter-service consultation became available through ENDS and other websites.
4. The Commission published the final legislative proposal on 29 October 2003. This paper gives an outline of the proposal.
5. The dossier is expected to go through Competitiveness Council with Defra retaining its role as the lead policy Department.. An adhoc working group reporting to the Competitiveness Council has been set up to enable representation from both industry and environment departments. The first meeting was held on 20 November.
6. In the European Parliament, Guido Sacconi (Italian Socialist) has been appointed Rapporteur in the Environment Committee and Elly Plooij-van Gorsel in the Industry Committee – a final decision on which committee (Environment or Industry) will lead is not expected until early December or maybe later if there is much disagreement. The EP is pushing for a first reading in the April plenary, however this is a very ambitious timetable for such a large and complex dossier.

### Outline of the Commission's Legislative Proposal

7. The proposed legislation consists of the following stages: a **pre-registration** procedure to encourage data sharing; **registration** on a central database of all substances manufactured or imported into the EU in quantities greater than 1 tonne per annum; **dossier evaluation**, consisting of mandatory review of testing proposals submitted at registration (primarily for substances supplied in quantities greater than 100 tonnes per annum) and a voluntary compliance check of the registration dossier; **substance evaluation**, consisting of voluntary further evaluation of substances where these may pose a risk to human health or the environment; **authorisation** of the use of substances of most concern; and **restrictions** on marketing and use of substances where the risks to human health and the

environment are deemed to be unacceptable. The system will be co-ordinated by a central **EU chemicals agency** established by the legislation with Member States responsible for a degree of the work and enforcement.

8. The legislation places a requirement to **pre-register** phase-in substances (i.e. substances which are already on the market) by submitting the name of the substance and a list of available test data. This is aimed at ensuring that duplication of testing is minimised and to encourage data sharing. The incentives for data sharing have been increased. However, there is still the possibility to repeat tests if the owner of the test does not wish to share the data (although sanctions will be imposed). animal test data, the proposal clearly states that the tests will not be repeated.
9. **Registration** of substances involves the submission of a technical dossier of information about the chemical including a testing package and a risk assessment (called a Chemical Safety Report, CSR). A CSR is only required for substances supplied in quantities greater than 10 tonnes. Registration of phase-in substances will be phased over 11 years on the basis of production volume. In addition, all existing CMRs supplied in quantities greater than 1 tonne per annum will have to be registered within the first 3 years.
10. **Polymers** are exempt from registration. The Commission may include polymers as soon as a practicable and cost-efficient way of selecting polymers is found. Registration requirements for isolated and transported (but controlled) **intermediates** are limited (new data only needs to be generated for transported intermediates in quantities greater than 1000 tonnes).
11. **One registration dossier is required per manufacturer/importer per substance.** Consortia-formation is encouraged (but not made mandatory) for example by financial incentives. For new registrants wishing to have access to an existing registrant's data, data-sharing has been made mandatory by insisting that, where there are existing vertebrate tests, these tests shall not be repeated.
12. Provision of **information in the supply chain** has been simplified by including the current Material Safety Data Sheet Directive (91/155/EC) provisions in REACH. The MSDS should be consistent with the results of the chemical safety assessment (if this has been carried-out). Where an MSDS is not required (i.e. where the substance or preparation is not classified as hazardous), a minimal list of information needs to be supplied to the users.
13. **Downstream users** have the right to make their use known to a manufacturer/supplier with the intention of making this an **intended use** and having that use covered in the supplier's assessment and MSDS. The downstream user will have to provide sufficient information to allow the supplier to prepare an exposure scenario.
14. If the use made by the user is outside the exposure scenario communicated by the supplier in the MSDS, the user should prepare a downstream user chemical safety assessment appropriate for that use. In addition, the downstream user will have to send a 'postcard' notification to the Agency before commencing their use of the substance. The notification will include, amongst other things, a brief description of the use and proposals for further testing which are considered necessary by the user to complete their chemical safety assessment.

15. The regulation places a duty to register any **substance supplied in an article** if; the total amounts to over 1 tonne per annum (per article type) and; the substance is classified as hazardous and; it is **intended** to be released during normal and foreseeable conditions of use and disposal. A limited 'postcard' notification will apply to substances in article which; are supplied in quantities over 1 tonne per annum (per article type) and; the substance is classified as hazardous and; the substance is **likely** to be released during normal and foreseeable conditions of use and disposal; and the quantity released may adversely affect human health or the environment. The Agency may decide that a full registration is required for these substances.
16. **Dossier evaluation** consists of a mandatory review of testing proposals (primarily applicable to substances supplied in quantities greater than 100 tonnes) aimed at reducing unnecessary animal testing. In addition, Member States may review the registration dossier to ensure compliance with the requirements of the legislation (although this is on a voluntary basis) and request further information which is deemed necessary.
17. **Substance evaluation** is voluntary and allows Member States to evaluate a substance where they have concerns over potential risks to human health or the environment. The Agency will develop criteria and priorities for evaluation. Member States will develop rolling plans covering 3 years (updated annually) in which they will identify substances for evaluation based on the Agency's prioritisation criteria. The Member State Competent Authority will be selected according to the rolling plans. Where more than one Member State wishes to evaluate the same substance, decisions will be taken by the Member States Committee or, failing this, the Commission.
18. **Evaluation of on-site intermediates** will not fall under either paragraphs 16 or 17. If the Member State in which the site is located identifies a risk equivalent to the level of concern arising from authorisation, they may require further information or take appropriate risk reduction measures as required.
19. Carcinogens, mutagens and substances toxic to the reproductive system (CMRs); substances which are persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); or of equivalent concern such as endocrine disruptors will be subject to **authorisation**. The Agency will prioritise action on substances identified as meeting the criteria for authorisation after consideration of expected regulatory outcome, resource demands and taking into account comments received as part of a public consultation.
20. Once identified, industry will have a limited time to apply for an authorisation per substance, per manufacturer/importer, per use. Authorisations will be granted if industry can demonstrate that the substance is adequately controlled as defined in the CSR. If the authorisation cannot be granted as above, it can be granted if the socio-economic benefits outweigh the risks and if there are no suitable alternatives or technologies. Applications for authorisation may include a socio-economic analysis and a substitution plan. Authorised substances can only be utilised for uses which have been authorised. **Downstream users** using an authorised substance must inform the Agency.
21. The legislation allows for **restrictions** on the marketing and use of substances to be agreed at Community level where there is an unacceptable risk to human health and the environment arising from the manufacture, use or placing on the market of that substance.

A substance which is subject to restrictions can only be used in compliance with the terms of that restriction.

22. Access to **non-confidential information** shall be made available by the Commission upon request, provided the registrant has not provided adequate justification supporting a claim that the information is commercially-sensitive. Certain information can never be considered confidential (e.g. test results) whilst other information shall always be considered confidential (e.g. precise use and precise supply tonnage).

### Preliminary timeline for developments on EU Chemicals Legislation

Timing	2003 (Nov-Dec)	2004 (Jan-June)	2004 (July-Dec)	2005 (Jan-June)	2005 (July-Dec)
Presidency	Italy	Ireland	Netherlands	Luxembourg	UK
Actions/events	<ul style="list-style-type: none"> <li>• Comp Councils</li> <li>• Establishment of Council working groups</li> <li>• EP Env Committee first exchange of views Env Council</li> </ul>	<ul style="list-style-type: none"> <li>• UK consultation</li> <li>• UK Commons' Science &amp; Technology Committee hearings</li> <li>• EP Env Committee exchange of views, with report</li> <li>• Other EP Committee meetings</li> <li>• EP Env Committee further discussions, with report and amendments Env Council Comp Council</li> <li>• Elections to the European Parliament</li> </ul>	<ul style="list-style-type: none"> <li>• EP Env Committee adopt revised text</li> <li>• EP First Reading?</li> <li>• Appointment of new Commissioners</li> </ul>	<ul style="list-style-type: none"> <li>• Common Position?</li> <li>• EP Second Reading?</li> </ul>	<ul style="list-style-type: none"> <li>• Possible conciliation or adoption of REACH (an optimistic expectation)</li> </ul>

## Objectives of the Scottish Executive and UK Government

The Scottish Executive (SE), along with the UK Government, is a strong supporter of the overall objective of REACH – to improve information about chemicals in order to protect human health and the environment. It believes that REACH can be made to work in a cost effective way.

In negotiating the proposal, the SE and UK Government has three key objectives:

- To develop a fast, efficient and workable process to test and screen chemicals and tackle those of most concern;
- To minimise animal testing; and
- To maintain the competitiveness of the chemicals industry and downstream users

### Key UK Concerns

**Overall:** We continue to have some concerns regarding certain aspects of the proposal, in particular the workability of a number of provisions. A system that isn't workable will fail to deliver the environmental and human health benefits we all wish, whilst placing unnecessary burdens on industry public authorities. Whilst the final proposal shows improvements, there remains room for further development.

**Evaluation:** In their final proposal the Commission have introduced the concept of prioritisation in the evaluation stage. This is key success for the UK and something we have pushed hard for inclusion. This should ensure a risk-based approach to prioritising substances for further evaluation based on the information submitted as part of the registration package. There may still be an issue around who carries out these evaluations. Although Member States must submit an evaluation plan, there is still some discretion as to how many evaluations they undertake and may not, in reality; yield an acceptable throughput of substances being reviewed. An alternative might be a prioritised system of evaluation to ensure a harmonised approach and focuses on substances of concern first.

**Registration:** Measures aimed at minimising animal testing through data sharing also need to be strengthened. Although the Commission has included financial and other incentives to encourage data sharing at registration, we feel that the proposal must find a way of making data sharing compulsory if we are to avoid duplicate animal testing. We believe that a system of one substance one registration would simplify the system, lead to a reduction in animal testing and reduce the impact on industry whilst maximising the benefits to human health and the environment. The Commission has also gone some way to reducing the cost of registration, by reducing the testing requirements. We will be considering the implications of these changes for the effectiveness and workability of the new regime.

**Scope:** The scope of the system has been reduced by excluding polymers from the first stages of registration and limiting the requirements for intermediates. These were key industry concerns, and, as a matter of scope, directly related to the workability of the REACH system. We welcome the changes, but here, too, we will be considering the implications. Our initial

view is that, while welcome, it would be desirable for the Commission to consider indicating a timescale for the development of criteria for identifying hazardous polymers.

One of our main concerns regarding the draft proposal was the complexity of supplying information up and down the supply chain using Chemical Safety Reports. We welcome the change in the proposal whereby information will be supplied via the existing system of Material Safety Data Sheets. The Commission has also reduced the burden on smaller manufacturers by reducing some of the testing requirements and removing the requirement to provide a Chemical Safety Report for substances supplied between 1 – 10 tonnes (believed to be around 20 000). We are currently considering the impact of this change.

**Role of the Agency:** The Commission has taken steps towards simplifying the administrative arrangements and clarifying the relative roles of the Central Agency and the Member States. In particular, we welcome the move towards increased decision-making power for the Central Agency at registration, on data sharing, research and development exemptions and confidentiality. This should go some way to addressing industry's request for a more harmonised approach across the EU and we will be considering whether the system could be streamlined further by giving the Agency a greater role.

**Downstream users:** The potential impact on downstream users has also been reduced. The proposal allows downstream users to inform their suppliers of a use they wish to be covered under the supplier's Chemical Safety Report. This should greatly reduce the burden on small and medium-sized companies.

**Authorisation:** In the authorisation process, the proposal encourages applicants to submit substitution plans to replace harmful chemicals with cleaner, safer alternatives. This was to address the key concern that there was not enough emphasis on substitution in the previous draft. Green NGOs have welcomed this change, but they believe the legislation should be go further in requiring substitution to take place. Greenpeace has very recently issued a study which suggests a mechanism for introducing the substitution principle into the proposal and we are currently analysing this issue further. Although we are still trying to establish the nature of these substitution plans, we broadly welcome this change, as it will encourage applicants and authorities to consider the availability of substitutes prior to taking authorisation decisions. This is also likely to give a clearer timetable to industry in advance of substances being substituted.

There is however concern among NGOs that there is still a loop-hole in the legislation whereby a substance of high concern will receive an authorisation for use as long as the emissions are "adequately controlled". While the NGOs would clearly prefer any reference to adequate control deleted, the Commission has gone some way to define and limit the scope of what is meant by adequate control. We have yet to assess whether this limits the scope sufficiently to meet these concerns

**Confidentiality:** The proposal includes specific information that should be considered as confidential. Clearly, there needs to be adequate protection of intellectual property rights, but also greater transparency about information made publicly available.

**Substances in Articles:** The Commission has further specified requirements for registration of substances imported into the EU as finished articles. We are still considering the implication of these changes, as this is a difficult issue to resolve with important trade

implications. The pressure groups have indicated that they have concerns about this aspect of the proposal. In their opinion, the provisions are such that very few substances supplied in articles will require registration.

## **ENVIRONMENT AND RURAL DEVELOPMENT COMMITTEE**

### **WEEED**

We published, with the other UK administrations, a second consultation paper in November 2003, setting out our proposals for the implementation of the WEEE Directive. I remain of the view that the interests of the Scottish environment - and of Scottish consumers, retailers and producers of electronic and electrical equipment - is best served by pursuing common implementation of the WEEED across the UK. Final decisions on the transposition in Scotland will, of course, be made in Scotland on the basis of Scottish interests.

The proposals place the obligation on retailers to provide for the collection of WEEE. It is proposed that they can do this either on an individual basis, or through compliance schemes. We shall be looking for the retailers' compliance schemes to provide a network of appropriate collection points, information to consumers, and funding for upgrades to WEEE collection facilities at civic amenity sites. The proposals place the obligation on producers and importers of electronic and electrical equipment to fund target levels of recovery of waste equipment. They could discharge this obligation either on their own, or through compliance schemes. There are developing proposals for a central "clearing house" that would link together the collection network, the approved treatment facilities, and the funding from producers.

The proposals also contain measures for encouraging better design to enable reuse and recycling, and to encourage reuse. We see an ongoing role for the charitable and social organisations doing excellent work in facilitating reuse of electrical equipment.

We are consulting with Scottish interests in the electronics sector, through the consultation paper and through meetings. There are also ongoing discussions at the UK level, which are appropriate in particular for retailers with national coverage. Our proposals are that public information will be for the retailers to arrange, once the form of their collection scheme is clear. We are also working with DEFRA to produce practical guidance on WEEE treatment standards. We believe that treatment to WEEED standards will involve relatively straightforward extension and adaptation of existing processes.

### **Batteries Directive**

We welcome the proposed Batteries Directive, which if passed will extend producer responsibility to an important and growing element of the waste stream. I do, however, think that it is too early to consider advice to retailers or planning for collection schemes. The final form of the Directive is not clear, but it is likely that producers and importers shall have to provide for collection from consumers, and it would be for them to determine the efficient pattern of collection under the Directive.

The Directive shall now proceed to negotiation in Council at the EU, and to consideration by the European Parliament. The UK Department of Trade and Industry shall lead for the UK, and the Scottish Executive shall be consulted on the negotiating position. We shall aim to ensure realistic targets based on evidence, and appropriate flexibility in the delivery of collection and recycling. Once agreement has been reached on the Directive, it is likely that we would initially consider transposition in co-operation with the other UK administrations.

## **EXPLANATORY MEMORANDUM ON EUROPEAN COMMUNITY LEGISLATION**

Draft Instrument 15409/03 of 28 November 2003 concerning a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}

Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

Commission staff working paper on the proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}  
EXTENDED IMPACT ASSESSMENT.

Submitted by the Department for Environment, Food and Rural Affairs,  
December 2003

### **SUBJECT MATTER**

1. In February 2001 the Commission issued a White Paper on a ‘Strategy for a Future Chemicals Policy’ (COM(2001) 88) based on a review of the

existing EU system for regulating the safe use of chemicals (see Explanatory Memorandum 6671/01 of 23 March 2001). The Commission concluded that reform of the current legislation was necessary and the proposals are based on the White Paper.

2. The present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date. Existing substances are regulated by Regulation 793/93 and new substances by Directive 67/548.
3. There are approximately 3,000 new substances which have been tested and assessed for some possible risks to human health and the environment before being marketed in volumes starting at 10 kg per annum under Directive 67/548.
4. Existing substances amount to more than 99% of the total volume of all substances on the market and are not subject to the same testing requirements. The number of existing substances reported in 1981 was 100,106, although the current number of existing substances marketed in volumes starting at 1 tonne per annum is estimated at 30,000. Approximately 140 of these substances have been identified as priority substances and are subject to comprehensive risk assessment carried out by Member State authorities under Regulation 793/93.
5. Where necessary, restrictions on the marketing and use of certain dangerous substances and preparations are applied under Directive 76/769. Risk assessments and adequate analyses of the costs and the benefits are required prior to any proposal or adoption of a regulatory measure controlling the marketing and use of chemicals.

6. The proposal for a Regulation establishes the REACH system (Registration, Evaluation, Authorisation and Restrictions of Chemicals), creates a European Chemicals Agency and amends current legislation in view of the proposed Regulation.
7. A separate proposal amends Directive 67/548 to adapt it to the proposed Regulation.
8. The proposals address the short-comings of the current system which were identified in the White Paper. These include; the lack of available information on risks to human health and the environment of the majority of substances on the EU market; the slow and resource-intensive nature of the current system; the need for responsibility for the assessment of chemicals to shift from the regulatory authorities to industry; and the lack of information on uses of substances.
9. The proposals create a single system to replace over 40 pieces of existing legislation for gathering information, assessing risks to human health and the environment, authorising and restricting the marketing and use of individual chemicals produced or supplied in the EU.
10. The main focus of the proposals is the management of generic industrial chemicals. Although the proposals establish links with existing legislation that controls the use of chemicals in specific applications (e.g. pesticides, cosmetics), it is not intended to replace these instruments.
11. REACH consists of the following elements:
  - Registration requires industry to obtain relevant information on chemical substances produced or supplied in quantities greater than 1 tonne per annum and to use that data to manage the chemicals safely.

- Evaluation provides the opportunity for regulators to assess whether the information provided by industry is sufficient, allows the clarification of the risks posed by a chemical and will contribute towards preventing unnecessary testing.
- Risks associated with uses of substances having hazardous properties of very high concern will be reviewed and, if they are adequately controlled, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substitutes or technologies, then the uses will be granted an Authorisation.
- The Restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system.

12. The Commission's White Paper on a 'Strategy for a future Chemicals Policy' (COM(2001) 88) was debated by the House of Commons European Standing Committee "A" on 12 June 2002 and the House of Lords Select Committee on the European Union on 7 January 2003. The Parliamentary scrutiny history relevant to this proposal is contained in the attached Annex.

## **MINISTERIAL RESPONSIBILITY**

13. Responsibility for this proposal lies with the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, and Ministers of the Welsh Assembly Government. In Northern Ireland, matters arising from this proposal would normally be the responsibility of Northern Ireland Executive Ministers. Whilst the Northern Ireland Assembly remains suspended, these functions will be discharged by Northern Ireland Departments subject to the direction and control of the Secretary of State for Northern Ireland.

14. The Department of Trade and Industry, The Department of Health, The Health and Safety Executive, The Environment Agency and The Scottish Environment Protection Agency also have an interest.

## **LEGAL AND PROCEDURAL ISSUES**

- (i) **Legal Basis**  
Article 95 of the EC Treaty.
  
- (ii) **European Parliament Procedure**  
Co-decision for the Regulation.  
Co-decision for the Directive
  
- (iii) **Voting Procedure**  
Qualified Majority for the Regulation.  
Qualified Majority for the Directive
  
- (iv) **Impact on UK law**

The Regulation will be directly applicable in the UK. Once the Regulation has been adopted, the UK will need to introduce legislation to supplement it, including providing for new offences and penalties for non-compliance. Further, as the proposals would replace a number of existing measures, the repeal or amendment of several UK legislative instruments will be necessary.

## **EUROPEAN ECONOMIC AREA**

15. This proposal will apply to the European Economic Area.

## **SUBSIDIARITY**

16. The Government agrees that this proposal complies with the three elements of the principle of subsidiarity as laid down in Article 5 of the EC treaty.

17. In considering the issue of subsidiarity, it should be taken into account that the present legislation on chemicals already provides for an extensive control over the classification, labelling, marketing and use of substances and preparations. The new Regulation will replace a substantial number of pieces of legislation and will extend it to areas that have hitherto not been adequately dealt with. The subsidiarity issue therefore only arises with regard to this extension.

18. As chemicals are being traded across borders and as many of them can lead to cross-border contamination, Member States cannot by themselves achieve the objectives of the proposal sufficiently. Community wide legislation is therefore appropriate. In this context, it should be recalled that the opinions of both the Council and the European Parliament call for a strong system of EU legislation in order to achieve a high level of protection of health and the environment while at the same time ensuring a level playing field for all economic actors in the Internal Market.

## **POLICY IMPLICATIONS**

19. The proposal has implications for environmental policy in relation to chemicals, health and safety, consumer protection and industrial competitiveness.

20. The Government is a strong supporter of the overall objective of REACH – to improve information about chemicals in order to protect human health and the environment – and the principles of the Commission’s White Paper on a ‘Strategy for a Future Chemicals Policy’. It believes that REACH can be made to work in a cost effective way.

21. In negotiating the proposal, the Government has three key objectives:

- To develop a fast, efficient and workable process to test and screen chemicals and tackle those of most concern first;

- To minimise animal testing; and
- To maintain or enhance the competitiveness of the chemicals industry and downstream users.

22. The Government will examine the Commission's proposal in detail to see how far the proposal goes towards achieving the three main objectives highlighted above.

23. The Government welcomes the improvements that have been made to the draft Regulations as a result of the public consultation in May 2003, such as; streamlining the registration procedure; prioritisation at evaluation; reducing the impact on downstream users and small and medium-sized enterprises; and ensuring the scope of the regime is more manageable, especially during the initial stages when all parties will be on a learning curve. We do, however, continue to have some concerns regarding certain aspects of the proposal, in particular the workability of some provisions. A system that is not workable will fail to deliver the intended environmental and human health benefits, whilst placing unnecessary burdens on industry and public authorities.

24. We are of the opinion that in order for the system to be made workable, prioritisation of resources – both in industry and in the regulatory authorities – is essential and we will be considering ways in which further prioritisation can be introduced in the system.

25. Measures aimed at minimising animal testing through data sharing need to be strengthened. Although the Commission has included financial and other incentives to encourage data sharing at registration, we feel that the proposal must find a way of making data sharing compulsory if we are to avoid duplicate animal testing. We believe that a system of one substance one registration would simplify the system, lead to a reduction in animal

testing and reduce the impact on industry whilst maximising the benefits to human health and the environment.

## **REGULATORY IMPACT ASSESSMENT**

26. A Regulatory Impact Assessment of the Commission proposal is currently being prepared and will be made available as soon as possible.

27. The Commission services have prepared an Extended Impact Assessment of the economic, social, and environmental impacts of the proposal (15409/03 Add. 6).

## **FINANCIAL IMPLICATIONS**

28. The costs to UK industry, as well as the benefits, will be investigated as part of the Regulatory Impact Assessment which is currently being prepared. The costs fall into two broad categories: direct costs (i.e. for testing and registration) and indirect costs (i.e. to downstream users). The partial Regulatory Impact Assessment will be made available with the formal UK Government consultation document, in early 2004.

29. The Commission's impact assessment estimates that the testing and registration cost of REACH (including € 0.3 billion [£ 0.21 billion] Agency fees) will be €2.3 billion (£1.58 billion) in present value terms. On the one hand this may increase by €0.9 billion (£0.62 billion) if progress with the validation of alternative techniques for identifying hazards and assessing risks is slower than currently expected. On the other hand, the lower limit of the range might be reduced by a further € 0.4 billion (£0.32 billion) if progress on these techniques is faster than currently anticipated. These estimates assume a high level of sharing of information and co-operative actions between stakeholders.

30. Indirect costs are more problematic to quantify, not least because of the complexity of supply chains. The Commission considers that whilst some substances may be withdrawn from the market, their number is likely to be limited. Nevertheless, there will be economic consequences of the withdrawal of substances, notably in a situation in which the adjustment of industry to the new requirements does not proceed smoothly. Additional costs to downstream users will arise from (i) higher price of chemicals; (ii) the need to find substitutes for those chemicals substances and preparations that have been withdrawn from the market; and (iii) some increase in market power that remaining suppliers might temporarily exploit.
31. The costs to downstream users of the introduction of REACH are assessed by the Commission to be in the range € 2.8 – 5.2 billion (£1.92 – 3.57 billion) depending on the assumed costs of substituting chemicals.

## **CONSULTATION**

32. The UK Government and the Devolved Administrations published a Position Statement on the White Paper in December 2002. This was prepared in consultation with stakeholders.
33. In May 2003, the Commission launched an Internet consultation to consider the workability of the draft legislation, including the technical requirements. The consultation took place between 15 May and 10 July 2003. The UK Government responded to the Commission's consultation, taking into account views obtained during a stakeholder workshop.
34. A formal UK Government consultation document following publication of the Commission proposal will be published in early 2004. There continues to be wide consultation with industry, environment and consumer groups, other Government departments, Member States and third countries.

## **TIMETABLE**

35. The proposal was published on 28 November 2003 and will go through the co-decision procedure requiring joint agreement with the European Parliament. Initial discussions in Council have started under the Italian Presidency, but substantive discussions are unlikely until the Irish Presidency, commencing in January 2004. Common Position may be reached by the end of the Dutch Presidency (end of 2004) although this represents an optimistic timetable. The European Parliament is aiming for a first reading by May 2004, although this again represents an optimistic timetable.

**ALUN MICHAEL**

**MINISTER OF STATE (RURAL AFFAIRS AND LOCAL  
ENVIRONMENTAL QUALITY)**

**DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS**

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