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HEALTH AND SAFETY COMMISSION

UPDATE ON THE EUROPEAN COMMISSION'S 'STRATEGY FOR A FUTURE CHEMICALS POLICY'

A Paper by Graham Tompkins

Advisors : Peter Galsworthy and Bob Warner

Cleared by Sandra Caldwell on 18 July 2003

Issue

1. The European Commission's (EC) Strategy for a Future Chemicals Policy (REACH) – UK response to the EC's internet consultation on the workability of the proposed scheme.

Timing

2. Routine.

Recommendation

3. That you note the UK response attached at **Annex A**.

Background

4. The EC published its White Paper a 'Strategy for a future Chemicals Policy' in February 2001. The paper proposed a new scheme of **Registration, Evaluation and Authorisation of Chemicals (REACH)** to manage their manufacture, importation and supply.

5. In the absence of formal proposals the UK Government's objectives for REACH were set out in a position paper in December 2002. This paper was subject to extensive consultation in Whitehall in which HSE were closely involved (reported in HSC MISC/03/04).

6. In May 2003 DGs Environment and Enterprise jointly published a draft proposal (not yet formally adopted by the EC) for an EU Regulation to introduce the new REACH system. The draft regulation proposes that chemicals manufactured or imported at quantities greater than 1 tonne be registered, greater than 100 tonnes evaluated, and certain chemicals of high concern (such as carcinogens) to be subject to authorisation before use. More detail is attached at Annex B.

7. The EC decided that for this complex proposal a Stakeholder check on system workability would be appropriate. This was launched as an 8 week public Internet consultation on 16 June 2003. Defra have consulted other Government Departments, including HSE, and drafted the UK response (Annex A) which was sent to the EC on 10 July 2003.

8. The response does not attempt to address all of the aspects of the draft proposal that the might be of concern to the UK Government and does not represent the final UK negotiating position.

9. We understand that the next stage, following consideration of consultation comments, will be consultation with other DGs. The EC anticipate formal adoption of the proposal in autumn 2003 paving the way for consideration by the European Parliament and detailed negotiations.

ARGUMENT

10. The draft proposes an ambitious scheme that will bring major change to the existing laws that manage the supply and use of chemicals (many of which are the responsibility of HSE). Key challenges to the UK are to ensure that the negotiations deliver the declared objectives of simplification and transparency and that the scheme does not incur excessive animal testing.

11. The UK Response sets out general concerns about the scope, complexity and resource demands of the proposal.

12. The REACH proposal is driven by environmental and public health concerns. It is not intended to address explicitly issues relating to occupational health, but it does provide opportunities for improvement, for example through better information on the chemicals used at work and control of high risk chemicals.

13. It is clear that although REACH may provide occupational health and safety (OHS) benefits there are dangers that the considerable demand on resources may challenge the operation of existing OHS schemes and policies. In addition, our initial studies of the proposal indicate that the overlaps with current OHS legislation will need to be more carefully considered and managed. These concerns are set out in the UK response. We will explore them further as the proposal becomes more refined.

Consultation

14. DEFRA held a workshop on the workability of the system on 29 May. They sought stakeholder views including those of HSE officials and our Standing Committee on Hazard Information and Packaging (SCHIP) REACH sub group on the workability of the system.

15. We organised a workshop on 3 June to explore issues with members of the SCHIP REACH Sub Group and those members of Advisory Committee on Toxic Substances (ACTS) who were able to attend. Many of their views have been incorporated into the UK response. SCHIP & ACTS have received copies of the response.

Presentation

16. DEFRA and DTI Ministers have taken an active interest in this issue which is considered the most important legislative proposal affecting the viability of the chemical industry for many years. DWP Ministers have been briefed on REACH and have formally agreed the UK response to the EC.

Costs and Benefits

17. The EC has estimated the EU-wide costs of the proposals to be in the region €18-32billion (£13-24billion) over a period to 2020 taking into account both direct and indirect costs.

18. However, a recent report produced for the EC estimates occupational health benefits of €18-54billion over 30 years. Whilst we welcome information about potential benefits we believe the report gives far greater weight to occupational health benefits than may actually be realisable. They are, for instance, based on a presumption that 500 new carcinogens will be identified, and yet it is likely to take over 50 years for existing carcinogens to be processed and authorised. We are studying the report findings in more detail to establish a clearer view on the extent of their validity.

Financial/Resource Implications for HSE

19. Defra have commissioned a Regulatory Impact Assessment on the proposal; this work is at an early stage. The financial/resource implications for HSE/UK government remain highly uncertain. At this stage we are unclear how much the draft proposal will change as a result of the Internet consultation. These aspects will be dealt with in a further paper when we have details of the finalised legislative proposal.

Environmental Implications

20. Defra have the policy lead on REACH, which covers environment and human health via the environment.

Action

21. HSE officials will continue to work with DEFRA and OGDs on the development of the new system. In addition, we will continue to up date the HSC on progress with REACH, and inform them of resource implications, and the possible impacts for OHS.

Draft Legislative Proposals for the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH): UK Government Response

INTRODUCTION

1. This paper outlines the UK Government's initial views on the draft REACH proposals. It is based on the UK's current level of understanding of the draft proposals and does not represent a final national position. This paper also does not seek to address all the aspects of the draft proposal that might be of concern to the UK Government and thus the absence of comments on any issue does not signify agreement with the draft.
2. The UK Government continues to support the overall aims of this policy and its approach to the design of the legislation continues to be informed by its three overarching objectives as set out in its Position Statement of December 2002:
 - Creating a fast, efficient and workable process of testing, screening and assessing substances of concern, starting with the most harmful, because of their impact on human health or the environment;
 - Keeping animal testing to the minimum necessary to protect human health and the environment; and
 - Maintaining or enhancing the competitiveness of the chemical industry and downstream users.
3. The UK Government considers that a number of significant changes are required to the draft proposal in order to ensure that the REACH system can be made workable. Some specific suggestions are therefore made below. Overall, the UK Government is particularly concerned about the complexity of the proposals (partly the result of the chosen approach of "one registration per manufacturer" rather than "one registration per substance"), the lack of effective prioritisation on chemicals of most concern in the early stages of implementation and the potential inclusion of large numbers of low-priority substances. It considers that if these issues are not resolved then the new regulatory regime is unlikely to deliver the required results in a reasonable timescale, nor to make the most efficient use of the limited resources that will be available to the Member States, industry or the proposed new Agency. In addition, it is vital to ensure that the new regulatory regime is compatible with the EU's WTO commitments (in particular that it is not seen as disproportionate), since it would be pointless to expend so much effort developing a system that is later successfully challenged.
4. The UK Government is also concerned that the administrative complexity of the proposal will limit the potential benefits. There are a wide range of interfaces between the authorities, industry and other stakeholders that, if not carefully managed, could lead to confusion and possible disputes. In such a complex

structure, it is easier to lose sight of a primary objective to generate practical risk reduction measures (RRM) that will lead to improved control.

5. Initial studies of the proposal indicate that the overlaps with current Occupational Health and Safety (OHS) legislation will need to be more carefully considered and managed. The risk of confusion, particularly for downstream users, could undermine benefits. Without an integrated and straightforward approach, REACH may present an extra layer of requirements. This would present difficulties for prioritisation, and result in loss of credibility in the overall OHS framework.

DUTY OF CARE

6. The UK Government recognises the value of a basic level of duty of care to apply to all substances even those below 1 tonne. However the requirement to prepare a full chemical safety assessment in accordance with Annex I as outlined in Point 4 is likely to be over-burdensome and unduly restrictive and to undermine mechanisms in the rest of the proposal to promote data sharing. Consideration needs to be given to the amount of data necessary to demonstrate compliance with the duty of care, particularly as many producers below 1 tonne will be SMEs. Enforceability of such a general requirement also needs to be taken into account and provisions in place to ensure it is applied consistently across Member States.

CHEMICAL SAFETY ASSESSMENT

7. The UK Government believes that the Chemical Safety Report (CSR) will present enormous challenges for industry, particularly for problematic substances just as with the approach currently used under the Existing Substances Regulation (ESR).
8. Experience in the UK (e.g. Safety Reports for Seveso II) shows that despite the availability of written guidance (and even software tools in the case of the current new substances regime) industry has difficulty in generating reports of this nature without significant input from the Competent Authority (CA), particularly since it will be important to avoid a “tick-box” approach to testing as that can lead to unnecessary testing, extra cost and undue animal usage. More detailed guidance and support (e.g. software tools) will be necessary for SMEs. There is no mechanism for introducing flexibility e.g. grouping substances, or focusing on end points and exposure scenarios of particular concern.
9. The CSR requires Risk Reduction Measures (RRM) to be summarised (Part A.1) but the detail is contained in the section of the report addressing exposure assessment (Part B.8). It could be difficult for a downstream user to find easily the relevant RRM. A clear conclusion section is necessary, so that the downstream user can easily identify relevant exposure scenarios & RRM. The conclusion section should form the basis of information to be passed along the supply chain. The detailed content of a CSR (e.g. technical dossier) could be made available, e.g. on internet, for consultation by downstream user if necessary.

10. The risk characterisation section of the CSR requires the author to confirm if adequate control has been achieved – but doesn't describe what should be done if it isn't. In this case RRM listed earlier may be inadequate. The CSR should include details of steps being taken to address adequate control and how these will be passed on to downstream users. This should be included in the conclusions section.
11. To simplify information exchange, the downstream user could receive the CSR conclusions rather than the full report. The full report could be posted on the Internet for use if necessary.
12. A number of other concerns relating to downstream users and the CSR are set out in paragraphs 43 and 44.

INFORMATION FLOW

13. Information flow between suppliers and their downstream users could be hampered by the range of EU languages. Will suppliers be required to translate their chemical safety report? This will be a particular issue for downstream users, many of which will operate across the EU and be SMEs.
14. There are also concerns about the feasibility of requiring manufacturers, importers and downstream users to prepare a CSR for phase in substances on first delivery following entry into force of the regulation. The UK Government would question the value of such a document, given the limited data available and limited time to prepare them. It could result in additional testing being carried out as there is no scope for data sharing at this stage. Industry would then be required to repeat the process at registration.
15. There are concerns about the workability of Point 96(3) which acknowledges the problem of having multiple registrations and that different knowledge or interpretations of data for the same substance will lead to different entries on the inventory. Registrants are required to make every effort to resolve these difficulties, however it not clear how this will happen and what happens if agreement cannot be met.
16. Given the implications for downstream users, it will also be very important to ensure that all actors in the supply chain are engaged in preparatory communications for registration. Downstream users, in particular, will need to be made aware at the earliest possible stage of any up-stream supply decision to cease production of substances or preparations for reasons of cost due to REACH. That will enable them to take early action to investigate alternative substances for use in products or preparations. It will also enable them to form links with registrants to ensure that their uses are included in the registration. The proposals should therefore contain provision for information sharing related to potential substance withdrawal and downstream uses to be included in the registration dossier.

REGISTRATION PROCEDURE

17. The phased approach to registration is welcome. In the draft proposal, prioritisation for registration is based on tonnage and classification as CMR. The UK Government would, however, strongly urge the Commission to refine further its phased approach to achieve more effective prioritisation. This is essential to the workability of the proposals. Relying so heavily on tonnage would mean resources being spent in the early years dealing with many low risk, high tonnage substance while other much more hazardous but low tonnage substance would not be registered for another 8 years. Improved prioritisation for registration would mean a comparatively manageable number of substances of high concern, regardless of tonnage thresholds, could be brought within the system in a shorter period of time through efficient use of existing resources. This would meet legitimate public expectations that any new regulatory regime should deliver results sooner rather than later.
18. The UK Government welcomes the suggestion of a pre-registration phase to allow registrants the opportunity to come together and share data and avoid duplicate testing. However the phase in dates for pre-registration means that while someone producing a smaller amount of a chemical might have a significant amount of data, there is no requirement to share this data until their phase in date – which could be up to 8 years later, after many of the tests have been duplicated. The legislation should therefore include provisions for comprehensive data sharing by all manufacturers or importers irrespective of tonnage as part of the pre-registration phase.
19. The complicated arrangements for registration and the time and resources needed to complete the registration process are of concern. Given that the expectation is for much of the system to be automated, it is not clear that the Member State competent authority requires as long as 60 days to request further information under Point 19(3)(b). There are also no timescales given for the Agency to carry out a further completeness check or for the CA to reject the registration. On submitting a registration a company is given a registration number, however there is no procedure for removing the registration number if information is not submitted and the registration denied. It would therefore help if the publicly available database of registrations could indicate the status of each registration (i.e. “submitted and pending decision”, “accepted” or “rejected”).
20. Registration is made complicated by having one registration per manufacturer. This will result in a number of different registration packages being submitted with data of varying quality (or even different results) for the same substance. Requiring registration per manufacturer significantly increases the number of registrations and hence places a major burden on the system. It also increases the number and costs of tests which need to be carried out and hence increases the number of vertebrate animals used. In particular, a requirement for an increased number of registrations would be likely to have a disproportionate effect on SMEs which could have implications for competition in the markets in which they operate.

21. The procedures for submitting registration data by members of the consortia appear complex. Point 12 requires parts of the registration to be submitted by one registrant of the consortia and other parts to be submitted by each manufacturer. This will make it very difficult to carry out completeness checks.
22. The UK Government welcomes the provision that at least 90% of downstream uses should be covered by the registrants dossier, which can be subject to priority evaluation under Point 38(b).
23. The registration process could be significantly simplified and the above registration problems resolved by requiring one registration per substance. Having industry come together to provide one registration package would improve the quality of the registration package and bring greater simplicity and transparency to the overall process. Completeness checks carried out as a consequence of the registration will be far simpler if they are based on one package and enforcement on companies not complying with the Regulations will be simpler with one agreed consortium package as long as all manufacturers/suppliers were named in the registration package. Those who are interested in the registered uses of the substance will only have to access one package.
24. The UK Government recognises that some manufacturers or downstream users may not want their competitors knowing what substances they are producing or using. This need to retain a degree of commercial confidentiality – and to avoid anti-competitive practices – can be accommodated within a system of one registration per substance by allowing industry to have an independent third party to hold sensitive information apart from the other members.
25. Having a system based on one registration per substance and linking the name of the supplier to the registration number means that only those party to the registration of a substance can produce it, supply it or cause it to be supplied (i.e. use of distributor) in the EU. Those wishing to enter the market will have to join the consortium and compensate proportionately the original registrants for the costs of data collection, application fees and any further work done for targeted risk management or authorisation, but should not otherwise be penalised for “late” entry. One registration per substance would also avoid some of the anti-competitive problems that have been encountered with other legislation where consortia formation has been voluntary such as the Biocides Directive.

POLYMERS

26. Including all polymers in the REACH system could add as many as 30 000 substances or more. Even when allowance is made for an extended period of implementation, registering and testing every new and existing polymer would overburden the system. It is essential to develop a proportionate approach to regulating them which focuses on those polymers which have specific characteristics which may make them potentially hazardous to human health or the environment (once criteria have been agreed), while allowing non-hazardous polymers to be exempted.

27. There are concerns that the criteria defined in the draft proposal are too broad in scope and could result in a significant number of additional registrations. The UK Government strongly prefers a prioritisation approach that limits the regulatory burden to only those polymers of concern by approaching the issue in three stages as set out in its December Position Statement.
28. By focusing on those polymers of highest concern, the system would in effect be exempting the lower hazard polymers from the REACH system. As well as the benefit of reduced regulatory burden, having an exemption rule should also encourage innovation in the manufacture of lower hazard polymers.
29. Where the monomer is not registered under REACH, the system should be flexible enough to allow the manufacturer or importer to register the polymer instead.
30. There should also be maximum appropriate use of a family type approach to deal with both registration and exemptions. The concept of grouping polymers into families is based on the assumption that, in principle, the members of a family of polymers possess a similar hazard potential. Although it is recognised that the effects might not always be linear throughout a family, testing polymers on a family basis is accepted in order to reduce tests to a reasonable and yet sufficient number. The decision to group polymers should not be mandatory but left to the notifier. The concepts of data sharing should still apply.

INTERMEDIATES

31. It is not known exactly how many intermediates are in use in the EU, but estimates vary from 50 000 to 120 000. By their very nature, most intermediates tend to have low exposure and are subject to other regulatory regimes that place the responsibility on employers to ensure that appropriate risk assessments are carried out for workers who handle chemicals, including intermediates. A risk assessment is also carried out for the transport of chemicals by road, air, rail or sea to ensure safe handling and transportation.
32. In the light of the low risk of exposure, and the availability of existing safeguards, the UK Government does not consider that the registration of all intermediates under REACH should be a priority. Furthermore the inclusion of such a large quantity of additional registrations would overwhelm the system and stop it from addressing substances of much higher concern.
33. The specific proposal to exclude non isolated intermediates is very welcome. The UK Government is however concerned that even a limited registration for isolated intermediates used on site or transported in quantities under 1000 tonnes per year could impose a disproportionate burden on industry and Member State. A very basic form of notification, which would need be no more than the submission of a list of the substance names and CAS numbers to enable the Member State enforcing authorities to assess compliance, would be better. The supplier should then hold on site, for inspection by authorities, a set of core information to provide a consistent and transparent level of information to assist in compliance with existing legislation.

34. This approach would achieve the desirable objective of ensuring competent authorities could obtain the necessary data on a case by case basis, or through random spot checks, rather than place a formal administrative requirement on companies to supply information that the competent authorities may not wish to receive on a routine basis, and which they may not have the resources to scrutinise on a routine basis. The notification suggested here would also provide a greater certainty on the question of exactly how many intermediates there are so that any future plans to address the issue more comprehensively will be based on better information.
35. Given that the number of isolated intermediates is still uncertain, requiring full registration for those intermediates transported in quantities over 1000 tonnes per year is very problematic, especially given existing regulations relating to transport of chemicals which deal with unintended releases. Any decision to include intermediates in this way should be deferred until after REACH has been in operation for several years and the majority of commercial substances registered.

DATA SHARING AND CONSORTIA FORMATION

36. The UK Government welcomes the approaches to encourage the development of consortia and promote data sharing, though this must of course be conducted in such a way that does not infringe competition law (i.e. constitute concerted practices for the purposes of Articles 81 or 82 of the Treaty). The UK Government would also be concerned if the pooling or publication of confidential information, such as the formulations of chemicals produced by manufacturers as part of data sharing, were to lead to a reduction in competition. The system needs to provide mechanisms to avoid this (for example the use of third parties as suggested in paragraph 24 above).
37. In generally supporting the need for the formation of consortia, the UK Government notes that for phase-in substances data sharing is not compulsory. There are concerns that the incentives for data sharing are insufficient, that there will be variations in the number of associations that exist across sectors which will have implications for data collection and that as a result uptake to form consortia will be low.
38. Data sharing is not only essential to avoid unnecessary duplicate animal testing, it is also an important cost issue particularly for SMEs. Without a stronger requirement to counter reluctance from manufacturers or importers arising from confidentiality concerns or perceptions of market advantage, larger manufacturers may be reluctant to share data with their smaller competitors within or outside consortia.
39. In Point 27(4), where cost sharing cannot be agreed the proposal is for the previous registrant to claim 50% of the cost. However it is not clear what costs are being recovered. Costs for data packages may need to be standardised to prevent unreasonable or excessive costs being reclaimed. One concern would be if companies were able to acquire property rights for commonly produced substances as a result of the registration process and clarification on whether this would indeed be the case would be welcomed.

40. The registration process is made more complex by having different databases at different stages. For instance, registrants of phase-in substances are required to submit data to the substance information exchange forum (SIEF), whereas registrants of non phase-in substance refer to either the database mentioned in point 67(2)(d) or enquire to a Member State CA. The process could be simplified by having a single database and source of information. Limiting access to the SIEF only to potential registrants also limits the potential for data sharing. It means that other manufactures who may have test data but do not want to register the substance are unable to access the SIEF and hence share their data. Data sharing should be encouraged between all actors in the supply chain not just registrants.
41. The UK Government is also concerned about the additional burden on Member States competent authorities in the duty to enquire prior to registration and promoting data sharing for non phase-in substances outlined in points 27 and 28. This could require a significant input from CAs. The provision to include an arbitration board in Point 28 to resolve data sharing disputes is welcome. However, it is not clear how this board will be set up who will be responsible for administering it and clarification on this would be appreciated.
42. Many of the above problems associated with data sharing could be resolved by having a system of one registration per substance which would make data sharing compulsory.

PROCEDURES FOR DOWNSTREAM USERS

43. One of the UK Government's concerns about the position of downstream users in this scheme is the sheer volume, complexity and unfamiliarity of the information that will come their way in the form of a Chemical Safety Report. In the case of SMEs, all such information is unlikely to be relevant or, where it is, there will be difficulties of assimilation. Also, the 'top-down' approach, whereby the up-stream registrant makes judgements about "undesirable uses" and risk management measures could create difficulties (a) where the former is not well enough placed to make such a judgement and (b) where the downstream user is already applying customised risk management measures already. The UK Government believes the system should allow some flexibility to encourage such two-way flows of knowledge and information. At present, it is not clear if that is likely to work given the up-stream suppliers' role in registration.
44. More generally, the creation of complex and lengthy Chemical Safety Reports for each substance and preparation holds out the prospect of a large number of these documents being out to circulation throughout different supply chains. Even if carried out mostly by electronic means, this could create an administratively onerous regime. It is difficult to see how companies, particularly SMEs, will be able to avoid information-overload in the form of innumerable Chemical Safety Reports for each the many substances and preparations that they use. As suggested in paragraph 11, one option that could reduce the burden of transmitting the Reports throughout extended supply chains would be to make them available on the proposed Agency's website, with only the conclusions actually being transmitted through the supply chain.

EVALUATION PROCEDURE

45. The proposal for standard evaluation as outlined in points 35-37 requires any Annex VII and VIII testing proposals to be examined by the evaluating authority regardless of tonnage or level of concern (although in principle this will be primarily substances supplied in quantities > 100 tonnes per year). The UK Government would question how effective this stage is given the limited resources available in Member States, especially if the interpretation is correct that justifications for “no testing” will have to be examined as part of the standard evaluation to satisfy the evaluating authority that the reasoning proposed for not testing is acceptable. It may also be difficult to properly assess testing proposals without looking in detail at chemical safety report – which would make evaluation a more resource intensive process. The resources needed should not be underestimated. As standard evaluation is mandatory, it may mean that the majority of Member State resources will be spent on this.
46. If the home Member State for the first registrant is assigned as the evaluating authority, there could be linguistic difficulties in dealing with registration packages from other Member States, which may therefore require more time.
47. There are concerns about the lack of certainty for industry after having gone through the evaluation process. Dossiers may be open to priority evaluation at any time by another Member State so some form of science-based criteria for opening a priority evaluation might be needed, perhaps overseen by the Agency. Aggregation of tonnage at this stage will also re open the question of which test package they need to comply with.
48. The UK Government is concerned about the lack of prioritisation in the evaluation process. Prioritisation will be essential to ensure Member State resources are concentrated on the substances of most concern. This is a clear workability issue as it will be very difficult to assign sufficient resources to adequately evaluate all substances > 100 tonnes per year. Furthermore, the UK Government’s reading of the draft proposal is that any clarification of PBT/vPvB properties (i.e. testing to see if the confirmatory criteria are met following identification based on screening data) will be done under evaluation (there appear to be no provisions for this under authorisation). Prioritisation will, therefore, be important to ensure that these cases are examined first.
49. The new system must be a fast, efficient and workable process of testing, screening and assessing chemical substances to provide the information necessary to control those substances of concern, starting with the most hazardous, because of their potential impacts on human health and the environment. The UK Government’s approach is to streamline the system by having an evaluation phase which will prioritise substance for further action.
50. The problems described above could be resolved by having a process involving an initial screening assessment based on the data submitted in the registration package. Prioritisation would be based on an assessment of hazard, exposure and tonnage bands. The initial screening of this data, which could be done electronically to speed up the system, would identify and prioritise chemicals for further action quickly and easily. Those of highest concern would be identified

at the start and move straight to authorisation. While the remaining chemicals, not identified as being of lowest concern, would progress onto the next stage of risk assessment and, if necessary, have restrictions placed on their use.

AUTHORISATION PROCEDURE

51. The UK Government is concerned about the scope of authorisation. Point 48(2) indicates that the granting authority shall not consider the risks to human health and the environment of emissions covered by IPPC or by binding emission limit values under the WFD. The implication is that emissions of PBTs/vPvBs are adequately controlled by IPPC or WFD. It may be advisable to cover consideration of the risks from all emission points (even if regulated by other regimes) in the authorisation dossier in order to fully assess whether a substance is adequately controlled or whether further controls on marketing and use are required where for example exposure is through both point and diffuse sources.
52. The proposal to grant authorisations per user could have resource implications and create the potential for inconsistency (and thus market distortion and legal challenge) and hence affect the workability. Although there is provision to allow joint applications, there are insufficient incentives to promote this. It could seriously increase the number of individual authorisations and over-burden the system making enforcement extremely difficult. This could be resolved by having one authorisation per substance per use with all known manufacturers and importers identified on the authorisation as recommended in the registration process. This would streamline the system and make it far more effective and efficient to look at all the proposed uses at one time. Such an approach would require potential users of a substance to refer to a single authorisation and make it easier to identify acceptable uses.
53. Under Point 52, the Member State shall be responsible for authorisations where the applicant does not intend to place the substance on the market. There still appears to be some uncertainty regarding the exact scope of the Member State authorisation. This needs clarification for resource implications to be assessed. Also if a Member State is responsible for authorising substances not placed on the market, how does this sit with protection of the single market and a level playing field for industry, particularly given the scope of the legislation (especially with regard to large numbers of non-marketed intermediates and polymers)?
54. Point 50(5)(a) allows applicant to submit a socio-economic analysis (SEA). The UK Government would question whether industry should be solely responsible for this, given the need to take into account a wider range of stakeholder views (in a clear and unbiased way) in demonstrating that the benefits outweigh any potential health or environmental risks. There needs to be greater apportionment of responsibility between the rapporteur and the industry. The UK Government suggests that there should be a standard format for SEA to ensure clarity of methodology and to set out what data is required, which would help ensure a consistent approach in preparing them and to facilitate their assessment.

55. There is no mandatory data sharing under the authorisation process. A subsequent applicant “may refer, by means of a letter of access granted by the previous applicant,” to the testing data and SEA submitted by the previous applicant. There are concerns that without some form of mandatory data sharing, as in registration for non phase in substances, the costs of gathering data could force small users out of the market because of the disproportionate cost of separate registration where they are not part of a consortium. Again this problem could be overcome by requiring one authorisation per substance per use.
56. Consideration needs to be given to how many dossiers are dealt with at one time. In terms of timescales and workability 30 days seems insufficient for Member State to review and comment on whether a substance meets the criteria for authorisation (Point 47) particularly if several dossiers (of varying complexity) are sent for comment at the same time.
57. Given the potential for around 2000-3000 substances requiring authorisation, the UK Government is concerned about the lack of prioritisation in the proposed system. The issue of prioritisation is crucial both for the workability of the system and for transparency. The priority list therefore may need to be further structured in order to give regulators and industry (particularly downstream users) a clear sense of when a substance will be subject to authorisation. This allows sufficient planning time. One suggestion may be the early publication of list with clear “sunset” dates (and dates between which authorisation dossiers will be accepted) even if years ahead. There should be an opportunity for Member State involvement in the prioritisation process.
58. General provisions (Point 45(5)) states that substances in preparations below the concentration limit will not need to be addressed. This may be applicable for CMR properties where classification and labelling (and concentration limits) can be assigned. There is, however, no classification for PBT properties, let alone the ability to set concentrations limits. This is not, therefore, workable as currently phrased.

RESTRICTIONS PROCEDURE

59. The restrictions process as outlined in Point 61 indicates that previous Marketing & Use restrictions that have gone through the EU process as part of the Existing Substances Regulation (ESR) regime can be re-opened by a member state or the commission if they think there is sufficient risk or the substance is not adequately controlled. This could lead to situations where member states re-open substances that are being adequately controlled through Marketing & Use restrictions. It is therefore important that ESR-based work is accepted under REACH as part of the practical utilisation of existing information.
60. There are concerns about the bureaucracy and efficiency of the restrictions procedure. The proposal is to have one rapporteur for risks assessment and one socio economic analysis. In terms of workability and on the impact on resources it could be more effective to have one rapporteur covering both issues.

61. The proposals are also unclear as to how they interact with the authorisation process. Without further clarification, this will create confusion and uncertainty for competent authorities and those seeking to comply with the requirements of the regulation.

THE AGENCY AND DECISION-MAKING PROCESSES

62. The draft legislation makes provision for potentially complex interfaces between the new Agency, Member State Competent Authorities and individual companies. The UK Government recognises the logic of that in most cases, but would invite the Commission to consider if simpler decision-making mechanisms can be proposed. Workability will be directly linked to the new Agency having a key management role. Without a more streamlined decision-making process, the deadlines in the draft legislation could be missed, simply by default, as a result of delays at too many decision-making and information points between the various actors in the process.

63. The REACH system will involve a large volume of information flowing through different decision-making points. Clearly, that cannot work efficiently if there is scope for challenge at every point. There must however be an appropriate appeals mechanism, particularly for those using substances subject to a Community or Member State authorisation or restriction, which would need to exclude frivolous or vexatious claims.

OTHER

Access to information

64. The proposals are very unclear about what data will be made publicly available. Care needs to be taken in protecting information provided at different points in the regime, most notably in the Chemical Safety Report where details are given about particular downstream uses, and relating to the use of intermediates and polymers. It is important that intellectual property rights relating to confidential information and information submitted to obtain marketing approval are respected. It is especially important that the provisions of the World Trade Organisation's Trade Related aspects of Intellectual Property Rights (TRIPs) Agreement are not contravened. The UK is committed to having transparent system and would expect to see as much information as possible, given these constraints, is made publicly accessible.

Exemptions and exclusions

65. The draft legislation would be easier to understand for exemptions and exclusions if they were placed together in the legislation. At the moment, these provisions are to be found in Points 1, 7 and 9, and under Annexes II and III. It is not clear as to how Annex II was arrived at – how additions and deletions are made – and clarification would be welcome.

Substances in articles

66. The equal application of the provisions relating to substances in articles to indigenous EU manufacturers and importers does not avoid potential difficulties under the WTO, particularly on grounds of proportionality. Due consideration needs to be given to the need to accept, wherever possible, the results of conformity assessment procedures carried out by non-EU members to standards that are equivalent or similar to those in the EU. One of the difficulties that can be foreseen, notwithstanding the expected guidance that is mentioned under Point 64(4), is the scope for differing interpretations of “sufficiently high amounts”. Such issues have been the subject of dispute in the past under the Marketing and Use Directive (76/769/EEC), but on a selective basis. In this case, REACH is proposing a systematic approach, and that may give rise to many disputes. In addition, applying the tonnage threshold to substances in articles that may be sourced from a large number of suppliers within and outside the EU is likely to create formidable obstacles to effective enforcement.

Main themes for the new REACH system

- **Duty of Care:** This broad provision requires all those manufacturing, importing or using substances to carry out a chemical safety assessment and take appropriate risk reduction measures to address any risks identified. The requirement applies regardless of the quantity of the substance being manufactured or used.
- **Registration:** A requirement on industry to collect, collate and submit data on the hazardous properties of all substances manufactured or imported into the EU in quantities above 1 tonne per year. In addition, industry should prepare risk assessments and provide safety information to downstream users.
- **Evaluation:** There are two types of evaluation.
 - Standard evaluation covers all substances manufactured or imported into the EU over 100 tonnes per year. It requires Member States to assess and agree any testing proposals put forward by industry as part of their registration package.
 - Priority evaluation provides a mechanism for Member States to review registration packages and consider whether more information is required.
- **Authorisation:** Industry will need to gain authorisations for the use of substances considered to be of very high concern. These are substances that are identified as carcinogenic, mutagenic or toxic to reproduction (CMRs); persistent, bioaccumulative and toxic substances (PBTs); substances that are very persistent and very bioaccumulative (vPvBs); and substances demonstrated to be of equivalent concern, such as endocrine disruptors.
- **Restrictions:** The provisions enable risk reduction measures to be introduced across the European Community where this is shown to be necessary. Member States or the Commission prepares proposals for restrictions.
- **European Chemicals Agency:** The provisions create an agency for managing the technical and administrative aspects of the REACH system at Community level.

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