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(Ad-hoc Working Party on Chemicals)

SUBJECT: Impact Assessment of alternative approaches to registration of low-volume substances

Delegations will find, in the Word-document accompanying this note, an assessment of the impact of the approach to registration of substances in the 1-10 tonnes per annum range proposed in the first version of the UK Presidency proposal (doc. 11844/05) as compared to the approach presented in the Commission room-paper of 20 September 2005. This impact assessment has been prepared by the Commission services.

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REGISTRATION OF SUBSTANCES IN THE 1 – 10 TONNE CATEGORY

AN IMPACT ASSESSMENT OF ALTERNATIVE APPROACHES

1. Introduction

Following the adoption by the Commission of the REACH proposal in October 2003 and its Extended Impact Assessment (ExIA)¹, the Commission services concluded a Memorandum of Understanding with UNICE and CEFIC to perform further impact assessment work. This work was completed in April 2005 and the Commission services drew a number of conclusions from it². One conclusion was that lower volume substances are vulnerable to being made less or non profitable by the registration requirements.

Early this year, Malta and Slovenia presented a prioritisation proposal addressing this special situation of the lowest tonnage band, from 1 to 10 tonnes. Since then, some Member States and Parliamentary Committees have developed their own versions of this proposal and the UK Presidency has asked Member States to agree on its compromise. At the Council ad hoc Working Group meeting on 19-20 September 2005, the Commission services presented a non-paper addressing this issue.

2. Scope

Following the discussion in the Working Group and by Ministers in the Competitiveness Council of 11 October, the Commission has examined the impact of the *UK Presidency compromise proposal* and the Commission non-paper in comparison to the original Commission proposal. This note summarises the outcome of this exercise.

A short description of the registration and testing requirements is given, highlighting the differences between the discussed options. Subsequently, estimates are provided for the respective average registration costs of industry and the required number of vertebrate test animals, before the consequences for health and the environment and the work load for the Agency are discussed. Finally, an estimate is presented for the total registration costs for 1-10t substances, split between Industry and Agency/Member State Competent Authorities.

¹ Commission staff working paper “Extended Impact Assessment of the REACH proposals” (COM(2003)644 final).

² Note by DG Enterprise & Industry and DG Environment on Further Work on Impact Assessment of 27 April 2005, on the website http://europa.eu.int/comm/enterprise/reach/docs/reach/note_further_ia.pdf

3. The 1 – 10 tonne registration and testing requirements

The Commission's 2003 proposal requires that manufacturers or importers of substances with an annual volume between 1 and 10 tonnes submit physicochemical and (eco)-toxicological information as described in Annex V of the proposal text.

The UK Presidency compromise proposal requires that registrants examine whether their substances in this tonnage band meet any one of 3 predefined criteria. If so, they should for such substances provide a complete registration dossier, including the results of all Annex V information requirements, extended with 3 additional tests: acute (oral) toxicity, growth inhibition of algae and ready biodegradability (hereafter “extended dataset”). The prioritisation criteria are:

- (a) No toxicological or eco-toxicological information is available.
- (b) The substance is a potential CMR, PBT, or vPvBs.
- (c) Widely dispersed use or consumer use of the chemical in question.

The Commission's non-paper suggests four major changes to this approach.

First, the criterion (a) would relate only to the information submitted and not the available information.

Second, substances are only prioritised if they meet two or more of six criteria. In addition to the criteria proposed in the *UK Presidency compromise proposal*, three criteria are introduced:

- (d) Substances that have been registered by at least 10 registrants³.
- (e) Substances that have been identified as possible substitutes for other substances subject to authorisation or restriction⁴.
- (f) Substances for which results of enforcement or monitoring activities in the Member State have identified suspicious of risk to human health or the environment

Third, the prioritisation will be carried out by the Agency, assuming that this will be more efficient and more homogenous than if every registrant has to do this.

Fourth, all prioritised substances as well as some not-prioritised (together reaching about 5% of all substances registered in this tonnage band) will undergo a thorough verification as to which additional information has to be requested from the registrants. The Agency may ask for all or some information from the extended dataset, depending on circumstances.

³ Provided those registrants have not shown that there is no significant exposure, or QSARs or other evidence have not indicated a possible hazard.

⁴ Unless QSARs or other evidence have not indicated a possible hazard.

4. Economic Impact

The following table presents the results for the three approaches as regards the testing and administrative costs of Industry and the number of vertebrate test animals required.

Average registration costs and number of vertebrates used (per substance)

		COM 2003 Proposal	A) The UK Presidency compromise			B) Commission non-paper		
			Non-prior. ²	Prior. ³	Total	Non-Prior.	Prior.	Total
Number of substances	share	100%	53%	47%	100%	95%	5%	100%
Testing costs ¹	€per substance	7 700	0	11 000	5 200	0	16 200	900
Administrative costs	€per substance	4 400	4 400	5 700	5 000	1 800	3 100	1 800
Registration costs	€per substance	12 100	4 400	16 700	10 200	1 800	19 300	2 700
Number of vertebrate animal tests		20	0	23	11	0	36	2

¹ The assumptions of the ECB cost scenario "Average testing needs" have been used in line with the Commission's 2003 ExIA.

² Substances for which only physicochemical & available information will need to be provided by the registrants to the Agency

³ Substances for which additional information (extended dataset) will need to be provided by registrants to the Agency

The average registration costs consist for industry of testing costs and administrative costs not including Agency fees. As explained in more detail below, the estimates of the average testing costs and the number of vertebrate test animals within the 1-10 tonne volume category take account of the assumptions on data availability; on the applicability of alternatives to testing such as QSARs, read-across and the possibilities of waiving, as used in the Extended Impact Assessment of the Commission's 2003 proposal. The estimates for the administrative costs take account of the benchmark of the workload used in the Extended Impact Assessment⁵. The level of the Agency fees has not been included in order to avoid the use of arbitrary assumptions on the part of the additional Agency costs financed by fees and on the allocation of the assumed change in the fee on the different volume categories. In the Commission's 2003 proposal it was assumed that 80% of the budget of the Agency would be covered by non-community funding⁶.

One should also realise that the table only contains average cost figures while the actual testing cost can range between the minimum cost of close to zero, if all required data are easily available to the registrant, and the maximum cost, in the unlikely case that all the tests need to be performed. This upper bound of the cost would then be €64 000 for both the non-paper and the *UK Presidency compromise proposal*, and €45 000 for the Commission's 2003 proposal, albeit in most cases a lower value will occur.

⁵ The administrative costs for firms in the Commission's 2003 proposal were estimated to be 5 person days at 875 Euro a day.

⁶ Section 2.1 of the financial statement to the Commission's 2003 proposal.

A. Specific assumptions for the UK Presidency compromise proposal

With regard to the three prioritisation criteria of the UK Presidency it is estimated that:

- (a) no substances will be without toxicological or eco-toxicological data because registrants will either have some test data available or will choose performing one cheap test such as skin irritation;
- (b) 12% of substances in this category are a potential CMR, PBT or vPvB⁷. This estimate is based on a recent study of the Danish EPA and must be seen as a conservative assumption because expert judgement would likely reduce the number of suspected substances to around 6%⁸;
- (c) 40% of 1-10t substances have a widely dispersed use or are used in consumer articles⁹.

The *UK Presidency compromise proposal* requires the submission of the extended dataset if one of the conditions (a) to (c) applies. This is estimated to happen for 47 % of the substances, namely the sum of the percentages for the separate conditions, 0%, 12% and 40%, corrected for the overlapping of the conditions of 5%. For the other 53%, the non-prioritised substances, industry has to provide at least the minimum dataset as defined in article 9, but above that only the data it has available.

When calculating the average *testing costs* for prioritised substances, account was taken of the availability of data, the applicability of QSARs and other alternatives to testing, and the possibilities to waive tests as specified in Annex V. For this, the same assumptions were used as under the Extended Impact Assessment of the Commission's 2003 Proposal. For the triggered test "further mutagenicity"¹⁰, it has been conservatively assumed that almost 35% of the prioritized substances will require this test, as compared to 30% for the entire volume band under the Commission's 2003 proposal.

The estimation of the *administrative costs* for industry to prepare the registration dossiers, takes account of the auto-evaluation of the three prioritisation criteria that the industry has to make. This prioritisation process has to be carried out for all 1-10t substances and it is assumed that this will require on average three expert days per substance. When preparing the complete dossier for a prioritised substance, part of the information generated in this prioritisation process can be re-used, thus reducing the workload to 3,5 person days per substance. Consequently, industry will on average need 6,5 person days for putting together a priority substance dossier containing the full extended dataset as compared to 5 person days assumed for the Commission's 2003 proposal.

⁷ More than 97% of these substances would qualify as CMRs, 60% of which are carcinogens.

⁸ "Report on the Advisory list for self classification of dangerous substances", Environmental project N.636, Danish EPA, 2001.

⁹ Note that this estimate is larger than the 20% for wide dispersive use only, an ECB estimate from 2000.

¹⁰ The "further mutagenicity" test is required when the so-called Ames test renders a positive result. The ExIA overall percentage for Ames-positives for the whole volume band (30%) is respected with the conservative assumptions that such will be the case in 70% of the substances suspected to be a CMR and roughly 25% of the cases without such a suspicion.

For a non-prioritised substance, industry needs only to provide the information readily available. Putting together such a dossier will take two person days per substance. Together with the three expert days required for the auto-evaluation, the entire workload for preparing a registration dossier for a non-prioritised substance amounts to 5 person days.

As a result, under the *UK Presidency compromise proposal* the industry's administrative workload is slightly higher than under the Commission's 2003 proposal. The extra workload related to the auto-evaluation of all the 1-10t substances is partly offset by a reduction in the workload related to the lower data requirements for non-prioritised substances.

B. Specific assumptions for the non-paper

With regard to the 3 additional screening criteria, it is estimated that very few substances will meet these requirements because:

- (d) the criterion that there are at least 10 registrants per substance does not apply when registrants have shown that there is no significant exposure or when QSARs or other evidence have not indicated a possible hazard;
- (e) the criterion that the substance is a possible substitute for other substances subject to authorisation or restrictions does not apply when QSARs or other evidence have not indicated a possible hazard;
- (f) enforcement or monitoring activities in the Member States will not yield high numbers of low volume substance with suspicions of risks to human health or the environment.

Targeted testing is required if two or more criteria are satisfied and the initial registration dossier is incomplete in the sense that it is not containing the complete annex V information. Mathematically, criteria (b) and (c) apply together for 4.8% of the substances in this volume category (namely 40% times 12%). The additional criteria (d) to (f) are expected to increase to a very small extent the numbers of substances being prioritised. However, as satisfying one of the two important criteria may be correlated with satisfying the other criterion, the possibility cannot be excluded that the real percentage may be higher. At the same time, the assumption that 12% of all substances are potential CMRs is conservative. It is therefore possible that the real value might end up somewhere between 3% and 10% but the calculations have been based on a prioritisation rate of 5% as this figure can be readily traced back to the assumptions.

For these prioritised substances the Agency will assess the additional information needs and may request less than would be needed for a complete extended dataset¹¹. It is, for example, possible that read-across, structural similarities or intelligent testing strategies would allow this, thus reducing testing requirements.

¹¹ As stated in Article 38 of the non-paper: "... further information limited to some or all of that specified in [the extended] Annex V" shall be submitted." Consequently, the Agency may ask for all or some information from the extended Annex V dataset, depending on circumstances.

Notwithstanding the targeted testing as foreseen in the non-paper approach, the calculations have conservatively assumed that this arrangement will not reduce the test needs as compared with the Commission's 2003 proposal and the *UK Presidency compromise proposal*.

Concerning the triggered "further mutagenicity" test, the assumptions are the same as mentioned above. It is regarded safe to assume that 70% of the prioritised substances will satisfy the requirement to execute the "further mutagenicity" test. As a consequence, the incidence of the triggered test in the prioritised set will be more than twice as high than for the whole volume group under the Commission's 2003 proposal.

In conclusion, the administrative costs of the industry are significantly lower than for the Commission 2003 proposal or the *UK Presidency compromise proposal*. Initially for all substances only the available data need to be submitted and the initial administrative costs are therefore about 2 person days per substance. Only for the prioritised substances additional information will be requested, in some cases this might be less than the extended dataset. Relatively low administrative costs are expected for this, because only a targeted, well determined information set is requested by the Agency. As a result only 1.5 additional workdays are needed to put together the requested additional information for prioritised substances.

C. Conclusions on economic impacts

The table shows that the non-paper approach renders on average significantly lower registration and testing costs for industry per substance with an annual volume of 1 to 10 tonne than the Commission's 2003 proposal, and also requires a considerably lower number of test animals. This is also true for the *UK Presidency compromise proposal*, though the reductions in comparison to the Commission's 2003 proposal are considerably less than for the non-paper approach, due to the considerably larger number of prioritised substances and the higher administrative cost for industry. However, the reductions in the non-paper are partly offset by the increased workload for the Agency

For both approaches, the average testing costs for a prioritised substance are higher than in the Commission's 2003 proposal. This reflects the extended dataset and the impact of the "further mutagenicity" tests which is more frequently triggered in the set of prioritized substances. The latter factor also accounts for the average testing costs and the average number of test animals required, being higher than for the non-paper approach than for the *UK Presidency compromise proposal*. However, these higher burdens apply to a significantly smaller number of prioritised substances. Note also that for the non-paper approach the higher testing cost are partly offset by lower administrative costs for industry.

The higher average registration costs for prioritized substances under the *UK Presidency compromise proposal* and the non-paper approach as compared to the Commission's 2003 proposal could render these substances significantly less attractive. In so far as the passing on of the registration costs is possible, the rise of the market price of such a substance could diminish its appeal as input for industrial processes and consumer articles. If specific market conditions do not allow for cost pass-through, the manufacturer or importer would be obliged to absorb the costs or withdraw the substance from the market. Prioritised substances, while being potentially of concern from a health and environment perspective, are more prone to become vulnerable to de-selection than is on average the

case in the Commission's 2003 proposal. Consequently, the share of substances prioritised is the most important factor for the economic impact of the registration requirements on the substances in this tonnage band.

5. Health and Environment Impact

Both new approaches target substances combining highest potential hazard with possibly high exposure. A screening is foreseen, focussing on a combination of classic risk factors that come from use and exposure and from criteria based on potential hazards. The latter are related to the similarity of endpoints with known substances of high concern and other "cross reading" as well as, in case of the non-paper, experience from Member State enforcement measures. Thereby, the screening is expected to identify a high proportion of chemicals with a potential risk to man and environment and the subsequent analysis of the information needs, under the non-paper approach to be carried out by the Agency, will allow focusing on the necessary additional tests (rather than all).

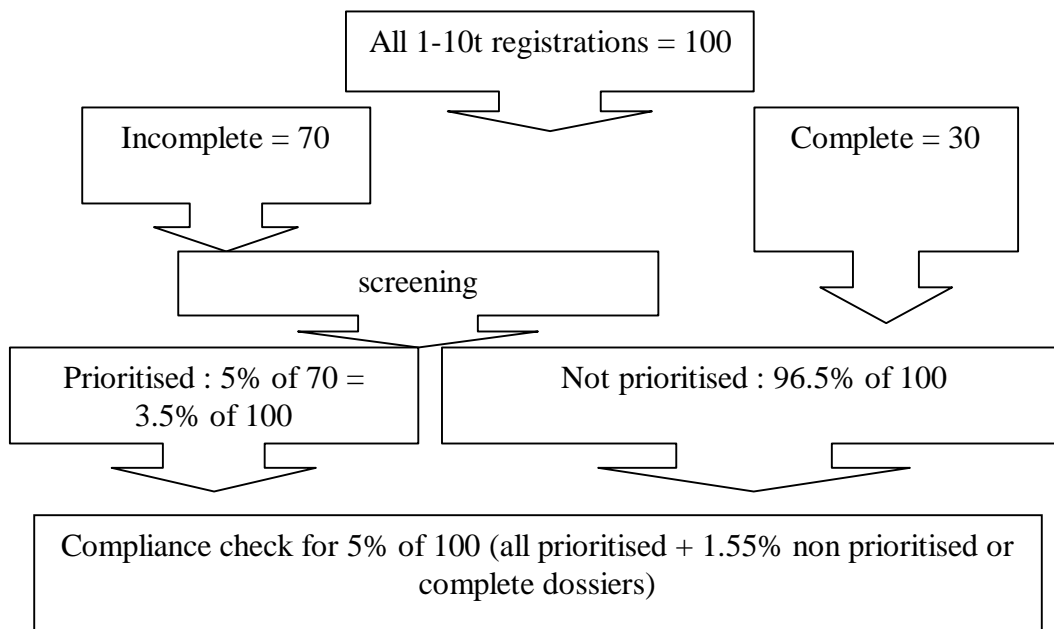
However, it cannot be excluded that certain 'suspicious' substances could slip through the system, i.e. would not be prioritised. For example, many CMRs that have non-dispersive uses but are used in well contained environments, are unlikely to be detected by the non-paper screening procedure. It can also be expected that skin sensitizers, toxic substances, or skin and eye irritants will normally not be prioritised by any of the envisaged screening procedures. This could reduce the health benefits of the system¹².

It is worth noting, in this context, that any non-prioritised substance can be subjected, later in the process, to a substance evaluation or even the restriction procedure whenever potential risks such as the above mentioned are suspected.

6. Administrative Impact on the Agency

Several suggestions have been made in Council and Parliament to allocate additional tasks to the European Chemicals Agency, consequently making more staff necessary for the Agency. This chapter compares the original Commission proposal from 2003 with the Commission's latest non-paper, exclusively taking account of the change in the registration procedure for 1-10 tons substances and its impact on the compliance check for these. The following graphic summarises the impact of the non-paper on the Agency workload. Of all substances in the 1-10t range, it is assumed that 70% will have an incomplete registration dossier. These have to be screened against the 6 criteria listed above and as a result 5% of the screened files will be prioritised, i.e. earmarked for a special compliance check. It should be noted that, in order to reach, over time, the general target value of 5% of all registration dossiers to be verified for compliance, also some non-prioritised files will have to be checked.

¹² According to the Danish EPA study (see note 8) up to 20% of chemicals in this tonnage band are potentially skin sensitizers. Likewise, approximately 20% of these chemicals show acute oral toxicity properties.



In general terms the non-paper describes a scenario where, for low volume substances, significant tasks are moved from industry to the Agency. It allows industry to register 1-10t substances with incomplete dossiers and requires from the Agency to establish if a more complete dataset is necessary. To this end the Agency collects information relevant to the screening criteria to facilitate the screening of all incomplete registrations against the 6 criteria mentioned above. Subsequently, the Agency establishes for those substances meeting at least two of these criteria, which additional data have to be requested, taking account of all available data. The latter part of this process is equivalent to a dossier evaluation, here including an active search, by the Agency, for all available information, albeit for the limited dataset requested for this tonnage range (Annex V extended dataset). It is assumed that the additional time needed for this data search is accounted for in the average used for estimating the work time needed for a dossier evaluation. This process is repeated annually, where the Agency will need to maintain the information it collects up to date.

For being able to screen the incomplete dossiers with an automatic process, the Agency needs an information base and a decision support tool. It is estimated that producing such a tool would require two person days per substance for extended data mining and for developing the IT tool. This has to be carried out for all 1-10t substances thus requiring about 213 person years of effort. As a consequence of this investment the Agency can carry out the screening as such largely automatically, nearly 0.5 person days per substance are assumed for the screening process as such, amounting to about 37 person years. The additional workload resulting from the screening process foreseen in the non-paper therefore is assumed to be equivalent to about 250 person years, 213 of which have to be spread over the years 1-10 of the Agency (21.3 in average) and 37 over the years 10, 11, and 12, probably 3 person years in year 10, and 17 in years 11 and 12 respectively.

As a result of the screening process, it is expected that 5% of all incomplete dossiers, i.e. 3.5% of all 1-10t dossiers, will be prioritised and therefore undergo a special compliance check. For these, by definition incomplete dossiers the Agency has first to establish all available information. Collecting this will require some effort but the agency is perfectly placed for this and the screening efforts will contribute to this task too. Given the experience and capacities of the Agency, it is therefore assumed that the workforce

needed is about the same as the average anyway assumed for other dossier evaluations. To reach the target of 5% of all incoming registrations to be checked for compliance, another 1.5% of all registrations for substances of 1-10t must be verified. They should be sampled from the 96.5% not prioritised dossiers. Also for these compliance checks normal efforts are assumed. As a consequence the staff time needed for all compliance checks linked to 1-10t dossiers will be about the same as the effort needed under the Commission's 2003 proposal or the *UK Presidency compromise proposal*. Given the fact that the number of dossier evaluations is similar in all approaches and that appeals only can be made against decisions of the agency requesting additional information, the same assumption holds true for any efforts linked to appeals against request for information decisions. However it is assumed that about 50% of the decisions to prioritise will be appealed against. This would require an additional 24 person years in the years 10 to 13.

The Commission non-paper therefore requires additional efforts of about 22 person years per year during the years 1-9 and 21 person years per year for the years 11-13 with a slight peak of 28 person years in year 10. This increase has to be compared to the average size of the Agency, estimated to be around 320 person years per year for the Commission's 2003 proposal and 470 person years per year for the *UK Presidency compromise proposal*¹³.

7. The overall costs of the registration of 1-10 tonnes substances including the Agency's workload¹⁴.

As mentioned in the Extended Impact Assessment, the total costs companies have to bear for the registration of substances with an annual volume of 1 to 10 tonnes¹⁵ amounts to €50 million (at present cost) in the Commission's 2003 proposal, €150 million of which are testing costs.

For the *UK Presidency compromise proposal*, the total registration costs (excluding Agency fees) companies have to bear for the 1 to 10 tonnes volume category are of the order of €70 million, €85 million administrative costs and €85 million testing costs. The registration costs for the non-prioritised substances alone amount to about €40 million.

In the latest Commission non-paper approach, the total registration costs (excluding Agency fees) for the 1 to 10 tonne volume category amounts to €50 million to be incurred by companies. Their administration cost take up the larger share of €30 million. The prioritised substances, 5% of the total number, bear about one-third of the total registration costs (€15 million), including the costs for providing the additional information requested from the Agency. The costs companies incur for appeals, additional to those made under the Commission's 2003 proposal and the *UK Presidency compromise proposal*, amount to €5 million.

¹³ The high increase for the *UK Presidency compromise proposal* results from the request to carry out compliance checks for all required CSA and CSRs, i.e. for substances above 10 tonne.

¹⁴ All figures rounded to the nearest 5 million

¹⁵ As in the ExIA, the total costs figures also take into account the isolated and transported intermediates with yearly volume over 1 000 tonnes. This group accounts for 10% of the total number of the Annex V substances. Note that the average cost calculations are not affected by this specific group of high volume intermediates as the same requirements apply as for substances with an annual volume of 1 to 10 tonne.

The following table compares the total costs linked to the registration of 1-10t substances for the three above described approaches. For companies, it covers the cost items linked to the preparation of the registration dossiers, including the cost of generating additional information requested after a compliance check but not the Agency fees. For the Agency it covers the cost linked to registration as such, as well as to the compliance check of the technical dossiers of 5% of all substances in the 1-10t range and appeals against this. It should be noted that under the Commission's 2003 proposal the latter costs are to be carried by the Member State Competent Authorities while under the *UK Presidency compromise proposal* and the non-paper approach the Agency is in charge of this evaluation.

	Registration costs of Annex V substances, current values					
	(mio Euro)			(relative to Commission's 2003 proposal) (mio Euro)		
	Companies	Agency/MSCA	Total	Companies	Agency/MSCA	Total
Commission's 2003 proposal	250	15/20	285	-	-	-
UK Pres. compromise proposal	170	30/5	205	-80	+15/-15	- 80
Non-paper approach	50	55/5	110	-200	+40/-15	- 175

The table shows that the *UK Presidency compromise proposal* costs €80 million less for companies than the Commission's 2003 proposal because the savings from the reduced requirements for non-prioritised substances outweigh the costs of the auto-evaluation of the prioritisation criteria.

The non-paper approach costs overall € 175 million less than the Commission's 2003 proposal. The more targeted prioritisation leads to cost savings for companies of €200 million. The additional costs for the Agency, due to the screening of the substances amount to €40 million including the cost increase that is related to the shift of dossier evaluations from Member State Competent Authorities to the Agency as well as the screening and prioritisation cost.

It should be noted that the Commission Services have not modelled in detail the workload of the Agency, Member States or Industry after year 11. Under the Commissions 2003 proposal the workload will overall decrease after the registration of the last phase-in substances. After the testing proposals have all been examined, the main tasks according to the Commissions proposal of 2003 in this period would be related to evaluation, restrictions and authorisation. The UK Presidency's compromise proposal will add some significant tasks to dossier evaluation and move the workload on dossier evaluation from the MS CAs to the Agency. Thus the workload for the Agency will be greater after year 11 under the Presidency's compromise proposal compared to the Commissions proposal of 2003, resulting from the additional workload in compliance checking the CSR.

The proposal in the Commissions non-paper will add to the Commissions 2003 proposal the tasks associated with the establishment, annually, of a list of prioritised substances, including the maintenance of the databases and priority setting software tools, and the

determination of the information needs for the prioritised substances. Also here the workload will be greater for the Agency after year 11 than in the Commissions 2003 proposal and the UK Presidency's compromise proposal.