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Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

IMPACT ASSESSMENT

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IMPACT ASSESSMENT RELATED TO THE IMPLEMENTATION OF THE GHS IN COMMUNITY LAW

The Globally Harmonised System of classification and labelling of substances and mixtures (GHS), formally adopted by UN ECOSOC in July 2003, aims to have the same criteria worldwide to classify and communicate through labelling the hazards of chemicals and so to promote their responsible handling. This should facilitate the worldwide trade in chemicals and at the same time protect human health and the environment.

This impact assessment concerns the implementation of the GHS in the EU through a proposed Regulation and its consequential changes to other related Community Legislation on chemicals (downstream legislation). It is based on impact assessment studies of RPA and London Economics, and on own work by the Commission services, such as on the consequences for downstream legislation on chemicals and the responses to the Public Stakeholder Consultation.

The analysis shows that in the long term, the GHS implementation seems worthwhile as the (recurrent) benefits which have the form of trade-related cost savings will ultimately overcome the one-off costs of the implementation. The cost savings, which in all estimates amount to an average of a few labour days per company per year, occur through a substantial reduction of the regulatory barrier to trade caused by worldwide differences in classification and labelling. Consequently, it will lead to more chemicals trade with countries outside the EU and thus contribute to more growth and jobs through a better external competitiveness of the EU industry.

However, the implementation costs need to be kept in check so as to arrive at net benefits also in the foreseeable future and to avoid unnecessary costs and administrative burden for SMEs. Foremost, this requires a smooth transition from the current system to the GHS which maintains the current high level of environment and health protection and minimises the burden for companies. The transition period needs to consist of two subsequent phases for substances and mixtures respectively, set in such a way so as to prevent major workability problems, to allow for synergies with the reviews of the classification in the context of the REACH phase-in registrations and so as to align with the pace of implementation of GHS in other parts of the world in order not to forego part of the trade benefits.

The impact assessment supports that the transition period for substances coincides with the deadline for the REACH classification and labelling inventory. A shorter transition period would be difficult to implement in practice and might create the need to re-label a significant amount of existing stocks. A longer transition period would also cause problems to mixture manufacturers wishing to apply the GHS early.

For the subsequent phase of the transition period for mixtures, the assessment supports a length of 4.5 years. It is clear that seemingly moderate extensions of the mixture transition period beyond that time run up against the ever increasing burden of managing simultaneously two classification systems, thereby overshadowing the relief to mixture suppliers operating in long supply chains, among which many SMEs, to better accommodate the required changes and spread out the costs. A shorter period would mean that fewer mixture suppliers could profit from the substance and upstream mixture GHS classifications arriving through the supply chain. The preference for 4.5 years has also been informed by the

responses to the Public Stakeholder Consultation largely in favour of medium length transition periods.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The GHS was formally adopted by UN ECOSOC in July 2003. Technical experts from the Commission, EU Member States and industry were heavily involved in the drafting. This technical input goes on as the GHS needs continuous adaptation to account for innovation in the chemicals sector.

The Directorates-General Environment and Enterprise and Industry have had the co-responsibility for drafting the proposed Regulation and its consequential changes to related downstream legislation and the impact assessment while the European Chemicals Bureau of the Joint Research Centre has given extensive technical support.

The impact assessment activities over the years 2004 to 2006 have been supported by two closely related reports of RPA and London Economics[1]. These reports have involved interviews with companies and industry associations from various sectors in a number of rounds. The Directorate-General Trade was represented in the group overseeing the work. The results of the impact assessment activities have provided useful input into the proposal (for example, on the length of the transition period for mixtures).

Before the launch of the Public Stakeholder Consultation on 21 August 2006, the draft proposal and impact assessment consultant reports were put up for an informal inter-service consultation. This final impact assessment document has taken account of these consultations as well as the formal Inter-Service Consultation launched on 8 November 2006.

2. PROBLEM DEFINITION

The safe use, storage and transport of chemicals require proper communication of their hazardous properties. A classification and labelling (C&L) system categorises the various hazards and codes them in convenient shorthand phrases and symbols for systematic use on the labels on the product and in the accompanying Safety Data Sheets (SDS). A C&L regulatory system essentially imposes on companies the obligation to classify their portfolio of chemicals on the basis of the available information, to communicate to their clients through SDS and labels about the hazards of these chemicals, and to review the classification, labels and SDS when new information comes in.

The trade in chemicals has become ever more global in the last decades with an expanding number of countries taking part. For instance, between 1990 and 2003, the extra-EU exports and imports of chemicals grew more than twice as fast as the

[1] RPA & London Economics, "Impact Assessment of Implementing the GHS" – final reports of Work Package 1 and of Work Package 2, May 2006.

corresponding turnover in the EU25 area. However, the major trading partners of the EU have different C&L systems which apply different hazard criteria, resulting in divergences in health and safety information on the same goods. Moreover, in many developing countries, a C&L system is lacking or rudimentary. This situation hampers the effective communication on hazards and poses an obstacle to further growth in chemicals trade.

While a global C&L system for the transport of chemicals has been in place for decades, a similar system for the use and storage of chemicals has only been formally adopted by UN ECOSOC in July 2003. In Johannesburg, September 2002, all EU Member States (27) along with more than hundred countries have signed up to the recommendations of the UN World Summit on Sustainable Development, which included the plan to have the GHS fully operational at a global scale in 2008. As C&L had already been regulated at the Community rather than the national level, the Member States have called on the Commission to come forward with a proposal to implement the GHS in the EU.

3. POLICY OBJECTIVES

The GHS aims to have the same criteria worldwide to classify and label the hazards of chemicals and so to promote their responsible handling. This should facilitate the worldwide trade in chemicals and at the same time protect human health and the environment. As part of the Implementation Plan agreed at the September 2002 Johannesburg World Summit, the GHS is expected to promote sustainability on a global scale, in particular through the intended improvement in human health and environmental protection, through higher economic efficiency as a result of increased trade and through the inclusion of developing countries in the global trade in chemicals. These goals are in line with the global and EU sustainability objectives identified in the EU Sustainable Development Strategy. With these goals, the GHS proposal is also expected to contribute to the Lisbon agenda of the EU and in particular to the revised EU Strategy for External Competitiveness[2] through the removal of regulatory barriers to trade.

Another objective of the proposal is to guarantee a smooth transition from the current system to the GHS. The current high level of environment and health protection should be maintained and the burden for companies should be minimised. The pace of implementation should be in line with that in other parts of the world. In this context, it should be noted that the classification of chemicals is used in other Community legislation on chemicals as a tool to trigger specific legislative requirements and actions. The implementation of the GHS does not intend to change the goals and scope of this "downstream legislation".

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[2] European Commission, "Global Europe: competing in the world. A contribution to the EU's growth and jobs strategy", October 2006.

The GHS proposal is meant to complement the REACH Regulation[3] and thus reflects the close connection between the two pieces of chemical legislation. Although REACH can also function in combination with the current C&L system, synergies should be exploited by synchronising the implementation of the two regulations, as appropriate. Finally, in line with Better Regulation, the proposal seeks to enhance the transparency of classification and labelling legislation through replacing 2 directives including 10 amendments and more than 30 adaptations to technical progress.

4. OPTIONS

This section will first look at the basic options as regards the adoption of the GHS in the EU, and will subsequently consider the options as regards the modalities of the GHS implementation.

"No-action" option: maintain the current system

As the current C&L system functions satisfactorily, the natural "non-action" option is simply not to implement the GHS and keep the old system. This option has been used as the *baseline*, i.e. the option to set off the GHS impacts of the other options.

Implementing GHS

The GHS has been agreed as a package at international level. It is a consistent system and a hybrid of the GHS and the EU C&L system would be incoherent and unworkable. Therefore, the main parts of the GHS can only be implemented as a whole or not at all. As the system is aimed at ensuring globally harmonised classification and labelling, the implementation of the GHS within the Community must also be harmonised. Therefore, the form of a regulation was chosen to lay down the criteria and the labelling and packaging rules while the appropriate consequential changes to related downstream legislation are done through acts corresponding to the original acts. Other options bear the risk of fragmenting the Internal Market: a directive would require the transposition of the GHS into national legislation which could lead to one or more Member States requiring different or additional classification and labelling; with a voluntary agreement, the adherence to the GHS would depend on the supplier and thus become arbitrary. The form of a regulation was also chosen for REACH, to which the GHS is closely related. 96% of the respondents to the Public Stakeholder Consultation agreed that the GHS should be introduced by regulation.

Although the fundamental choice is about adopting the GHS in the EU or not, there are possible *policy options within the GHS implementation*, namely with respect to:

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[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

– A *transition period* for the implementation; in this exercise the consequences of various lengths have been assessed, namely the options of 3 years for substances and 2, 4 or 5 additional years for mixtures respectively; 6 years for substances with 5 extra years for mixtures; and 11 years for substances with 6 additional years for mixtures.

– *Additional hazard categories*, of which acute toxicity Category 5 is the prime example.

In order to ensure a smooth transition from the current EU C&L system, the implementation of the GHS requires that companies get a certain amount of time to prepare for and comply with the requirements. This *transition period* can be relatively short for substances but ought to be longer for mixtures as the classification of mixtures builds on the classification of substances and can only be carried out when the classifications of its ingredients are available.

Therefore, the transition period needs to consist of two subsequent phases as set out in the table below:

	Substances	**Mixtures**
Phase I	Current EU system: Obligatory GHS: Voluntary	Current EU system: Obligatory GHS: Voluntary
Phase II	Current EU system: Obligatory to the extent that information should be supplied in Safety Data Sheet (SDS) GHS: Obligatory	Current EU system: Obligatory GHS: Voluntary

During the whole transition period, two C&L systems are operational. In the first phase, the current EU C&L system remains obligatory. With the end of the first phase, GHS becomes obligatory for substances but during the second phase the information in the Safety Data Sheets needs to be provided in "dual form", namely in both GHS and EU C&L nomenclature. After the end of the second phase, the GHS will become obligatory not only for substances but also for mixtures, while the current EU C&L system is revoked. In the impact assessment, various options on the duration of the transition period which cover in varying degrees the REACH registration phase-in period are assessed. Section 5.4 introduces the concrete options on the transition period after explaining the interaction between GHS implementation and REACH registration; their appraisal is reported in section 6.7.1.

An *additional category* is an optional category for a specific hazard class that reflects a lower hazard than in the scope of the current EU system. Such a category thus concerns hazards which would not lead to a classification under the current system and would therefore constitute an extension of the scope. Therefore, the inclusion of additional categories such as acute toxicity Category 5 is only briefly considered in section 6.7.2.

5. SCOPE OF THE IMPACT ASSESSMENT

5.1. On the geographical scope

It is of note that this impact assessment concerns the effects of the implementation of the GHS within the EU, and not those of a global implementation of the GHS, as the latter would require legal acts by the various responsible administrations of non-EU countries.

For methodological and budget reasons, the scope of the impact assessment studies was limited to the EU where the main impacts of the EU's adoption of the GHS are expected to occur. Nevertheless, there is no doubt that a global harmonisation of the classification and labelling of chemicals would reduce the burden to address the incongruent systems in force in the different parts of the world. Moreover, implementation in non-EU countries would also lead to similar kind of benefits and implementation costs as described in this impact assessment. Such benefits and costs should for the largest part, if not completely, be attributed to the GHS introduction in those regions themselves and not to that within the EU. Reflecting the general endorsement for the GHS, including of developing countries, the Johannesburg World Summit's Implementation Plan identifies the GHS as one of the first actions to realising the "sound management of chemicals throughout their life cycle."[4]

Furthermore, this impact assessment considers the contributions of the GHS implementation in the EU to the various policies at Community level, notably the EU trade and development policy. It is through these policy objectives that the effects outside of the EU are appraised.

5.2. On downstream legislation

An analysis[5] of the effects of introducing the GHS on other Community legislation has concluded that any effects of changes in the limit values of the various hazard categories are either minimal or can be minimised through modifying the reference in these pieces of legislation without changing their scope. This conclusion was supported by half the respondents in the Public Stakeholder Consultation and only one third disagreed[6]. Such legal actions are either already included in the proposals or they require further decisions independent from the GHS proposal. Consequently, *the effects of changes in this downstream legislation need not to be addressed in this impact assessment*.

In a similar vein, national (and regional) legislation on chemicals may also use classification references; although largely out of view at Community level, it can be

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4 See point 23 of the "Plan of Implementation of the World Summit on Sustainable Development", which can be found on the UN DESA website: http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf

5 Commission Services Working Document, "Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation", August 2006; http://ec.europa.eu/enterprise/reach/docs/ghs/ghs_sc_study_final_110806.pdf

6 A quarter of the respondents expressed concerns about other acts than mentioned in the analysis but only a limited number of responses give specific details which nearly always concern legislation at the national or regional level.

safely assumed that the relevant authorities will use their discretionary powers to adapt the relevant legislation as they see fit. Consequently, these effects also fall out the scope of this exercise.

5.3. The GHS implementation outside the EU

The rationale of the GHS is founded on its worldwide implementation. The major trading partners of the EU are following up on their commitment made at the Johannesburg World Summit of 2002. For example, Japan is implementing the parts of GHS they need for worker protection; in the USA two of the four major agencies responsible for classification and labelling have announced to implement the GHS in the near future. Moreover, UNITAR organises capacity building programs in order to help developing countries to implement the GHS (such as currently ongoing in Thailand and Gambia) and also supports implementation plans (such as in South-Africa). However, a complete picture on the global state of implementation is not available, as UNITAR and OECD intend to come in 2007 with a comprehensive study on the global state of play of the GHS implementation.

Consequently, on the basis of the currently available information[7], it is assumed in all options under consideration that the world outside the EU implements the GHS with a transition period of 3 years for substances and 2 for mixtures[8].

Because of the GHS implementation elsewhere in the world, the EU exporters of chemicals need to implement the GHS regardless of whether the EU implements the GHS or not. Therefore, their implementation costs should not be attributed to the Commission's GHS proposal. This does not hold for importers of chemicals from outside the EU as by law any import good must comply with the C&L system of the place of destination.

5.4. The phase-in period of REACH registration

REACH enters into force on 1 June 2007.

Classification and labelling activities are most affected by the phase-in period of REACH registration. The classification and labelling of a specific substance and the mixture which includes this substance as an ingredient must be reviewed in the light of the new information collected or generated to meet the information requirements under REACH. This is true regardless of the C&L system in place, the current one or the GHS. *Consequently, the corresponding costs of (re)-classification and (revised) labelling have to be attributed to REACH and not to the GHS implementation*. They are part of the assumptions, and not a GHS impact.

Nevertheless*, the transition period of the GHS implementation needs to be carefully aligned with the REACH phase-in period*. This is because during the substance phase of the transition period, any reclassification and re-labelling required for a specific

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7 For now, the UNECE website http://www.unece.org/trans/danger/publi/ghs/implementation_e.html is the best source of up-to-date information on the details on the evolving state of play.

8 This differs from the impact assessment studies, where on the basis of considerably less information, a period of 3 years for substances and 5 for mixtures was assumed.

substance can be carried out in one go with the switch to the GHS classification and labelling. However, this should be compared with the burden of having both the current and the GHS system operational. Similarly, the classification and labelling of mixtures may be affected by the new information on their ingredients collected through the REACH registration. The ease and cost advantage of giving a mixture a GHS classification only after its ingredients have got a stable GHS classification needs to be weighed against the burden of a dual system including the confusion on the market on the communication of hazards.

In order to find an appropriate length of the transition period, the costs and benefits of the option of a GHS implementation have been appraised for transition periods of different lengths. The options considered were:

1. *3 years for substances followed by 2 for mixtures* (hence called "***3+2***"). The first 3 years were assumed to start with the entry into force of REACH and to end with the REACH deadline for the registration of high production volume chemicals (i.e. over 1000 tonnes annually) and submissions to the classification and labelling inventory. This period of 3 years is in line with the versions of REACH then under discussion. After finalisation of the work, this period was extended to 3.5 years. Sensitivity analysis has shown that modest changes in the length of the first phase of the transition period do not have a large effect on the estimates. Therefore, it has been decided to leave the options unchanged.

2. *3 years for substances followed by 4 to 5 years for mixtures* (hence "***3+4/5***"). These options follow the same reasoning for the first phase of the "3+2" option but give more time for mixtures.

3. *6 years for substances followed by 5 for mixtures* (hence "***6+5***"). Here, the first phase of the transition period is aligned with the REACH deadline for the registration of substances with annual volumes between 100 and 1000 tonnes, whereas the whole transition period covers the full REACH phase-in period.

4. *11 years for substances followed by 6 for mixtures* (hence "***11+6***"). In this option, the transition period for substances covers the full REACH phase-in period.

6. ANALYSIS OF IMPACTS

6.1. The effects on human health and environment

There is no indication that the GHS scope of classification is significantly different from the current system. Generally, the number of substances within the scope of classification does not change significantly. In certain cases, there will be upward or downward classification within this scope. However, the evidence does not point clearly in one direction and overall the level of classification is likely to be comparable to the current system. Consequently, the protection level to health and environment is not expected to change.

6.2. The direct economic costs and benefits for companies

The direct costs for companies of the GHS versus the current EU C&L system include both ***one-off costs related to the transition*** from the current EU C&L system to the GHS and ***the recurring costs*** of operating the GHS compared to those of operating the current EU C&L system. The ***benefits*** of the GHS for companies follow from the facilitation of the global trade in chemicals. In the sub-sections below these consecutive items will be discussed in more detail, followed by the conclusion on the overall net benefit of the GHS for companies.

6.2.1. The one-off costs during the transition period

Companies incur the following one-off costs during the transition period from the current EU C&L system to the GHS:

– *Overhead costs* in the form of investment in a new IT module for the GHS and related additional training efforts;

– *Costs for reclassification of substances and mixtures solely for the reason to step over to the GHS* (only re-classifications additional to those that would happen anyway during the REACH phase-in period) which includes the review work, the re-labelling and disposal of old labels and revision and subsequent distribution of the SDS downstream in the supply chain; these are the *administrative costs* of the GHS implementation.

– The *workability costs of prematurely classifying mixtures*, i.e. the costs of having to GHS-classify a mixture without the availability of the proper information on the ingredients and without proper co-ordination with suppliers of the same of similar product (in particular relevant for short transition periods and SMEs in complex supply chains).

– The *costs of operating a dual C&L system*; i.e. the need during the transition period to have simultaneously two C&L systems fully operational and related confusion, (risks of) mistakes et cetera (in particular relevant for long transition periods);

– In so far the GHS implementation is out of step with the implementation outside the EU, the *costs of foregone trade benefits* because of a temporary barrier to chemicals trade with the rest of the world.

The extent of these costs depends on the duration of the transition period which is further discussed in section 6.6.1.

6.2.2. The recurring costs to operate the GHS

The (recurring) costs to operate the GHS include the following types of costs: maintenance costs for the IT system; training to keep staff up-to-date; labels and Safety Data Sheets; in case of new information, the review of the existing classification, possibly leading to reclassification and consequently new labels and new Safety Data Sheets which need to be distributed downwards in the supply chain. These operational costs are not significantly different whether the current C&L

system or the GHS is in place. Consequently, the GHS does not constitute an increase of the administrative burden.

6.2.3. The benefits

On the benefit side the GHS has a clear (recurrent) benefit for companies as compared to the current system. With a harmonised C&L system, exports to outside the EU would require far fewer adaptations in order to comply with the C&L requirements of the country of destination (as soon as the GHS is adopted by the major trading partners of the EU). Imports from outside the EU would become somewhat easier to obtain for EU companies as the obstacle of different C&L would be largely removed.

The companies interviewed for the RPA study recognised the recurrent benefits of the trade–related cost savings but most of them were not able to give an estimate as their cost accounting systems do not identify the trade-related costs as a separate item. The Public Stakeholder Consultation asked companies about these savings in a different way, namely whether they think them to be larger than a few labour days per year[9]. However, the majority of companies state they are not able to say. London Economics concluded on the basis of the limited interview evidence that the cost savings would be about 2,5% of all the costs related of the non-tariff-barriers to external trade.

6.2.4. Conclusion: the net benefits of the GHS for companies

In the very long term, the GHS implementation seems worthwhile as the (recurrent) benefits will ultimately overcome the one-off costs of the implementation incurred in the transition period which in all estimates amount to an average of a few labour days per company per year. However, the implementation costs need to be kept in check so as to arrive at net benefits in the foreseeable future.

The next sub-sections will subsequently show that these cost savings will stimulate the extra-EU trade of chemicals and so will lead to benefits for a far wider group than the companies directly involved in this trade. The net benefits are however not evenly distributed over companies. The last sub-section deals with the options within the GHS implementation and so reveals the choices that are most appropriate from costs and workability perspective.

6.3. The wider economic effects: the effects on trade and external competitiveness

As regards the *exports with destinations outside the EU*, it is likely that the involved companies will choose to translate a large part of the cost savings into lower prices to their customers so as to maintain or increase their sales revenues. The competitive pressures on the global market for chemicals render it unlikely that this cost pass-through will not occur. Moreover, worldwide harmonised classifications and labels will enhance the transparency of the market and thus increase the opportunities to find new customers outside the EU. Consequently, the exports to outside of the EU are expected to increase.

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[9] That is the equivalent annual value of the GHS costs per company as quantified by RPA.

An analogous effect applies to the *imports from outside the EU*. Due to the GHS adoption in the EU, companies that export chemicals to the EU incur a cost saving as they no longer have to change the classification and labelling of these products towards the EU system. Again, importers are expected to pass on this advantage to their EU customers in the form of lower prices and increased economic efficiency.

For both exports to and imports from outside the EU, *this effect is small per company but of relevant size on the macro-level* due to the large size of the aggregated trade flows. The result from the statistical exercise from London Economics is that for each EUR 1000 of export an extra EUR 0,63 will be exported. For the current export flow to outside the EU (about EUR 100 billion), it would amount to about EUR 6¼ million additional export per year. On current imports it would be roughly EUR 4 million per year. Due to the limitations of the data, these effects are rather uncertain: a 95% confidence interval ranges from 50% lower to 50% higher than the point estimate.

The increases in exports and imports are both indications that the adoption of the GHS contributes to the external competitiveness of the EU. Firstly, the extra exports lead to more production for the EU industry.

Secondly, the increase in imports reflects the better access to non-EU chemicals for EU companies, which helps these EU firms to improve their efficiency and thus stay competitive on both the EU and the non-EU markets. Although part of this import penetration will hurt the least competitive chemicals producers in the EU, the wider effects of more exports and imports *promote the external competitiveness of the EU to the benefit of the EU economy and citizens in general*.

6.4. The social impacts and effects on employment

The advantages of the increased trade and enhanced external competitiveness will not be limited to exporters and importers. The production increase of the additional exports requires intermediary goods which for a significant part are sourced from the EU. Hence, the extra chemicals export will lead to *more production in the wider EU economy, and consequently to more jobs*. As the production increase is realised in the more competitive and productive parts of the EU industry, this also leads to the prospect of better job opportunities, wages and labour conditions.

6.5. The effects on developing countries

Part of the expected import increase will come from the developing countries, which furthers their integration into the world economy and also promotes a sound chemicals management as the investment in the GHS becomes more worthwhile for the governments and chemical sectors of these countries. These benefits apply to all developing countries with chemicals industry, for the more mature ones, such as can be found in emerging economies and middle–income countries, but significantly so as well for the fledging ones in the low-income countries.

6.6. The effects on SMEs

As indicated in the Public Stakeholder Consultation, SMEs may have a lower capacity to incur the one-off implementation costs, in particular the smaller firms that

mainly serve local markets. SMEs also stress the possible workability bottlenecks of the GHS implementation. This underlines the need for setting appropriate transition periods.

However, GHS also offers opportunities for those SMEs which are capable to be active on the global market yet have until now refrained from doing so because of the technical barriers of trade with other parts of the world, and for SMEs sourcing companies which export chemicals to outside of the EU.

6.7. On the options in the GHS implementation

6.7.1. The options for the transition period

The different types of implementation costs of the GHS as mentioned in section 6.2.1 vary with the length of the transition period in diverging ways. The overhead costs and the costs related to newly required work on classification and labelling fall when the transition period gets longer as synergies with the REACH registration can be better exploited.

However, a longer transition period implies postponing the harmonisation of classification and labelling with the EU's major trade partners and consequently higher costs in the form of foregone trade benefits. The estimates of these costs are considerably more uncertain than for the cost items mentioned above because of the uncertainty in the statistical relation between the trade barrier of C&L differences and chemicals trade flows and because of the conversion of gross trade flows into trade benefits.

The problems of quantifying the costs related to the two specific workability bottlenecks are even more difficult as laid down in the note from the Commission Services submitted to the Public Stakeholder Consultation[10]. The qualitative information from the impact assessment work and the responses from the Public Stakeholder Consultation suggest that the costs and risks of prematurely classifying mixtures would rise exponentially as the length of the transition period gets shorter. The same sources also suggest that the dual system costs steadily increase along with longer transition periods, in a similar vein as the foregone trade benefits. However, any quantification needs to rely so heavily on additional assumptions that at best the result should be seen as indicative of the size of the effect.

Options of the transition period: a quantification of the main costs categories

(in million Euro)

Options	***"3+2"***	***"3+4"***	***"3+5"***	***"6+5"***	***"11+6"***
Cost items					
Costs quantified by RPA	391	358**	342	276	n.a.
Foregone trade benefits	0	18	27	80	269

[10] "Technical note on the optimal lengths of the transitional period ", 20 July 2006; included as Annex I of this report

Options of the transition period: a quantification of the main costs categories					
*Workability costs of prematurely classifying mixtures**	100	44	25	0	0
*Dual system workability cost**	53	106	132	212	370
Total costs	**544**	**526**	**526**	**568**	n.a.

* The figures for the workability costs are meant to be indicative only of the (relative) size of the effect.

** Calculated through linear interpolation between the cost figures of "3+2" and "3+5"

The table brings the quantitative appraisals for the different cost categories together for the various options of the transition period under consideration. The costs quantified by RPA and the foregone trade benefits are directly derived from the impact assessment studies. The quantification of the two workability costs categories are documented in a note from the Commission services[11], the work builds on the information from impact assessment studies and Public Stakeholder Consultation.

The table indicates that the total costs are the lowest for transition periods of medium length. When the transition period gets shorter, the costs related to the premature classification of mixtures dominate the picture. This reflects the impracticability of such short adaptation times for mixture manufacturers. It should be noted that the lead time in the supply chain from the basic ingredients to complicated mixtures may very well take years as it involves many production steps; in specialty mixtures, some preceding steps may only occur at intermittent dates. Accelerating mixture classifications within this lead time requires repacking already labelled products in stock and also leads to double efforts, confusion and (compounding) inconsistencies in mixture classifications. The indicative cost figure does not fully express the downward risks of precipitate classifications, namely the possibility of serious mistakes which may affect the human health and environmental protection level and which may bring costs weighing on the more vulnerable parts of the chemicals sector. Precedents such as the Dangerous Preparations Directive revision where biocides and plant protection product were given a 5 year transition period as they were new to classification and labelling also lend support to the conclusion that medium length periods have been seen as suitable solutions in the past.

When the transition period gets longer, the cost savings of a better alignment with the REACH phase-in registrations are outweighed by the steady costs increases of the foregone trade benefits and the workability problems of having a dual system. Firstly, there will be confusion and extra work for chemicals suppliers throughout the transition period as regularly an ATP[12] has to be accommodated in and coordinated between two systems one of which is on the way out. Secondly, the industrial and professional users and, where applicable, also the consumers of chemicals will get confused by the two kinds of classification and labelling occurring in the range of the

[11] "Technical note onbackground calculations on the various lengths of the transition period", 28 October 2006; included as Annex II of this report

[12] Such an Adaptation to Technical Progress currently takes place with a frequency of about two years.

chemicals they use; perhaps even with identical products. This will happen over the whole transition period as the suppliers will time the transition of the classification and labelling with their REACH registration requirements.

The dual system costs do not fully include the corrosive effect of the dual system on the credibility of the GHS which is judged to *render the "11+6" option unsustainable for economic, legal and political reasons*. Consequently, this option which had been suggested by some stakeholders was not fully quantified during the impact assessment studies. For over 17 years companies would incur the costs for maintaining a dual system and forego parts of the trade benefits. The risk of degradation of the "outgoing" system during such a long phase-out may also trigger a market-induced yet uncoordinated GHS adoption which would fragment the Internal Market, infringe legal certainty and raise regulatory costs. Seen from a political perspective, the EU would lose influence on updates of the GHS system it would ultimately have to adopt.

Considering the appraisal of these divergent cost items has led to the following conclusion:

– *For substances,* re-classification and re-labelling is less costly and difficult than for mixtures. Therefore, the first phase of *the transition period can best be set in accordance with the deadline in REACH for the C&L inventory.* Here this has been assumed to be *at* 3 years after REACH enters into force; the estimates and hence the conclusions are not affected for the actual time of 3.5 years. .All manufacturers and importers have at the latest at that date to report to the European Chemicals Agency the classification and labelling of the substances they place on the market. A transition period that would end before that time would be difficult to implement in practice and might create the need to re-label a significant amount of existing stocks. A longer transition period would also cause problems to mixture manufacturers wishing to apply the GHS early, as not all ingredients may be available with the necessary GHS classification and labelling.

– *For the subsequent phase of the transition period for mixtures, a length of 4 to 5 years seems appropriate* but the uncertainty of the cost appraisals do not point to a clear-cut choice between transition periods of medium length. The proposed time of 4.5 years reflects this indeterminacy. However, it is clear that seemingly moderate extensions of the mixture transition period beyond the five years run up against to the ever increasing burden of managing two systems in place which then overshadows the relief to mixture suppliers operating in long supply chains, among which many of the chemical SMEs, to better accommodate the required changes and spread out the costs. A shorter period would mean that fewer mixture suppliers could profit from the substance and upstream mixture GHS classifications arriving through the supply chain. The preference for 4.5 years has also been informed by the responses to the Public Stakeholder Consultation largely in favour of medium length periods[13].

[13] For mixtures, the option of 5 years was the most popular choice, with almost half the responses supporting this and with nearly equal numbers of the remaining responses preferring either a longer

6.7.2. The options of adding additional hazard categories

As indicated in section 4, the implementation of the GHS in the EU is based on the principle of maintaining the same level of protection as under the current system. Consequently, it has been considered useful to have a check on the validity of this fundamental choice. For example, RPA has estimated the costs of including the optional acute toxicity Category 5. This does not give evidence to suggest that the benefits of the inclusion of this hazard category would be of a size so as to outweigh the additional costs. As acute toxicity Category 5 has been the most significant example of the optional hazard categories, it is not expected that other instances of optional categories would give a significantly different picture. Therefore, none of these options have been considered further.

In the Public Stakeholder Consultation, 59% of the respondents agreed that no additional hazard categories should be part of the GHS proposal, while 36% favoured a different approach[14].

7. MONITORING AND EVALUATION

The Commission services will align the monitoring and evaluation activities on the Regulation with the corresponding efforts at UN level and those for REACH. Firstly, UNITAR and OECD will review the extent of convergence of the C&L systems over the world as realised by the GHS, firstly to see whether the expected benefits of harmonisation are realized and also to identify the appropriate next steps towards even more uniform C&L requirements. The Commission services will provide their expert input to this review work, based on the GHS classifications as registered in the REACH classification and labelling inventory.

Secondly, based on the five-yearly reports from the Member States (as required by Article 46 of the Regulation), the Commission will evaluate to which extent the Regulation is applied correctly and whether there are bottlenecks in the application. The first evaluation (i.e. the one after five years) will focus on the transition of substance classifications towards GHS with a view on the then ongoing transition of mixture classifications and also informing the review of REACH foreseen at seven years after entry into force. The second evaluation (i.e. the one after ten years) will be able to assess the complete transition period. Both evaluations can use a sample of chemicals with their "old" and "new" classifications so as to check whether any significant change of scope has occurred, and to assess the (change in) quality of the classifications and labelling.

There seem to be two candidate indicators of the net benefits of the GHS, the trade-related cost savings of companies and the trade flows of chemicals. The cost indicator seems to be less suitable as companies have clearly indicated during this impact assessment that their cost accounting systems do not record such trade-related

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period or a shorter period. This applied also for the sample of the industry responses and that of exclusively SMEs.

[14] See the Explanatory Memorandum for the different reasons given by respondents to the Internet Consultation.

costs as separate items. This fact also points to the problems of monitoring and evaluating the implementation costs of companies. The trade indicator avoids this data problem; however, statistical analysis seems required in order to filter out the effect of the GHS introduction from other impacts on trade such as may come from REACH or from business cycles diverging between the EU and other parts of the world.

Annex I
GHS Implementation: Technical note on the optimal length of the transition period[15]

1. INTRODUCTION

In order to ensure a smooth transition from the current EU classification and labelling system, the implementation of the GHS by companies requires a certain amount of time to prepare for and comply with the requirements. This transition period can be relatively short for substances but ought to be longer for mixtures as the classification of mixtures builds on the classification of substances and can only be carried out when the classification of its ingredients are available.

Therefore, the transition should be made in two phases as set out in the below table:

	Proposed length of transition period	Substances	Mixtures
Phase I	Up to 3 years after EiF[16] of REACH	Current EU system: Obligatory GHS: Voluntary	Current EU system: Obligatory GHS: Voluntary
Phase II	From 3 to 3+4/5[17] years after EiF of REACH	Current EU system: Obligatory to the extent that information should be supplied in SDS GHS: Obligatory	Current EU system: Obligatory GHS: Voluntary

After the end of the second phase, the GHS will become obligatory not only for substances but also for mixtures, while the current EU system looses its legal status.

The length of these transition periods is a trade-off between the necessary adaptation time for companies, the burden and possible confusion of applying two systems in parallel and the delay in trade-related benefits from applying the harmonised system. The optimal length of the transition period cannot be determined exactly as not all costs and benefits can be quantified with a sufficient degree of certainty. Nevertheless, too short transition periods would leave insufficient adaptation time and too long transition periods would significantly increase workability problems, increase costs and confusion due to the application of two systems and reduce trade benefits. This note sets out to find the most appropriate length of the transition period based on the Impact Assessment material collected so far.

2. THE RESULTS OF THE IMPACT ASSESSMENT STUDIES

The costs and benefits of different transition periods have been assessed by RPA & London Economics in their study "Impact Assessment of Implementing the GHS" (May, 2006).

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15 This note originally dated 20 July 2006 was attached to the internet consultation on the GHS proposal

16 Entry into Force

17 The proposed duration of the additional transition period for mixtures (4 or 5 years) is to be decided in the light of the internet consultation.

The study was able to quantify only a part of the costs, namely the **administrative costs of re-classifying and re-labelling as well as the increased costs for IT and training** for shifting to GHS. These costs were estimated at around € 390 million for a transition period of 3+2 years, € 340 million for 3+5 years and € 280 million for 6+5 years (for substances and mixtures, respectively and in all cases after entry into force of REACH). The reduction in these costs for longer transition periods is the result of more synergy between the GHS implementation and the efforts related to meeting the REACH registration deadlines and also of discounting[18]. It is important to note that these costs are essentially one-off: once the new system is applied, the annual costs are more or less the same as under the current classification and labelling system. Of these administrative costs (around 55-65% of total costs), around 15-20% relate to substances and 80-85% to mixtures; the overhead costs of training and IT (35-45% of total costs) bear relatively heavily on SME suppliers of chemicals.

However, the additional costs resulting from applying two systems in parallel and the related **workability problems** have not been quantified as it is difficult to predict the amount of confusion and mistakes that may arise as a result of applying and updating two systems in parallel. These costs may be substantial and will not necessarily occur evenly throughout the entire transition period, but concentrated in certain peak periods. This is of particular relevance for SMEs as they have generally limited resources to implement new legislation

On the basis of company interviews and the use of a simple model, the study also calculated an order of magnitude of the **likely increases in trade flows** resulting from the introduction of the GHS. Under the GHS, non-tariff barriers are reduced because it is no longer necessary to apply different classification and labelling for different parts of the world. The study estimates a Present Value from the resulting increase in exports and import of roughly € 500 million and € 420 million respectively, when the GHS implementation in the EU fully concurs with those of its trading partners.

A delayed implementation in the EU as compared to elsewhere renders lower trade gains. For instance, a moderate delay[19] results in estimates of roughly € 390 million for exports and € 350 million for imports, amounting to a loss of € 110 million and € 70 million respectively. However, in a worst-case scenario[20], non-tariff barriers rise, which leads to trade *losses*: an estimated decrease of € 660 million for exports and € 550 million for imports. Note that these trade flows do not constitute in themselves a benefit; however, as the related profits are proportional to these gross flows, the latter help to give an indication of the size of these benefits.

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18 These synergy effects occur, when, for a substance, the reassessment of classification and labelling within REACH and the application of the GHS can be done at the same time. The longer the transition period under the GHS, the more substances and mixtures will benefit from this opportunity as a result of the staggered deadlines for the different tonnage bands under REACH.

19 this scenario, the transition period in the EU is assumed to be 6+5 years and 3+5 in the rest of the world.

20 This scenario assumes that a long delay in implementation by the EU will lead to the break-down of GHS. EU trading partners will adopt each their own classification and labelling systems; consequently, the EU system will then no longer be accepted elsewhere as is the case today among many trading partners.

3. THE REASONS FOR THE CHOICE OF THE 3+4/5[21] YEARS TRANSITION PERIOD

For the reasons outlined above, it is difficult to identify an exact number of years reflecting the optimal trade-off between the reduced administrative and overhead costs of longer transition periods and the increased costs relating to operating two systems in parallel as well as the foregone trade-related benefits. If the transitional period exceeds its optimal length, the further reduction in the one-off costs is more than offset by the increases in the other costs and the foregone benefits. The evidence collected in the study suggests that the optimal length is somewhere around 3+4/5 years.

The first phase of the transition period of **3 years** after entry into force of REACH **for substances** was chosen because the RPA and London Economics study showed that the re-classification and re-labelling of substances is clearly less costly and less difficult for substances than for mixtures. Moreover, a transition period of three years after entry into force of REACH coincides with the deadline for the REACH classification and labelling inventory. All manufacturers and importers have at the latest at that date to report the classification and labelling of the substances they place on the market to the European Chemicals Agency. A shorter transition period would be difficult to implement in practice and might create the need to re-label a significant amount of existing stocks. A longer transition period would also cause problems to mixture manufacturers wishing to apply the GHS early, as not all ingredients may be available with the necessary GHS classification and labelling.

Due to the many uncertainties in estimates and actual responses in the various supply chains, it is difficult to determine an exact optimal period. The choice of an additional 4/5 years for mixtures in a second phase of the transition period reflects the workability needs of mixtures, in particular those in the more complex chemicals supply chains. The "slash" indicates that a transition period of 4 or 5 years is currently seen as the most appropriate, so as to ensure a smooth transition for mixtures classification. It should be noted that a significant number of SMEs is involved in the formulation of mixtures; a longer time would provide them with better opportunities to cope with the required changes coming directly from GHS or indirectly, through their suppliers, and to spread the implementation costs over a longer period. However, with longer durations, these advantages are offset by the workability problems and costs related to the need of managing two systems in place. A shorter time than 4/5 years would increase the risk that mixture suppliers have to carry out the GHS classification of their products without having received proper information from their suppliers leading to mistakes, inconsistencies and double efforts. These two opposite effects of two non-quantified costs categories imply that the transition period for mixtures must neither be too short nor too long. In comparison, the revision of the Dangerous Preparations Directive had a the transition period of three years for chemicals in general and five years for biocides and plant protection product as the requirement to classify and label these two groups was introduced for the first time with this amendment.

The total transition period of 3+4/5 should be largely sufficient to exclude any major problems in obtaining the necessary information to apply the GHS.

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[21] The proposed duration of the additional transition period for mixtures (4 or 5 years) is to be decided in the light of the internet consultation.

4. CONCLUSION

The proposed transition period of 3+4/5 years aims at ensuring an appropriate balance between early availability of GHS classification and labelling for both substances and mixture suppliers, the co-ordination with the REACH classification and labelling inventory and registration deadlines, and giving the necessary time to adapt for mixture manufacturers, many of which are SMEs. Longer transition periods would not only undermine the EU's credibility towards its international partners and its commitment to implement the GHS by 2008[22] but it would also cause additional costs and reduced benefits for the EU suppliers, exporters and users of chemical products and thus the EU economy as a whole.

[22] See Johannesburg plan of implementation from WSSD September 2002

Annex II
GHS Implementation: Technical note on background calculations on the various lengths of the transition period[23]

1. INTRODUCTION

The note "GHS Implementation: On the optimal length of the transition period" of 20 July concluded that the most appropriate duration is 3 years for substances and 4 to 5 subsequent years for mixtures (after REACH enters into force). It argued that such a transition period provides a good coordination with the REACH classification and labelling inventory and registration deadlines and gives mixture manufacturers the necessary time to adapt while it limits the additional costs and reduced benefits for the companies due to workability problems and costs related to the need of managing two classification and labelling systems.

This technical note corroborates this conclusion with some additional calculations aimed at giving *a more quantitative comparison of the various cost items* also involving an explicit appraisal of the option of "3+4" (3 years for substances followed by 4 years for mixtures). *This comparison suggests that a transition period for mixtures between 4 and 5 years (say 4 ½ years) would have the relatively lowest costs*.

The calculations take the quantitative findings of the reports of RPA and London Economics (on the cost of companies and the trade effects respectively) as starting point. For contractual reasons it was not possible to use the datasets and instruments of the consultants. Neither has new quantitative evidence come available.

The calculations need to fill in the qualitative observations of these two reports and also the results of the Public Stakeholder Consultation. The companies responding to the Public Stakeholder Consultation have confirmed the workability needs mentioned as qualitative costs in the 20 July note, specifically to have for the more complex mixture supply chains sufficient time to implement the GHS and to avoid having a dual system in place for too long. In particular, almost half the responses indicated a preference for a mixture transition period of 5 years with a nearly equal amount of responses preferring a longer period and a shorter period, 13% and 11% for 4 year and shorter than 4 year respectively.

The next sections subsequently report on the outcomes of the new calculations on the trade benefits; the quantitative cost items of the RPA report appraised for the "3+4" option; plausible quantifications of the two workability issues in the form of cost curves; a comparison of various options for the transition period based on fully quantified costs. Annex III gives details on the quantification of the workability costs.

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[23] This note originally dated 28 October 2006 was drafted to further develop considerations on the transition period as part of the discussions between the Commission services.

2. THE COSTS OF FOREGOING TRADE BENEFITS

The trade effects have been recalculated with the assumption that outside the EU the GHS will be implemented with a transition period of "3+2", i.e. 3 years for substances followed by 2 additional years for mixtures. The report of London Economics on the estimation of the trade effects had assumed that the major trade partners of the EU would implement the GHS with a transition period of "3+5". Such an assumption was unavoidable, as at the time of the calculations there was hardly any information on the timing of the GHS implementation outside the EU.

In the meantime, various countries have made announcements on the national implementation of the GHS. Their respective choices on the transition period are not uniform, but are in all cases shorter than "3+5". Although the assumption of a transition period of "3+2" does not capture the variation in duration, it is closer to the actual situation than "3+5".

As can been seen in Table 1 below, this change in background does not change the overall picture nor the order of magnitude of the effect; the recalculations are merely a shift in the point of reference, namely from "3+5"to "3+2". However, this recalculation is needed as a first step of translating the trade effects into estimates of the foregone trade benefits which can be used a comparison of the various options on all the cost items. Moreover, the trade effects for the options "3+2" and "3+4" are here calculated for the first time.

Table 1
Analysis of options for EU exports

	Predicted reduction in exports per year (in million Euro)							
Year(s)	***3 - 4***	***5***	***6***	***7***	***8 - 10***	***11 - 16***	***≥ 17***	**PV sum**
Baseline	19	19	38	38	38	38	38	**549**
Option "3+2"	0	0	0	0	0	0	0	**0**
Option "3+4"	0	19	19	0	0	0	0	**31**
Option "3+5"	0	19	19	19	0	0	0	**45**
Option "6+5"	19	38	19	19	19	0	0	**133**
Option "11+6'	19	38	38	38	38	19	0	**269**
"Worst case" (downward risk)	76	76	76	76	76	76	76	**1164**

Note: PV = present value over 30 years

The recalculation has been done on the basis of the assumptions and figures out of the London Economics report, specifically Table 8 and 9 without any additional assumptions or data. Only the trade barriers needed to be assessed vis-à-vis the situation in the "3+2"-option instead of the "3+5"-option. The resulting additional export flows for a transition period of "3+5" outside the EU can be directly derived from Table 2.1 by subtracting from the different

total sums the 45 million Euro reported for the option "3+5". It appears that the London Economics report contains a reporting error on the option "6+5"; instead of the correct amount of 88 million, it mentions a sum of 113 million Euro.

The calculations for the EU import flows are fully analogous to those on the EU export flows. Consequently, they are not reported here.

The trade figures in Table 1 cannot be directly compared with the cost figures as reported in the RPA report, as the former are gross production flows and not (foregone) benefits. A transformation from gross trade flows to costs figures which exploits the statistical regularities between on the one hand import and gross production and at the other hand value added falls out of the scope of this note as it would involve calculations with an economic model and quite a few additional assumptions. Consequently, a rough plausible rule of thumb is used instead.

The foregone trade benefits of transition periods longer than the "3+2" period which is assumed to apply for outside of the EU are simply calculated by a rule of thumb, namely taking 60% of the different gross export flows. This would reflect that an (assumed) 15% of the gross import flows induced by the GHS constitutes a (foregone) benefit and 47½ % of the gross export flows[24].

Note that these cost estimates can only be regarded as indicative because of the uncertainty of the estimations of the corresponding trade flows[25]. As underlined in the London Economics report, the trade flows could be 50% higher or lower than the mentioned point estimate. The other assumptions necessary for the calculations add to the very considerable uncertainty as well.

3. COMPANIES COSTS OF THE GHS IMPLEMENTION AS QUANTIFIED BY RPA

Table 7.17 of the RPA report summarises an elaborate appraisal of the cost incurred by companies when implementing GHS in the different scenarios. Table 2 below summarises these outcomes and also presents an estimation for the "3+4" option. As explained in the report, no calculations on the "11+6" are available as this options had been excluded for economic, legal and political reasons. The report also acknowledges that the figures only give a partial picture of the costs as not all of the identified cost items are quantifiable on the basis of the collected company data.

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[24] These figures are deemed plausible for the following reasons. Note that exports are part of domestic gross production. In the EU25, the share of value added in gross production is about 30% for the chemicals industry. The higher percentage share used here for exports (47½ %) reflects the fact that the production of the extra export induced by the GHS implementation requires intermediary chemical products sourced from within the EU . The share of benefits in the import flow needs to be lower than for exports, as the import flows partly consist of intermediary chemicals from outside the EU, and partly of imports reflecting the enhanced allocation efficiency from the reduced barriers to trade. This share is assumed to be (a bit more than) one third of that for exports (namely 15 %). The percentage for the share of total (foregone) benefits as part the export flows only is found by weighing with the relative size of the total export of and import to the EU25 (55 and 45% of total external trade flow respectively).

[25] This is a direct consequence of the estimated trade elasticity which has a 95% confidence interval around the point estimate of ± 50%.

The quantified costs consist of three main parts: the overhead costs of the IT-system for classification and labelling and the introductory training; the costs related to the classification and labelling of substances and mixtures respectively. The latter two costs concern only those reviews which are solely due to the GHS implementation and are therefore not aligned with the registrations in the REACH phase-in period.

Table 2
The GHS implementation costs for companies as quantified by RPA (discounted at 4% over the scenario time horizon)

	(in million Euro)				
Options	***"3+2"***	***"3+4"***	***"3+5"***	***"6+5"***	***"11+6"***
Cost items					
Overhead costs	140	140	140	128	n.a.
C&L activities for substances	40	40	40	32	n.a.
C&L activities for mixtures	211	*178*	163	117	n.a.
TOTAL	**391**	**358**	**342**	**276**	n.a.

Note: C&L = classification and labelling

As can be seen in the table, the option "3+4" only differs from the options "3+2" and "3+5" in the costs related to the work of classification and labelling of mixtures. The overhead costs and the costs related to the work of classification and labelling of substances are identical as the timing is identical for these costs categories. As the model of RPA which underlies the calculations is not available, the mixture related costs for the "3+4" option have been estimated through a linear interpolation of the corresponding costs of the other two options. This is a fair approximation as over small periods of time both the discounting effect and the mixture related costs is nearly linear.

Table 1 and 2 together show that the cost items quantified by RPA fall with longer transition periods and that this is partly compensated by the rising costs of the foregone trade benefits. The next section deals with the counterbalancing effects of the workability costs.

4. AN INDICATIVE QUANTIFICATION OF THE WORKABILITY ISSUES RELATED TO IMPLEMENTING THE GHS

A qualitative description of the two major workability issues

In the Impact Assessment studies and the Public Stakeholder Consultation, ***two workability issues have been identified that can lead to significant costs*** in case the transition period has an inappropriate length:

(1) ***When the transition period is too short***, mixture manufacturers incur costs as they have to assign a GHS classification to their products before having the GHS

classifications of the ingredient substances and input mixtures and without a proper coordination with the suppliers of similar products.

The responses to the Public Stakeholder Consultation confirm these ***premature mixture classification costs*** identified in the note of the Commission services on the transition period, namely that this workability problem pertains to the mixture manufactures situated in the more complex chemicals suppliers and that it gets more significant as the transition period gets shorter[26].

(2) ***When the transition period gets longer***, chemicals suppliers and their customers have to put up longer with a ***dual system***, i.e. having both the old classification and labelling system and the GHS operational.

These dual system costs *do not include the costs of foregoing trade benefits* because of having the GHS fully implemented at a later date than outside of the EU. See the previous section for a quantitative appraisal of these costs. The dual system costs should *neither* be seen as *a mere correction of the estimated overhead costs*, namely the part that relates to maintaining two IT systems and keeping expertise up-to-date for two systems instead of one. RPA has not found evidence that such additional overhead costs are significant.

However, RPA noted that the major part of the dual system costs would lie in the ***confusion*** originating from having two legally accepted classification and labelling systems on the market. However, they saw no way in quantifying this confusion factor on the basis of the collected data; consequently, they gave a purely qualitative analysis. Firstly, there will be confusion and extra work for chemicals suppliers throughout the transition period as regularly an ATP[27] has to be accommodated in and coordinated between two systems one of which is on the way out. Secondly, the industrial and professional users and, where applicable, also the consumers of chemicals will get confused by the two kinds of classification and labelling occurring in the range of the chemicals they use; perhaps even with identical products. This will happen over the whole transition period as the suppliers will time the transition of the classification and labelling with their REACH registration requirements.

It is precisely these phenomena that on the longer term erode the legal certainty and the credibility of the GHS system, perhaps with repercussions on its acceptability on a worldwide scale. The worst case option in the appraisal of the trade effects (namely a fall back to national classification and labelling systems) demonstrates in sufficient degree how costly this erosion of confidence is. *This note will therefore abstract from this systemic confidence factor and appraise only the dual system costs*.

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[26] The latter follows from the distribution of the responding companies' preferences over the various durations put up for choice in the Consultation (see the last paragraph of the Introduction for these results). Moreover, a number of companies submitted a detailed account about this point.

[27] Such an Adaptation to Technical Progress currently takes place with a frequency of about two years. Apart from the very first years of REACH and GHS, there is no reason to assume why this frequency would not apply in the future. In fact, the new information generated on the phase-in substances may give occasion for a larger need of ATPs – only the dual system aspect of it is attributable to the GHS implementation as the rest is an effect from REACH occurring under any classification and labelling system.

In the Public Stakeholder Consultation, a number of companies confirm the costly effect of the confusion due to two systems. It is observed that in such circumstances companies risk to land in a "grey area" leading to protracted discussions with national regulators; also that it raises the costs of agreeing between companies on the classification and labelling of a substance or mixture.

A plausible quantification of the two types of workability costs

The information from above, in particular the Consultation responses, give some indications on the likely development of the two types of workability costs when the duration of the transition period changes but no quantitative information, apart from the likelihood that these costs cannot be substantially larger than the cost items quantified by RPA[28].

Based on the available evidence, it is attempted here to quantify both cost items for the different options. The primary goal is to check whether the assertions in the note of 20 July on the appropriate length of the transition period do not rely on implausible implicit assumptions on the size of these workability costs. As the little information available renders far going assumptions unavoidable, this quantification should not be regarded as proper estimates of these costs but more as an indication of the order of size.

As regards the shape of the cost curves related to the two respective workability costs, it seems very likely that the ***premature mixture classification costs*** *rise exponentially when the transition period gets shorter*. For this exercise, it is assumed that the period "6+5" provides enough time to prevent such costs altogether[29]; tentatively, for the period "3+2" a cost of 100 million Euro is assumed. *Assuming a negatively sloping quadratic relation between these costs and the length of the transition period*, only moderate costs are found for the periods "3+4" and "3+5"[30].

For the dual system costs*, a linear relation with the length of the transition period is assumed* here, in line with the observation that such costs occur more or less evenly over the period[31]. *The slope of the curve of the dual system costs is determined by assuming equal total costs for the options most close to one other, namely the "3+4" and "3+5" options*. As the larger part of the dual system costs occurring in the first three years of the transition period should not be attributed to the GHS but to the deadline of classification and labelling inventory imposed by REACH, an intercept with a negative value is added to the linear curve for the dual system costs. A tentative quantification of the main costs categories of the GHS implementation.

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28 Otherwise, these costs would have figured more prominently in the responses to the RPA questionnaire and the Internet Consultation. However, this can for a part also have to do with a distribution of these costs over a larger number of companies.

29 It may be that for shorter periods these costs are already negligible; likewise, more time could be required to avoid such costs. However, the quantification necessarily has to take as starting point the limited set of transition periods put up as option.

30 See the Annex for a more detailed account of the derivation of the curve for the premature mixture classification costs.

31 It is recalled that the erosion of legal certainty and (worldwide) confidence in the GHS have not been taken into account. These factors could perhaps have an exponential relation with the length of the transition period.

Table 3 provides the result of this tentative quantification of the workability costs and with that of the total cost for the different options. It should be noted that an explicit discounting of the workability has not been carried out in line with the tentative, mere illustrative nature of these figures.

Table 3
A tentative quantification of the main costs categories of the GHS implementation

(in million Euro)

Options	***"3+2"***	***"3+4"***	***"3+5"***	***"6+5"***	***"11+6"***
Cost items					
Costs quantified by RPA	391	358	342	276	n.a.
Foregone trade benefits	0	18	27	80	269
Workability costs of prematurely classifying mixtures	100	44	25	0	0
Dual system workability cost	53	106	132	212	370
Total costs	**544**	**526**	**526**	**568**	n.a.

5. COMPARING THE COSTS FOR TRANSITION PERIODS OF VARYING LENGTH ON THE BASIS OF TENTATIVELY QUANTIFIED TOTAL COSTS

As all the cost factors are quantified, Table 3 can be used to compare the total costs of the different options for the transition period as long as the relative uncertainty of the figures for the various cost items is taken into account. *The table indicates that the total costs are the lowest for transition periods of medium length*.

When the transition period gets shorter, the rising costs of prematurely classifying of mixtures dominate the picture. This reflects the impracticability of such short adaptation times for mixture manufacturers. It should be noted that the lead time in the supply chain from the basic ingredients to complicated mixtures may very well take years as it involves many production steps; in specialty mixtures, some preceding steps may occur at intermittent dates. Accelerating mixture classifications within this lead time requires repacking already labelled products in stock and also leads to double efforts, confusion and (compounding) inconsistencies in mixture classifications. The indicative cost figure does not fully express the downward risks of precipitate classifications, namely the possibility of serious mistakes which may infringe on the human health and environmental protection level and which may bring costs weighing on the more vulnerable parts of the chemicals sector. Precedents such as the Dangerous Preparations Directive revision where biocides and plant protection product were given 5 year transition period as they were new to classification and labelling also lend support to the conclusion that medium length periods have been seen as suitable solutions in the past.

When the transition period gets longer, the cost savings of a better alignment with the REACH phase-in registrations are outweighed by the steady costs increases of the foregone trade benefits and workability problems of having a dual system. Firstly, there will be confusion and extra work for chemicals suppliers in the case throughout the transition period as regularly an ATP[32] has to be accommodated in and coordinated between two systems one of which is on the way out. Secondly, the industrial and professional users and, where applicable, also the consumers of chemicals will get confused by the two kinds of classification and labelling occurring in the range of the chemicals they use; perhaps even with identical products. This will happen over the whole transition period as the suppliers will time the transition of the classification and labelling with their REACH registration requirements.

The dual system costs do not fully include the corrosive effect of the dual system on the credibility of the GHS which is judged to *render the "11+6" option unsustainable for economic, legal and political reasons*. Consequently, this option which had been suggested by some stakeholders is not fully quantified (namely the overhead costs and the costs related to the classification and labelling of substances and mixtures). For over 17 years companies would incur the costs for maintaining a dual system and forego parts of the trade benefits. The risk of degradation of the "outgoing" system during such a long phase-out may also trigger a market-induced yet uncoordinated GHS adoption which would fragment the Internal Market, infringe

[32] Such an Adaptation to Technical Progress currently takes place with a frequency of about two years.

legal certainty and raise regulatory costs. Seen from a political perspective, the EU would lose influence on updates of the GHS system it would ultimately have to adopt.

Considering the appraisal of these divergent cost items leads to the following conclusion:

– *For substances, the transition period can best be set on 3 years*. For them, re-classification and re-labelling is less costly and difficult than for mixtures. Moreover, the end of this phase of the transition period coincides with the deadline for the REACH classification and labelling inventory. All manufacturers and importers have at the latest at that date to report to the European Chemicals Agency the classification and labelling of the substances they place on the market to the European Chemicals Agency. A shorter transition period would be difficult to implement in practice and might create the need to re-label a significant amount of existing stocks. A longer transition period would also cause problems to mixture manufacturers wishing to apply the GHS early, as not all ingredients may be available with the necessary GHS classification and labelling.

– *For the subsequent phase of the transition period for mixtures, a length of 4 to 5 years seems appropriate* but the uncertainty of the cost appraisals do not point to a clear-cut choice between transition periods of medium length. The proposed time of 4½ years reflects this indeterminacy. However, it is clear that seemingly moderate extensions of the mixture transition period beyond the five years run up against the ever increasing burden of managing two systems in place which then overshadows the relief to mixture suppliers operating in long supply chains, among which many of the chemicals SMEs, to better accommodate the required changes and spread out the costs. A shorter period would mean that fewer mixture suppliers could profit from the substance and upstream mixture GHS classifications trickling down along the supply chain. The preference for 4½ years has also been informed by the responses to the Public Stakeholder Consultation largely in favour of medium length periods[33].

[33] For mixtures, the option of 5 years was the most popular choice, with almost half the responses supporting this and with nearly equal numbers of the remaining responses preferring either a longer period or a shorter period. This applied also for the sample of the industry responses and that of exclusively SMEs.

ANNEX III
the workability quantification of the workability cost functions

Timeline

For both cost functions, the number of years since the start of the transition period serve as time indicator t: consequently, the option "3+2", "3+4", "3+5" and "6+5" correspond with the values t = 5, 7, 8 and 11 respectively

The costs of prematurely classifying mixtures

The exponential shape of the cost curve is approximated by the downward sloping part of a quadratic function which is anchored through:

(1) A high value attached to the "3+2" option

(2) The value zero attached to the "6+5" option

In order to warrant that the function remains above zero in between the "3+2" and "6+5" option, the first and second order conditions for the "6+5" option are set to correspond with a minimum value.

Thus, the functional form is: $F[t] = at^2 + bt + c$. The parameters a, b, and c can be derived from the conditions for "6+5" and "3+2" respectively:

$$\begin{cases} F[11] = 0 \\ F'[11] = 0 \\ F''[11] > 0 \end{cases} \Rightarrow \begin{cases} 121a + 11b + c = 0 \\ b = -22a \\ a > 0, \quad b < 0 \end{cases} \Rightarrow \begin{cases} b = -22a \\ c = 121a \end{cases}$$

$$F[5] = 25a + 5b + c = a\ (25 - 110 + 121) = 36a \quad \Rightarrow \begin{cases} a = \frac{1}{36}\ F[5] \\ b = -\frac{11}{18} F[5] \\ c = \frac{121}{36}\ F[5] \end{cases}$$

The cost levels for the options in between can also be expressed in terms of $F[5]$:

$$\text{"3+4"} \qquad F[7] = 49a + 7b + c = \tfrac{4}{9} F[5]$$
$$\text{"3+5"} \qquad F[8] = 64a + 8b + c = \tfrac{1}{4} F[5]$$

The dual system costs

The dual system cost curve is assumed to be linear over the transition period. Take y as the annual cost accrual, and assume that the total costs level of the two adjacent options "3+4" and "3+5" are (nearly) equal:

$$y \approx (358 - 342) + F[7] - F[8] + (18 - 27) = \tfrac{7}{36} F[5] + 7$$

As the costs for the first three years are for a significant part captured by RPA and for another part are more related to the REACH requirement of the classification and labelling inventory, an intercept with a size of 3y is introduced so as not to overstate this cost item.