Synthesis of GHS Cost Benefit Papers

Gregory G. Bond, PhD, MPH, FACE
Principal, Manitou View Consulting, LLC

Background and Purpose

The Globally Harmonized System for Classification and Labeling of Chemicals (GHS) is considered to play an essential role in achieving sound chemicals management. Implementing GHS enables those who progressively handle chemicals along the value chain to recognize and reduce potential risks by employing best-practice handling, storage, and disposal methods. In order to take the necessary steps to regulate and manage chemicals safely and sustainably throughout their life cycle, their hazard characteristics (e.g., toxicity) must first be established.

GHS was developed based on what was considered to be the four major existing systems: (1) USA requirements for the workplace, consumers and pesticides; (2) requirements of Canada for the workplace, consumers and pesticides; (3) the European Union directives for classification and labelling of substances and preparations; and (4) the United Nations recommendations on the transport of dangerous goods (Persson et al, 2017).

The two major elements of GHS are:

1. Classification of the hazards of chemicals according to the GHS which provides guidance on classifying pure chemicals and mixtures according to its criteria or rules; and
2. Communication of the hazards and precautionary information using Safety Data Sheets and labels.

Labels – GHS requires that certain information will appear on the label. For example, the chemical identity may be required. Standardized hazard statements, signal words and symbols will appear on the label according to the classification of that chemical or mixture. Precautionary statements may also be required, if adopted by the local regulatory authority.
Safety Data Sheets (SDS) - The GHS SDS has 16 sections in a set order, and minimum information is prescribed.

There are three major hazard groups:

- Physical hazards.
- Health hazards.
- Environmental hazards.

Within each of these hazard groups there are classes and categories. Each of these parts is called a building block. Each country can determine which building blocks of the GHS it will use in their different sectors (workplace, transportation, consumers). Once the building blocks are chosen, the corresponding GHS rules for classification and labels must be used.

Although the need for an internationally harmonized system was first formally recognized at the United Nations (UN) in 1992 in Agenda 21, it wasn't until ten years later, in 2002, at the World Summit on Sustainable Development (WSSD), that UN member states decided to; "[e]encourage countries to implement the new globally harmonized system for the classification and labelling of chemicals as soon as possible with a view to having the system fully operational by 2008." Although significant progress has been made to adopt GHS around the globe, as of this writing it has still not been implemented in more than 120 countries (from Asia Pacific Helsinki Chemicals Forum, also see UNECE website which tracks GHS implementation by country).

Some countries have chosen to implement GHS as a non-binding, voluntary standard for companies, and others as a legally binding requirement. Persson et al, 2017 have conducted and published a global overview of current GHS implementation status in national legislation using primary and secondary data, and attempted to explain differences between countries which have and haven't adopted GHS based on their theory of motivational and capacity-related factors for implementation of international standards. They found that there are significant regional differences in GHS implementation coverage and that both financial and regulatory capacity likely play a role in GHS implementation, although regulatory capacity appeared to be more directly associated in their data. For the motivational factors, the commitment to international collaboration and to occupational health and safety stand out as important factors for countries, as well as the degree of trade openness. From their analysis, Persson et al suggest that it is possible to increase the global implementation coverage by using a combination of motivational and capacity related strategies.

It is believed that convincing countries that the benefits of implementing GHS far outweigh the costs will provide strong motivation for them to do so. Although several estimates of the costs and benefits of GHS have been independently published, no effort has been made thus far to synthesize them in a coherent manner to demonstrate benefit to those countries that have yet to implement GHS. That is the purpose of this paper, which proceeds from an enumeration of non-quantified benefits, through a summary of more generic studies which attempt to quantify the economic burden of disease and disability caused by chemicals, and finally to a few, more refined studies that have estimated the specific costs and benefits directly attributable to implementation of GHS. Included in this paper is some high-level commentary on the strengths and limitations of the various estimates to provide additional perspective on their credibility. **Although uncertainties in the cost and benefit analysis certainly exist, this paper presents substantial evidence that the benefits of GHS implementation far outweigh the costs, likely by a factor of 3 or more. For a variety of reasons that are explained below, it might be expected that for many countries that have yet to implement GHS the costs of implementation will be even lower and the benefits even more substantial than the estimates summarized herein.**

Unquantified Benefits of GHS Implementation

Stated in the simplest of terms, the main benefits of GHS implementation are to **prevent disease and disability caused by chemical exposures** and to **facilitate international trade** in products that contain chemicals.

The US Occupational Health and Safety Administration (OSHA) has elaborated on the benefits of GHS as follows:

"The basic goal of hazard communication is to ensure that employers, employees and the public are provided with adequate, practical, reliable and comprehensible information on the hazards of chemicals, so that they can take effective preventive and protective measure for their health and safety. Thus, implementation of effective hazard communication provides benefits for **governments**, **companies**, **workers**, and **members of the public**.

The GHS has maximum value if it is accepted in all major regulatory systems for chemical hazard communication. In the USA, implementation of the GHS would harmonize hazard definitions and label information among various U.S. regulatory agencies (Consumer Product Safety Commission, Department of Transportation, Environmental Protection Agency, OSHA and others). If the GHS is implemented globally, consistent information will be communicated on labels and SDSs.

It is anticipated that application of the GHS will:

- Enhance the protection of human health and the environment by providing an internationally comprehensible system,
- Provide a recognized framework to develop regulations for those countries without existing systems,
- Facilitate international trade in chemicals whose hazards have been identified on an international basis,
- Reduce the need for testing (including the use of laboratory animals) and evaluation against multiple classification systems.

The tangible benefits to **governments** are:

- Fewer chemical accidents and incidents,
- Lower health care costs,
- Improved protection of workers and the public from chemical hazards,
- Avoiding duplication of effort in creating national systems,
- Reduction in the costs of enforcement,
- Improved reputation on chemical issues, both domestically and internationally.

Benefits to **companies** include:

- A safer work environment and improved relations with employees,
- An increase in efficiency and reduced costs from compliance with hazard communication regulations,
- Facilitate future growth by expanding into international markets and facilitate trading,

- [Support the compliance principles of the chemical industry's Responsible Care® program]
- Application of expert systems resulting in maximizing expert resources and minimizing labor and costs,
- Facilitation of electronic transmission systems with international scope,
- Expanded use of training programs on health and safety,
- Reduced costs due to fewer accidents and illnesses,
- Improved corporate image and credibility.

Benefits to **workers** and **members of the public** include:

- Improved safety for workers and others through consistent and simplified communications on chemical hazards and practices to follow for safe handling and use,
- Greater awareness of hazards, resulting in safer use of chemicals in the workplace and in the home."

Other governments around the world have also published their own very similar summaries of the benefits of GHS (see Canada, European Union, Japan).

"Burden of Disease" or "Cost of Inaction Studies"

The UNEP Global Chemicals Outlook II (2019) (GCOII) report provides a useful summary of the various studies that have been done to estimate the economic benefits of action taken to reduce or avoid exposure to harmful chemicals, and the so-called "costs of inaction" if current chemicals management policies are simply maintained without substantial improvement (i.e., status quo). Much of the economic evidence available focuses on Europe and the United States (Trasande *et al.* 2016; Landrigan *et al.* 2018), although there are a few studies that suggest disproportionate health and environmental burdens are being experienced in low- and middle-income countries attributable to higher exposures to a handful of selected chemical agents (Attina and Trasande 2013; UNEP 2013;). Although these studies do NOT attempt to estimate the economic benefits that would be specifically attributable to implementation of GHS, and are plagued by large uncertainties, they nevertheless provide some useful perspective for consideration and support for making improved chemicals management a priority for governments. Since GHS is regarded as an essential, yet modest first step, in chemicals risk management, to be augmented by further risk management actions, the economic benefits identified by these studies likely overstate the case solely for GHS implementation and thus must be interpreted cautiously. Care should be taken not to exaggerate their credibility with audiences who have not been made privy to their large uncertainties.

At a high level, GCOII arrived at the following conclusions:

- Robust economic analysis is challenging and is associated with uncertainties. For example, it requires several analytical inputs with high level of uncertainties that have been subject to debate (Bolt, 2017; Bond and Dietrich 2017; Gallagher, 2015; Middelbeek and Veuger, 2015; Swaen, 2016). These inputs include information on

substance-disease pairings, specific dose-response relationship data, and information on exposure (across populations and over time) that are needed before judgements can be made about economic effects. While all economic analysis is subject to uncertainty and revision, significant data gaps and methodological challenges remain. Further analysis is required in order to verify effects and refine analytical methods. Drawing thematic conclusions from existing analysis becomes difficult due to differences in method, scoping and the time periods assessed, as well as differences in unit cost, valuation assumptions and approaches used.

- There is a need for more retrospective economic assessment, and for improved assessment of causal relationships, unintended consequences, and the effects of interactions among multiple chemicals and mixtures and among multiple regulations (Dudley 2017).
- There is evidence that unmanaged chemical exposures places an economic burden on health care systems, and that it reduces the productivity and capability of the workforce and the well-being (or utility) of wider populations through reduced disposable incomes and increased suffering.
- **The costs associated with exposure to harmful chemicals are estimated to be in the range of several per centage points of global GDP; likewise, the economic benefits of action from preventing chemical exposure are significant.**
- A study of the economic and social effects of using harmful chemicals could help to raise awareness of the global scale of chemicals and catalyze further action.

Since 2010, the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) has produced comprehensive assessments of risk factor burden by age, sex, cause, and location. Reports are prepared on a regular basis, and comparative risk assessments (CRAs) are updated to incorporate improved methods, new risks and risk-outcome pairs, and new data on risk exposure levels and risk-outcome associations. The most recent report published in 2018 examined global, regional, and national CRA for 84 behavioral, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990–2017. The authors reported that behavioral risk factors (e.g., tobacco use, alcohol consumption, diet, unsafe sex, etc.) accounted for 43.6% (95% Confidence Interval 41.7–45.5) of all Disability Adjusted Life Years (DALYs or years lost due to ill-health, disability or early death), followed by environmental and occupational risk factors (e.g., unsafe water sources, household burning of solid fuel, lack of access to handwashing, etc.) at 17.4% (15.9–19.0) and metabolic risk factors (e.g., high fasting blood glucose, high Low Density Lipoprotein cholesterol, high Systolic Blood Pressure, high Body Mass Index, etc.) at 10.3% (9.63–11.1). Broadly, since 1990, in terms of their relative importance, metabolic risks have risen in rank whereas environmental and occupational risks fell.

The GBD study attempts to attribute risks to several categories of chemicals, e.g., residential radon and lead exposure; and occupational exposure to 13 proven or suspected carcinogens (i.e., asbestos, arsenic, beryllium, benzene, cadmium, chromium, diesel engine exhaust, formaldehyde, nickel, PAHs, silica, sulfuric acid, and trichloroethylene); occupational exposure to asthmagens; and occupational exposures to particulate matter, gases and fumes. They have variously estimated the range of % DALY attributable to these exposures at somewhat more than

5% (GBD, 2013; GBD, 2019) However, there are significant limitations with the underlying data that have been acknowledged by the authors and elaborated on by others (see Shaffer et al, 2019).

Prüss-Ustün, et al 2011 conducted a systematic review of the literature for global burden of disease estimates from chemicals using the standard methodology of the GBD study. They reported finding 4.9 million deaths (8.3% of total) and 86 million Disability-Adjusted Life Years (DALYs) (5.7% of total) were attributable to environmental exposure and management of selected chemicals in 2004. However, their definition of chemicals was quite liberal and the largest contributors, including indoor smoke from solid fuel use, outdoor air pollution, second-hand tobacco smoke, exposure to occupational particulates and pesticides involved in self-poisonings with 2.0, 1.2, 0.6, 0.4 and 0.2 million deaths annually, respectively are NOT actually in scope and relevant for GHS implementation. However, other chemicals possibly relevant for GHS implementation were included and were found to be involved in acute poisonings, with 240,000 annual deaths.

The authors acknowledged that their figures present estimates of burden due to a small number of chemicals for which data are available, therefore, they are more likely an underestimate of the actual burden. Chemicals with known health effects, such as dioxins, cadmium, mercury or chronic exposure to pesticides were not included in their article due to incomplete data and information.

Grandjean and Bellanger 2017 have been critical of the GBD studies and suggested that reported Burden of Disease attributed to environmental exposure to chemicals, estimated from the GBD methods to be in the range of 5.18% to 5.7%, is a gross underestimate of the actual costs. They note that the DALY metric, "while useful, disregards subclinical dysfunctions, adheres to overly stringent causal criteria, and is hampered by gaps in environmental exposure data, especially from industrializing countries." Grandjean and Bellanger then combined and extended cost calculations for exposures to environmental chemicals, including purported neurotoxicants, air pollution, and endocrine disrupting chemicals (Trasande *et al.* 2016), where they judged there were sufficient epidemiology and/or toxicology data available to determine dose-dependent adverse effects. Environmental exposure information allowed cost estimates for the U.S. and the EU, for OECD countries, though less comprehensive for developing countries.

As a complement to these health economic estimations, Grandjean and Bellanger used attributable risk valuations solicited from experts as a third approach to assessing the environmental BoD. For comparison of the different estimates, they used country-specific monetary values of each DALY. They advised that their economic estimates based on available exposure information and dose-response data on environmental risk factors need to be seen in conjunction with other assessments of the total cost for these environmental risk factors, as in their judgment their estimate overlaps only slightly with the previously estimated environmental DALY costs and crude calculations relying on attributable risks for environmental risk factors. They concluded that their three approaches complement one another and suggest

that environmental chemical exposures contribute costs that may exceed 10% of the global domestic product and that current DALY calculations substantially underestimate the economic costs associated with preventable environmental risk factors.

Because the Grandjean and Bellanger paper relied so heavily on the work of others that was also cited in the GOCII paper (see Trasande *et al.* 2016), it is subject to the same methodological issues and uncertainties (see Bolt, 2017; Bond and Dietrich 2017; Gallagher, 2015; Middelbeek and Veuger, 2015; Swaen, 2016) which have been discussed above.

Studies Which Have Directly Estimated Costs and Benefits of GHS Implementation

As of this writing, we are aware of GHS implementation cost-benefit studies that have been published by the EU, Switzerland, Australia, Canada and the U.S.A. If there have been studies published by other governments, they could not be located either by an Internet search or by contacting GHS experts at UNITAR, from various national or regional governments or from industry. South Africa has announced that it is also conducting a socioeconomic analysis, but thus far results are unavailable.

Some caution needs to be exercised in trying to extrapolate the results of these cost-benefit studies which are all from regions/countries that previously had systems for classifying and labeling chemicals, some of which were in existence for decades before the adoption of GHS, to regions/countries that did not. The costs and benefits, while directionally useful for developing countries, are unlikely to be directly comparable. The cost estimates largely reflect the costs of making a change from the previous systems to adopting GHS rather than the costs for implementing a *de novo* classification and labeling system. One might expect that the costs to implement GHS for many of the countries that have not already done so will be less for two reasons: (1) they will not have to bear the costs of making changes to classifications, SDSs and labels which can often be more expensive than starting from scratch; and (2) they have the advantage of leveraging the lessons learned and work done by those countries that have already implemented GHS.

The magnitude of benefits from implementing GHS are also likely to differ greatly between countries that previously had NO system for classifying and labelling of chemicals and those that did. Those with no previous system are likely to see greater reductions in unnecessary exposures and consequently larger reductions in adverse health and environmental effects. For countries that had well developed systems, the health and environmental benefits are certainly much smaller/more incremental since they already had a high level of protection, and are likely to be outweighed by the trade benefits. Countries that had no prior system should also experience relatively substantial trade benefits.

One must also acknowledge that, long before GHS, some of the larger, multinational companies who have been manufacturing and selling chemicals globally for decades, were already voluntarily classifying and labeling their products and providing SDSs and warning labels in the local languages, even in developing countries. Such behavior has tracked with the increasing

global adoption of the industry's Responsible Care® program. However, this is likely to have been somewhat uneven over time and thus can be expected to only partially mitigate against the expected economic benefits of GHS implementation across the globe.

EU Cost-Benefit Studies

The EU adopted GHS into law in 2009 as something they refer to as their CLP regulation. They have conducted two cost benefit studies specific to GHS implementation, the first in 2006 (see *Impact Assessment of Implementing the GHS, Study Summary for DG Enterprise and Industry, European Commission, RPA, London Economics & DTC, May 2006*) prior to adopting GHS (and CLP), and the second in January 2017 as part of a study on the fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation.

The 2006 study included two work packages as follows:

- Work Package 1: provided empirical and factual evidence on the likely impacts (costs and benefits) of GHS implementation on chemical companies that have to classify and label substances and preparations/mixtures for EU and non-EU markets, based on questionnaire responses and interviews with relevant companies and industry associations. The cost implications were predicted using three different scenarios for the timing of GHS implementation linked to timing of REACH registration and concomitant obligations, and to provide a long enough transition period for mixtures so as to ensure the workability of the move to the GHS. This work package also included an examination of assumptions that the GHS was unlikely to deliver new health and environmental benefits because the existing EU classification and labeling system was widely considered to already provide a high level of protection for workers, consumers and the environment; and
- Work Package 2: provided an assessment of the global trade implications of GHS implementation, with an emphasis on the impacts on chemical exports from and imports to the EU. Quantitative estimates of the trade effects were provided for a range of different scenarios based on well-founded assumptions and in conformance with best academic practice in such modelling.

The authors of the 2006 study found that the amount of information available to carry out the above analyses was limited. This was due to the fact that, at the time the interviews were conducted, most companies in the EU were primarily focused on understanding the implications of REACH for their activities; they had not yet turned their attention to understanding the implications of the GHS. As a result, those responding to the questionnaires for Work Package 1 and national experts were reluctant or were unable to attach quantitative figures to what they believe might change under the GHS, given the uncertainty surrounding such outcomes. In addition, responses suggested that companies were also focusing on the short-term impacts of GHS implementation rather than also looking to the medium to longer-term benefits that may arise. This affected not only the robustness of the findings of Work

Package 1, but also those of Work Package 2 which also relied on responses to the questionnaire. The modelling carried out for Work Package 2 was also affected by the nature of the data available as measures of tariff and nontariff barriers affecting trade flows of chemicals and related products.

The total predicted costs for each of the scenarios were reported as (discounted at 4% over each scenario time horizon):

- Scenario 1 (6 years for substances and a further 5 for mixtures): €276 million (€211 million excluding IT costs) ;
- Scenario 2 (3 years for substances and a further 2 years for mixtures): €391 million (€319 million excluding IT costs); and
- Scenario 3 (3 years for substances and a further 5 years for mixtures): €342 million (€270 million excluding IT costs).

The authors thought it important to note the large share of total costs comprised by the costs associated with new IT systems and the one-off training of staff. These accounted for €65 million and €72 million respectively for Scenario 1 and then Scenarios 2 and 3 (which have the same IT and training costs).

The additional costs associated with adoption of the optional new classification criteria under the GHS (i.e. the Cat 5 criteria) were estimated at between €358 million (Scenario 1) and €539 million (Scenario 2). This corresponds to additional costs compared to the total (direct) costs of the introduction of the GHS of between 30% and 38%. Not included in these increases were the additional costs of testing against the new criteria.

The 2006 study considered the benefits of GHS implementation to the EU would largely accrue from increased trade flows. The scenarios considered in Work Package 2 focused on the timing of the GHS implementation in the EU as compared with that elsewhere in the world, in particular to differences in the respective transition periods which give rise to temporary reversals of trade effects. The baseline adopted in Work Package 2 is consistent with the one in Work Package 1, assuming: that the GHS is implemented by non-EU countries; that the transition period adopted by non-EU countries is 3 years for substances and 5 years for mixtures; and that EU C&L and SDS are no longer accepted by non-EU countries, with GHS-based information required.

The four scenarios examined in this part of the study were:
(1) “GHS global with EU lagging behind”

- The GHS is globally implemented;
- The transition period for non-EU countries is 3 years for substances and 5 years for mixtures; and
- The transition period for the EU is 11 years for substances and 6 years for mixtures, lagging behind the rest of the world.

(2) “GHS global and simultaneous”

- The GHS is globally implemented; and
- The transition period for non-EU countries and the EU is 3 years for substances and 5 years for mixtures. (Note that the 3-year period in the EU corresponds to the timing for notification of the C&L of substances to the REACH Inventory).

(3) "GHS global with EU delay for partial REACH implementation"

- The GHS is globally implemented;
- The transition period for non-EU countries is 3 years for substances and 5 years for mixtures; and
- The transition period for the EU is 6 years for substances and 5 years for mixtures, with this linked to the first two tranches of substance registration under REACH.

(4) "Fragmented Global C&L" or "worst case scenario"

- The GHS is not implemented;
- All countries/trade blocks fall back to national C&L systems (either one already in place or newly created where none currently exists); and
- EU C&L not assumed to be automatically accepted.

In order to assess the impact of the different scenarios on trade costs and trade flows, the analysis was separated between imports and exports. From the analysis we conclude that the impact on chemicals trade flows into and out of the EU that can be expected to result from the different possible scenarios of GHS adoption/non-adoption are summarized by:

- Scenario 1 (GHS global with EU lagging behind): the lengthy delay to the adoption of GHS (at 11+6 years) results in a loss of roughly €224 million for exports and €184 million for imports.
- Scenario 2 (GHS global and simultaneous): there are no significant trade impacts compared to the current situation under this scenario, as the EU position vis-à-vis its trading partners is not affected. Note that due to the uncertainty of the statistical estimates, this conclusion would also effectively apply for EU transition periods which are a bit shorter or longer as compared to the one in the non-EU countries (as for example a 3+2 transition period).
- Scenario 3 (GHS global with EU delay for partial REACH implementation): a less delayed adoption of GHS (at 6+5 years) results in a loss of roughly €113 million for exports and €74 million for imports.
- Scenario 4 (Fragmented global C&L or worst-case scenario): non-adoption of GHS results in a loss of roughly €504 million for exports and €420 million for imports.

The 2017 EU fitness study had as its objective to evaluate the CLP Regulation and its interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. **The evaluation is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value** in accordance with the Commission's Better Regulation guidelines.

On balance, the study found that the CLP Regulation is effective. It is considered to contribute towards ensuring a high level of protection for human health and the environment with respect to the hazard classification, labelling and packaging of substances and mixtures. However, there are areas where the effectiveness of the legislation with respect to achieving single market objectives could be improved through greater harmonization of implementation, particularly with respect to classification of mixtures. Issues that impact negatively on the effectiveness of hazard communication measures include the lack of consumer understanding of some of the CLP pictograms and information overload due to the level of information that must be included on labels, and which may result in consumers and downstream users not taking account of the warnings related to certain products, thus undermining the objectives of the CLP. Also, the lack of differentiation between certain hazards (i.e. products may be labelled with the same pictogram despite the actual hazards being markedly different) is considered to be leading to consumer confusion. There may be the potential for the increased use of more innovative tools to supplement current labelling requirements to increase the quality of the information being communicated and increase effectiveness of communication.

A cost benefit study was undertaken to assess the efficiency of the CLP and reported the following:

- Ongoing costs of CLP Implementation: ongoing (annual) costs to industry include direct costs arising from annual up-dates to IT systems in line with adaptations to CLP and new harmonized classifications (CLH), staff training costs, ongoing compliance activities, hassle costs and packaging related costs. All costs (and benefits) were calculated on the basis of a 'null counterfactual' reflecting a present where there is no regulation. **The central estimate of total ongoing costs was around €1.3 billion (€0.97-1.7 billion) excluding poison centre reporting costs (around €1.7 billion). This compares with a maximum figure of €1.47 billion as calculated by the Cumulative Cost Assessment**;
- Costs of transition to CLP: **the total classification, labelling and SDS costs for substances and mixtures were estimated at around €1.2 billion (upper bound estimate for the number of mixtures with a range €820-1.6 billion). Direct transition costs relating to new/updated IT and staff training were estimated at around €310 million (€220-400 million). Transitional costs relating to packaging have not been estimated. Indirect costs associated with reformulation of mixtures were estimated at between €68 million (±€20 million) and €140 million (±€42 million) depending on what is assumed for numbers of hazardous substances.**
- The human health and environmental benefits of the legislative framework stem from the availability of classification information and the role this plays in hazard communication, providing incentives for the use of less hazardous substances, and reductions in accidents/incidents and exposures to hazardous substances. As found by other studies, methodological and data constraints do not enable consideration of the full range of human health and environmental parameters. There is, however, statistical evidence that there has been a significant change in the level of information available on environmental and human health classifications, which will have fed through to better risk management. **The study's (necessarily partial) analysis of human health benefits suggested that the annual value of reductions in poisoning incidents,**

occupational skin and respiratory diseases and occupational cancers since 2000 is between €391 and €512 million per year and since 2008 between €217 and €338 million per year. However, this does not include any quantification of the environmental benefits or of benefits to consumers and society more generally from reduced chemical exposures.

- With respect to the linkages between CLP and downstream legislation, the study identified various risk management measures based on generic risk considerations, for example, the Biocidal Products Regulation, the Plant Protection Products Regulation, the Toy Safety Directive and the Regulation on plastic materials intended to come into contact with food. All of these include automatic risk management linked to CMR classifications, with the first two also having automatic measures linked to PBT/vPvB and to endocrine disruption properties. These automatic linkages were put in place on a precautionary basis to ensure that people and the environment were protected against exposures to the most hazardous substances, and due to the potential for non-controllable or widespread exposures. In the case of the Toy Safety Directive, they also help ensure protection of a vulnerable population – children. In addition to providing a high level of protection, this approach is also considered to provide industry with a clear and consistent indication of the substances/mixtures that they can and cannot use in their final products.

The objectives of the legislative framework were found to be relevant given that the reduction of exposure to hazardous chemicals remains important, while at the same time recognizing that chemicals will remain fundamental to economic activities within the single market and be present in day to day products. **In general, the study found that labelling information is relevant and appropriate to enabling downstream users and consumers to make informed choices regarding the products they purchase and use** (positive examples include obligatory ingredient lists for cosmetics and personal care products). However, some consumers indicated that the lack of detailed ingredient lists (e.g. in relation to detergents, biocidal products, toys) restricts their ability to make informed decisions and thus avoid products containing certain substances. In addition, there may be a need for considering more innovative communication approaches, to reduce information overload and to enable consumers to access additional information on the properties of products and on safe use.

The legal acts of the chemicals legislative framework all have the same objective of ensuring a high level of protection to human health and the environment, ensuring the efficient functioning of the single market and enhancing innovation and competition. **Each of the pieces of legislation covered by this study takes steps to meet these objectives and are, therefore, coherent.**

Finally, the 2017 study found that the EU chemicals legislative framework is considered to provide added value at the EU level. In general, stakeholders from all groups are of the opinion that in order to reach the objectives of the EU chemicals legislative framework, having a harmonized community-wide approach is appropriate.

Switzerland Cost-Benefit Study

Prior to adopting GHS in January of 2009, Switzerland undertook a GHS Impact Assessment modeled after the one conducted in 2006 by the EU. The Swiss noted that all enterprises in the country would have to bear costs of GHS implementation:

- Costs associated with change to a new system of classification and labelling
- Indirect costs associated with changing product compositions to avoid using newly, more strictly classified substances
- Marketing costs

The authors of the Impact Assessment started with the premise that should Switzerland elect not to implement GHS there would also be higher costs as imports and exports would need to be classified and labeled according to both their existing system and also made GHS compliant.

To conduct their Impact Assessment, the Swiss selected 15 enterprises chosen to represent the various industry sectors expected to be impacted by GHS and to represent both large and small companies. They then interviewed them to develop qualitative impacts and used a simple model to translate this into quantitative impacts.

Their sample size was considered too small to reliably extrapolate to the whole of the Swiss economy. Also, similar to the findings of the 2006 EU study, they found that the companies they interviewed had not had sufficient opportunity themselves to study GHS and analyze the potential impacts on them so that the results were necessarily considered as rough estimates, marked by considerable uncertainty.

The costs of transitioning from their existing system to GHS were estimated to range from 0.7 million CHF for small companies to 1.6 million CHF for large companies, although there was considerable uncertainty in these estimates. The costs of implementing GHS were judged to be smaller overall for Swiss companies; however, than if Switzerland didn't adopt GHS, because those costs would not be a one-time event, but would be recurring given the ongoing maintenance associated with having to live under two systems (i.e., for the internal Swiss market and for Swiss imports and exports).

All companies interviewed supported Switzerland adopting GHS in sync with the EU adopting GHS since the EU is the major trading partner for Swiss companies. **The major benefit of adopting GHS was seen to be to ensure a higher level of protection in other parts of the world.**

Australia Cost-Benefit Study

In 2009, Australia conducted a Regulatory Impact Study (RIS) on their proposed changes to workplace hazardous chemicals regulations. At that time Australia had hazard classification, SDS and labelling requirements that had been in existence for more than 25 years. The proposed new chemicals regulations were based on implementing the GHS and indicated a net

cost at least over the next decade. Since then Safe Work Australia has revised their general, labelling and SDS regulations. As a result, all hazardous chemicals regulations now show a small net benefit over the 10-year timeframe of this analysis. Costs to companies were based on a survey, public consultations and submissions. Benefits were solely based on the survey.

The RIS considered the following options in the economic assessment and compared the net benefits of Options 2 and 3 with Option 1, and Options 2A and 3A with Option 1A, with emphasis on Option 3, where:

Option 1: Maintain the status quo. The existing regulations for workplace chemicals would be maintained in their current form with no changes.

Option 2: Consolidation without GHS. Review the existing workplace chemicals framework to produce a consolidated standard and supporting Codes of Practice for workplace hazardous substances and workplace dangerous goods without implementation of the GHS.

Option 3: Consolidation with GHS. Review the existing workplace chemicals frameworks for dangerous goods and hazardous substances to produce a consolidated standard and Codes of Practice for workplace hazardous chemicals that implements the classification, SDS and labelling principles of the GHS.

Options 1A, 2A and 3A: Revised label requirements for agricultural/veterinary (agvet) chemicals. Labels on agvet chemicals would be required to include hazard information for all hazards and this information would be incorporated into Australia's regulatory approved label as part of the normal registration process.

For the purposes of the impact analysis, the RIS considered GHS implementation commencing in 2012, with full implementation by the end of 2016. A Cost-Benefit Analysis (CBA) was used to assess the net benefits of those items where there was data to support quantitative estimates of costs and benefits. This applied to the one-off costs of training, the costs of reclassifying, relabelling and revising SDS for implementation of the GHS, and the ongoing benefits or cost savings to the industry from international trade as a result of implementation of the GHS. The CBA also allowed for risk assessment cost savings arising from consolidation of regulations for dangerous goods and hazardous chemicals but used less precise data. There was no data suitable for estimating the health and safety benefits of the GHS and consolidation. Potential savings were calculated on the basis of credible estimates and were included in the analysis for the purposes of illustration.

The results of the net benefit analysis of Options 2 and 3 relative to Option 1, and Options 2A and 3A relative to Option 1A, for the period 2012 to 2036 were summarized in the following table. These results were based on best estimates of the underlying parameters, together with illustrative estimates of benefits for health and safety.

Net benefit analysis for Options 2/2A and 3/3A relative to Option 1/1A, 2012 to 2036, $ million measured in 2009 dollars

Cost Item	Option 2 consolidation	Option 3 GHS	Options 2A & 3A Agvet labels
CBA			
One-off costs (training etc.)	-29	-57	-0.7
CLS for continuing products		-97	-4.2
CLS for imports		156	
CLS for exports		17	
Risk assessment (consolidation)	34	34	
Total CBA	**5**	**53**	**-4.9**
Estimated health and safety impacts (illustrative)			
Consolidation	28	28	
GHS		21	
Dual regulations during phase-in		-12	
Revised agvet labels			5.4
Net benefit	**33**	**90**	**0.5**

The total CBA results indicated a net present value (NPV) out to 2036 of $5 million for Option 2 and $53 million for Option 3; Option 3 was therefore the preferred option on the basis of its greater NPV, followed by Option 2 and then Option 1. Incorporation of potential health and safety benefits into the calculations increased all the NPVs and reinforced the finding that the NPV of Option 3 exceeded those of both Options 1 and 2.

The benefits for Option 3 were driven mainly by reductions in the costs of re-classification, labelling and safety data sheets for imports. The RIS noted that the results of the CBA and the net benefit analysis would still apply, with little change, if the commencement date and implementation period changed by a year or two.

The RIS noted that most agvet chemicals are workplace chemicals and are included in the analysis of Options 2 and 3 compared with Option 1. The separate issue of revised regulations for the labelling of agvet chemicals was addressed in Options 2A and 3A compared with Option 1A. The CBA generated an NPV of -$4.9 million, although this was considered to be an overestimate. While also noting that the reductions in health and safety costs were difficult to estimate, it was noted that for Option 3A, a savings of $0.5 million a year in health costs would be sufficient to achieve a net benefit and it was expected that improved hazard warnings would almost certainly generate such a result.

On the basis of the net benefit analysis the RIS recommended Option 3 as the preferred option. The RIS noted Option 2 was also preferred over Option 1. The CBA conclusions noted that the net benefit analysis did not provide unambiguous support for implementation of the GHS by Australia when sensitivity analysis, based on uncertainties in the data, was taken into account.

However, nearly all Australian stakeholders that were surveyed were found to support implementation of the GHS and consolidation of the regulations for dangerous goods and hazardous substances, provided that its content was aligned with Australia's major trading partners in chemicals and it was implemented no earlier than Australia's major trading partners. It also noted that many industry concerns over consistency of implementation in the jurisdictions would be addressed through consistent implementation of the model WHS Regulations in 2012.

In relation to labelling of agvet chemicals the RIS noted that work health and safety regulators, many individual chemical companies and unions support the inclusion of comprehensive hazard warnings on labels for agvet chemicals and recommended that the current exemption from work health and safety labelling for agvet chemicals be discontinued.

The impact on not for profit organisations was consistent with the impact on other businesses engaged in work requiring hazardous workplace chemicals. If these organizations were carrying out work with hazardous workplace chemicals, for example in clinical settings, they were already required to meet the requirements for handling and storage of hazardous chemicals in the workplace. The organizations would be required to comply with work health and safety regulations for hazardous workplace chemicals in the same way as other businesses. Manufacturers and importers of workplace chemicals would be required to classify and label hazardous chemicals and communicate the hazards for employees and workers. Small businesses that use those chemicals in the workplace must be provided with the hazard information for the chemicals. If small businesses reformulate chemicals they would be required to classify and label in accordance with the work health and safety requirements using the information provided in the GHS.

The 2009 Chemicals RIS identified that small and medium sized enterprises (SMEs), which were estimated to account for about 45 per cent of chemicals production, were expected to have higher unit costs for training and CLS. This generated higher training costs, higher CLS costs for pre-2012 products that continued to be used after 2016, and lower CLS costs for imports and exports from GHS countries. If training and CLS costs were 10 per cent higher for SMEs than for large businesses, then the benefit of the reductions in costs for imports ($7.0 million) and exports ($0.8 million) would exceed the increases in costs for training ($2.5 million) and CLS ($4.4 million) in 2016, so that the NPV to 2036 would be just $0.9 million greater than if all businesses were large. Given some uncertainty about the sizes of the cost increases for SMEs, but recognizing that their effect on the overall results was very small, they were not allowed for explicitly in the CBA.

The RIS also formed the view that overall there were likely to be small improvements for SMEs because of less confusion about the regulations. Work health and safety regulators in jurisdictions also believed that there would be better understanding of the chemical hazards, especially chronic hazards such as carcinogenicity, reproductive toxicity and specific target organ hazards, and hence slightly improved health and safety over the longer term.

U.S.A. Cost-Benefit Study

The U.S.A. Occupational Health and Safety Administration (OSHA) modified its Hazard Communication Standard to incorporate GHS on May 26, 2012. As part of the final rule they published their own cost-benefit analysis (see Section VI of the preamble to the standard) and reported the following:

- While the current Hazard Communication Standard (HCS in place since 1983) serves to ensure that information concerning chemical hazards and associated protective measures is provided to employers and employees, OSHA has determined that the revisions adopted in this final rule will substantially improve the quality and consistency of the required information. OSHA believes these revisions to the HCS, which align it with the GHS, will enhance workplace protections significantly. Better information will enable employers and employees to increase their recognition and knowledge of chemical hazards and take measures that will reduce the number and severity of chemical-related injuries and illnesses.
- OSHA also believed that adoption of GHS reflected the best science available to improve the comprehensibility of hazard warning information.
- **The total annualized cost of compliance with the final rule was estimated to be about $201 million.** The major cost elements associated with the revisions to the standard include the classification of chemical hazards in accordance with the GHS criteria and the corresponding revision of safety data sheets and labels to meet new format and content requirements ($22.5 million); training for employees to become familiar with new warning symbols and the revised safety data sheet format ($95.4 million); management familiarization and other management-related costs as may be necessary ($59.0 million); and costs to purchase upgraded label printing equipment and supplies or to purchase pre-printed color labels in order to include the hazard warning pictogram enclosed in a red-bordered diamond on the product label ($24.1 million).
- **The net benefits of the modifications to the standard were estimated to be $556 million annually, using a discount rate of 7 percent to annualize costs and benefits.**
- Because compliance with the standard would result in cost savings that exceed costs, OSHA did not provide estimates of costs per life saved or other metrics of cost-effectiveness. However, they noted that **the estimated benefits exceed costs by more than a factor of three.**

More detail from the OSHA analysis is included in the table below which is copied from the published standard.

The point estimates below do not reflect the uncertainties described throughout the analysis. While OSHA is reluctant to provide quantified ranges, OSHA recognizes that these estimates are uncertain. OSHA provides a Sensitivity Analysis on these estimates in Section VI.K of this preamble.

Table SI-1: Annual Benefits, Costs, and Net Benefits of OSHA's Final Hazard Communication Standard (2010 dollars)	
Annualized Costs (discounted at 7 percent)	
Reclassification of Chemical Hazards and Revision of SDSs and Labels	$22.5 million
Employee Training	$95.4 million
Management Familiarization and Other Costs	$59.0 million
Printing Packaging and Labels for Hazardous Chemicals in Color	$24.1 million
Total Annualized Costs	$201 million
Annual Health and Safety Benefits	
Number of Non-lost-workday Injuries and Illnesses Prevented	318 (159 -1,590)
Number of Lost Workday Injuries and Illnesses Prevented	203 (101 – 1,015)
Number of Chronic Injuries Prevented	64 (33 – 320)
Number of Fatalities Prevented	43 (22 – 215)
Annualized Benefits	
Monetized Benefits of Reduction in Safety and Health Risks	$250.0 million
Savings from Productivity Improvements for Health and Safety Managers and Logistic Personnel	$475.2 million
Savings from Periodic Updating of SDSs and Labels	$32.2 million
Savings from Simplified Hazard Communication Training	Unquantified
Savings from Reductions in Non-tariff Trade Barriers	Unquantified
OSHA Standards that Are Consistent with International Standards, Consensus Standards, and Standards of Other Federal Agencies	Unquantified
Contribution towards Achieving International Goals Supported by the U.S. Government	Unquantified
Total Annual Monetized Benefits	$757 million ($632 – $1,757 million)
Net Annual Monetized Benefits (Benefits Minus Costs)	$556 million ($431 - $1,556 million)

Source: U.S. Dept. of Labor, OSHA, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, 2011.

Canada Cost-Benefit Study

Canada modified its Hazardous Products Act and its Workplace Hazardous Materials Information System (WHMIS in place since 1988) to adopt GHS on February 11, 2015. The resultant changes made to Canada's workplace chemicals hazardous communication system were considered to be substantial. As a result, a transitional approach was designed to gradually phase in the implementation of the GHS whereby, suppliers and employers were given several years to fully adopt the new system.

With the publication of their modified WHMIS, Canada also reported a regulatory impact statement that included the following highlights:

- The Government of Canada is revising the classification and hazard communication requirements related to workplace hazardous chemicals in order to align the system with that of the United States (U.S.3) and other key trade partners. **This is expected to reduce costs for industry while simultaneously enhancing the health and safety of Canadian workers.** Despite the substantial integration of the Canadian and U.S. markets, and generally similar risk tolerances in areas related to workplace health and safety in both countries, regulatory differences continue to hinder two-way trade in areas such as workplace hazardous chemicals. In addition, expanding global trade in this area makes it increasingly complex to maintain clear, consistent, and easily accessible information for workers. The U.S., along with many of Canada's other trading partners, are now in the process of implementing the new global standard for the classification and labelling of workplace hazardous chemicals known as the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS). **The results of analysis and consultations suggest that not moving to the international standard in this area would result in increased costs for industry; growing difficulty in ensuring that consistent and coherent hazard information is provided to employers and workers; and negative trade consequences for Canadian companies operating in this sector.**
- **The adoption of this regulatory package is expected to result in health and safety benefits for Canadian workers, including fewer personal injuries, fewer acute and chronic illnesses, and fewer fatalities.** While there will be costs associated with adapting to the new system in the first few years of implementation, including the costs for reclassification and training, it is estimated that there will be net benefits for industry in the medium and long terms. **Over a 20-year period, costs to industry are estimated at $285.5 million (present value), and benefits are estimated at $687.5 million (present value). Costs to government are estimated to be $10.4 million (present value). This will yield estimated benefits of $391.6 million (net present value). In addition, although they have not been fully quantified, there should be substantial benefits resulting from decreased barriers to trade. These trade benefits could start to accrue immediately after implementation.**

Conclusions

This paper presents a summary of the expected benefits of GHS implementation vs. available estimates of the costs. It has enumerated the non-quantified benefits which can be simply stated as:

- to **prevent disease and disability caused by chemical exposures** and to **facilitate international trade** in products that contain chemicals.

While noting that robust economic analysis is challenging and is associated with uncertainties, a summary of generic studies which have attempted to quantify the economic burden of disease and disability caused by chemicals concluded the following:

- There is evidence that unmanaged chemical exposures places an economic burden on health care systems, and that it reduces the productivity and capability of the workforce and the well-being (or utility) of wider populations through reduced disposable incomes and increased suffering.
- **The costs associated with exposure to harmful chemicals are estimated to be in the range of several per centage points of global GDP; likewise, the economic benefits of action from preventing chemical exposure are significant.**

Finally, the few more refined cost-benefit studies were described with the following conclusions:

- **Although uncertainties in the cost and benefit analysis certainly exist, this paper presents substantial evidence that the benefits of GHS implementation far outweigh the costs, likely by a factor of 3 or more. For several reasons that are explained in the paper, it might be expected that for many countries that have yet to implement GHS the costs of implementation will be even lower and the benefits even more substantial than the estimates summarized herein.**