APEC Chemical Dialogue, Consumer Products Working Group

Submitting Economy: Australia

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Case Study Title: Clarifying unclear regulatory boundary between consumer products and workplace chemicals

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1	Aim	Implementation of GHS for Workplace chemicals.
2	Summary of relevant hazard classification and communication systems prior to achieving the aim	Prior to the implementation of GHS in 1 January 2012 by the Commonwealth and some States and Territories in Australia (GHS is still to be adopted by some States), the Australian workplace chemicals labelling was based on the EU Dangerous Substances and Preparations Directives for human health hazards, and the <i>United Nations Recommendation on the Transport of Dangerous Goods</i> for physicochemical hazards. Currently the requirements for labelling of consumer products are mainly dictated by the <i>Standard for the Uniform Scheduling of Medicines and Poisons</i> (the Poisons Standard, sometimes referred to as the SUSMP). The Poisons Standard applies to all chemicals that are available to the general public, including medicines, agricultural chemicals and consumer goods (with additional requirements for medicines and agricultural chemicals dictated by two separate regulatory agencies, the Therapeutic Goods Administration (TGA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA)). The Poisons Standard is a compendium of risk management decisions based on chemical ingredients in products. The Poisons Standard can impose various risk management conditions. E.g. set limitations on allowable concentrations, ban chemical substances from public use, mandate child-resistant packaging and dictate wording on labels. The Advisory Committee on Consumer Products (ACCS) is an expert advisory body that performs risk assessments and advises on risk management decisions for the Poisons Standard.
3	Any identified overlaps with other	In Australia, due to "workplace" being defined as anywhere where a worker can be, the proposed implementation of GHS for workplace
	Overlaps with other	worker can be, the proposed implementation of GH3 for workplace

chemical sectors chemicals caused potential overlaps with existing consumer products regulations, agricultural and veterinary chemicals regulation and therapeutic goods regulations. As this case study is for the consumer products sector, the discussion in the case study is limited to overlaps between workplace chemical and consumer products regulations. **Identification of** When a proposal was drafted to apply GHS to all chemicals in a "workplace" this caused concerns for consumer products sector as issues these products can be used in workplaces. e.g. dish washing detergents used in an office kitchen. In such cases, use of consumer products in a manner that is in line with normal consumer use, these products could be easily exempted from workplace chemicals requirements. The more difficult problem arises when a product is equally likely to be used in a workplace and by consumers. Examples of the types of products include paints, automotive oils and greases and adhesives and sealants used in home renovation and/or by professionals in e.g. construction. We will refer to these as "dual use" products. All potential Four potential solutions were considered. solutions considered 1) "Dual Labelling" for these products. i.e. Mandate workplace (including pros and cons of each labelling requirements as well as consumer products labelling solution) requirements. Pros: Simpler for both workplace regulators and public health (consumer products) regulators. Cons: Costly for industry; potentially duplicative or conflicting information on the same label, including two signal headings; not enough space to accommodate both sets of requirements on consumer labels. 2) Workplace labelling only for all dual use products. i.e. GHS hazard communication only. Pros: Aligns with other workplace chemicals; lower cost than dual labelling requirement. Cons: Cannot take advantage of risk assessments conducted by the expert advisory body, compiled into a risk management compendium, the Poisons Standard; GHS communication elements alone may be confusing to Australian consumers without the background in GHS communication system; the ability of consumers to conduct adequate risk assessment based on GHS hazards alone is questionable. 3) Consumer products labelling only for all dual use products. i.e. Use of labelling elements dictated by the Poisons Standard. *Pros:* Aligns with other consumer products; as all workers are also consumers, consumer product labelling should be easily understood by both workers and consumers; lower cost than dual labelling requirement. Cons: Where a dual use product is mainly marketed to a workplace

alignment with other workplace chemicals may be more desirable for consistency.

4) Allowing industry the choice between workplace labelling and consumer products labelling depending on marketing channels *Pros:* Provides flexibility for industry; allows consideration of product uses and the end user; lower cost than dual labelling requirement. *Cons:* Potential for industry to choose the labelling that they prefer rather than labelling that suits the end user.

6 Final solution implemented Reasons for choosing the implemented solution

The option implemented by workplace regulators was the fourth option. i.e. Allowing industry the choice between workplace labelling and consumer products labelling depending on marketing channels.

In considering all options available for implementation, this option provided the greatest benefit with minimum cost. While some concerns were raised that industry may mis-use the flexibility, it was generally felt that in almost all cases, industry wanted to provide the most relevant information to end-user in a manner that is most suited to the situation. Also, it was agreed that even in the worst case scenario the labels must meet either GHS labelling requirements or consumer products labelling requirements, and this was considered acceptable.

7 Learning outcomes

- 1) Consider impacts of new/updated legislative requirements on other legislative requirements at an early stage. Identifying impacts on existing legislative requirements early on allows time to:
 - amend the proposal for the new/updated legislative requirements, or
 - consider amendments to existing legislative requirements.
- 2) Consider the reasons behind GHS implementation within the context of APEC Principles for Best Practice Regulation before looking for solutions to any identified problems. Principles 1,2 and 7 were particularly relevant for this example. i.e. chemical regulation should be minimum required to achieve stated objectives; chemical regulations should adopt a risk management approach to developing and administering regulations; and chemical regulations should be flexible, not prescriptive, and be compatible with business operating environment.

Understanding that the aim of GHS implementation in workplace sector in Australia was <u>not</u> to increase regulatory requirements for consumer products, helped in deciding on the final option.

3) Work cooperatively with all relevant stakeholders and regulatory agencies to achieve the best possible outcome. Finding a solution early on that is acceptable to all parties involved can save years of negotiation and make implementation of new legislation quicker and easier.

APEC Chemical Dialogue, Consumer Products Virtual Working Group

Submitting Economy: New Zealand

Contact person details:

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Case Study Title: Development of Group Standards for the Regulation of Consumer Products

1	Aim	Implementation of CHS for Concumer Products
2	Summary of relevant hazard classification and communication systems prior to achieving the aim	Implementation of GHS for Consumer Products The Hazardous Substances and New Organisms (HSNO) Act came into effect for hazardous substances in July 2001, with a five year transition period providing for hazardous substances to be transferred from existing legislation to the framework of the HSNO Act. Prior to the implementation of the HSNO Act, consumer products were covered under the Toxic Substances Act 1979, with a provision that people who manufacture, import, or pack toxic substances must provide the Ministry of Health with basic information about these substances including the trade names and composition of the products. This information was used by the Ministry of Health to compile a database of the chemicals and chemical products used in New Zealand. Apart from notification to the Ministry of Health, consumer products were not classified or controlled under chemical legislation in New
3	Any identified overlaps with other chemical sectors	Zealand prior to the HSNO Act. None.
4	Identification of issues	The Hazardous Substances and New Organisms (HSNO) Act is New Zealand's chemical legislation for the implementation of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and the Hazardous Substances (Classification) Regulations 2001 were based on proposals for the GHS as developed in late 2000. The framework is based on the identification, classification and assessment of chemical products, and the assignment of controls to manage the risks associated with the substances throughout their lifecycle.

		There were approximately 215,000 notifications of chemicals and chemical products (including consumer products) under the Toxic Substances Act, which required identification, assessment and transfer to the HSNO Act framework.
5	All potential solutions considered (including pros and cons of each solution)	In order to achieve this, the EPA (formerly the Environmental Risk Management Authority) proposed an amendment to the HSNO Act to enable it to group substances for transfer, based on substances which are of similar nature, similar type, or have similar circumstances of use. Without the amendment to the HSNO Act, the EPA would need to individually assess and transfer each notified chemical product. Resources estimated to achieve this were unrealistic in both costs and timeframes. The ability to group substances was a key provision enacted to deal with over 100,000 substances notified to the Ministry of Health.
6	Final solution	Group Standard Approvals
	implemented Reasons for choosing the implemented solution	The HSNO Act was amended in 2005 to enable the EPA to issue and amend and revoke approvals for groups of hazardous substances of similar nature, similar type, or have similar circumstances of use (called Group Standard approvals). The substances covered by the Group Standard approvals are subject to a single set of controls and conditions.
		What is a Group Standard?
		A group standard is an approval for a group of hazardous substances of a similar type or nature, or that are used in a similar way. For example, paints and the raw ingredients used in paint manufacture are controlled under a group standard.
		To date, group standards have been issued for over 30 different categories of hazardous substances. When a substance is 'assigned' to a group standard ¹ it is deemed to be an approved substance under HSNO.
		What substances are covered by a Group Standard?
		Group standards cover a wide variety of products used in many different situations – everything from substances for home use (consumer products), such as detergents and drain cleaners, to highly specialised industrial chemicals.
		There are group standards for paints, adhesives, flavours and fragrances, lubricants, industrial and domestic cleaners, cosmetics, polymers and many more.
		Currently there are over 200 group standards, covering 30 categories of substances. Most categories are based on the use of a substance. For example, there are separate group standards for cleaning products, leather and textile products, and water treatment chemicals.
		A smaller number of group standards are based solely on a substance's hazardous properties, rather than the way it is used. For example,

 $^{^{\}rm 1}\,{\rm A}$ substance can be 'assigned' to a group standard if it meets the scope of the group standard.

group standards for aerosols include substances with quite different uses, such as spray paints and aerosol cleaning products.

There is a list of current group standards on the EPA website:

http://www.epa.govt.nz/hazardous-substances/about/approvals/group-standards/Pages/default.aspx

How do Group standards manage risk?

Group standards set conditions to manage risks to people and the environment from hazardous substances. They cover a substance's full lifecycle, from its manufacture or importation, to storage, transportation and use, through to final disposal. The conditions cover matters such as how to label a substance, or whether a user needs protective clothing. If the substance is flammable, the conditions say what needs to be done to avoid a fire.

The conditions are generally based on the Hazardous Substances Regulations, but are written in a more user-friendly way. In some cases, particularly for information requirements, the conditions are more prescriptive than the regulations.

The conditions of a group standard must be complied with, and are legally enforceable.

How do group standards apply for new hazardous substances?

Any hazardous substance imported or manufactured for the first time can be approved under a group standard. A new hazardous substance which meets the scope of a group standard is an approved substance and an application for approval of a new substance is not required. This allows importers and manufacturers to make changes to their formulations without the need for a new approval, as long as the new formulation stays within the scope of the group standard.

The scope of a group standard basically sets out the allowed uses and hazardous properties of the substance (for example, substances covered by the group standard may be flammable and/or toxic).

For a new substance to be approved under a group standard, it must:

- be used for the purpose given in the group standard, and meet the relevant definition(s);
- comply with any use restrictions specified in the group standard.
 For example, group standards may exclude pesticide and veterinary medicine active ingredients and formulated pesticide and veterinary medicine products;
- have only those hazardous properties that are specifically allowed under the scope of the group standard; and
- if it is a hazardous chemical, must be listed on the Inventory of Chemicals www.epa.govt.nz/hs/compliance/inventory.html

Any chemical that is 'new' to New Zealand (not listed on the Inventory) must have an individual HSNO approval before it can be imported or manufactured here.

Using a Group Standard Approval

For a new hazardous substance that is manufactured in or imported into New Zealand, it is the responsibility of the manufacturer or

importer to identify an existing group standard for that substance (if one exists). The manufacturer or importer must undertake their own hazard classification assessment using the composition of the substance and other hazard information available with the substance such as that given on a Safety Data Sheet. Any new substance that fits within the scope of a group standard is automatically an approved substance under HSNO. There is no requirement for a manufacturer or importer of the substance to contact the EPA for an approval. For guidance on the self-classification process, refer to the document Assigning a hazardous substance to a Group Standard:

http://www.epa.govt.nz/Publications/hsnogen-gs-assigning.pdf

APEC Chemical Dialogue, Consumer Products Virtual Working Group

Submitting Economy: Japan

Contact person details:

Name	Shigeo Ishii
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Case Study Title: Development of a GHS guidance document for consumer products

1	Aim	To implement GHS compliant labelling on consumer products
2	Summary of	Prior to implementation of the GHS for consumer products in Japan,
	relevant hazard	products in most cleaning product categories were all labelled with the
	classification and	same sorts of warning statements regardless of their composition or
	communication	intrinsic properties.
	systems prior to	
	achieving the aim	
3	Any identified	No
	overlaps with other	
	chemical sectors	
4	Identification of	Different producers, with different levels of experience and
	issues	technical resources, all must be able to understand the provisions of
		the GHS in order to be able to self-classify and label their products in
		compliance with GHS.
		The GHS includes a host of options (e.g., Building Blocks,
		concentration cut-offs, etc) among which choices must be made
		carefully to protect the best interests of the target audience; in this
		case, consumers.
5	All potential	Several options were considered:
	solutions considered	Apply the provisions of Annex 5 of the Purple Book, along with all of
	(including pros and	the key principles contained in Chapter 1 of the Purple Book, while
	cons of each	selecting the most relevant Building Blocks to implement for this target
	solution)	audience. This was somewhat more complex to construct initially
		because many choices had to be made and guidance needed to be
		developed. However, actual use of the system is straightforward and
		the resulting labelling is most meaningful to consumers.
		Apply a strictly hazard-based approach to classification and
		labelling, utilizing all of the hazard classes and categories contained in
		the GHS Purple Book. This possibly would have been the most
		undemanding to put in place, but it was rejected because it would
		result in inactionable labelling for consumer products, and as such
		would be labelling that would distract product users from labelling that
		required their attention.
6	Final solution	With consultation with METI, Japan Soap and Detergent Association

implemented **Reasons for** choosing the implemented solution

(JSDA) voluntarily developed a GHS guidance document for consumer cleaning products, such as laundry detergents, laundry bleach, dishwashing detergent etc. Labelling of products in these categories according to the JSDA guidance is compliant with GHS, using the GHS criteria and appropriate selected hazard Building Blocks.

The Building Blocks implemented include human health hazard classes and communication, i.e. labelling decisions based on the likelihood of injury (risk-based labelling) as described in Annex 5 of the GHS official text. The applied health hazard classes and categories are:

Table Health hazard classes and categories applied

١	Table Health Hazard classes and categories applied
	Hazard class Category
	Acute toxicity - oral 1, 2, 3, 4
	Acute toxicity - dermal 1, 2, 3, 4
	Acute toxicity - gases 1, 2, 3, 4
	Acute toxicity - vapours 1, 2, 3, 4
	Acute toxicity - dusts and mists 1, 2, 3, 4
	Skin corrosion/irritation 1, 2
	Serious eye damage/irritation 1, 2A, 2B
	Respiratory or skin sensitization 1
	Germ cell mutagenicity 1A, 1B, 2
	Carcinogenicity 1A, 1B, 2
	Reproductive toxicity 1A, 1B, 2
	Specific target organ toxicity (repeated exposure) 1, 2
	Specific target organ toxicity (single exposure) Under discussion
	Aspiration hazard 1
	The guidance is available at
	http://isda.org/w/01_katud/isda/ISDA_GHS_guidance2011_E.ndf

http://jsda.org/w/01_katud/jsda/JSDA_GHS_guidance2011_E.pdf.

In addition, JSDA developed a GHS brochure for consumers, and is posting it on

http://jsda.org/w/01 katud/jsda/JSDA ghs laflet100225.pdf

Learning outcomes

JSDA's pilot program for the GHS implementation started from January 2011 for hand dishwashing liquids, chlorine bleaches, chlorine cleaners and acid cleaners. Currently most of the products in these product categories utilize GHS compliant labels, including the standardized label elements (signal words, hazard statements and symbols). To date, manufactures have received only a small number of inquiries on the labels from consumers.

Key items learned from this exercise so far include:

- 1. It is important to carefully consider which of the available GHS Building Blocks are relevant and actionable to the target audience of the consumer sector; not all of them are.
- 2. Labelling according to the provisions of Annex 5 of the GHS is possible for a variety of different companies, with different levels of resources, by following the JSDA Guidance.
- 3. Consumers seem to be accepting of the kind of labelling resulting from the application of the JSDA Guidance to these product categories; future investigation will be undertaken to confirm this.
- 4. Industry [engagement/leadership] in this GHS implementation program facilitated the pace of implementation and was a significant

	factor in arriving at a practical and protective approach.

APEC Chemical Dialogue, Consumer Products Virtual Working Group

Submitting Economy: Japan

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Case Study Title: Implementation of GHS in consumer products

1	Aim	To check how consumers perceive GHS labelling on c	onsumer products
2	Summary of	The Japan Soap and Detergent Association (JSDA) dev	
_	relevant hazard	guidance document for consumer cleaning products,	•
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	classification and	detergents, laundry bleach, dishwashing detergent.	
	communication		
	systems prior to	The Building Blocks implemented include human hea	
	achieving the aim	and communication, i.e. labelling, with the need for o	
		decided on the basis of the likelihood of injury (risk-b	· · ·
		described in Annex 5 of the GHS official text. The app	plied health
		hazard classes and categories are:	
		Table Health hazard classes and categories app	olied
		Hazard class	Category
		Acute toxicity - oral	1, 2, 3, 4
		Acute toxicity - dermal	1, 2, 3, 4
		Acute toxicity - gases	1, 2, 3, 4
		Acute toxicity - vapours	1, 2, 3, 4
		Acute toxicity - dusts and mists	1, 2, 3, 4
		Skin corrosion/irritation	1, 2
		Serious eye damage/irritation	1, 2A, 2B 1
		Respiratory or skin sensitization	
		Germ cell mutagenicity Carcinogenicity	1A, 1B, 2 1A, 1B, 2
		Reproductive toxicity	1A, 1B, 2 1A, 1B, 2
		Specific target organ toxicity (repeated exposure)	1, 2
		Specific target organ toxicity (single exposure)	Under discussion
		Aspiration hazard	1
		The guidance is available at	
		http://jsda.org/w/01 katud/jsda/JSDA GHS guidand	ce2011_E.pdf
3	Any identified	No	
	overlaps with other		
	chemical sectors		
4	Identification of	JSDA's pilot program for the GHS implementation sta	rted from January
	issues	2011 in hand dishwashing liquids, chlorine bleaches,	chlorine cleaners
		and acid cleaners. Currently most of the products in	
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		categories utilize GHS compliant labels, including the standardized label elements (signal words, hazard statements and symbols). To date, manufactures have received quite a small number of inquiries on the labels from consumers, i.e. just 50 inquiries in about 100 millions of bottles.
5	All potential solutions considered (including pros and cons of each solution)	In the near future, JSDA plans to conduct a consumer survey to identify consumers' acceptance of GHS, such as how consumers perceive the GHS labels on consumer products, if consumers perceive GHS as useful, etc.
6	Final solution implemented Reasons for choosing the implemented solution	To be decided. JSDA would consider what label information is really necessary for consumers based on the survey above, and would develop a final solution or next steps.
7	Learning outcomes	Not available at this time