

To: AICIS via their website

<https://www.industrialchemicals.gov.au/proposed-changes-categorisation-reporting-and-record-keeping-consultation/listed-introductions-more-practicable-record-keeping-requirements>

Re: Option 5 - If the introducer does not have any of the above information (in Options 1-4)

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Comment re: Listed Introductions: For More Practicable Record-Keeping Requirements – re: Option 5

The Option 5 Record-Keeping Proposal for Listed Introductions (Listed Intros) has significant changes & issues compared to the existing requirements for Written Undertakings.

The Listed Intro chemicals that are covered by CAS No.s on the AIC statement in Section 15 of the SDS, that are not disclosed in an SDS nor in the TDS, don't contribute to a GHS Hazard. There is no specific information for these chemicals in the SDS or in the TDS.

There may be 20-30 such Listed Intro chemicals in a single product ranging from say 0.001% to 50%. The maximum concentrations of these chemicals are not normally known to an importer as this is normally Confidential Business Information (CBI). It is therefore not logical or practical to calculate/confirm a meaningful quantity estimate for each chemical annually. Especially given that many importers have product ranges spanning many hundreds of products, that would result in many thousands of data points to be checked. Any such check would require to be undertaken in conjunction with the overseas manufacturer and/or supplier.

A manufacturer is currently required (via a Written Undertaking) to provide such information confidentially direct to the AICIS (when requested). The "draft rule" now proposes that manufacturers will be expected to provide an indication of the %s and overall quantity across a product type range of each confidential chemical to the importer. This is very unlikely to be agreed to by a manufacturer, as such composition and quantity information is usually highly confidential CBI.

So effectively (as Haztech Environmental (HTE) interprets), this is very like the current Written Undertaking required, with additional composition (maximum %s) and quantity (general) information for a highly similar product range required now to be known by the importer. This will be more complex and more time consuming for Listed Introduction chemicals on the AIC that don't contribute to any GHS Hazard for the product.

There is a likelihood that some manufacturers will not be prepared to provide such CBI information to the importer. This may result in preventing new and existing products, with non hazardous (to the GHS) chemical ingredients, from entering Australia!

What happened to the "risk-proportionate regulatory scheme that aids" Australia test, versus the cost to obtain and maintain this degree of CBI information for ingredients that don't contribute a GHS Hazard, that must be legally signed off as correct each year.

Minister's SOE Regulatory Reform Agenda: "The Government is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs." (see *Background on page 2*)

AICIS's SOI Function and Purpose: "Consistent with the policy intent and legal framework set out in the IC Act, AICIS is a risk-proportionate regulatory scheme that aids in the protection of the Australian people and their environment. (see *Background on page 2*)

Based on the above comments, what is proposed is NOT a "risk-proportionate regulatory scheme that aids" Australia, so should not go ahead as proposed. It needs to be simplified (as in the **1/** suggestion following) & be risk focused (as in the **2/** suggestion following) for information that IS a "risk-proportionate regulatory scheme that aids" Australia. There is nil benefit to collecting information on chemicals that are not GHS hazardous at ANY percentage.

Suggested information to be requested for Option 5 Record-Keeping Proposal for Listed Introductions under a "risk-proportionate regulatory scheme".

1/ HTE suggests that a *chemistry of potential concern* (not currently identified as a GHS Hazard at any %) for a new Serious Health Effect Risk or a new Serious Environmental Effect Risk be chosen and the specific CAS No.s identified with that chemistry be identified. HTE suggests it would be a much simpler arrangement to ask Yes or No if a manufacturer's products contain such a CAS No. which the importer could be alerted to (with a simple YES) that AICIS had been contacted (so there is a link at the importer), BUT then only AICIS would liaise directly with such overseas manufacturers for these potential concern CAS No.s, %s and quantities.

2/ Currently the industry works to Cut-Off concentrations and formulates under them to classify their products as “Not GHS Hazardous”. For Serious Health Effect Risks these cut-off concentrations are 0.1%, 0.3%, and 1%, as above 1% all ingredients with GHS hazards are disclosed, even if the product doesn’t classify with those hazards.

To protect persons who are more at risk from a chemical exposure with serious hazards, HTE suggests that AICIS could be asking about chemicals in an importer’s products with ingredients that are in the range of 10% to 99.9% of an existing cut-off concentration for a Serious Hazard, to be alerted directly to AICIS (by the manufacturer).

This would alert AICIS to Serious Health Effect Risk chemicals that are currently in a product, that may need the current Hazardous Chemicals System (in AU and Worldwide) to be adjusted. E.g. This has previously occurred with specific Skin Sensitisation Cut-off %s.

The detailed CBI information should only go back to AICIS from the manufacturer (with no alert to the importer).

This information check process for **2/** to be reviewed at least every 5 years (or when a formulation is updated).

3/ For chemicals NOT in 1/ nor in 2/, the “CAS No.s on the AIC” statement, only be required to be informed.

Background:

Comment: The Statement of Expectation (SOE) and Statement of Intent (SOI) need to be fully complied with for the latest proposed AICIS changes, BUT it is not clear to HTE that all the proposed changes adequately comply!

Extracts from SOE:

“The rationale for industrial chemicals regulation is to leverage the fullest possible benefits that can be derived from making regulatory effort more proportionate to risk. AICIS promotes safer innovation by encouraging the introduction of lower risk chemicals and will continue to aid in protecting the Australian people and the environment from harmful effects of industrial chemicals.”

Regulatory Reform Agenda

“The Government is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs.”

“I expect AICIS to contribute to the regulatory reform process by:”

“Seeking opportunities to reduce duplication and streamline processes to improve efficiency and lift productivity,”

Acting in accordance with regulator best practice in its decision-making, policies, processes and communications practices, to maximise transparency and minimise compliance costs.

Principles of regulator best practice

Risk-based and data-driven: e.g. • Actively understand, engage with and effectively mitigate strategic risks to successfully manage its regulatory functions without unnecessarily impeding the operations of regulated entities.

Extracts from SOI:

FUNCTION AND PURPOSE

“Consistent with the policy intent and legal framework set out in the IC Act, AICIS is a risk-proportionate regulatory scheme that aids in the protection of the Australian people and their environment, while promoting safer innovation by encouraging the introduction of lower risk chemicals.”

PRIORITIES AND OBJECTIVES

“Under my direction, AICIS will achieve its regulatory objectives through risk-proportionate chemical assessments and evaluations, compliance monitoring and enforcement.”

“Exercising regulator best practice in our decision-making, policies, processes and communications, to minimise regulatory burden and compliance costs, and maximise transparency of operations.”

Principles of regulator best practice

2/ Risk-based and data-driven: We will:

“actively understand, engage with and effectively mitigate strategic risks to successfully manage our regulatory functions without unnecessarily impeding the operations of regulated entities.”

Innovation and regulatory change

AICIS will continue to explore opportunities to streamline chemical introducer obligations while maintaining critical safeguards to protect human health and the environment.