Productivity Commission

National Competition Policy analysis 2025

ACCORD SUBMISSION

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accord 50 YEARS
hygiene, personal care & specialty products industry
PARTNERSHIP & EXPERIENCE

Contents

Executive Summary

Accord welcomes this PC study and supports the intent of the policy of adopting international standards.

For the policy to be successful:

- international standards for adoption should be considered broadly, from the perspective of providing improved international harmonisation and regulatory efficiency
- local standard setting and regulatory adoption processes should be simplified
- the role of standards and regulations should be clarified and delineated
- the scope of application should align with international application
- local environment, regulation and infrastructure needs and limitations need to be carefully considered
- the goal of improving regulatory efficiency should be the focus of every step of the implementation process

Accord has identified our complex, fragmented and inefficient chemicals regulation system to be a significant impediment to legitimate competition. However, the regulations appear to have no negative effect on the trade of illegal goods that are low risk.

Reform of the sector, with a focus on broad outcomes, rather than a focus on regulators, is needed.

International Standards

Accord supports the intent of the policy of adopting international standards as stated in the PC Study. To paraphrase, we need to reduce the negative impact of the many unique Australian requirements applied through various mandatory and non-mandatory standards that increase cost to businesses and stifle business dynamism, resilience and productivity. This cost, borne by businesses, is inevitably passed on to consumers, who experience it through increased cost of goods and services and reduced choice.

Information request 2 – responses

- *Are there examples of Commonwealth, state, territory or local government regulation where there should be greater harmonisation with international or overseas standards and related conformity assessment or approvals? What sectors should be prioritised for reform?*

Yes. One significant example (of many) in the formulated products sector is the lack of recognition of International Fragrance Association (IFRA) standards and related controls for risk management of fragrance ingredients.

IFRA maintains standards on fragrance substances, setting limits on their use, based on the safety profile of the ingredient and the type of use, e.g., body lotion, fine fragrance, cleaning product, room fragrance, etc.

IFRA standards are recognised globally as the standard for fragrances. All reputable fragrance houses adhere to them, and they are recognised by regulators internationally. For example, in the EU, fragrance components used in cosmetic products, including all sunscreens, are deemed to meet the safety requirements set out in regulation if they meet IFRA standards. This also applies in ASEAN and New Zealand.

Australian regulators do not currently recognise IFRA controls. They separately regulate fragrance components in different ways through multiple regulations, adding significant compliance costs to industry, and in some cases, jeopardising the intellectual property (IP) of fragrance IP owners.

This could be a simple reform with the potential to deliver significant regulatory efficiency if implemented well.

Our past attempts to raise this reform discussion were met with objections from regulators. The main objection of Australian regulators to recognising IFRA standards appears to be that IFRA is an industry body, not a government body or a standard-setting body, even though IFRA's standards are broadly accepted by other regulators globally.

Regarding sectors that should be prioritised for reform, it is our view that chemicals regulation should be considered.

In the 2008 Productivity Commission Study into Chemicals and Plastics Regulations[1], the Commission found that '*the current institutional and regulatory arrangements are broadly effective in managing the risks to health and safety… Efficiency could be enhanced by… reducing costs and delays in obtaining regulatory approvals; and by attaining economies of scale in regulatory administration*'. Industry has not experienced improvements in regulatory efficiency since that time and has faced increasing regulatory costs.

- *What is the impact of a lack of harmonisation (e.g. on compliance costs for export, import or multinational businesses, product range, prices, quality, competition, innovation and international trade and investment)?*

Continuing with the IFRA example, there are significant regulatory, administrative, and non-tangible costs to industry and regulators due to the lack of recognition of IFRA risk management controls. As some of these regulators are industry cost-recovered regulators, costs for both industry and regulators are borne by industry. Due to the impact of multiple regulations and some non-tangible costs, it is not easy to identify all impacts or quantify costs. Example 1, below, provides an idea of the costs faced by industry.

[1] Productivity Commission 2008, Chemicals and Plastics Regulation, Research Report, Melbourne.

Example 1:

A company imports a range of sunscreen products.

Some of the sunscreen products are regulated as therapeutic goods by the Therapeutic Goods Administration (TGA) (therapeutic sunscreens), and some are cosmetic products and are regulated by the Australian Competition and Consumer Commission (ACCC) with ingredient imports controlled through the Australian Industrial Chemicals Introduction Scheme (AICIS) (cosmetic sunscreens). All sunscreen products must also meet the controls set out in the Poisons Standard, maintained by the TGA and implemented via state and territory legislation.

The fragrance mix used in all these sunscreen products is the same. There are approximately 50–100 separate components in the fragrance mix, and the mix is in the sunscreen product at <1%; i.e., some components are in the product in extremely low quantities, e.g., 0.000001%.

TGA compliance

To meet the TGA requirements, the company must check whether the fragrance mix is already known to the TGA and has a Proprietary Ingredient (PI) number. If it does, compliance for the fragrance mix is complete, except for checking the Poisons Standard.

If a PI number is not assigned, the fragrance mix supplier (not the company importing, but the overseas supplier to the company) must lodge a PI request with the TGA and provide a full list of the components in the fragrance mix. If one of the components is not listed on the Permissible Ingredients Determination, then the TGA may request that the company go through a full ingredient assessment, which costs >$30,000 for the application fee alone, and requires a very significant data package (see Example 3 for more information). Often, companies find that multiple fragrance components are not on the Permissible Ingredients Determination, at which point the company gives up on the import.

AICIS compliance

To meet the AICIS requirement for the same fragrance mix, the company must go through a 'categorisation' process. As the responsibility for the import sits with the importing company but the fragrance IP is held by the overseas fragrance supplier, this is often the first hurdle to clear. Some fragrance mix information is provided readily to the importer so that the importer can do the categorisation. Other fragrance mix information is not shared so readily, and the company must ask that the overseas company go through the categorisation and share their own business' confidential information, e.g., products that use the fragrance mix.

Inevitably, some of the 50–100 fragrance components will be on the AICIS 'Inventory' and are categorised as a 'Listed Introduction'. These can be imported without further work, unless there are 'inventory terms of listing', e.g., a Specific Information Requirement. This requires the company to search for the assessment report for the substance and meet the conditions specified in the assessment report. If the import conditions are 'significantly different', then the company is obliged to inform AICIS of the conditions of import. Sometimes, the assessment reports are not available as they are confidential to the business that lodged the

application for the assessment. In such cases, the company must lodge a report to inform AICIS of the import conditions, e.g., imported in a sunscreen product at <1%.

Some of the components will not be listed on the Inventory, but it may be possible to find a 'Reported' or 'Exempted' introduction pathway. There are a significant number of possible pathways, and there is no obvious choice; the pathway can depend on the amount of data that is held and the annual import volume of the chemical for the company. There are two specific fragrance 'Reported' pathways, and one that requires companies to meet IFRA controls in addition to multiple other requirements, but neither is suitable for all fragrance components.

For Listed introductions with Inventory terms of listing, Reported introductions and Exempted introductions, the administrative work for the importer is ongoing, as requirements can vary depending on the annual import volume. Consumer product import volumes are hard to forecast, as sales volumes can depend on whether marketing campaigns have been successful, economic conditions, consumer sentiment, etc.

As the administrative burden for Listed, Reported or Exempted pathways is very high for the overseas supplier of fragrance mixtures contained in formulated products, they can opt to lodge an assessment (Assessed Introduction pathway). The assessment fee for a health- and environment-focused assessment is $36,050 per component (i.e. one out of the 50-100 components in the mix; need to multiply by the number of components that need assessment for the cost impact on the fragrance mixture) and will require a significant data package.

Poisons Standard compliance

If the company decides to go ahead with either or both the therapeutic sunscreens and cosmetic sunscreens imports and can clear the TGA and AICIS hurdles, it must then comply with the restrictions set out in the Poisons Standard. Apart from some minor errors in the Poisons Standard, it is mostly 'compatible' with IFRA risk management controls. However, any time an application is lodged for a fragrance component that has not been considered for inclusion in the Poisons Standard (e.g., by AICIS after its assessment of the ingredient), it must go through the full consideration process, which takes approximately 12 months. This is a government-funded process.

Decisions on fragrance components have generally aligned with the IFRA standards to date; however, due to the different structures of the Poisons Standard and IFRA standards, the Poisons Standard risk management controls are not as nuanced as IFRA risk management controls.

A better way

All this regulatory effort can be replaced by changes to relevant regulations to recognise IFRA standards. This would remove significant administrative burden from both industry and regulators, increase the 'palette' of fragrance ingredients (and products that contain them) available on the market, and simplify the trade of goods containing fragrance components, while maintaining equivalent safety for Australian consumers.

Note on ingredient disclosure on labels

Cosmetic sunscreen labelling must also meet the ACCC labelling standard. The ACCC allows 'fragrance' or 'parfum', or listing of individual fragrance components, as acceptable labelling practices. This is compatible with international practice, and industry does not propose any changes in this space.

International compliance process using IFRA

In comparison, in the EU, ASEAN and New Zealand, fragrance components meeting the IFRA standards can be used in sunscreens, with only labelling requirements to consider.

One of the reasons for IFRA industry self-regulation is to safeguard the IP of fragrance houses. Due to the complexity of the regulatory clearance through AICIS, fragrance IP can be under threat. The fragrance supplier may decide that working with SMEs is not worth the risk. The decision is usually more difficult when working with larger companies.

- *What are the barriers to greater harmonisation?*
    - *For sectors where regulators can mandate standards by incorporating international standards as in force from time to time or accept conformity assessments and approvals (e.g. road vehicles, therapeutic goods, agricultural and veterinary products, maritime, industrial chemicals and, most recently, consumer products), how is this operating in practice?*

There are multiple barriers to greater harmonisation, with different 'stages' of international standards implementation presenting different challenges. However, most of the barriers could be addressed by ensuring that there is a focus on outcomes at each stage of implementation.

1. Identifying the right standards that can provide the greatest harmonisation

An example of this was provided in the response to the previous question, using IFRA standards as an example. IFRA standards are widely recognised by regulatory systems globally, and their adoption in Australia would significantly streamline the introduction of fragrance-containing goods, facilitating innovation, legitimate competition and consumer choice.

2. Minimising local complexity

Adopting international standards becomes more difficult when there are multiple steps to adopting the international standard. Each step provides an 'opening' for divergence from international harmonisation. Each step also adds regulatory cost and makes it more difficult to apply best-practice regulation. Example 2 describes this situation.

Example 2:

The Australian/New Zealand Standard *AS/NZ 2604 Sunscreen products – Evaluation and classification* (Sunscreen Standard) is a uniquely Australian standard that adopts multiple ISO standards.

Standards Australia consideration

The Standards Australia Committee for Sunscreen Agents, CS-042, is responsible for the technical aspects of AS/NZS 2604. CS-042 is made up of a range of stakeholders, including industry, governments and community groups.

The decisions that are included in AS/NZS 2604 include whether to adopt an existing international standard.

For example, Australia has decided to only adopt one of the two available ISO test methodologies for determining 'broad spectrum', ISO 24443:2021 (Cosmetics — Determination of sunscreen UVA photoprotection in vitro), but not ISO 24442:2022 (Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection). This means that any overseas product with an *in vivo* test must be retested for the Australian market, using the *in vitro* test.

While some members of CS-042 suggested moving away from human testing as the reason for only adopting an *in vitro* test, this does not explain why there is also current opposition to adopting the two new *in vitro* ISO test methodologies for SPF determination that are alternatives and equivalent to an *in vivo* test that is currently adopted in AS/NZS 2604[2]. Also, as far as is known, moving away from human testing for products like sunscreens is not a stated policy objective of the Australian Government, meaning that CS-042 is applying a significant regulatory policy, that is not a stated Australian Government policy, inconsistently and in an *ad hoc* manner.

The process of adopting new international standards into the existing Australian Standard must be initiated by someone, then supported by the CS-042. If there is opposition, the process takes longer, if it is not 'killed off' altogether.

There is also a current proposal to amend the Sunscreen Standard to add more labelling requirements, which will further remove our sunscreen labelling from international alignment. It is unclear what this proposal aims to achieve. Currently, in New Zealand, many sunscreen products meeting the EU labelling requirements can be imported without reworking the label. If additional labelling requirements are added to the Sunscreen Standard, this will no longer be the case. Australia will move further away from international alignment, and we are already not aligned.

Adoption into regulation

AS/NZS 2604 is adopted into regulation by the TGA in Australia and by the Commerce Commission in New Zealand.

Before the Sunscreen Standard can be adopted into regulation, the TGA must consider the regulatory impact and conduct an Impact Analysis. However, as the Sunscreen Standard is already finalised, the TGA cannot consider any changes that may have a significant impact, such as choosing to adopt all available international standards, as the decision not to do so may already have been made by the Standards committee and written into the standard, without consideration of regulation impact.

The TGA (and other federal regulators) normally takes a broad approach to international standards adoption. For example, for child-resistant packaging, the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95) allows the use of a range of international standards for compliance. Some Australian Standards e.g. AS/NZS 2604, due to their structure, take away these regulatory decisions with regulation impact away from regulators.

This two-step process adds time to adopting internationally accepted standards, during which time products that are currently available overseas and meet international standards must continue to meet separate Australian requirements.

3. Scope of application to achieve harmonisation

The scope of application of the international standard should be aligned with and limited to the same scope of application of that standard in international jurisdictions.

To achieve this, those involved at every stage of implementation must understand the reasons for the adoption of the international standard and be empowered and accountable to achieve better regulatory alignment and efficiency. Example 3 illustrates this point.

Example 3:

The Therapeutic Goods Administration (TGA) is Australia's regulator of medicines and other therapeutic goods. It adopts international standards to apply across the products it regulates, with some exceptions. Pharmacopoeial standards, such as the US Pharmacopeia (USP), British Pharmacopoeia (BP) and European Pharmacopoeia (Ph. Eur.), are all well-recognised medicine ingredient standards that are adopted by the TGA to control impurity levels in medicines.

The TGA also regulates sunscreen products. As these are important public health products due to our high skin cancer rates, this allows the TGA to ensure that sunscreens are safe and effective. Globally, sunscreen products are primarily regulated as cosmetic products[3].

[2] ISO 23675:2024 (*In vitro determination of sun protection factor (SPF) (Double Plate Method*)), and ISO 23698:2024 (*Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy (HDRS*)) are equivalent alternative methods to ISO 24444:2019 (*Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF*))

[3] Even in the USA where sunscreens are regulated as medicines, medicine pharmacopoeia standards do not apply to the ingredients, except for the listed UV filters.

The application of medicine-level impurity controls on ingredients that are not medicine ingredients globally has no identifiable benefit. We are effectively 'gold-plating' our sunscreen products, with Australian consumers paying the higher cost.

Where a pharmacopoeia does not exist, companies wishing to use new sunscreen ingredients are required to establish their own test methods to the pharmacopoeial standard. One company was informed by their supplier, who supplies the ingredient globally, that developing the test would cost $300,000 because no one else, globally, is asking for such data.

In a recent example of internationally consistent regulation relating to unique device identifiers (UDIs), the TGA exempted some medical devices—such as adhesive plasters and condoms—in recognition of the high cost of implementation and lack of identifiable benefit. It was very unlikely that anyone would record the UDI for a condom or an adhesive plaster before use, and there would be no identifiable benefit if they did. This 'carve out' saved our industry, and in the end, consumers, millions of dollars[4].

Pragmatic decisions, such as the one made by the TGA for UDI implementation, should be the norm for adopting international standards.

- *Are there any reforms that should be made to Australia's standards and conformance infrastructure to support greater harmonisation while still addressing specific Australian risks and objectives?*
    - *What measures could support access to international standards incorporated in Australian regulation?*

One of the reforms that can be undertaken to support greater harmonisation while still addressing specific Australian risks and objectives is to provide greater clarity and standardisation for information to be contained in standards versus information to be contained in regulations.

To give an example, it would be perfectly reasonable to have a sprinkler standard for buildings that sets out the design, installation and maintenance of fire sprinkler systems to protect life and property. But it should be regulation that picks up the standard and applies it appropriately, considering regulatory impact, e.g., new vs old buildings, retrofitting requirements, transition time for compliance if retrofitting, size/type of building that requires the sprinklers (a rural barn? a chemicals warehouse?), etc. The standard setting process does not consider the regulatory impact and is not an appropriate forum for such analysis.

When a requirement exists in a standard that is not adopted in regulation, the compliance rate is questionable. Standards cost money to purchase, and there may be hundreds of standards to purchase to understand the requirements (e.g., chemicals storage standards). Where the requirement is important for the protection of life, property and the environment, these should

[4] Accord is currently gathering data from member companies for better quantification.

be regulatory requirements. If they are not important, they should not be in standards or regulations.

Untangling existing standards and regulations may take many years or even decades. However, setting clear guidance now on when standards should be used and when regulation should be used will be helpful for current and future standard and regulation consideration.

Where standards are called into regulation, they should be freely available: the cost of purchasing standards should not be a barrier to compliance. For Australian Standards, this could be achieved by an agreement between Standards Australia and Australian governments, recognising that Standards Australia provides a service to governments by producing the standards that can then be adopted into regulation. For some international standards, it may be possible to have an identical adoption as an Australian Standard, providing access through Standards Australia.

Other competition reform options

Information request 3

- *Which sectors or policy areas need reform to further promote competition?*

Current regulation of formulated chemical products is complex, fragmented and inefficient, and has a dampening effect on legitimate competition.

An SME will find it difficult to meet all regulatory requirements. Over the past few years, Accord has been informed by some regulatory consultants that they will no longer work in some regulatory areas, e.g. AICIS, as it is too difficult to explain to their customers why they need so much information and why it is so time-consuming to navigate the system.

However, non-compliant products thrive on online platforms. Regulators are busy with products that pose an actual risk to consumers, or are too focused on legitimate companies that pay for the cost-recovered regulator (an irony of the 'user pays' system) to act on low-risk non-compliant products that our legitimate members compete with.

Reform of the chemicals regulatory system is needed to make it more broadly outcomes-focused, rather than regulator-focused.

Need for central coordinating chemical policy body

One of the reasons for the inefficiency in chemicals regulation is that Australia has multiple regulations in silos that apply to the same products, and no 'coordinating body' that pulls the regulations in the same direction.

Accord's past reform experience has been that, when a reform is achieved in one section of chemical regulation, the benefits of the reform can be immediately negated by being captured in a different regulatory section. As the new regulatory section was not part of the reform process, it does not agree that it needs to deliver the efficiencies promised through the reform

process. One example is the 'cosmetics reform' in the 2000s, where some products were moved from the TGA to AICIS (then NICNAS).

While that experience was 20 years ago, Accord has not seen any changes to suggest any improvements.

A central coordinating chemical policy body would be better able to navigate the reforms to deliver real benefits, by not only considering the benefits of carving products out of one set of regulations, but also considering the cost of applying the new regulations to come to a net benefit consideration.

A central coordinating body may also be able to consider more complex policies and regulation impacts that go across regulatory responsibilities, such as balancing the implementation of new standards for a product and sustainability goals such as reducing waste, or balancing sustainability goals such as recycled content in packaging with the need for appropriate/safe packaging and the availability of recycling infrastructure.

Competition for GMP auditing, establish a national audit body

Currently, the auditing of manufacturing sites is regulation- and regulator-focused rather than manufacturing site–focused, making it inefficient.

An interesting fact we learnt from a visit to one of our member manufacturing sites recently was that their manufacturing site is audited approximately 26 times per year. That's one audit every two weeks, with each audit lasting multiple days. See Example 4.

Example 4

An Accord member is a contract manufacturer of cosmetics/personal care products, therapeutic goods like sunscreens, and some products on the food/cosmetic and food/medicine interface.

For each type of product, there is a separate audit process to ensure Good Manufacturing Practice (GMP). For example, the TGA will not accept any third-party audits for Australian manufacturing sites (they must be audited by the TGA). The TGA will also not audit beyond their scope of products.

For cosmetics, third-party audits are the norm. There is no mandatory requirement for cosmetic GMP, but most reputable manufacturers manufacture to GMP.

For cosmetics exports, a GMP certificate is necessary to meet most other market requirements. In some markets, like China, a Government-certified cosmetic GMP audit can support the export of 'ordinary cosmetics' without the need for animal testing[5]. In Australia, this means that the company must have a third-party cosmetic GMP audit, or leverage the

[5] Animal testing for cosmetics is banned in Australia via the Industrial Chemicals Act 2019.

TGA audit, then have it certified by the Department of Agriculture, Fisheries and Forestry (DAFF)[6].

Other audits include meeting other specific local regulatory requirements (e.g., food), meeting overseas regulatory requirements (e.g., US FDA) and customer audits.

The number of audits could be reduced if a single audit addressed all local needs according to the standard required. This may be achieved by establishing a national audit body to service all regulatory agencies that require GMP audits.

Further efficiency could be gained through agreements internationally, e.g. through free trade agreements (FTAs), for acceptance of Australian Government audits.

Approved third-party auditors could provide competition for the Government audit body.

This would be similar to the way the National Measurement Institute (NMI) Analytical Services Branch provides government-run analytical services, in competition with other NATA[7]-accredited analytical laboratories.

[6] This was a difficult process to establish due to the lack of a government auditing body. While industry is grateful that DAFF stepped in to provide a workable solution, it is not an easy fit, and the process is not as efficient as it could be (due to no fault of DAFF).

[7] National Association of Testing Authorities

About Accord

Accord is the national industry association representing the formulated hygiene, personal care and specialty products. Our members make and market everyday products for use in homes and in our public facilities to keep them clean, hygienic and functioning well (e.g. laundry products, hard surface cleaners, drain unblockers) and personal care products such as soaps, deodorants, sunscreens and fragrances. A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

We are a significant industry sector contributing to a prosperous Australian economy. Accord commissioned EY to prepare a State of the Industry Economics Report for the Australian Hygiene, Personal Care and Specialty Products industry[8].

Some topline results based on 2021 economic data:

- Total turnover: $28.2bn (17th largest industry sector in Australia)
- Industry value-add: $5.5bn (upstream and downstream value added by our industry to the Australian economy—an indicator of how our sector drives economic activity)
- Jobs: 72,585
- Wages: $3.5bn
- Import value: $4.0bn
- Export value: $1.5bn

The Report identified several other significant observations regarding our industry, including:

- Diversity in production, with businesses operating across all aspects of the supply chain from production through to the retail of final goods.
- Varied client base, with industry products consumed by a wide range of end-users and spanning a wide range of product types from basic consumer necessities to janitorial cleaning supplies to luxury cosmetics.
- Resilience to changes in economic conditions (likely arising from the above two characteristics).
- Higher growth in our industry's value-add than the Australian GDP over the past five years, meaning that our industry added proportionately more value than some other industries in the economy.

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[8] Hygiene, Personal Care and Specialty Products industry: Economic State of the Industry report Accord Australia Ltd Final report 31 October 2022: https://accord.asn.au/about/economic-state-of-the-industry-report/

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