

INTERNATIONAL REGULATORY COOPERATION: the case of the ASEAN cosmetics regulation

Executive summary

The harmonisation of ASEAN cosmetics regulation was one of the first concrete instances of intensive economic integration between ASEAN countries. It is a surprisingly successful example of relatively rapid implementation of harmonised technical standards and an unusual balancing of the free trade agenda and consumer protection. Its history tells the story of how a potential regulatory 'race to the bottom' became an immediate 'trading up' to the world's highest standards.

The ASEAN Cosmetics Directive essentially allows all ASEAN member states to adopt the main features of the regime of technical standards for cosmetics ingredients in the EU Cosmetics Directive. Rather than prior approval, compliance with the Directive is backed by pre-market notification and post-market surveillance for 'negative list' banned ingredients and 'positive list' permitted agents.

A key feature was industry interest in harmonisation based on EU standards, as the major cosmetic export manufacturers were already having to comply with those standards to access their major export markets in Europe and elsewhere in the world.

Harmonisation of cosmetics regulation across the ASEAN member states was achieved through a two-phase process:

- The first phase was in partnership with industry and dominated by voluntary action. Progress in the voluntary phase was driven by ASEAN cosmetics regulators working closely with the cosmetics industry associations.
- The second phase involved a more formal commitment by governments to fully harmonise. This second phase was mainly pushed forward by government regulators.

The important lessons from this case study for other examples of IRC are:

- *Focus IRC where the gains are greatest:* this is a case study of full policy harmonisation to achieve access to major export markets and improve consumer safety, but harmonisation is not the only destination as IRC can take a number of forms
- *Consider 'trading up' when access to major export markets is the primary objective:* setting high technical standards from the start may be easier than trading up later
- *Partnership with industry can lay the groundwork to facilitate faster implementation and a simpler approach:* industry is well placed to see the opportunities to reduce the burden of compliance without compromising future options
- *Political mandate helps but it's not sufficient:* commitments to freer trade and consumer safety brought industry and regulators together and provided legitimacy to what was initially an initiative in partnership with industry
- *Context and capability matters:* IRC between different countries of different levels of development and pre-existing regulation can be particularly difficult but progress can still be made where there is a burning imperative.

How it works – compliance, notification and surveillance

The ASEAN Cosmetics Directive allows all ASEAN member states to adopt the main features of the cosmetics ingredients listings of the EU Cosmetics Directive, with minor modifications if required. The regime includes simpler compliance rules based on a 'negative list' of banned ingredients, a 'restricted list' of ingredients subject to specified limits, and a 'positive list' of permitted agents. Compliance with the Directive is backed by pre-market notification and post-market surveillance.

The ASEAN Cosmetic Directive reduces the burden of compliance on manufacturers and importers as well as on government regulators by requiring manufacturers and importers to:

- Comply with a single set of rules on ingredients, claims and labelling, instead of multiple sets of rules
- Notify regulators in any state where cosmetics are to be marketed before marketing takes place, instead of having to first obtain approval from government
- Keep the product's technical and safety information, supporting data for any claims, manufacturing methods and adverse event reports readily accessible to the regulator for post-market surveillance.

How the ASEAN Cosmetics Directive was developed

Harmonisation of cosmetics regulation across the ASEAN member states was achieved through a two-phase process:

- The first phase was initiated in partnership with industry and legitimised by the ASEAN governments' free trade agenda and was characterised primarily by voluntary action. Progress in the voluntary phase was achieved by ASEAN cosmetics regulators working with the cosmetics industry through the Cosmetic Product Working Group (CPWG) of the ASEAN Consultative Committee for Standards and Quality (ACCSQ)
- The second phase involved a more formal commitment by governments to fully harmonise. This second phase was mainly pushed forward by wider concerns about consumer safety and associated health issues. These imperatives allowed the more developed ASEAN member states to gain the cooperation of the less developed member states' governments.

In 1998, partly in response to pressure from large, influential cosmetics exporting manufacturers, ASEAN cosmetics regulators began working with the cosmetics industry associations to address the barriers to trade that faced the sector.

The ASEAN Cosmetics Directive was agreed on just four years after the ASEAN member states had committed in 1999 to the ASEAN Economic Community (AEC). This was the first Mutual Recognition Agreement (MRA) within ASEAN. It facilitated the move toward a fully harmonised regime of common technical standards and national regulator powers in the cosmetics industry.

The presence of major European cosmetics manufacturers in ASEAN member states was an enabling factor because manufacturers focused on exporting faced significant regulatory burdens. Different jurisdictions had differing approaches to standards and compliance (pre- and post-market controls).

Box 1 highlights the role of key events in the process since the initiative was launched.

BOX 1 The journey from concept to adoption

1992: ASEAN Free Trade Area (AFTA) agreement signed.

1998: ASEAN Framework Agreement on MRAs and establishment of the Cosmetic Products Working Group.

1999: Announcement of the ASEAN Economic Community to take effect 2025.

2003: Agreement on the ASEAN Harmonized Cosmetics Regulatory Scheme including a 5-year grace period, adoption of the ASEAN Cosmetics Directive (Phase 1) – voluntary measures and establishment of the ASEAN Cosmetic Committee.

2007: ASEAN member states agree to accelerate progress towards the ASEAN Economic Community to 2015.

2008: Intended complete adoption of the ASEAN Cosmetics Directive (Phase 2).

2009: Adoption of three ASEAN community blueprints including advancing the ASEAN Economy Community to 2015.

2011: Final ratification of the ASEAN Cosmetics Directive (Phase 2) after a 3-year extension.

2013: Complete adoption of the ASEAN Cosmetics Directive into domestic laws.

There are several features of the brief chronology above that deserve comment.

The most obvious is the relatively rapid adoption of first world standards amongst a diverse group of countries at different stages of development. There were a number of factors that worked together to secure adoption: shared commitment to freer trade through the AEC, the need to address consumer safety (in the more developed ASEAN states) and health development objectives (in the less developed ASEAN countries), combined with the ease of implementation for countries with no pre-existing regulation. Unlike other examples of IRC when development stages of ASEAN countries did hinder achievement, such as IP harmonisation, it wasn't the case with cosmetics. **This case highlights how context and capability matter but don't always have the expected effect.**

The second was the role of the major exporting manufacturers who were active partners in the process and set a high standard for harmonisation from the start. Having a higher standard used through the world meant that the potential pay-off from achieving harmonisation was greater, with access to world markets, not just ASEAN markets. Had an ASEAN standard had been developed first, then harmonisation to EU standards would have been a difficult sell to the less developed member states. **This illustrates that an immediate 'trade up' to the highest standards can sometimes be easier than trading up later.**

The partnerships between the regulators and the major exporting manufacturers were pivotal to the success of cosmetics harmonisation and laid the groundwork during the pre-2007 voluntary phase, through the Cosmetic Product Working Group (CPWG). By working with industry, the CPWG was able to identify a simple approach that could reduce the burden of compliance both

for government regulators and the industry while simultaneously improving consumer safety. The result was a win-win deal for ASEAN governments, which highlights how **partnership with industry can lay the groundwork to facilitate faster implementation and a simpler approach.**

A regionally focused regulatory process under the AEC agenda, could have resulted in a unique cosmetics ASEAN standard. Industry interests however ensured convergence on a common international standard. This **highlights how a government mandate may be necessary to provide legitimacy to the process but the mandate is not sufficient to get the best outcome.**

Throughout the process, the major exporting cosmetics manufacturers played a significant role. Later, when the major players were already voluntarily complying with the new standards and processes, the focus shifted to smaller manufacturers whose activities mainly concerned marketing to domestic markets and across ASEAN borders. In this later phase, the primary concern was consumer safety. Consumer safety is particularly compromised where systems for following up on adverse effects are lacking. **This illustrates the importance of focusing IRC where the gains are greatest.** The major benefits from convergence were achieved in this case before full policy harmonisation was complete.

Phase 1: The voluntary stage – industry ambition meets the AEC agenda

The first phase of harmonisation was able to be achieved through voluntary participation. The general lifting of standards that ensued enabled the ASEAN member states to implement the ASEAN MRA of Product Registration Approvals for Cosmetics which allowed individual member states to agree to permit the import of cosmetic products that simply met another member state's regulatory requirements. This agreement provided further incentive for member states interested in improving the export potential of domestic industries to raise domestic standards in order to encourage ASEAN export markets to reduce barriers.

The first phase of the process involved exploring two tracks. One track involved primarily voluntary compliance of larger scale manufacturers who had supported the development of MRAs to reduce the burden of complying with different standards and regulation across the ASEAN member states. Government support for this phase was fully consistent with the ASEAN commitment to a Free Trade Area in that it helped to remove non-tariff barriers to trade between ASEAN member states.

However, if economic integration in the ASEAN area had been the main objective, advocates of the common standard may have settled for a lower standard instead of setting their sights on the European model. ASEAN member states have generally rejected EU approaches on the basis that their members are faced with greater challenges of diversity in culture, politics and economic factors, so much so that EU approaches are generally considered ill-suited to ASEAN.

It is clear, therefore, that although the main objective of governments would have been to reduce trade barriers between ASEAN member states, the major exporting manufacturers had a longer-term objective of facilitating trade with the rest of the world. This longer-term objective, and the limited progress under the MRA track, motivated the move towards the European model – specifically the 1976 EU Cosmetics Directive – as a means to facilitating exports to the rest of the

world by adopting and adapting the most stringent standard, which was also being adopted by many other non-European countries.

For manufacturers located in countries whose consumer safety standards may be seen as behind those of first world countries, adopting a high and recognised standard, and ensuring that the region does so in an official capacity, would be an important marketing strategy. It would minimise the ability of even small, non-exporting players to 'tarnish' the region's reputation through media reports of major safety issues.

Phase 2: The ASEAN Cosmetics Directive – full implementation under the health and consumer safety agenda

It is particularly interesting that it was wider concerns about consumer safety in ASEAN member states that pushed forward the second phase of harmonisation. In 2009, as part of the agreement to accelerate progress to full economic integration by 2015, ASEAN member states also committed to improve and harmonise consumer law.

This commitment reflected two concerns:

- That consumer safety would be reduced by increased competition associated with freer trade. Awareness that with freer trade, manufacturers of consumer goods associated with safety risks would face increased competition raised fears that existing standards may come under pressure to be reduced by governments (particularly governments of the less developed member states) as a means to give the domestic industry a competitive edge. Although this regulatory race to the lowest standards of safety has been shown not to be a necessary outcome of free trade (Vogel, 1995), ASEAN member states were motivated to ensure that their own citizens would not face increased risks as a result of possible future deterioration in standards
- That consumer safety was directly linked to health, a priority area under the ASEAN Socio-Cultural Community agenda: to improve human development through improvements in areas including not only education, work and community participation, but also health.

A new Committee encouraged member states to enact strict product liability regimes which would make it easier for consumers to be compensated for harms caused by unsafe products. ASEAN states have also introduced new or revised laws allowing regulators to set mandatory safety standards before products are put into circulation, and to enforce post-market controls such as bans and recalls of unsafe products.

Interestingly, although implementation of first world standards is generally thought to be more challenging in less developed countries, the ASEAN experience with cosmetics shows that this is not always true. ASEAN countries with existing cosmetics regulation (generally the more developed countries) faced more challenges to implementation than those with no pre-existing regulation (Jinachai and Anantachoti, 2014). However, the very same countries with well-established regulatory regimes also had the major economic interest in cosmetics export growth and influential exporting industry players to help push forward with the complex legal process

Significant implementation capability constraints still exist in the less developed ASEAN states which limit the extent to which regulation will be fully harmonised. This is mainly in relation to post-market surveillance capability.

The ASEAN experience with a Free Trade Agreement triggering improved consumer safety is not unique. In the case of the European Union (EU), the Treaty of Rome (1957) as interpreted in 1979, required mutual recognition of goods produced to safety standards required in one EU country would satisfy standards in an importing country. This mutual recognition or 'negative harmonisation' subject to safeguard measures if harm arose, was replaced a more active 'positive harmonisation' phase of EU-wide instruments setting agreed minimum safety standards. In order to avoid a regulatory race to the bottom, the EU also developed a new and more effective approach to setting joint minimum safety standards and a harmonised compensation regime for consumers suffering injuries.

This increased focus on consumer safety in ASEAN states provided governments with the motivation to push forward the second stage of the ASEAN Cosmetics Directive to achieve full implementation by 2013.

Conclusions

A key feature of industry interest in harmonisation was that the major exporting manufacturers were already having to comply with EU standards to access their major export markets in Europe and elsewhere in the world. The ideal outcome of harmonisation for them, therefore, was not just any harmonised ASEAN regime, but harmonisation of ASEAN cosmetics regulation with European cosmetics regulation. As part of the initiation of the process of harmonisation, these influential exporters and their governments were able to set the standard, so that once consumer safety became the chief concern, the prospect of 'trading down' to a lower standard would be unpalatable.

Because of the groundwork having already been established pre-2007, commitment to full harmonisation in the non-voluntary phase was achieved in six years. However, delays did occur in adopting updates to the EU ingredient lists. In addition, the extent of compliance by small non-exporting manufacturers of less developed member states is not clear.

Although the process of harmonisation was relatively fast (compared with the EU or other ASEAN harmonisation), there were and are still important challenges:

- The more developed member states face the legal difficulties of aligning existing standards, definitions, and processes of cosmetics with the European model. If the ASEAN members wish to remain consistent with the EU, these difficulties will be repeated every time the EU updates the ingredients listings. This is in contrast with countries with no existing regulation, like Singapore, which were able to implement the ASEAN Cosmetics Directive more quickly
- The less developed member states have experienced delays due to a lack of human and technical resources for full implementation and are likely to continue experiencing such difficulties in their ongoing commitment to post-market surveillance. Important supporting systems are lacking. Specifically, there is no single information portal by which national laws can be accessed, or to enable ASEAN-wide incident reporting (as exists for food). Well before the ASEAN member states agreed in 2007 to accelerate progress towards an ASEAN Economic Community with full liberalisation and facilitation of trade, the cosmetics industry had already identified a need for harmonisation of cosmetics standards as a means to address non-tariff barriers to trade, not just between ASEAN member states but with the rest of the world.

Implications for IRC generally

The important lessons learnt from this case study are:

- **Focus IRC where the gains are greatest:** this is a case study of full policy harmonisation both to improve consumer safety and to achieve access to major export markets, but harmonisation is not the only destination as IRC can take a number of forms.
- **Consider ‘trading up’ when access to major export markets is the primary objective:** setting high technical standards from the start may be easier than trading up later.
- **Partnership with industry can lay the groundwork to facilitate faster implementation and a simpler approach:** industry is well placed to see the opportunities to reduce the burden of compliance without compromising future options.
- **Political mandate helps but it’s not sufficient:** commitments to freer trade and consumer safety brought industry and regulators together and provided legitimacy to what was initially an initiative in partnership with industry.
- **Context and capability matters:** IRC between different countries of different levels of development and pre-existing regulation can be particularly difficult but progress can still be fast where there is a burning imperative.

Further Reading

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