

The Influence of Trade Blocs on Chemicals Regulation and Compliance

20 July 2021





Michael S. Wenk

Principal/Director,
m4 Global Consulting LLC

- ✓ Founded 2009. Specializing in Latin America and the Middle East;
- ✓ 25+ years in chemical and consumer product regulatory positions in global regulatory teams;
- ✓ Published author of over a dozen professional journal articles and two chemical regulatory handbooks; and
- ✓ Globally-recognized speaker on Latin American and Middle Eastern chemical regulations.

Agenda

1. Overview of the Latin American regulatory environment
2. Trade Associations - MERCOSUR and Andean Community
3. Questions



Overview of the Latin American regulatory environment

Common Themes

1. Generally, no formal chemical inventory in place (but work ongoing);
2. Generally, no formal pre-notification schemes;
3. GHS has been implemented to a fair degree;
4. Many unique, localized regulations exist;
5. Many “twists” on global regulations exist



Trade Blocs - MERCOSUR

- **MERCOSUR - *Mercado Común del Sur* (Common Market of the South);**
- Loose parallel to EU;
- Initially established by Argentina, Brazil, Paraguay and Uruguay, and subsequently joined by Venezuela and Bolivia (although Bolivia is still in the ascension process);
- Formed by Treaty of Asunción (1991);
- Trade alliance to boost the regional economy, moving goods, people among themselves, workforce and capital; and
- As of 1 January 1995, this area became a customs union, in which all signatories could charge the same quotas on imports from other countries (common external tariff).



Trade Blocs - MERCOSUR

- Official working languages are Spanish and Portuguese;
- The working documents' official version will be that of the host country language of each meeting;
- The Mercosur Parliament (*Parlasur* or *Parlamento*), was created in 2004 and as MERCOSUR's unicameral, independent, and autonomous legislative body.
- *Parlasur's* function is to add a dimension of popular representation, based on the number of parliamentarians in each country, but the body has no enforcement powers and its conclusions are only meant to advise; and
- Each country must transpose MERCOSUR regulations into own national law (in some cases, can take >3 years).



Trade Blocs - MERCOSUR

- MERCOSUR has been extremely proactive in putting forth a wide variety of chemical substance regulations:
 - Resolution GMC 39/19:
 - Lists the permitted additives for the manufacture of plastic materials and polymer coatings in food contact materials;
 - Draws primarily on the EU and U.S. Food and Drug Administration (FDA) lists of authorised Food Contact Material (FCM) substances;
 - The regulation lists approximately 1,150 substances, establishing the calculation methods for each and setting out:
 - Compositional limits;
 - Specific migration limits; and
 - Usage restrictions.
 - The positive list exempts unintentionally added substances, including:
 - Impurities in the substances used;
 - Intermediate reaction products formed during the production process; and
 - Any reaction formed from decomposition of the products (breakdown products).

*"Mercosur regulation lists permitted additives in plastics for FCMs". (07 August 2019). Chemical Watch.



Trade Blocs - MERCOSUR

- The positive list exempts unintentionally added substances, including:
 - Impurities in the substances used;
 - Intermediate reaction products formed during the production process; and
 - Any reaction formed from decomposition of the products (breakdown products).
- Substances can be added to the list if it can be proved they do not represent a significant risk to human health and "the technological need for their use is justified". They can be removed if new knowledge indicates such a risk exists;
- Manufacturers or importers of FCMs must allow competent authorities access to the composition of the product when requested;
- Paraguay was the notifying Member; and
- MERCOSUR member countries had to incorporate the regulation into their national law systems by 15 January 2020



Trade Blocs - MERCOSUR

- MERCOSUR GMC Resolution No. 18/10:
 - "MERCOSUR Technical Regulations For Products Disinfectants (Pesticides)"
 - This Regulation covers disinfectant products for home application and related common areas, such as interiors, public or collective buildings and related environments, to control insects, rodents, and other harmful to health pests.
 - The products at issue may be either direct to the consumer or restricted to institutions' or companies' specialized service providers (similar to the Certified Applicators provision of the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), codified at 40 C.F.R. Section 171 et seq).



Trade Blocs - MERCOSUR

- Food Contact Materials
 - All FCMs must comply with MERCOSUR's general safety standard, GMC Resolution No. 03/92 ("General Criteria for Packaging and Articles to Come into Contact with Foodstuffs: Terminology, General Criteria, and Classification of Materials").
 - Resolution No. 03/92 requires that all FCMs:
 - Must be manufactured per Good Manufacturing Practices (GMPs);
 - Be "suitably pure";
 - Not transfer harmful or toxic compounds from the packaging to the food; and
 - Not cause a change in composition, taste, or odor.



Trade Blocs - MERCOSUR

- June 2021: Established priorities for the chemicals and waste sectors over the next four years;
- Plan identifies 23 activities to be completed before 2024, in the following areas:
 - Increasing chemical substance management capacity;
 - Increasing regulatory cooperation;
 - Increase engagement with regard to international chemicals and waste conventions and initiatives; and
 - Increase the available environmental information for chemical substances and chemical products.
- Officials plan to propose a MERCOSUR Technical Standard that would implement at least the 5th revision of the Globally Harmonized System of Classification and Labeling (GHS);
 - Argentina and Brazil – have implemented the 5th revision of GHS;
 - Uruguay – has implemented the 4th revision; and
 - Paraguay – has not yet implemented any version/revision of GHS.



Trade Blocs – Andean Community

- *Comunidad Andina (CAN)*;
- Comprised of Bolivia, Colombia, Ecuador, and Peru;
 - Note Bolivia is also petitioning to be a member of MERCOSUR



Trade Blocs – Andean Community

- Fewer Trade Bloc regulations in place than MERCOSUR – Possibly due to “outsize” influence of MERCOSUR Member States (*e.g.*, Argentina and Brazil);
- Tends to focus chemical substance regulations more toward illicit substances;
- **DECISION 602**
 - “Andean Regulation for the Control of Chemical Substances Used in the Illegal Manufacture of Narcotic Drugs and Psychotropic Substances”;
- **DECISION 505**
 - “Andean Cooperation Plan for the Control of Illegal Drugs and Related Offenses”;



Trade Blocs – Andean Community

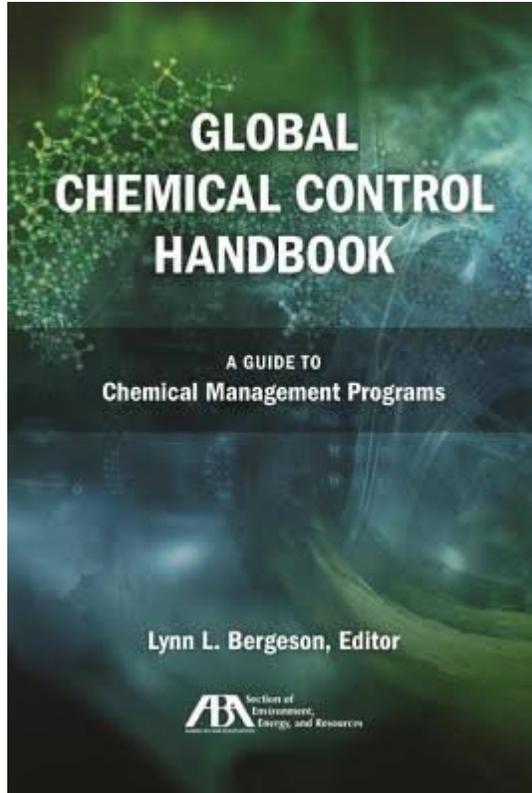
- Resolution No. 2109: “Andean Technical Regulations for the Labeling of Apparel”:
 - Establishes the minimum information that must be included on the labels of manufactured or imported clothing;
 - Labels must:
 - Be written in simple terms;
 - Be indicated with clear, visible and easy-to-read letters;
 - Be written in Spanish language without prejudice other languages;
 - Information cannot be covered by other labeled information;
 - Remain attached to the garment until the clothing reaches the consumer;
 - Be placed in a visible place of the product, or in an easily accessible place;
 - Fiber content, care instructions and country of origin must be permanently attached; and
 - Manufacturer or importer identification and size or dimensions can be permanently or non-permanently attached.



Trade Blocs – Andean Community

- **DECISION 833**
 - Intends to introduce control and surveillance of all cosmetic and personal care products sold in Member States to ensure they are both sanitary for humans and safe;
 - Mandates that products to be regulated are solely for topical use, and that formulation of such products should comply with the best recognized international regulations on ingredients (to determine banned or restricted substances);
- Includes the following international regulations/lists:
 - Lists and provisions issued by the U.S. FDA, where applicable;
 - The Personal Care Products Council's (PCPC) Cosmetics Ingredients List;
 - Leading trade association representing cosmetics and personal care products companies
 - EU Directives and Regulations applicable to cosmetic ingredients; and
 - The Cosmetics Europe – The Personal Care Association's Cosmetic Ingredients List
 - European trade association for cosmetics and personal care industry





CONTACT INFO

Michael S. Wenk
President/Director
m4 Global Consulting LLC

+(678) 836 6419 (mobile/office)

www.m4globalconsultingllc.com



michael@m4globalconsultingllc.com