



Role of co-formulants and the impact of global chemical regulations

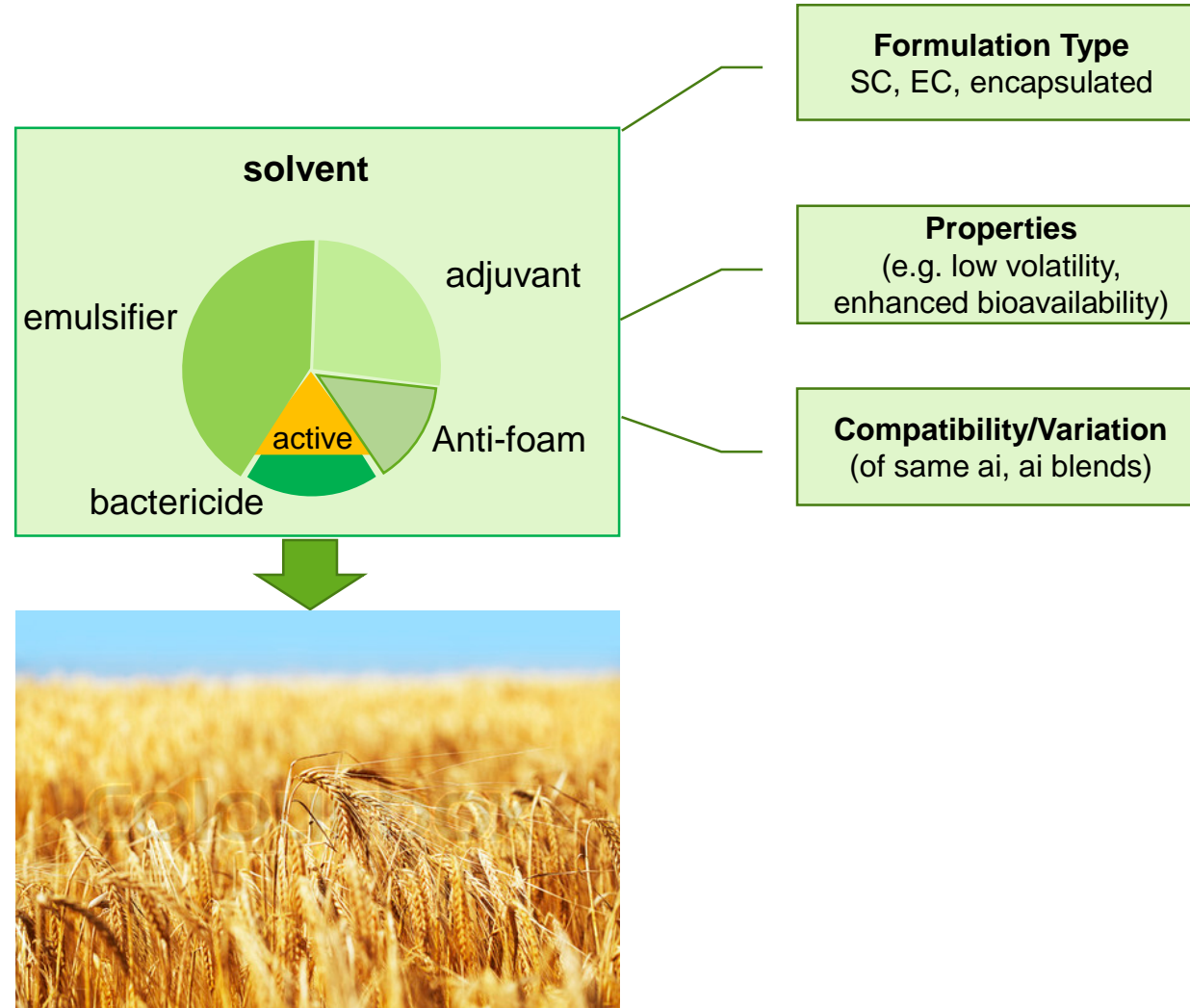
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Agenda

- Co-formulants complexity
- Global legislation for co-formulants – outside of North America
 - ▶ Europe
 - ▶ South America
 - ▶ Asia
- Trade control – Prior Informed Consent (PIC) regulation and co-formulants
- Conclusions

Function of co-formulants

- Facilitate application of active ingredient
- High Tech rather than just filling materials
- No performance without co-formulants
- Allows and effective products
- Improves consistency of formulation
- Stabilizes formulation



Co-formulant functional importance (i.e. surfactant)

- Increased wetting
- Improved coverage with less material
- Improved delivery of active ingredient

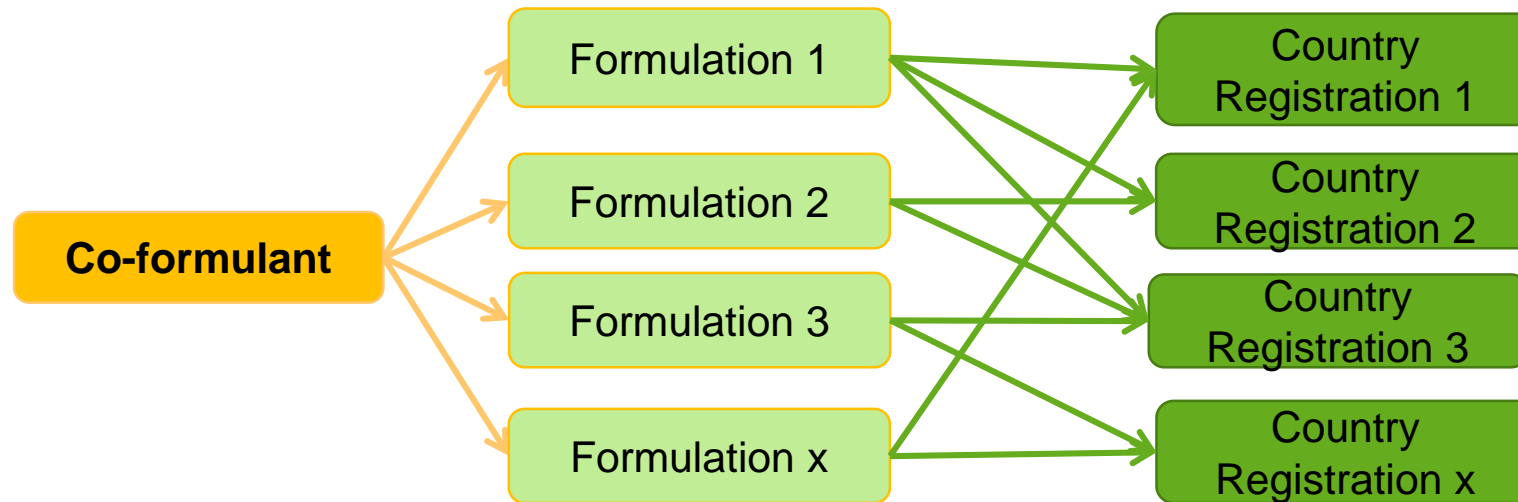


Equivalence of co-formulants

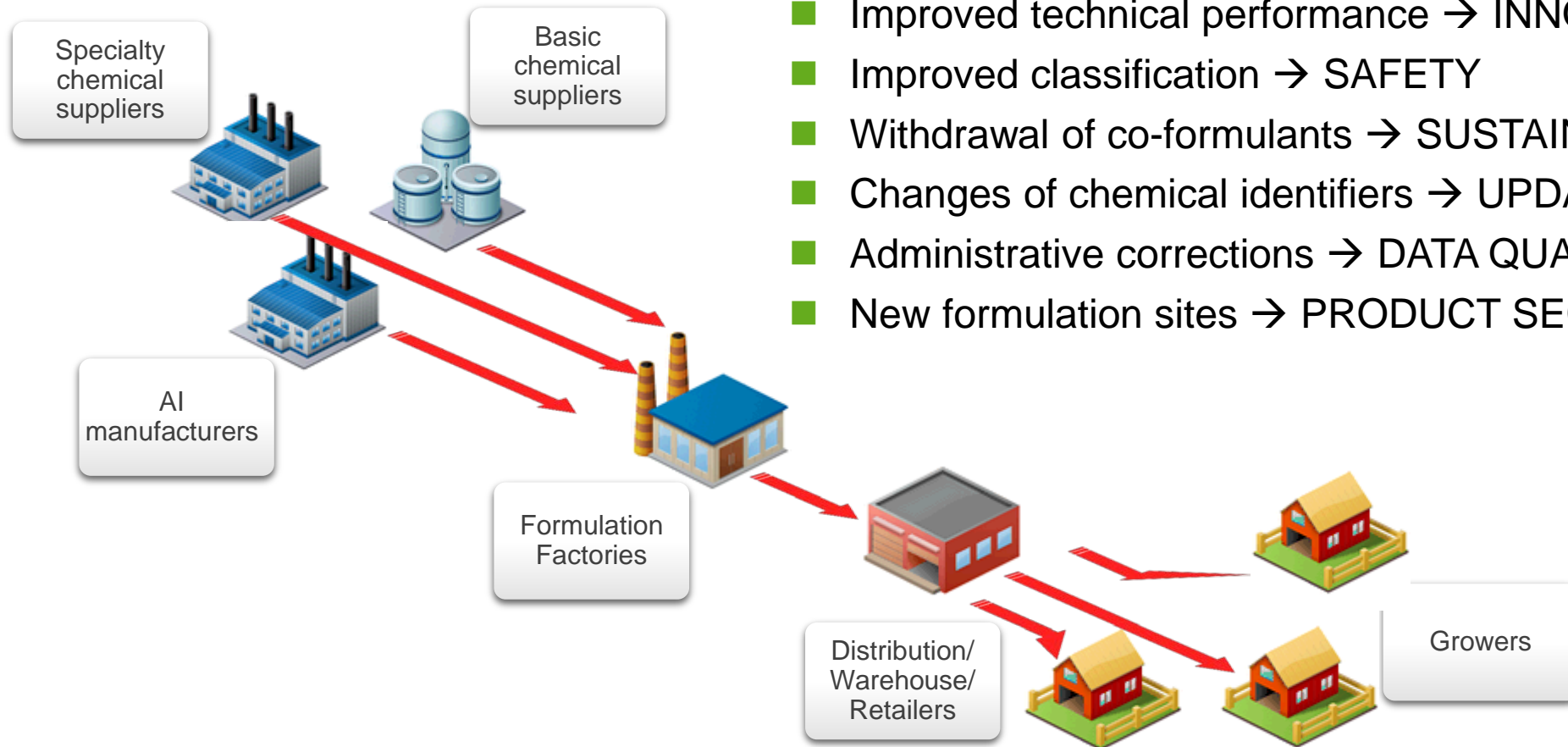
Aspect of equivalence	Some aspects of equivalence to check
Formulation	Is performance the same in the formulated product?
Regulatory	Equivalency determined by chemical composition? Country specific regulations? Is composition equivalent under all applicable laws? Registered productions sites?
Supply	Supply security? Quality? Specifications?
Procurement	Cost? Availability?
Production	Special production equipment? Worker safety? Powders vs. liquids handling?

Importance of co-formulant toolbox

- The loss of a single co-formulant can affect many formulations and hundreds of country registrations
- Each country has unique requirements that must be met for registration and any change in registration



Product supply chain – changes in co-formulants



- Improved technical performance → INNOVATION
- Improved classification → SAFETY
- Withdrawal of co-formulants → SUSTAINABILITY
- Changes of chemical identifiers → UPDATE
- Administrative corrections → DATA QUALITY
- New formulation sites → PRODUCT SECURITY

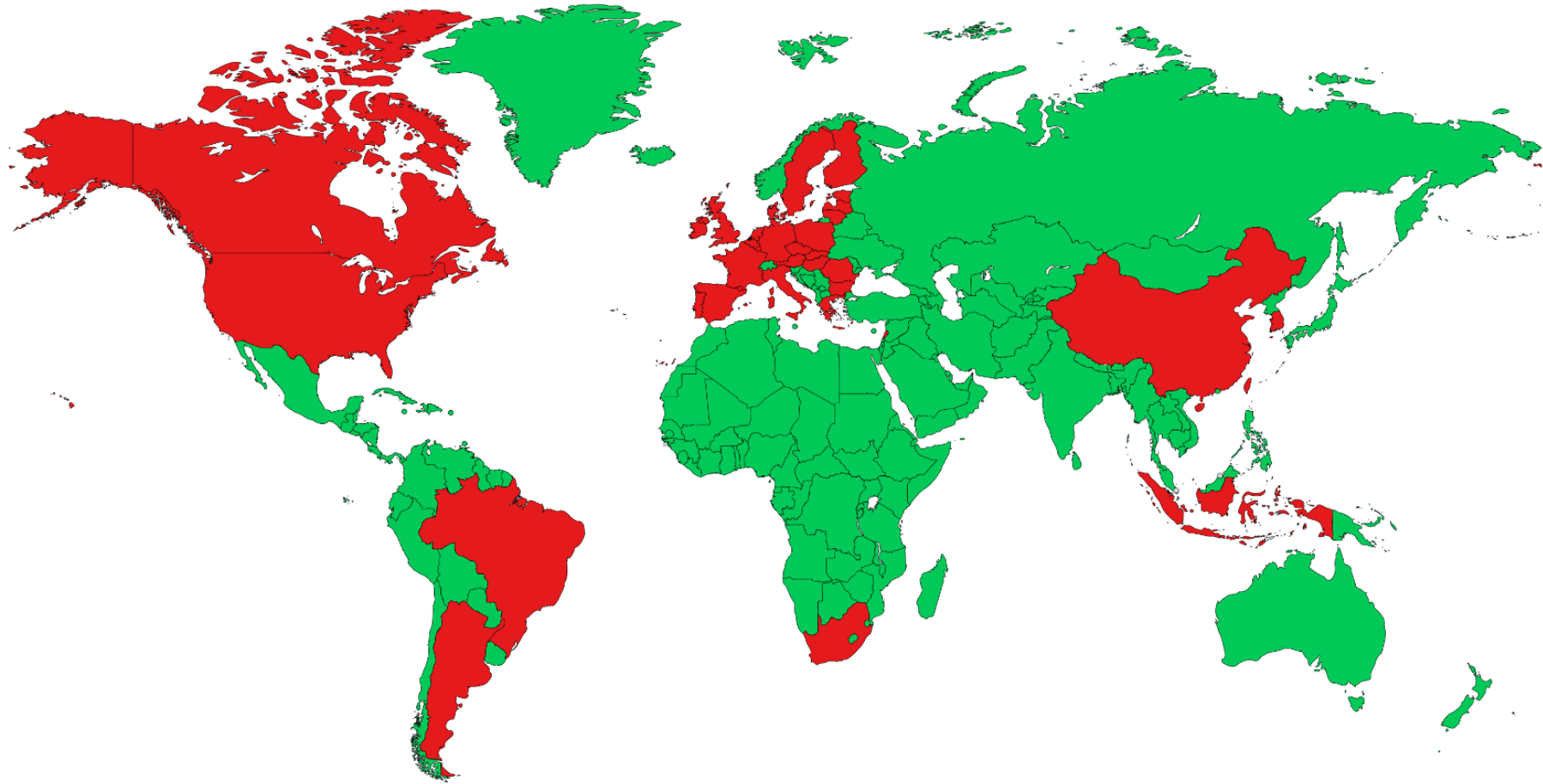
Chemical Identifier complexity

- Co-formulants can be described by different identifiers
 - ▶ Chemical names – CAS, IUPAC, common names, tradenames
 - ▶ Registration numbers – CAS, European INventory of Existing Commercial chemical Substances (EINECS)
 - ▶ Tradenames
- Different identifiers do not necessarily mean different co-formulants
- CAS number
 - ▶ Same should equal same chemical, but this is not necessarily true
 - ▶ Different does not necessarily equal different chemicals
- Assignment of CAS No and chemical names can vary among suppliers
 - ▶ Non-ionic C-11-polyethoxylate surfactant
 - 68439-45-2 – alcohols, C6-C12, ethoxylated
 - 68439-46-3 – alcohols, C9-C11 ethoxylated
 - 34398-01-1 – polyoxoethylene monoundecyl ether (C11 ether)

Compositional changes during product life cycle

- Regulatory Policies
 - ▶ Use restrictions for some chemicals
 - ▶ Industry's voluntarily approach to avoid the use of critical substances
- Shortage or unavailability of co-formulants
 - ▶ Phase-out of co-formulants caused by REACH (EU)
 - ▶ Raw material feedstock not available to co-formulant supplier
- Consolidation of the co-formulant Industry
 - ▶ product divestments (i.e. stop of production)

Countries with specific regulations for co-formulants



REACH requirements for co-formulants

- REACH is legal entity and substance dependent!
- 31 May 2018 – final registration deadline for all substances \geq 1t/a
- AIs (if not approved in the EU, EU approved AIs are regarded as registered), safeners, synergists, co-formulants and adjuvants used in Plant Protection Products (PPP) must be registered under REACH
- Manufacturer / importer must include a risk-assessment in its registration dossier
- The exposure scenarios and risk mitigation measures will be communicated to the downstream user in the annex of an extended Safety Data Sheet (eSDS)
 - ▶ Scenarios needed
 - PPP field uses
 - Production / Formulation
- All assessments must confirm a safe use

Co-formulants under Reg.(EC)1107/2009

- Article 27 establishes a negative list of co-formulants in Annex III
 - ▶ The detailed rules for the implementation of Art. 27 are still to be set
- Until 14th June 2016, member states can maintain national provisions (Art. 81(2))
 - ▶ These have continued in the absence of Annex III (ytd)
- To authorize a plant protection product (formulation), Art. 29(1)c requires no Annex III listed co-formulants
 - ▶ As a result of Art. 44(3) a Member State may withdraw the authorization
 - ▶ Art. 46 limits grace period to 6 months sell out, and 12 months use / disposal

1107/2009 Annex III: key aspects of the current proposal

■ Draft criteria

- ▶ Tier 1: CMR 1A/1B, PBT, vPvB, POP, ED
- ▶ Tier 2: CMR 2, STOT SE/RE, skin/resp. sensitization, 2/3 PBT, impurities
- ▶ Tier 3: Co-formulant toxicity > A.I. toxicity or co-formulant enhances toxicity, OEL
- ▶ Tier 1 cut-off criteria, Tier 2 & 3 result of risk assessment

■ Timelines

- ▶ Tier 1 substances in a first phase population of Annex III
 - based on legal harmonized classification and labelling (CLH)
- ▶ Earliest “banning” would be Q4 2018 of known Tier 1 substances
- ▶ Art 46: 6 months sell out + 12 months use-up
- ▶ EU Commission recognizes that Art 46 timelines “may not be long enough”

CMR – carcinogenic, mutagenic, or reprotoxic, PBT – persistent, bioaccumulative and toxic, vPvB - very persistent and very bioaccumulative, POP – persistent organic pollutants, ED – endocrine disruptor, STOT SE/RE – specific target organ toxicity – single exposure / repeat exposure, OEL – occupational exposure limit

Turkey REACH-like regulation (KKDIK)

- Registration (Kayit), Evaluation (Degerlendirme), Authorization (Izin) and Restriction (Kisitlama) of Chemicals (Kimyasallar) (KKDIK) re-approved on 23-Jun-2017, in force 23-Dec-2017
- Implementation timeline
 - ▶ 31-Dec-2020 – substance notification (pre-registration)
 - ▶ 31-Dec-2023 – substance registration \geq 1t/a
- Active ingredients and co-formulants may be regarded as registered if listed in the Turkish Official Gazettes (PPPs and biocides)
- Data requirements and risk assessment reports are similar to REACH
- Joint submissions are mandatory and information sharing forums are called MBDFs
- Only Representatives (OR) are appointed for companies outside of Turkey
- Only trained and qualified experts fluent in Turkish can sign-off registrations and notifications

Brazil – negative and positive lists

- Two new regulations proposals from Anvisa, under public consultation, addressing topic of co-formulants for use in crop protection products
- Regulations are partially aligned with international regulations (e.g. adoption of GHS approach for toxicological assessment, classification and hazard communication)
- New regulatory requirements for co-formulant registration and its use in crop protection products (Possibly high barriers for new co-formulants)
- Establish a negative and a positive list of co-formulants

Brazil – negative list

- Based on cut-off criteria (ED or CRM (CMR)* cat 1A and 1B).
 - ▶ * Cat 2 is unclear if it will also be considered in the cut-off criteria
- For a listed co-formulants
 - ▶ Registered formulated products: reformulated composition must be submitted within 30 months
 - ▶ New submissions will be denied
 - ▶ To remove the co-formulant from the list, complete new study data must be submitted
- So far, concentration limits are not included on this regulation
- Hazard based (cut-off) criteria
 - ▶ Not consistent with “draft bill of regulation for Chemical Substances from Ministry of Environment” in BR, which intends to establish the notification, evaluation (Risk Assessment) and control (Risk Management Measures) of chemicals (REACH-like regulation)

Brazil – positive list

- List of evaluated co-formulants or those currently used in registered formulations
 - ▶ Can be used in new pesticide formulations
- For new entries, co-formulant manufacturer or registrant of the crop protection product must request inclusion
 - ▶ Acceptance of evaluations from other regulatory agencies (similar to BR scheme) – however, negative lists from other countries can cause a denial of inclusion
 - ▶ Co-formulants that also meet the following requirements may be included
 - are in the Brazilian Common Denomination
 - have been published in official pharmaceutical compendiums
 - are present in food and cosmetic products registered by Anvisa
 - ▶ If none of the other apply, a petition with toxicological dossier / studies must be submitted

Co-formulants – South America (except Brazil)

- In South American countries (except Brazil) there is no specific legislation regarding co-formulants. Co-formulants are not registered, however they are declared on the certificate of composition (CoC)
- Argentina has a negative list that restricts the use of approximately 70 substances
 - ▶ These substances are allowed to be used only in a concentration up to 30% w/w within the formulated product
- In general the authorities are aware of the restrictions in EU and US and use this information as guidance

KOREA REACH-like Regulation

- Next step: Notification of substances 31.12.2016, transitional period 2018
- Crop protection products imported into Korea which have a registration under the local Korean crop protection law are exempted
- Active ingredients and concentrates imported into Korea are exempt
- Production of intermediates are subject under K-REACH; Non-isolated intermediates and On-site isolated intermediates are limited to handling within the site/process (without sending outside), are subjected to an exemption application with simplified data set. Transported-isolated intermediates are subjected to normal registration.
- Co-formulants imported into Korea are subjected to K-REACH
- Biocides are not exempted under K-REACH and they are listed on the first draft list. When they are imported as a Biocidal Product into Korea a registration is needed.
- Annual Report every year

Thailand REACH-like Regulation

Hazardous Product Notification List 5.6 (DIW)

- New regulation of hazardous product notification for DIW (Department of Industrial Works) List 5.6
- Next step: Notification of hazardous products by end of 2016; > 1t/a
- Crop protection products are out of scope. Products are already controlled by Department of Agriculture (DOA).
- Co-formulants imported separately into Thailand are in scope for notification under DIW List 5.6 if fulfilling the criteria
- Intermediates are subjected to DIW List 5.6 notification if not regulated otherwise

Taiwan REACH-like Regulation

- Next step: Notification of substances
- Crop protection Products are exempted: CPPs are not subjected to T-REACH, all substances contained are regulated by Agro-pesticides Management
- Intermediates are subjected to T-REACH; <1 t/a small quantity registration ; 1-10t/a simplified registration and over 10t/a standard registration
- Active Ingredients, co-formulants: import and production need a registration
- Annual Report every year
- Biocides are regulated by Agro-pesticides Management Act

Objectives and status of the Rotterdam Convention

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade



Objectives

- To promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals **in order to protect human health and the environment from potential harm**
- To contribute to the environmentally sound use of those hazardous chemicals

Status

- Adopted in 1998
- Entry into force: 24 February 2004 (after 50 countries ratified)
- 160 countries ratified (Apr 2018)
- USA is a non-Party state with observer status



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Key provisions of the Convention

Information exchange among Parties* about potentially hazardous chemicals

- Parties must notify final regulatory actions banning or severely restricting chemicals
- Notified bans and severe restrictions are published and available to other Parties for their consideration



PIC procedure for listed chemicals & Severely Hazardous Pesticide Formulations

- Provides importing Parties with information about chemicals and SHPFs listed in the Convention
- Requires importing Parties to make informed decisions on imports of listed chemicals: (i) consent, (ii) consent with conditions, (iii) refuse
- **Exporting Parties must ensure compliance with those decisions**
- If no decision is communicated, the export can proceed if:
 - (i) the chemical is registered in importing Party, or
 - (ii) there's evidence of previous use in or previous import into importing Party, or
 - (iii) explicit import consent was received by exporting Party from designated national authority of importing Party

Scope – Chemicals subject to the Convention

Pesticides and industrial chemicals



- Banned or severely restricted by participating Parties **in order to protect human health or the environment**
- Includes chemicals that have been refused for first-time approval or withdrawn by industry from the domestic market and where there is clear evidence that such action has been taken to protect human health or the environment

Severely hazardous pesticide formulations (SHPFs)

- An SHPF produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use in a Party that is a developing country or a country with an economy in transition

Out of scope:

Narcotic drugs and psychotropic substances, radioactive materials, wastes, chemical weapons, pharmaceuticals – human and veterinary drugs, chemicals used as food additives, food, **chemicals at limited quantities for research or analysis** or imported for personal use (amount not specified)

Facts about "PIC listing" in Rotterdam Convention

“PIC list” is not an FAO/UNEP blacklist or ban recommendation

- Clearly demonstrated by objectives and provisions of Convention
- Regularly stated at the Conferences of the Parties (decision-making body)

PIC listing is based on a very limited data set

- Chemical: Information on regulatory actions banning or severely restricting chemicals from only min. two parties (from min. two PIC regions)
- SHPF: Proposal to list a pesticide formulation from only one party

No risk evaluation by the technical body of the Convention

- Purely based on information provided by notifying Parties and, for SHPFs, some additional data provided by Parties and observers
- Does not automatically mean that a product cannot be used safely
 - Parties have varying regulatory requirements (e.g. hazard- vs risk-based decisions, precautionary threshold values such as EU groundwater limit)
 - Local prevailing conditions of use have to be considered – risk/benefit considerations

Conclusions

- Co-formulants are necessary to deliver active, stabilize formulation, use less AI
- Co-formulants are regulated differently in each country
- Chemical and agro regulations overlap in many countries requiring different registrations
- Co-formulants can be complex mixtures
- Inerts (formulants or co-formulants) play an important role in PPPs
 - ▶ Environmental, toxic & biological impact must be sustainable
 - ▶ Inerts should never impact PPP negatively
- Assessments should be risk and not hazard based
 - ▶ Restrictions should be sustainable and not only definition based
- Pragmatic formulation change procedures should be adapted
- PIC listings are not a ban but require information sharing



We create chemistry