



Integrating Devex PLM with Compliance Cloud
for Faster Regulatory Decisions

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Disclosures

- *Full-time employees at Cargill – US.*
- *The content, remarks, opinions presented here today are our own and do not necessarily reflect those of Cargill.*



Background to Cargill Implementation





Our purpose is
to nourish the
world in a safe,
responsible and
sustainable way.

At a glance

155,000
employees

Working in 70
countries

More than 155 years
of experience

A trusted partner for food, agriculture, financial and
industrial customers in more than 125 countries.



Agriculture



Food



**Animal nutrition
and protein**



**Financial and
industrial**

Fiscal 2021 revenue: \$134.4

Cargill R&D shared capabilities across food, agriculture and animal nutrition and protein

2,000+

global R&D employees

50+

R&D facilities including 10 major Innovation and R&D centers

20+

key technologies and sciences

1

integrated R&D team that leverages capabilities to support customers and businesses

0

harm goal, supported by lab safety standards and best practices



Understanding Cargill Job To Be Done in Product Design

Cargill Need for a solution fits two key areas

Two Main Cargill Product Development Needs

1. Product Group
Formulations move from testing into approved products for production in Cargill plants

and

2. Applications Teams in
Cargill integrate ingredients into Customers products that are sold to the customer to enable innovation.

Cargill Protein Business
NA, EMEA, APAC, Latam

CCC Chocolate & Compound
GEOS – Oil Blends
CSST – Truvia, Tea Syrups
Cargill Salt – KCL blends

CSST
GEOS
Plant Protein – Dairy, Alt
CHT - Epicor

New Opportunity – Launch Cargill SKU

Cargill manufacturing
Businesses project Brief. Goal sell SKU to Retailer or Convenience Store or Food Service Company.

Business Development – Ingredient sales

Sell ingredients to Cargill Retail customers through Demonstration of functionality of Cargill ingredients in customer new product development briefs

HIS, Clean label starches
EverSweet
Puris Pea Protein
Epicor

Project Vision

Cargill R&D will create a Global R&D Product Design PLM that will enable us to be a leader in designing products and sharing information between our teams safely and securely across the world.



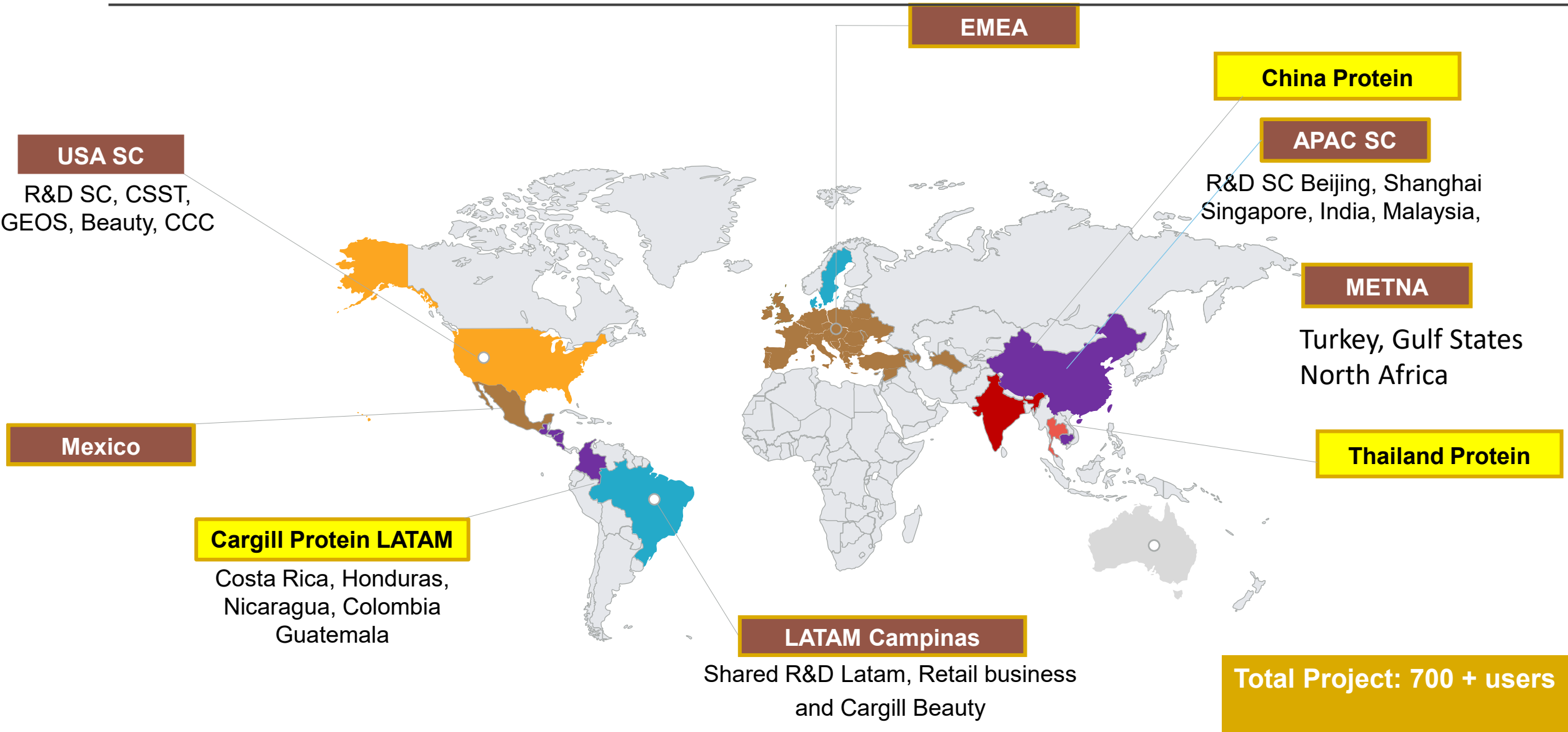
Project Scope



Product Group ingredients and formulations serve a diverse customer base globally with many regulations and language barriers. A multi-phase implementation will be deployed to the following R&D Applications and Product Groups:

- *Cocoa & Chocolate*
- *Branded Products*
- *Global Edible Oil Solutions*
- *Starches, Sweeteners, Texturizers*
- *Cargill Bioindustrial - Cargill Beauty*
- *Cargill Protein*
- *Shared Capabilities Application Team*

Cargill's Global Breadth Requires Regulatory Guidelines Across many countries.

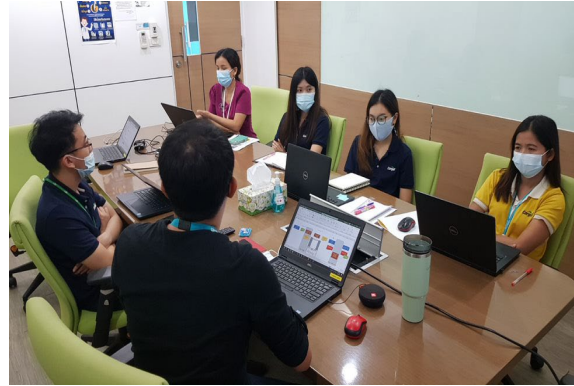


Digitalizing Product Designers label Needs

North America



Thailand



Nantong



Latin America



In 2023 Cargill will have the ability to create nutritional labels and ingredient decks to meet the requirements of 40 countries. This creates an ability to serve Global Partners on global product regulations

Beijing



Shanghai



Singapore



Malaysia



Customer
Project Brief

Ingredient
Innovation Brief

Ingredient
Innovation

Formulation
Technology

Processing
Technology

Cargill Cross functional teams need to collaborate across Marketing, R&D, SRA, FSQR, Operations, Packaging and Law to approve specifications.

Regulatory

New Product Launch

Shelf Stability
and Sensory

Product &
Package
FG Complete Bill of
Materials
Specifications

PACKAGING

Labeling



Progress on faster more efficient
regulatory results





Food News My Queries

- ✓ Early Warning System to catch
 - Safety Recalls
 - Regulatory Updates
 - Commercial News & Nutrition
- ✓ Email Alert System
- ✓ Over 1700 sources in a single place

1



Food Law Library

- ✓ 37k Legislative Documents
- ✓ 174 Countries Covered
 - Food regulations
 - Food product standards
 - Guidance documents
 - Draft regulations
 - English Translation

2



REGDATA®

- ✓ Food Regulatory Database
 - Additives
 - Contaminants
 - Pesticides
 - Flavors & more
- ✓ 88 Countries
- ✓ Over 17k Substances
- ✓ Over 2400 Data Revisions
- ✓ Possible Integration

3

Regulatory Harmonization vs Divergence

Pharma



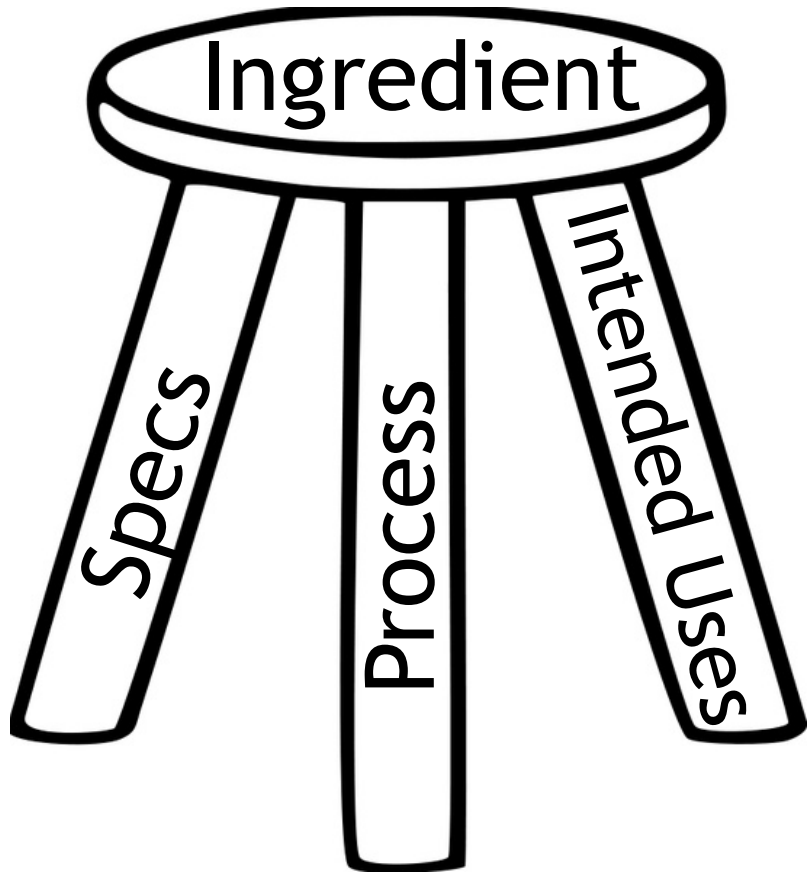
- >30 years since inception
- Global alignment on Quality, Safety, and Efficacy – Guidelines
- Accepted standards for global pharmaceutical development
- VICH – Veterinary equivalent >25 years
- Model for Regulatory Harmonization

Food



Little to no alignment!

Regulatory Challenges in Food



- **Specs**
 - Regulatory specifications
 - Quality specifications
 - Shelf-life
- **Process**
 - Manufacturing process steps (GM?)
 - Inputs and processing aids
 - Food contacts
- **Intended Uses**
 - Technical function(s)
 - Allowable food categories
 - Use levels



So many variables could impact the regulatory status of a single ingredient!

DevEx Materials Overview

Recipe/Formula



- Made of Ingredients/Raw Materials (RM)
- Formula Compliance Checks
- Ingredient Lines and Nutrition Data Created From



Raw Materials (RM)



- Compositional Component(s) of a Recipe
- Purchased Ingredients Added to a Recipe
- Nutrition Details for NFP
- Allergens/GMO/Religious etc.



Substances (SB)



- Compositional Component(s) of a RM
- Food Additives
- Food Law/Formula Compliance Checks
- Ingredient Statement Names

Compliance management daily tasks for:

⊗ No Compliance Tools



Innovation Process
Management

Product
Development

Regulatory
Compliance

Product Data
Management



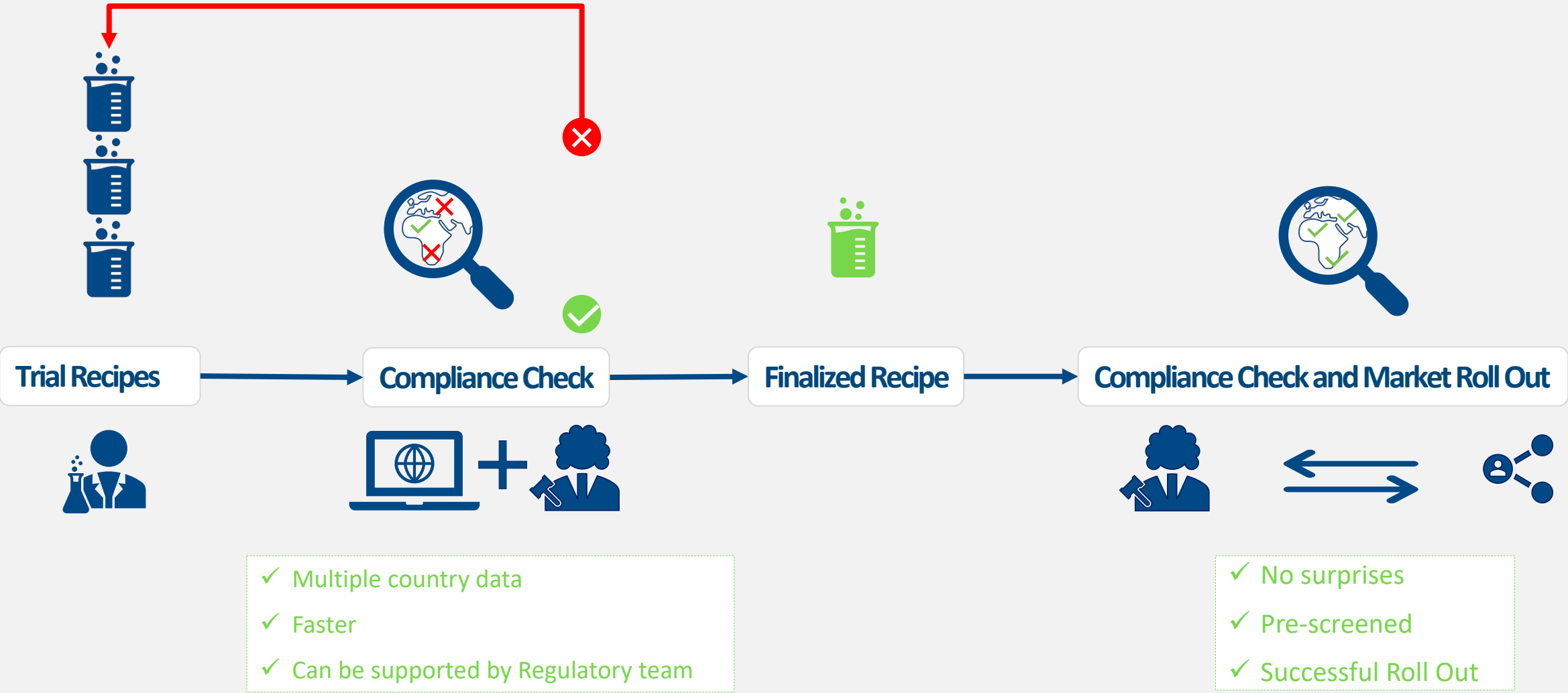
- ✓ Recipes developed using excel
- ✓ Approved by several stakeholders
- ✓ Create folders to store TDS's
- ✓ Approved files stored in folders



- ✓ Circulation via e-mail or SharePoint
- ✓ Approved by several stakeholders
- ✓ Approval made through constant consulting of TDS's
- ✓ Approver had to look for regulation limits while approving









Structure 4 – Automated check

✓ Using Compliance Tools (PLM)



Example – Carbonated Beverage for the US and Brazil Market

- Formulation is carbonated flavored beverage
- Compliance checks start with having complete and accurate substance data for your raw materials

▼	 Base (manufacturing) , Alternate:0, Version:0, 1
▶	 RO Water, None
▶	 Citric Acid, Anhydrous, Fine Granular
▶	 MALIC ACID ANHYDROUS
▶	 Trisodium Citrate Dihydrate, Granular
▼	 STEVIA/STEVIOL GLYCOSIDES, EVERSWEET™
▼	 RM Breakdown, Additives, Full or Partial , Alt
	 Steviol glycosides

Example – Carbonated Beverage for the US and Brazil Market

CREATE NEW PRODUCT POSITIONING

Profiles

Guideline Types

Guidelines

Applications ?

🔍 Food Additive Guidelines

Legislation for Brazil Food Additives

Brazil Food Additives v.0

⊕ Expand All

⊖ Collapse All

Category text

~

carbonated

Filter

Clear

☐ Category text

▼ ☒ All additives categories

▼ ☒ Beverages 16

▼ ☒ Non-alcoholic beverages 16.2

▼ ☒ Carbonated and non-carbonated beverages 16.2.2

▼ ☒ Carbonated and non-carbonated beverages ready for consumption 16.2.2.1


☒ Carbonated drinks

- Specific product positioning will enable the most accurate assessment of the components in the formulation

Example – Carbonated Beverage for the US and Brazil Market

Product Positioning

 New Product Positioning  Auto Populate  More ▾

Country ▾ Guideline Name ▾ Guideline Type ▾  

Country	Guideline Name	Guideline Type	Applications
BRAZIL	Brazil Food Additives v.0	Legislation for Brazil Food Additives	Carbonated drinks
UNITED STATES OF AMERICA	United States Food Additives v.0	Legislation for United States Food Additives	Carbonated beverages





Select the Countries for the Global Food Calculation

Global Food

Guideline profile  ▾

GUIDELINE SELECTION

 New Row  Insert  Delete  Duplicate  Move Up  Move Down  Move Row To  Export ▾

#	Compliance Date From	Compliance Date On/To	Country	Guidelines
1	 9/16/2022	 9/16/2022	UNITED STATES OF AMERICA ▾	United States Food Additives - 0
2	 9/16/2022	 9/16/2022	BRAZIL ▾	Brazil Food Additives - 0

Ready to run the compliance check!



Calculation Results: Global Food

DX_GLOBAL_FOOD.0



Need to look at the details!



Failed

Overall Result

Execution Mode

Standard

Comparison Result

⚠ Different from the Previous Calc.

[+ Input Parameters](#)

Summary Results



Filter



Result	Country Name	Application
✓	UNITED STATES OF AMERICA	All additives categories
⚠	UNITED STATES OF AMERICA	All additives categories; Carbonated beverages
✓	BRAZIL	All additives categories; Beverages 16; Non-alcoholic beverages 16.2; Carbonated and non-carbonated
✗	BRAZIL	All additives categories; Beverages 16; Non-alcoholic beverages 16.2; Carbonated and non-carbonated

1 - 4 of 4 items shown 5 per page

1 < 1 > 1

▼ BRAZIL

▼ Brazil Food Additives

▼ 9/16/2022

▼ Selected

✓	citric acid	All additives categories; Beverages 16; Nor	0.12523772571	ALLOWED	Acidity Regulator; Acid	Notes
✓	erythritol	All additives categories; Beverages 16; Nor	0.99960299880	ALLOWED	Flavour Enhancer; Hun	Notes
✓	malic acid	All additives categories; Beverages 16; Nor	0.10628731886	ALLOWED	Acidity Regulator; Seqi	Notes
✓	trisodium citrate	All additives categories; Beverages 16; Nor	0.08140024420	ALLOWED	Acidity Regulator; Seqi	Notes
✗	Steviol glycosides	All additives categories; Beverages 16; Nor	0.02850008550	No data found for the		

▼ UNITED STATES OF AMERICA							
▼ United States Food Additives							
▼ From 9/15/2022							
▼ Selected							
✓	citric acid	All additives categories	0.1252377257	ALLOWED	Miscellaneous/Other	Notes	
✓	malic acid	All additives categories	0.1062873188	0.10629 % w/w	0 - 0.7 % w/w	Flavour Enhancer; Flavouring agent; For all other food categories	Notes
✓	trisodium citrate	All additives categories	0.0814002442	ALLOWED	Miscellaneous/Other	Notes	
⚠	Steviol glycosides	All additives categories; Carbonated beverages	0.0285000855			No data found for the selected categories	
⚠	erythritol	All additives categories; Carbonated beverages	0.9996029988			No data found for the selected categories	

- Do I have the correct product positioning?
- Is my usage level correct?
- Do I need to reformulate?
- What other data do I need?

Brazil – Change product positioning

NEW RESULTS

Updated product category of indicates Steviol glycosides can be used in “Food and Drinks for Sugar Restricted Diets” with allowable limits. Now need to confirm usage of other food additives for this Application category or re-formulate with allowed ingredients

▼ BRAZIL

▼ Brazil Food Additives

▼ From 9/16/2022

▼ Selected

							Notes
✓		erythritol	All additives categories; Food for special purp 0.99%	ALLOWED	Sweetener		
✓	★	Steviol glycosides	All additives categories; Food for special purp 0.02% 0.03 g/100g	0 - 0.06 g/100g	Sweetener	0.024 g/100g as steviol e	Notes
✗		citric acid	All additives categories; Food for special purp 0.12%				No data found for the sel
✗		malic acid	All additives categories; Food for special purp 0.10%				No data found for the sel
✗		trisodium citrate	All additives categories; Food for special purp 0.081				No data found for the sel

US – Create a custom guideline

Countries

Profiles

Guideline Types

Guidelines

Applications

Category text

☐ Category text

☒ All additives categories

☒ Beverages

☒ Reduced- and Low-Calorie Carbonated and Non-Carbonated Beverages (excludi

- Created a guideline that allows us to capture GRAS information that is not specifically detailed in the regulations or enables us to set internal limits for substances

US – Create a custom guideline

Product Positioning

New Product Positioning

Auto Populate

More

Country

Guideline Name

Guideline Type

Filter

Clear

Country	Guideline Name	Guideline Type	Applications
UNITED STATES OF AMERICA	Global Apps Limits v.0	Global Internal Cargill	Reduced- and Low-Calorie Carbonated and Non-Carbonated Beverages

▼ UNITED STATES OF AMERICA			
▼ Global Apps Limits			
▼ From 9/20/2022			
▼ Selected			
	✓	erythritol	All additives categories; Beverages; Reduced 0.99873609 0.99874 % w/w 0 - 3.5 % w/w
	✓	Steviol glycosides	All additives categories; Beverages; Reduced 0.02847536 0.02847536 % w/w ALLOWED
	✓	malic acid	All additives categories; Beverages; Reduced 0.09991357 0.09991357 % w/w
	✓	citric acid	All additives categories; Beverages; Reduced 0.09986361 0.09986361 % w/w
	✓	trisodium citrate	All additives categories; Beverages; Reduced 0.19982714 0.19982714 % w/w



Calculation Results: Global Food

DX_GLOBAL_FOOD.0

Overall Result



Passed

Execution Mode

Standard

Comparison Result

⚠ Different from the Previous Calc.

Taking a long view of the benefits of bringing a one platform digital approach to regulatory needs. One step at a time

