

# Commercial *Bacillus thuringiensis*:

Advocating for Sustainable  
Agriculture & Vegetable  
Growers

Webinar 23 January, 2023

AVOIDING UNNECESSARY REGULATORY  
HURDLES FOR MICROORGANISMS &  
BIOCONTROL



# Bt: Essential for Farm2Fork objectives

- Insecticidal proteins in commercial Bt are biodegradable and highly selective to the targeted pest
- Most important insecticide for organic agriculture
- An essential tool for caterpillar control close to harvesting crops.
- Fast-acting for a biological with unique insecticidal mode of action for managing resistance to a shrinking toolbox of pesticides.
- Non-chemical & sustainable tool compatible with IPM strategies reducing quantities of synthetic pesticides applied
  - Allows farmers to contend with restricted number of chemical residues on produce
  - Grocery chains impose private standards

# Microorganisms & the draft SUR

- Not chemical Plant Protection Products (art.3)
- Not chemical active substances (art.3)
- ‘biological control’ means the control of organisms harmful to plants or plant products using natural means of biological origin or substances identical to them, such as microorganisms, semiochemicals, extracts from plant products...or invertebrate macroorganisms.
- Objective of the SUR: provide farmers with tools to reduce reliance on chemical plant protection products. By facilitating the placing on the market of these biological plant protection products, farmers – including those producing organic crops - will have more alternatives available for sustainable crop protection.

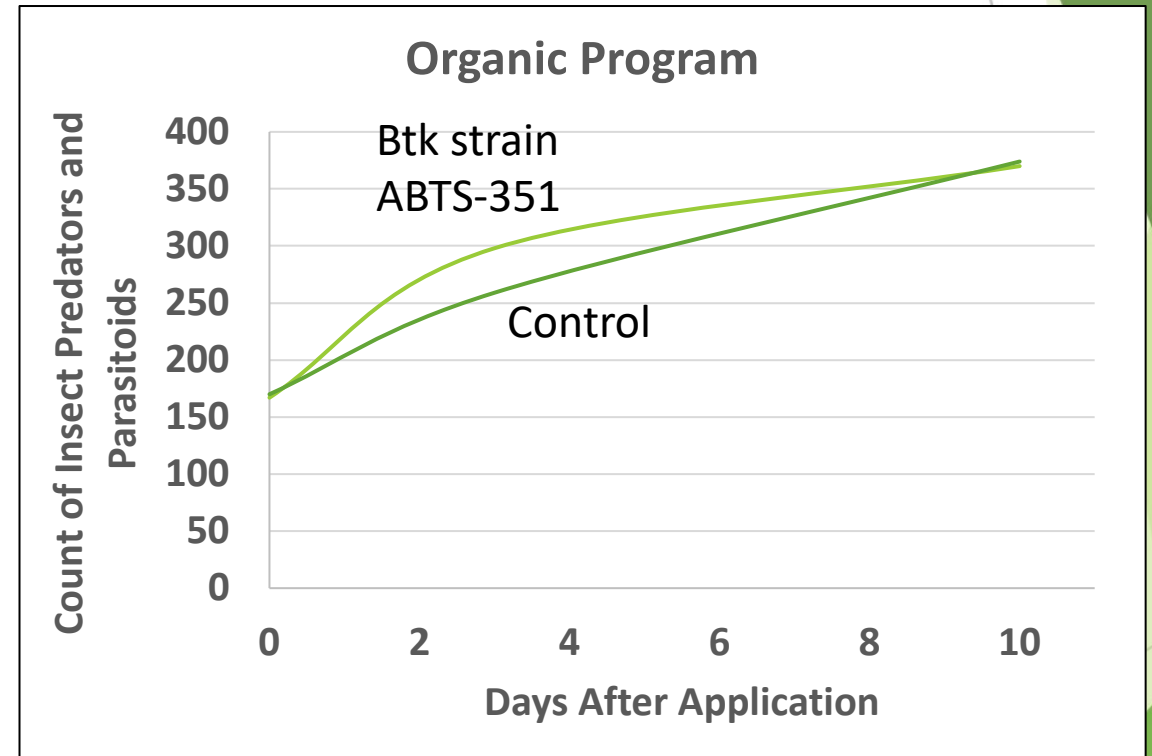
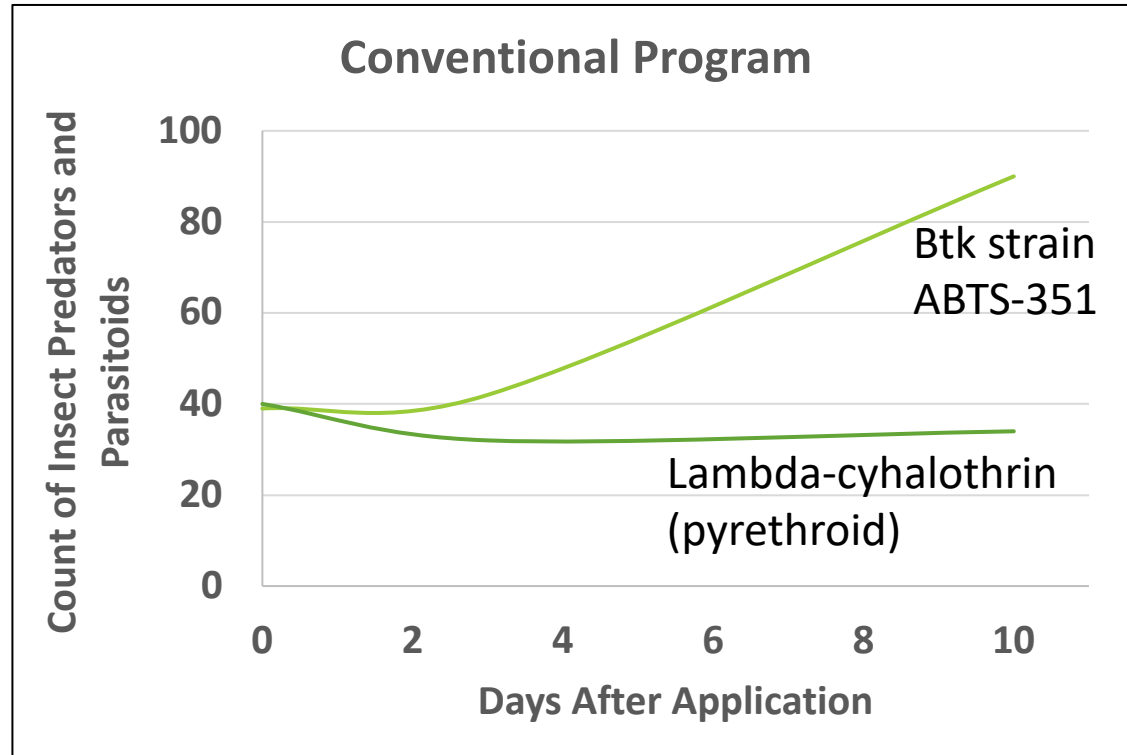
# Individual Isolates Selected for their Ecological Niche

- Commercial Bt strains were selected because of their ecological niche as insect pathogens, which makes them poorly adapted to multiply and persist in the environment, including on foodstuffs and in the human body.
- Commercial Bt strains are better adapted to complete their life cycle in susceptible insect hosts than in other environments
  - Bt requires specific nutrients and pH (~10) for germination (Akiba, 1986; West et al. 1985; Saleh et al. 1970)
- The production of insecticidal proteins by Bt is a large energy demand on the microorganism which changes their physiology.

# Bt, a Low-Risk Natural Solution

- Bt is indigenous and ubiquitous
  - Strains have been isolated worldwide from many habitats, including soil, insects, stored-product dust, and leaves of multiple plants.
- Bt does not tend to germinate and increase in the environment or on fresh produce - high nutritional demands for germination and growth
- Bt tend to be non-competitive microorganisms, even under conditions when *B. cereus* will grow.

# Example of Beneficial Insect Study on Olives in a Program to Control Olive Moth



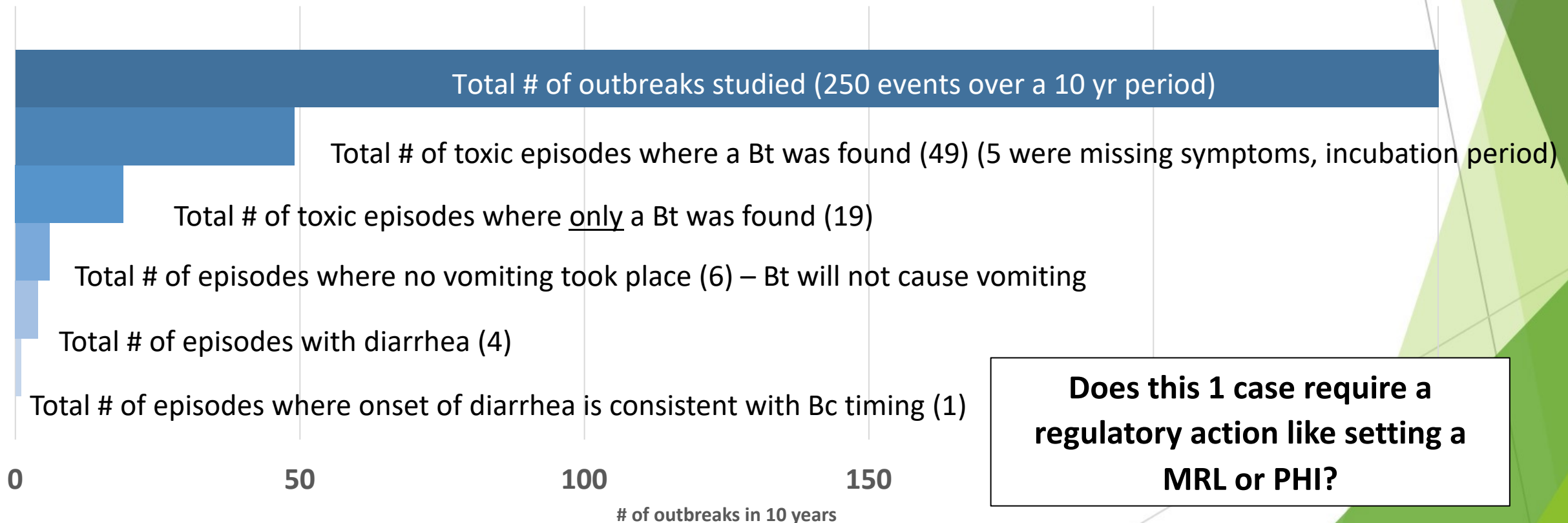
# Two recent publications attempted to link Bt use with food borne outbreaks

**Biggel et al. (2022)** revealed Bt commonly found in fresh produce from Swiss grocery stores:

- Of 100 samples of tomato, bell pepper, endives, rocket salad, baby spinach, baby leaf lettuce, 27% had a *Bacillus* with 14% having a Bt.
- This paper contributes to the understanding that Bt products are (and have been) part of our daily lives.
- The attempt to connect their collected strains and commercial Bt strains to strains assumed to be the causative agent of earlier FBO (Germany and Austria) is deceptive – e.g. Austrian samples not likely from fresh produce

# Two recent publications attempted to link BT use with food borne outbreaks

**2021 Bonis et al:** methodology widely criticized and results do not support their broad reaching conclusions on commercial Bt pathogenicity



**Does this 1 case require a regulatory action like setting a MRL or PHI?**



# Commercial Bt do not have an emetic toxin & are highly unlikely to cause diarrhea

- Strains are not pathogenic nor toxic to study animals/beneficial insects: E.g. Rat, fish, daphnia, beneficial insects, oysters, birds, long-term exposure of sheep
- No cereulide gene in any commercial Bt (heat stable toxin causing vomiting and potential organ damage)
- No diarrheal event has been conclusively proven to be from commercial Bt applications, even after >50 years of use.
- Some strains have disruptions in specific toxin genes which prevent their expression (Biggel et al., 2022)

# Let's look at tomatoes as an example...

- Europeans eat 5 tomatoes a week (EFSAP PRIMo rev3).
- A significant portion of tomatoes are grown in greenhouses.
- *Tuta absoluta* loves ripening tomatoes and is hard to control.
- Tomatoes are harvested on a daily basis.
- PPP sprays and harvest happen concurrently within a plan considering residues allowed by supermarkets and PHIs established by regulators.
- Fresh tomatoes make it to our table within a few days of harvest ready to eat.
- It is good and healthy to eat tomatoes.
- And... according to all the weight of evidence and infectious disease public statistics, the chances of getting a Bc diarrhea is much higher from eating spoiled starchy foods and meat than by consuming fresh vegetables.



Example of Pesticide Application in  
Greenhouse Tomatoes

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# EFSA Surveillance Study Reveals Overlap of Bc and Other Pathogens

- Most case believed to be caused by Bc also included Clostridium (65%) or Staph toxins (16%)
- Fresh fruits and vegetables have low likelihood for FBO with Bc
- Most cases were not confirmed, but causative agent determined from symptoms
- At the time French Authorities did not actively test for viruses (e.g. Norovirus which has similar symptoms to Bc) – 90% of cases reported in France.

<i>Bacillus cereus</i> as first causative agent:	Food vehicle										TOTAL
	Mixed	Other	Meat	Fish	Veg	Dairy products (other than cheeses)	Eggs	Crustaceans, products thereof	Sweets and chocolate + Cheese	Cereal	
With Bc	3	6	2	-	-	-	2	-	-	-	13
With Clostridium	30	74	39	9	11	-	6	4	-	-	173
With Salmonella	1	-	-	-	-	-	1	-	-	-	2
With Staph toxins	6	22	10	-	1	2	-	-	-	1	42
Unknown	3	28	4	-	1	-	1	-	-	-	36
Not available	-	1	-	-	-	-	-	-	-	-	1
<b>TOTAL</b>	<b>43</b>	<b>130</b>	<b>55</b>	<b>9</b>	<b>13</b>	<b>2</b>	<b>10</b>	<b>4</b>	<b>-</b>	<b>1</b>	<b>267</b>

**Table 1:** Extraction from annex of The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017 (published in December 2018) - French cases where *Bacillus cereus* is identified as “first causative agent” in various food vehicle.

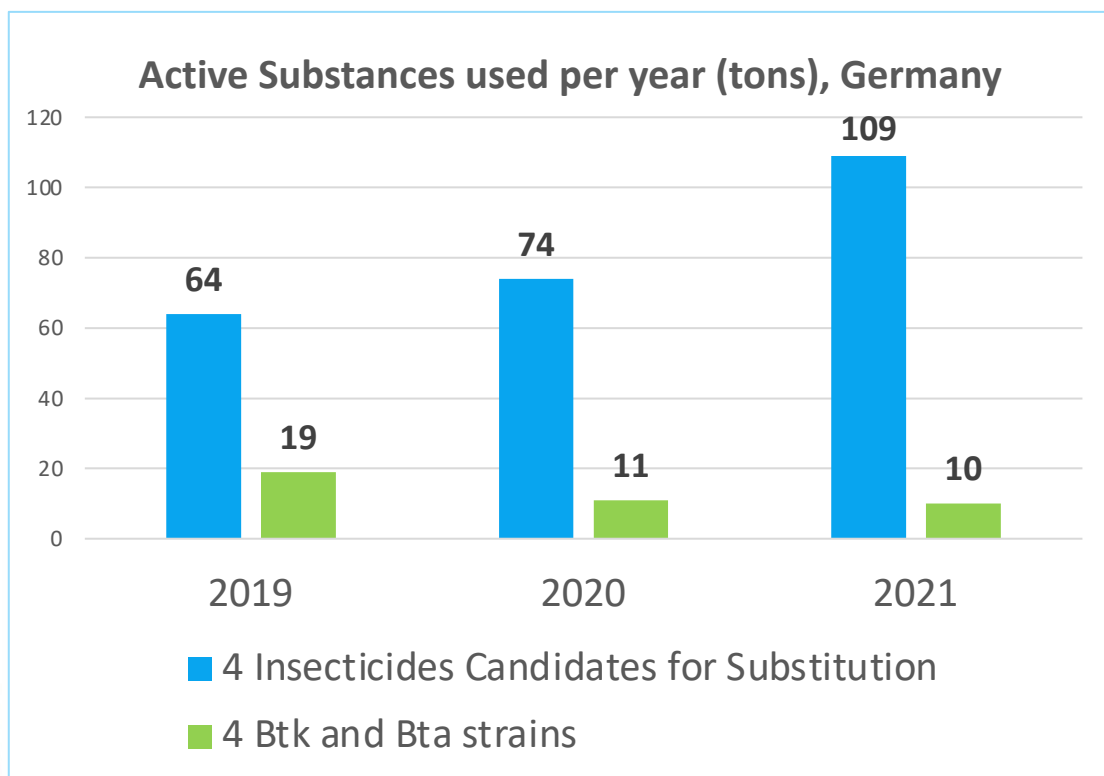
- ▶ In the 2021 Zoonoses report France started to track Norovirus more carefully resulting in dramatic increase in number of cases identified (43% of total EU cases) and coincidental reduction in Bc-related

# UNNECESSARY REGULATORY HURDLES HAVE DIRECT IMPACTS ON EU FOOD SECURITY

## E.g. PHI impact

Germany has PHIs in place for Bt strains and can be used as a forecast regarding the impact of PHIs on other MSs

Fruits & Veggies	Germany PHI (days)	France PHI (days)	Other MSs PHI (days)
Pome fruit/ Apple	5	3	0
Grapes	6	3	0
Solanaceae/ Tomato	3 to 7	3	0
Lettuce & fresh herbs	2 to 3	3	0
Cucurbits edible peel/ Cucumber	7	3	0
Leafy Brassica/ kale	9	3	0



### Impact of PHIs in Germany:

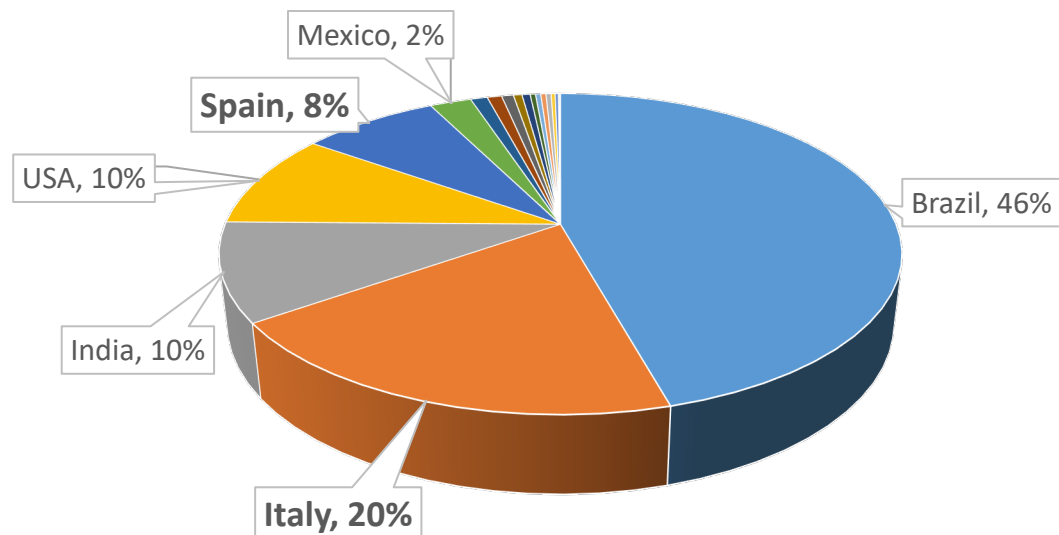
Reduction of Bt products year over year with increased tonnage of synthetic insecticides sprayed on the fields, including CfS (Candidates for Substitution) insecticides and Emergency uses.

**Source:** Data from the BVL Sales Quantities of Active Substances in Plant Protection Products from 1977 to 2021 (updated 2. December 2022)

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What is the alternative for Italy, Spain and The Netherlands?

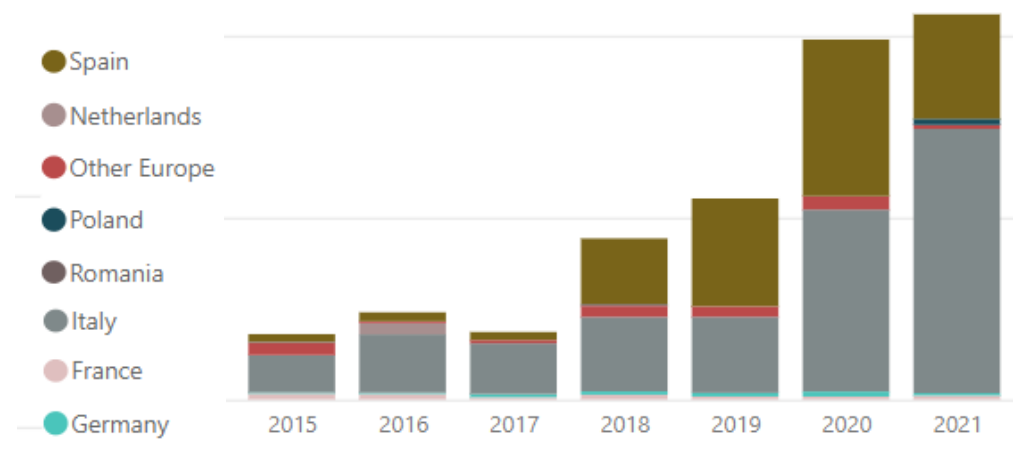
**Bt use (tons) in the World excl. China**



- Brazil
- Mexico
- Poland
- Pakistan
- Italy
- Argentina
- Colombia
- Germany
- India
- Thailand
- Indonesia
- Canada
- USA
- Chile
- Other Europe
- South Africa
- Spain
- Peru
- France

**EU use of Bt (tons) per Member State**

(Note: data from NL not yet available for 2021)

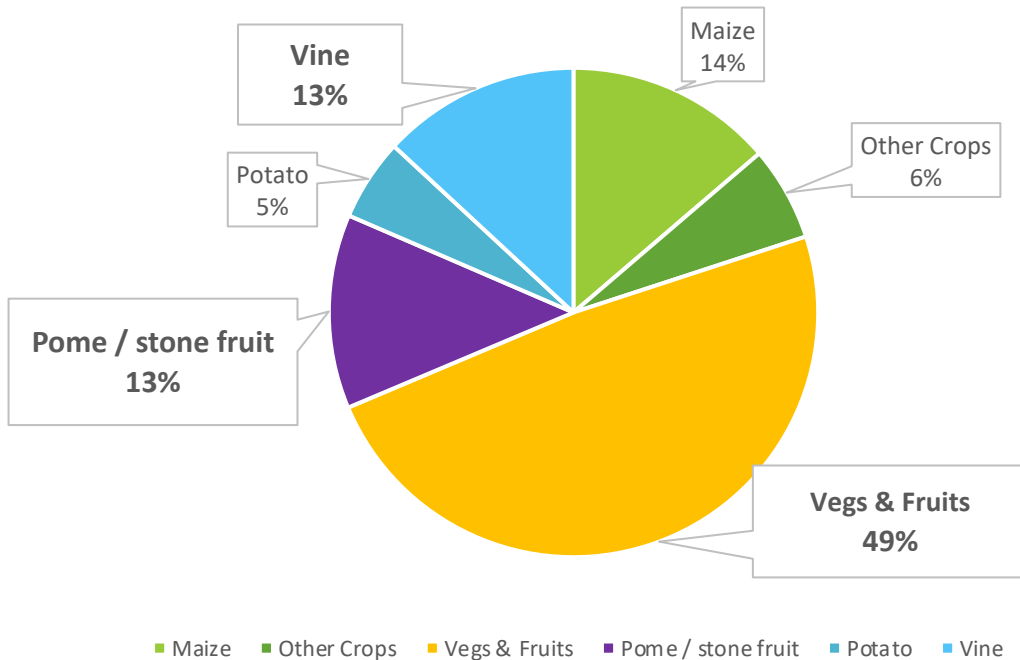


Source: Agbioinvestor database, accessed 20 Jan. 2023  
 (<https://agbioinvestor.com/agbioselect/>)

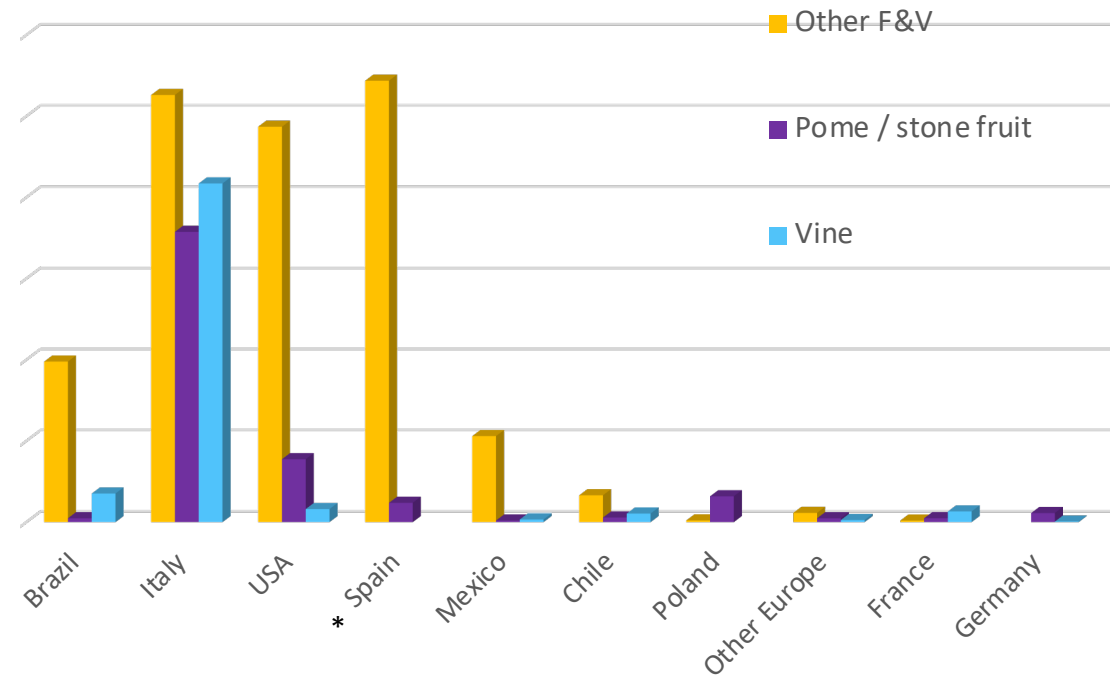
# UNNECESSARY REGULATORY HURDLES HAVE DIRECT IMPACTS ON EU FOOD SECURITY

## Where is Bt being used?

**Bt use per Crop Segment (World\*)**



**Bt Tons per Country and main Crop segment (excl. China)**



Bt use per country (tons) and the 3 main crop segments for Bt in Europe: Fruits & Vegetables, Pome/stone fruit and Vine.  
 (\*) Spain: data on Vines not available.

(\*) Word Bt use per crop (estimates 2021), excluding China, and excluding Soybean and Cotton.

Source: Agbioinvestor database, accessed 20 Jan. 2023  
 (<https://agbioinvestor.com/agbioselect/>)



# UNNECESSARY REGULATORY HURDLES HAVE DIRECT IMPACTS ON EU FOOD SECURITY

- Germany PHI implementation had direct consequences: growers stopped its use, reverting to CfS;
- Italy, Spain and the Netherlands are important producers of Vegetables in Europe and their growers will be directly impacted by PHI restriction (and Poland pome fruit);
- Nordic Countries have been shifting to biocontrol alternatives at a faster pace, high impact expected on growers as chemical alternatives have been phased-out;
- Wrong message to countries trying to operate the transition to sustainable solution (e.g. Poland, Romania).



# What to retain?

- Bt is essential for sustainable agriculture and works well with other tools, including chemicals, available to growers.
- Without Bt, there is no Farm2Fork as micro-organisms are the leading natural insecticides
- Studies with about a 1000 people directly exposed to Bt over 80 years, provides a weight of evidence that must be considered.
- PHIs are required only when toxicity is established, not based on speculative data on FBO, which cannot be attributed to an established cause, based on science. **Proof of a causality link is required.**
- Unnecessary PHIs would affect & reduce the availability of fresh fruits & vegetables treated with biocontrol solutions.