SUMITOMO CHEMICAL
AgroSolutions Division - International

VALENT BIOSCIENCES

Examining Nuances in Current EU Bt Regulation

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Creative Hybrid Chemistry

Three Core Considerations for EU Bt Regulation

1. Biopesticides as an essential part of the Farm to Fork strategy to achieve goals of the Europe Green Deal
2. Epidemiology of Bc infection and implications for commercial Bt strain
3. Need to support the food production industry with tools to provide safe, sustainable fresh fruits and vegetables

Bt Biopesticides are a Critical Tool to Achieve F2F Goals

Moving towards a more healthy and sustainable EU food system, a corner stone of the European Green Deal

- One of only a few widely used Organic crop protection tool for Organic agriculture (aspiring 25% target by 2030)
- A low risk pesticide option effective enough to replace alternatives in conventional Agriculture (target to reduce hazardous pesticide use 50% by 2030)

Historic Perspective to Decisions on the Regulation of Bt

2007 – EFSA Opinion on Bc establishes 10^5 cfu/g warning level

2011 – E. coli outbreak in DE affects ~4K people, 53 die

2012 – Food poisoning case in De implicates Commercial Bt

2015 – DGHM establishes 10^3 cfg/g Bc limit for mixed salads

Not specific to PPP strains

2016 – Bt re-registration submission within AIR-4

2016 – EFSA Opinion on Bt applied 10^5 cfu/g warning level to Bt

2020 – Expert meeting on Bt for re-registration

2020 – EFSA releases Opinions on commercial Bt as PPP

EFSA's Opinion on Bt Does not Account for Weight of Evidence of Safe Use of Commercial Bt Strains

- **EFS Expert Meeting held March 2020**
  - RMS for commercial Bt strains (NL, DK and others) agree that PPP strains should be considered a minimal risk to cause food poisoning
  - A small majority of experts disagreed and supported applying the presumptive Bc threshold 10^5 cfu/g to commercial Bt
  - Experts recommend spore decline curves for individual strains to establish pre-harvest intervals
- **EFSA Opinions on commercial Bt released starting October 2020**
  - Recommendation to apply presumptive Bc limits does not conform to EFSA regulation on PPP with respect to ARfD
  - Propose exclusion from Annex IV

IBMA Actively Supports Reasonable Regulation of Commercial Bt

- Microbial Professional Group Bacillus subgroup
- Meetings with Member States
- Workshop with Copa-Cogeca
- Support for COST 16110 projects on differentiation
- Letters to the EU Commission
- Q&A website on commercial Bt under development

COVID-19 has Taught Us All that Epidemiology is Tricky

	Food vehicle										
Bacillus cereus as first causative agent:	**Mixed**	**Other**	**Meat**	**Fish**	**Veg**	**Dairy products (other than cheeses)**	**Eggs**	**Crusta-ceans, products thereof**	**Sweets and chocolate + Cheese**	**Cereal**	**TOTAL**
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**
TOTAL	**43**	**130**	**55**	**9**	**13**	**2**	**10**	**4**	**-**	**1**	**267**

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. **90% of Bc cases reported for EU from France**

SURVEILLANCE DES TOXI-INFECTIONS ALIMENTAIRES COLLECTIVES (TIAC). DONNÉES DE LA DÉCLARATION OBLIGATOIRE, 2018

Point de janvier 2019

Comme les années précédentes, l'agent pathogène le plus fréquemment confirmé était *Salmonella* pour 35% des TIAC pour lesquelles un agent a été confirmé (30% en 2017). Les agents pathogènes les plus couramment suspectés, sur la base des informations épidémiologiques et cliniques, mais sans pouvoir être confirmé sur le plan microbiologique, étaient les agents toxiniques *Staphylococcus aureus, Clostridium perfringens* et *Bacillus cereus* correspondant à 70% des TIAC pour lesquelles un agent a été suspecté (74% en 2017). Aucun agent n'a pu être mis en évidence ni suspecté sur la base des informations épidémiologiques et cliniques dans 16% des TIAC déclarées (18% en 2017).

Limites des données

Un agent pathogène est suspecté en fonction de la durée d'incubation (durée entre la consommation et l'apparition des premiers symptômes), le type de symptômes et des aliments suspectés. Certains pathogènes ont des caractéristiques très proches en termes de durée d'incubation et de symptômes, notamment les agents toxiniques à durée d'incubation courte (entérotoxines de *Staphylococcus aureus* et toxines émétiques de *Bacillus cereus* par exemple) ou plus longue (toxines diarrhéiques de *Bacillus cereus* et *Clostridium perfringens*). Pour ces TIAC à agents toxiniques, les données sur l'agent en cause dans ce bilan doivent donc être interprétées avec précaution.

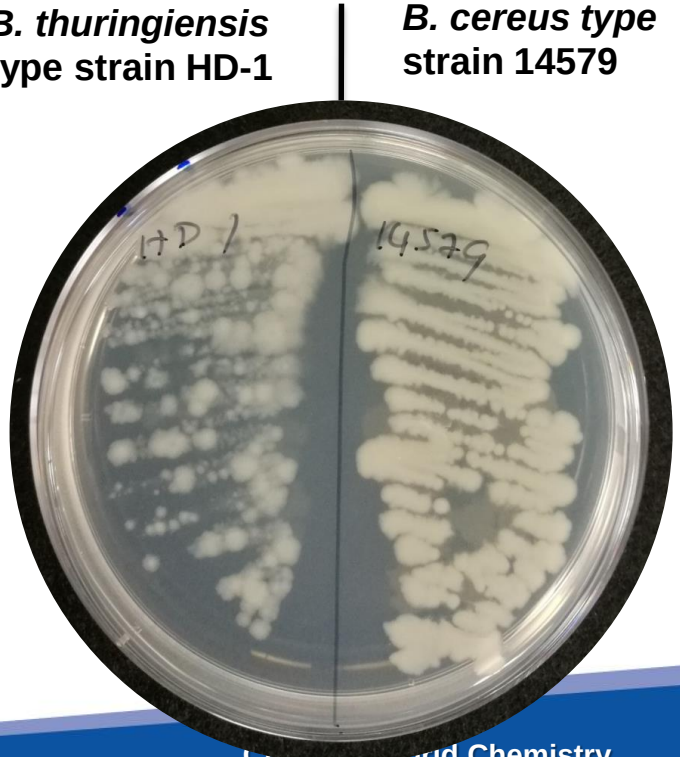
Establishing a Weight of Evidence (*OECD Doc no. 311*)

- A ***Hypothesis*** which involves a clear formulation and statement of the problem for which evidence is needed and possible alternative hypotheses.
- Be ***Systematic and Comprehensive*** in design by documenting a stepwise procedure integrating all evidence and indicating how evidence was collected, evaluated and weighed.
- Include a ***Treatment of Uncertainty*** arising from available data (knowns) and data and/or knowledge gaps (unknowns).
- Consider the ***Potential for Bias*** during collection, evaluation and weighing of evidence.
- Be ***Transparent*** by including clear documentation to assist the communication of WoE decisions so that they can be understood, reproduced, supported or questioned by all interested parties.

Food Producers Need the Right Tools to Meet Demand for Safe, Sustainable Fresh Produce

- Differentiating commercial Bt strains from presumptive Bc is necessary for food production, not within the scope of Regulation (EC) 1107/2009

- The Food Safety Industry and Microbial PPP Industry are parallel, cross infrequently
  - Food Safety testing needs to be a critical consideration for microbial biocontrol
  - Need to identify further opportunities for collaboration and education

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