



EFSA Opinion on Bt: Key points and recommendations

ABIM.
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Presentation overview

- General introduction:
 - Safety of Bt
 - Testing method for Bc

- Part 1: *B. thuringiensis*:
 - History of Bt use
 - Safety of commercial Bt
 - IBMA's support
 - The latest information ...

- Part 2: *B. cereus* testing:
 - Food safety testing carried out by the food value chain.
 - Overview of issues created by use of *Bacillus* biological control agents.
 - Details of IBMA activities.
 - The future.....

Two linked but separate issues

1. Questioning the safety of *Bacillus thuringiensis*.

Annex IV
(MRL exemption)
discussion ongoing.

2. Food safety testing accurately enumerating *Bacillus cereus*.

Problem: *B.t.* assumed to be responsible in alleged food poisoning event in DE resulted in EFSA mandate to review of *Bacillus* safety.

Problem: Differentiating *B.c.* from other *Bacillus*. Originating in IT, spreading to other EU countries.

Additional safety information provided during AIR4 re-registration.

B.cereus testing methods need to be improved.



Bacillus thuringiensis safety



History of use of Bt

- *Bacillus thuringiensis* subsp. *kurstaki* has been used and registered since the 1970s within Europe
 - Use for control of lepidopteran defoliating species in their larval stage
 - It is extremely effective and specific tool for the control of these pests in agriculture
 - Mode of action is from crystal toxins and spores which do not require germination
 - Commercial products contain no vegetative cells
 - Bt occurs ubiquitously in the environment as spores
- Since this time further Bts have been registered
 - *Bacillus thuringiensis* subsp. *israelensis* for control of dipteran culicidae species
 - *Bacillus thuringiensis* subsp. *tenebrionis* for control of coleopteran defoliating larvae
 - *Bacillus thuringiensis* subsp. *aizawai* for control of lepidopteran defoliators

Bt is the most used commercial biocontrol product worldwide

Safety of commercial use of Bt

- There have been questions for a number of years as to how to differentiate Bt from the potential food poisoning agent *Bacillus cereus*
 - This came to a head after a German family suffered from food poisoning in August 2012
 - Standard epidemiology was not followed
 - Bt spores were found on the lettuce from the same production
 - They concluded that Bt was the cause of the food poisoning
- EU COM mandates EFSA for an opinion on the safety of Bt on food in 2015
- This situation was brought up to IBMA as it concerned a number of Bt producers
- Limitation to Bt use for foods imported to Germany resulted from this case of food poisoning

There have been **no confirmed adverse effects** with any of the commercial strains of Bt on humans, animals or the environment

IBMA's support

- EFSA contacted IBMA to respond to a number of their questions
 - IBMA contacted the Bt producers
 - A meeting was held in Parma in January 2016
 - A Bt producer response was provided to general questions
 - Companies also provided confidential responses based on their specific data
- EFSA published their opinion in July 2016
 - Pathogenicity was strain dependent
- A Bt industry task force was created to work through these issues
 - Written response within two weeks to the EFSA opinion sent to the EU Com from IBMA
 - EU Com granted a meeting in September 2016
 - Meetings were granted by some member state authorities
 - EU Com confirmed that no position on MRL/Annex IV would be taken prior to the outcome of each active substance renewal

The latest information...

- Active substance renewal dossiers were submitted in October 2016.
 - Btk strains to Denmark
 - Bta strains to Netherlands
 - Bti strain AM65-52 to Sweden
 - Btt strain NB176 was not defended
- Awaiting the outcome of the evaluation towards end 2017 or early 2018





Bacillus cereus testing



Food safety testing

- Food to be consumed has to be tested for its safety.
 - Includes microbiological contamination testing with acceptable cut-off limits.
 - *Bacillus cereus* is one pathogen regularly screened. Some strains cause human illness.
 - Limits set can vary between MS (e.g. *B.c.* max 1,000 – 100,000 cfu/g)
- This is often by independent testing laboratories (e.g. Campden BRI and WFC).
- Testing laboratories are required to use internationally recognised methods (e.g. ISO).
- Protocols have to be simple, fast (short shelf life of fresh produce), give definitive answers with no interpretation required reproducible require low skill,
- Food safety testing is not moving at the same pace as our industry.

Issues faced by *Bacillus* biocontrol

- Testing laboratories use ISO methods to enumerate *B. cereus*.
- Current ISO 7932:2004 method is a presumptive test, assuming that a colony which grows in the test is *B.cereus*.
 - MYP (Mannitol Yolk Polymyxin) Agar is used.
 - However, other *Bacillus* also grow on this agar media.
- If a farmer has applied a *Bacillus* biocontrol agent near to harvest, a post-harvest assessment of crop with ISO 7932:2004 will show a high number of colonies on the agar.
- Conclusion is made high presumptive *B. cereus* and produce is not fit for human consumption.
- The presumptive result could be interpreted as due to recent *Bacillus* application, but does not rule out an underlying *B. cereus* population hidden by the *Bacillus* application.



Other *Bacillus* species
grow and halo on MYP

B. cereus

B. weihenstephanensis

B. thuringiensis

How is IBMA responding to this?

- IBMA Project team setup - IBMA needs to take ownership of this to drive change within the food safety testing industry.
- Regular project team meetings.
- *Bacillus thuringiensis* manufacturers have ongoing activities as part of AIR 4 re-registrations.
- Discussions with key food safety testing laboratories.
- Invited participant of COST Action 16110 “Control of Human Pathogenic Microorganisms in Plant Production Systems”.
- Workshop with stakeholders in the food value chain.

How is IBMA responding to this?

- Held at Copa Cogeca, Brussels, BE. 28th March 2017.
- Attended by representatives from manufacturers, growers, food processors, food safety testing laboratories and regulatory authorities.



- More information is available [click here](#).

The future...

- To ensure change, IBMA needs to remain a driving force on this issue.

	ISO 7932:2004 (currently used)	Selective agar	Positive crystal identification	qPCR for Bc	qPCR for commercial Bt strains	<i>ces</i> gene identification
Time	18-24 hrs	18-24 hrs	Up to 5 days	36-96 hrs	36-96 hrs	36-96 hrs
+ ve	Low technology	Low technology	Low technology	Species specific	Commercial Bt excluded	Commercial Bt excluded
- ve	Not Bc group specific	Still includes Bt	Estimate % as Bt, Variability in count	High technology, Unknown Bc genes	High technology, Bt strain primers	High technology

- Actively participate in COST Action with the aim of identifying pathogenic factors in *B. cereus* and testing methods for these.
- Follow-up cross-industry workshops.

Ultimate objective: An adoptable accurate, cheap and repeatable food safety testing method which excludes biological control products.



Any questions?

Thank you for your
attention

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