European Biostimulants Industry Council

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EBIC POSITION PAPER

Setting tolerances for analytical methods regarding biostimulant content

EXECUTIVE SUMMARY

- Regardless of which analytical methods are used, it is virtually impossible to perfectly replicate results. In addition, some variation in composition is normal in product quality, regardless of the production process. Therefore, a certain level of deviation from declared quantities must be tolerated in practice. These tolerances need to be defined in such a way as to be practical and meaningful.
- For micro-organisms, it is more meaningful to declare minimum potency rather than minimum content.
- Because of the inherent variability in UVCB substances/products, producers should not be subject to tolerances per se. Instead, they should be required to specify minimum and (where relevant) maximum values (with units) and ranges should be based on a realistic knowledge of production batches and not be overly broad. Tolerances should then be applied to the specific methods used to determine those minimums and maximums.
- For other biostimulant substances, rules for tolerances should take inspiration from Commission regulation (EU) n° 939/2010 of 20 October 2010 amending Annex IV to Regulation (EC) No 767/2009 on permitted tolerances for the compositional labelling of feed materials or compound feed as referred to in Article 11(5).

Keywords: tolerances, analytical methods, UVCB, micro-organisms

I. INTRODUCTION

- Regardless of which analytical methods are used, it is virtually impossible to perfectly replicate results. In addition, some variation in composition is normal in product quality, regardless of the production process. Therefore, a certain level of deviation from declared quantities must be tolerated in practice. These tolerances need to be defined in such a way as to be practical and meaningful.
- As well as well-known and well-defined chemical substances, tolerances for biostimulants need to be appropriate for:
    - micro-organisms;
    - UVCB substances as acknowledged by the REACH framework.
- Different fertilising material sectors should face similar constraints regarding tolerances (i.e. no subsector should have significantly stricter tolerances than the others), while taking into account the practical realities of the materials in each type of product.
- Tolerances applied should avoid situations where a small change in content creates a large jump in the tolerated range.

II. TOLERANCES FOR MICRO-ORGANISMS

> *Fundamental Principle:* ***Minimum content is not a meaningful concept with regard to micro-organisms. Instead, a declaration of minimum potency is more useful.***

- The very nature of micro-organisms makes it difficult to apply tolerances around a fixed value of minimum content, and the methodologies used to test minimum content of substances within tolerated ranges are not effective when evaluating the potency of micro-organisms. (Indeed, the presence of micro-organisms alone is not sufficient if they have perished.)
- The key issue is to **determine a minimum potency that will allow the micro-organisms to be effective once applied.** Therefore, manufacturers should be required to report the minimum guaranteed potency throughout the shelf life of the product (as declared on the label or package). That guaranteed minimum must take into account batch-to-batch variations and other aspects of industrial production of microbial products in order to be respected in all cases.

III. TOLERANCES FOR UCVB SUBSTANCES/PRODUCTS

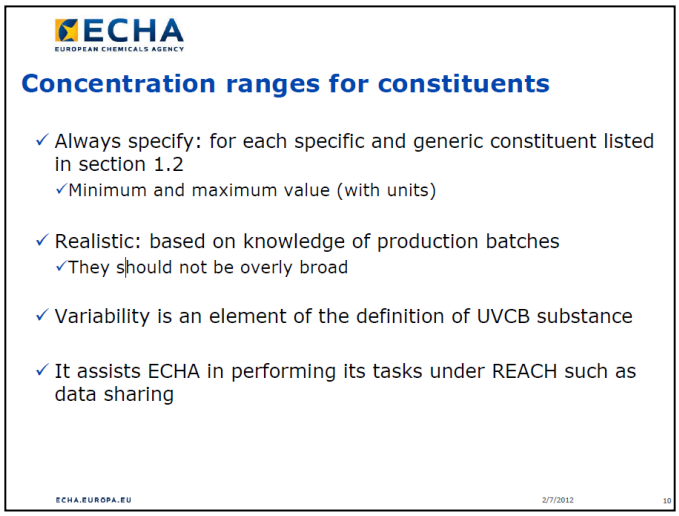
> *Fundamental Principle:* ***Because of the inherent variability in UVCB substances/products, producers should be required to specify minimum and maximum values (with units) and ranges should be based on a realistic knowledge of production batches and not be overly broad.***

Many biostimulants (plant, seaweed extract, humates, etc.) are considered "Unknown or Variable Composition, Complex Reaction Products, or Biological material (UVCB)" as defined by the REACH framework.

UVCBs are inherently variable and when methods and lab variances are added to the mix the issue of tolerances needs careful consideration to avoid future problems.

Tolerances can only really be considered when methods are agreed and evaluated for reproductability and accuracy. Establishing a methods manual for analytical methods is the first step. Once the methods are agreed, the reproductability and accuracy across a number of labs should be ascertained. This information will then inform the tolerances.

We need to place equal importance on the methods used for Quality Control and Quality Assurance (QC/QA) as we do on product QC/QA themselves. Proposing tolerances without first defining the methods and establishing reproductability and accuracy factors could result in unworkable tolerances which in turn will discredit biostimulant products and even the sector as a whole.



- ECHA notes that a UVCB substance/product cannot be sufficiently identified by its chemical composition, because:
  - The number of constituents is relatively large and/or
  - The composition is, to a significant part, unknown and/or
  - The variability of composition is relatively large or poorly predictable.
- ECHA says that because of the inherent variability in UVCB substances/products, registrants should specify minimum and maximum values (with units), but that ranges should be based on a realistic knowledge of production batches and not be overly broad (See figure on the left).

IV. TOLERANCES FOR OTHER BIOSTIMULANT SUBSTANCES/PRODUCTS

> ⊙ *Fundamental Principle: Rules for tolerances of other biostimulant substances should take inspiration from Commission regulation (EU) n° 939/2010 of 20 October 2010 amending Annex IV to Regulation (EC) No 767/2009 on permitted tolerances for the compositional labelling of feed materials or compound feed as referred to in Article 11(5).*

- To simplify the tolerances for plant biostimulants while ensuring reasonable requirements and preventing the "step function" problems created by some approaches (such as the FAO specifications for tolerances applied to pesticides), we propose adapting the approach used for the feed materials in the Commission regulation (EU) n° 939/2010 of 20 October 2010 amending Annex IV to Regulation (EC) No 767/2009 on permitted tolerances for the compositional labelling of feed materials or compound feed as referred to in Article 11(5) and summarized in the table and figure below.

Declared content	***Tolerance***	***Example***	
		Declared content	***Tolerance***
< 0,5 units*	40 %	0,4 units	± 0,16 units
≥ 0,5 units and < 1 unit	0,2 units	0,8 units	± 0,2 units
≥ 1 unit and < 500 units	20 %	40 units	± 8 units
≥ 500 units and < 1000 units	100 units	800 units	± 100 units
≥ 1000 units	10 %	4000 units	± 400 units

** 1 unit in this point means 1 g, 1 000 IU, or 100 enzyme activity units of the respective active constituent per kg or L plant biostimulant, as appropriate.*