



Bayer CropScience

# **Executive Summary**

## **Legal Opinion on the Implementation of Article 49 (4) of Regulation (EC) 1107/2009**

**Dr. Regine Gerards**

**BCS AG-Business Planning & Administration-Law & Patents**

# Overview: Labeling Requirements under the future legal regime

---

## ☐ **Labeling requirements for Plant Protection Products (“PPP”)**

- Article 65 Regulation 1107/2009 - refers to Article 16 and Annexes IV and V of Directive 91/414
- EU legislation on chemical substances, e.g. currently Directive 1999/45 and Directive 67/548 or Regulation 1272/2008 in future (2015)

## ☐ **Labeling requirements for treated seeds**

- Article 49 Regulation 1107/2009
- EU legislation on seeds (e.g. Directive 2002/55/EC; Directive 2001/57/EC; Directive 66/401/EEC; Directive 66/402/EEC)
- No labeling requirement under EU legislation on chemical substances as (treated) seeds can not be classified as „substances“ or „mixtures“

# Interpretation of Article 49 (4) of Regulation 1107/2009

---

**Question:** Interpretation of the reference to “*standard phrases for safety precautions as provided for in Directive 199/45/EC*”

- Reference to safety issues that were introduced by Directive 1999/45 in conjunction with Directive 67/548
- S-Phrases relate to treated seeds and not to the corresponding PPP

# Interpretation of Article 49 (4) of Regulation 1107/2009

**Question:** How can the scheme of S-Phrases be applied for treated seed?

- Formal approach:
  - ☐ S-phrases based on the criteria of Annex VI to Directive 67/548, and in addition according to the rules of Directive 1999/45
  - ☐ S-Phrases listed in Annex IV to Directive 67/548
- There are good arguments to oppose such formal approach:
  - ☐ Unclear wording of Article 49 (4) of Regulation 1107/2009
  - ☐ S-phrases listed in Directive 67/548 and Directive 1999/45 do not fit for the evaluation and classification of treated seed
- ☐ **Therefore, alternative approach can be chosen: Development of generic set of S-phrases**

# Interpretation of Article 49 (4) of Regulation 1107/2009

---

**Question:** Interpretation of the reference to “*risk mitigation measures set out in the authorization for that product where appropriate*” and “*the label and documents accompanying the treated seeds shall include*”

- Reference to authorization of PPP
- But, label and accompanying documents have to set out only those *risk mitigation measures* which are relevant with regard to treated seed

# Interpretation of Article 49 (4) of Regulation 1107/2009

---

**Question:** How must the labeling requirement of Article 49 (4) of Regulation 1107/2009 be fulfilled?

- **Risk mitigation measures:**

- ☐ Risk mitigation measure have to be included on the label and the accompanying document

- **S-phrases:**

- ☐ S-phrases required under Article 49 (4) – have to be included on the label as well as in the documents
- ☐ S-phrases not required under Article 49 (4) – possibility to choose between label and documents accompanying the treated seed

# Interpretation of Article 80 (6) of Regulation 1107/2009

---

**Question:** Does Article 80 (6) Regulation 1107/2009 applies also to seeds treated with PPP?

**Con:**

- Wording
- Legal systematic
- Purpose and function of Article 89 (6)

**Pro:**

- Principle of equal treatment

