

LEGAL OPINION
ON THE IMPLEMENTATION OF ARTICLE 49(4) OF REGULATION (EC) No.
1107/2009
APRIL 5, 2011

A.
Issues to be addressed

On October 21st, 2009, the EU adopted Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (“**Regulation 1107/2009**”), which replaces Directive 91/414/EEC concerning the placing of plant protection products on the market (“**Directive 91/414**”).

Our legal advice has been requested with respect to the implementation of the labelling requirements of Regulation 1107/2009 when seeds treated with plant protection products are placed on the market. Several questions arose regarding the labelling and documentation accompanying treated seeds. STISSC developed approaches to deal with those issues.

1. Regarding the labelling of seeds, Article 49(4) of Regulation 1107/2009 provides that the label and documents accompanying the treated seeds shall include, inter alia, “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*“. Since neither Directive 1999/45/EC nor Regulation (EC) No. 1272/2008 explicitly refer to the text “*standard phrases for safety precautions*”, the STISSC developed a generic set of standard phrases for safety precautions and risk mitigations which, in the experience of industry, shall depict “best practice” and address the risks for both the user and the environment from seeds treated with plant protection products. We were asked if this approach is compatible with the requirements of Article 49(4) of Regulation 1107/2009.
2. Furthermore, we were asked to review if such safety precautions and risk mitigations can – alternatively – be printed on seed bags or be provided on the documents accompanying the treated seeds.

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3. If Member States define specific risk mitigation measures which are relevant for treated seeds and which would not be part of the generic set of safety precautions in their authorization for the plant protection products, then it shall be assessed whether it is acceptable to include such risk mitigation measures solely in the documents accompanying the treated seeds.
4. Since treated seeds are not the plant protection products applied on seeds (usually a plant protection product contains a higher concentration of the active substance), STISSC does not consider it appropriate and/or necessary to include additional hazard or safety information related to the plant protection product used to treat those seeds in labels and documentation accompanying treated seeds. We were asked to examine the acceptability of this approach.
5. Finally, we were asked to review if Article 80(6) of Regulation 1107/2009 can be interpreted to include seeds treated with plant protection products, thereby allowing more time for compliance with the labelling requirements.

B. Legal Analysis

The legal analysis will start with a brief description of the relevant legal framework for labelling in the specific area (**cf. I.**). Then, the questions concerning the interpretation of Regulation 1107/2009 are answered, and the compatibility of the proposed approaches with said Regulation is assessed. We will distinguish between an interpretation of Article 49(4) of Regulation 1107/2009 (**cf. II.**) and of Article 80(6) of Regulation 1107/2009 (**cf. III.**) in this respect.

I. Labelling requirements under the EU legislation

Labelling requirements in the area of plant protection were already adopted under Directive 91/414 (**cf. 1.**). Those requirements were then modified when the EU enacted Regulation 1107/2009 (**cf. 2.**). In addition, labelling requirements result from the general EU legislation on chemical substances which also underwent major amendments in the recent past (**cf. 3.**). Finally, specific labelling requirements exist under the EU legislation on seeds (**cf. 4.**).

It needs to be emphasized that the transition from the old to the new regime (with regard to the plant protection legislation, but also the general legislation on chemical substances) not only modified the substantive requirements, but also exchanged the means by which the EU acted: While the former legislation used directives (Article 288(3) of the Treaty on the Functioning of the European Union, TFEU), the new regime now uses regulations (Article 288(2) of the TFEU) which are directly applicable in all Member States, and thus do not have to be transformed into national law by the

Member States. As a consequence, the seed industry has to comply directly with the labelling requirements as they are provided in Regulation 1107/2009.

1. Labeling requirements under Directive 91/414

Under the old regime (Directive 91/414), labelling requirements were only adopted for plant protection products (**cf. a**)), but not for seeds treated with plant protection products (**cf. b**)).

a) Labelling requirements for plant protection products

Article 16 of Directive 91/414 contains the labelling requirements for plant protection products. Pursuant to Article 16(1), all packaging must show, inter alia, the trade name or designation of the plant protection product, the name and address of the holder of the authorization and the authorization number of the plant protection product, the name and amount of each active substance, the nature of any special risks for humans, animals or the environment by means of appropriate standard phrases as provided in Annex IV, and safety precautions for the protection of humans, animals or the environment in the form of standard phrases selected as appropriate from those given in Annex V. **Annex IV to Directive 91/414** contains standard phrases for special risks for humans or the environment. **Annex V to Directive 91/414** lists standard phrases for safety precautions for the protection of humans or the environment.

b) Labelling requirements for treated seeds

In contrast to the labelling of a plant protection product itself, the **basic texts of Directive 91/414/EEC and its Annexes** do not contain any specific labelling provisions for seeds treated with plant protection products: Article 16 of Directive 91/414 does not apply, because that provision deals solely with the labelling of the packaging of the plant protection product itself. Annexes IV and V to Directive 91/414 are also inapplicable because both Annexes only contain specifications (in the form of standard phrases) for the labelling of plant protection products pursuant to Article 16.

However, specific labelling requirements for seeds can be found, in part, in **Annex I to Directive 91/414**, which lists the active substances authorized for use in plant protection products. Under Directive 91/414, the authorization of an active substance and its inclusion in Annex I may be subject to requirements which are listed as specific provisions in the last column of Annex I for the particular active substance. For example, specific provisions deal with the use of Clothianidin (CAS No 210880-92-5), listed under No. 123 of Annex I, as a seed treatment (e.g. that the seed coating shall only be performed in professional seed treatment facilities). Regarding labelling, Annex I No. 123 states that the Member States shall ensure that “[...] *the label of the treated seed includes the indication that the seeds were treated with Clothianidin and sets out the risk mitigation measures provided for in the authorization*”.

2. Labelling requirements under Regulation 1107/2009

a) Labelling requirements for plant protection products

Under Regulation 1107/2009 the labelling requirements for plant protection products are stipulated by Article 65. **Article 65 of Regulation 1107/2009** refers to the former scheme of labelling established under Directive 91/414 which shall be incorporated into a new **Regulation containing the requirements of the labelling of plant protection products**. That new Regulation shall contain the text of Article 16 of Directive 91/414 as well as the text of Annexes IV and V of Directive 91/414. Pursuant to Article 84(e) of Regulation 1107/2009 the new Regulation shall be adopted by 14 June 2011.

b) Labelling requirements for treated seeds

In contrast to Directive 91/414, Regulation 1107/2009 contains specific requirements for seeds treated with plant protection products. The rationale is explained in **recital 33 of Regulation 1107/2009**: “*Community seeds legislation provides for free movement of seeds within the Community but does not contain a specific provision concerning seeds treated with plant protection products. Such a provision should therefore be included in this Regulation*”.

Against this background, **Article 49 of Regulation 1107/2009** contains specific conditions for the placing on the market of treated seeds. One feature is the labelling requirement, laid down in paragraph 4 of Article 49 which will be discussed in detail below (**cf. B.II.**).

Besides the labelling requirements of Article 49(4) of Regulation 1107/2009, requirements for the labelling of treated seed may be set out, as described under B.I.1.b), in the **authorization of a particular active substance** which lead to an Annex I inclusion under Directive 91/414.

For the sake of completeness, it shall be noted that Article 65 of Regulation 1107/2009 and the upcoming Regulation containing the requirements of the labelling of plant protection products do not apply for treated seeds. For Article 65 and the upcoming Regulation only apply to a plant protection product on its own. In respect of treated seeds Article 49(4) of Regulation 1107/2009 contains a specific labelling requirement, which is *lex specialis* to Article 65 and the upcoming Regulation.

3. Labelling requirements under the general EU legislation on chemical substances

a) Labelling requirements for plant protection products

In addition to the labelling obligations under the EU legislation regarding plant protection products, plant protection products must be labelled in accordance with the requirements resulting from the general EU legislation on chemical substances,

essentially under Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (“**Directive 1999/45**”)¹.

As a general principle of Directive 1999/45, the labelling of preparations shall be applied in accordance with the criteria laid down in Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (“**Directive 67/548**”), save where special provisions of Directive 1999/45 apply (Art. 4(2) of Directive 1999/45). In particular, Article 10 of Directive 1999/45 contains requirements for an adequate labelling, inter alia, by marking not only the trade name or designation of the preparation and the chemical name of the substance or substances present in the preparation on the package, but also by giving the following information: the danger symbols and indications of danger (Article 10 (2.4) of Directive 1999/45), the risk phrases (R phrases) (Article 10 (2.5) of Directive 1999/45) and the so called safety advice (S phrases). In respect of the safety advice Article 10 (2.6) of Directive 1999/45 states:

“The indications giving safety advice (S phrases) shall comply with the wording in Annex IV and with Annex VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II and III to this Directive”.

Directive 67/548 defines the S-phrases as “*standard phrases relating to the safe use of the substance*” (cf. Article 23(1)(e) of Directive 67/548), while the wording of the S-phrases used for labelling has to comply with that laid down in Annex IV to Directive 67/548, e.g. S2 “Keep out of the reach of children”. Annex VI to Directive 67/548 provides under No. 6 general criteria on how S-phrases are assigned to classified dangerous substances and preparations. In addition, Annex VI, no. 6.1 of Directive 67/548 provides that for certain preparations, the safety advice listed in Annex V of Directive 1999/45/EC is mandatory.

The basics of this concept will not change under Regulation (EC) No. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (“**Regulation 1272/2008**”). Also, Regulation 1272/2008 requires the labelling of dangerous preparations (in the wording of Regulation 1272/2008: “hazardous mixtures”) and provides for the rules of labelling (cf. Article 17 of Regulation

¹ Pursuant to Article 1(4) of Directive 1999/45, the articles on labelling of this Directive shall also apply to plant protection products. Article 65 of Regulation 1107/2009 provides that the labelling requirements of Directive 1999/45 shall be complied with (cf. furthermore recital 42 of Regulation 1107/2009).

1272/2008). One component is labelling with the so called precautionary statements, which shall replace the former S-phrases. Pursuant to Article 3 No. 6 of Regulation 1272/2008 a precautionary statement

“means a phrase that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal”.

Article 17 of Regulation 1272/2008 provides that a mixture classified as hazardous and contained in packaging shall bear a label including, inter alia, where applicable, the appropriate precautionary statements in accordance with Article 22 of Regulation 1272/2008. Pursuant to Article 22, the precautionary statements for the label shall be selected from those set out in the tables in Parts 2 to 5 of Annex I, selected in accordance with the criteria laid down in Part 1 of Annex IV, and be worded in accordance with Part 2 of Annex IV (e.g. P102 “Keep out of reach of children”).

Regulation 1272/2008 shall modify and replace Directive 67/548 and Directive 1999/45. However, Regulation 1272/2008 contains a transitional period for preparations (mixtures) which runs until June 1st 2015. Until this deadline preparations (mixtures) can be still labelled under the labelling scheme of Directive 1999/45, but – as an option – can already be labelled according to Regulation 1272/2008. After June 1st 2015 preparations (mixtures) must be labelled as provided by Regulation 1272/2008².

b) Labelling requirements for treated seeds

The aforementioned labelling requirements under the EU legislation on chemical substances would apply if treated seeds are to be considered substances or preparations/mixtures in the meaning of the respective legal acts. Article 2(7) of Regulation 1272/2008 defines a “substance” as

“a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.

² This results from the following provisions of Regulation 1272/2008: Article 62 dealing with the entry into force states that, inter alia, title III which contains the labeling requirements shall apply in respect of mixtures from 1 June 2015. Article 61(1) provides that, until 1 June 2015, mixtures shall be labelled in accordance with Directive 1999/45/EC. However, pursuant to Article 61(2), by way of derogation from Article 62 mixtures may, before 1 June 2015, be labelled in accordance with Regulation 1272/2008. In that case, the provisions on labelling in Directives 67/548/EEC and 1999/45/EC shall not apply.

Pursuant to Article 2(8) of Regulation 1272/2008 a “mixture”

“means a mixture or solution composed of two or more substances”.

Similar definitions can be found in Directive 1999/45 (cf. Article 2(1)(a), (b)) and Directive 67/548 (cf. Article 2(1)(a), (b)) in respect of “substances” and “preparations”.

Seeds can be classed as small embryonic plants which are produced by the mother plant and develop themselves into plants. Thus, seeds have to be regarded as natural organisms that are structured into different parts and which perform complex biological functions. On this basis, seeds are far more than just chemical elements or its compounds, but rather have to be considered as complex natural organisms. Thus, seeds cannot be regarded as substances within the meaning of Article 2(7) of Regulation 1272/2008. Seeds are also not preparations/mixtures in the meaning of Article 2(8) of Regulation 1272/2008 as seeds are not simply a physical combination of substances³.

This assessment does not change if seeds are treated with plant protection products. While it is clear, that substances extracted from seeds (e.g. seeds oil) may be considered as substances, it is not a comparable degree of processing, if seeds just undergo treatment with plant protection products. Treated seeds are then still complex natural organisms which do not fulfill the criteria of a substance or a preparation/mixture in the meaning of EU Chemicals Law.

It has to be noted that the aforementioned view is not undisputed. In particular, in respect of the REACH Regulation it was discussed whether plants or other natural organisms can be regarded as a substance, preparation or an article and, thus, fall under the scope of the REACH Regulation (which contains the same definition of “substances” and “mixtures” as Regulation 1272/2008, cf. Art. 3(1), (2) of the REACH Regulation). In its current guidance on Annex V of REACH (cf. page 20), the European Chemicals Agency notes *“that whole living or unprocessed dead organisms (e.g. yeast (see Attachment 2), freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers etc.) are not considered as substances, preparations or articles in the sense of REACH and are therefore outside of the scope of REACH”*. However, Germany is of the opinion that this interpretation is not in line with the definitions as given in the REACH Regulation and refers to Article 3(39) of the REACH Regulation dealing with *“substances which occur in nature”*.

In our opinion, there are strong arguments that treated seeds are neither substances nor preparations (mixtures) in the meaning of the EU legislation on chemical substances. Thus, in our view, the labelling requirements under the EU legislation on chemical substances do not apply for treated seeds.

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Furthermore, seeds are also not articles as they are not manufactured objects.

4. Labelling requirements under the EU legislation on seeds

The EU also enacted an extensive legislation in respect of seeds. The respective legal acts and their content shall not be described here comprehensively. Yet, it shall be pointed out that the EU legislation on seeds (as well as the implementing law of the Member States) contains **specific labelling requirements**⁴. Examples are: Articles 28 et seq. and Annex IV of Directive 2002/55/EC on the marketing of vegetable seed, Articles 12 et seq. and Annex IV of Directive 2002/57/EC on the marketing of seed of oil and fibre plants, Articles 10 et seq. and Annex IV of Directive 66/401/EEC on the marketing of fodder plant seed as well as Articles 10 et seq. and Annex IV of Directive 66/402/EEC on the marketing of cereal seed.

In particular, **any chemical treatment of seed** has to be noted on the label and on the package or inside it (cf. Article 32 et seq. of Directive 2002/55/EC; Article 15 of Council Directive 2002/57/EC; Article 12 of Directive 66/401/EEC; Article 12 of Directive 66/402/EEC). On this basis, it is possible that the Member States require in their national legislation on seeds a labelling of seeds which were treated with plant protection products, e.g. by providing the designation and the authorization number on the label. One example is § 32 of the German *Saatgutverordnung*⁵ which provides:

„Ist Saatgut einer chemischen, besonderen physikalischen oder gleichartigen Behandlung unterzogen worden, so ist dies anzugeben. Ist dabei ein Pflanzenschutzmittel angewendet worden, so ist dessen Bezeichnung und die Zulassungsnummer anzugeben; anstelle der Bezeichnung und der Zulassungsnummer kann der Wirkstoff oder dessen Kurzbezeichnung angegeben werden. Die Angaben sind unverwischbar aufzudrucken

- 1. auf dem Etikett und, falls ein Einleger erforderlich ist, auf dem Einleger,*
- 2. auf einem Zusatzetikett und, falls es nicht aus reißfestem Material besteht, auf dem Einleger oder einem zusätzlichen Einleger oder*
- 3. auf einem Klebeetikett oder im Aufdrucketikett.“*

II. Interpretation of Article 49(4) of Regulation 1107/2009

The issues listed under A.1.-4. are related to Article 49(4) of Regulation 1107/2009 which states:

„Without prejudice to other Community legislation concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety

⁴ In Germany, the *Saatgutverkehrsgesetz* authorizes the Government to enact specific labelling requirements for seeds. One respective decree is the German *Saatgutverordnung*.

⁵ A similar provision can be found in § 26 of the German *Pflanzkartoffelverordnung*.

precautions as provided for in Directive 1999/45/EC and risk mitigation measures set out in the authorisation for that product where appropriate. “.

1. The reference to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*”

Article 49 (4) of Regulation 1107/2009 requires that the label and documents accompanying the treated seeds include, inter alia, “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*”. Although it is clear that the European Legislator wanted to implement a specific labelling requirement for treated seeds, it is not clear how this obligation shall be fulfilled with respect to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*”. For neither Directive 1999/45/EC nor Directive 67/548 nor Regulation 1272/2008 explicitly refer to the text “*standard phrases for safety precautions*”: Directive 1999/45 refers to “*indications giving safety advice (S phrases)*”, Directive 67/548 defines the S-phrases as “*standard phrases relating to the safe use of the substance*”, Regulation 1272/2008 contains “*precautionary statements*”.

In this regard, it is important to keep in mind that no performance of duties can be required if a clear interpretation of legal obligation cannot be reached. A reference to a legal act within another can therefore be useless if the respective legal act does not contain the appropriate terminology as cited by the referring legal act⁶. In this case, Article 49 (4) of Regulation 1107/2009 refers to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” and therefore to terms which are not explicitly used in Directive 1999/45/EC (as well as in Directive 67/548 and Regulation 1272/2008).

Although the term “*standard phrases for safety precautions*” is not directly mentioned in Directive 1999/45, it seems reasonable that the European Legislator meant to refer to the phrasing in respect of safety issues which was introduced by Directive 1999/45 in conjunction with Directive 67/548. Even though the Directives use a different wording (“*indications giving safety advice (S phrases)*”, “*standard phrases relating to the safe use of the substance*”), the European Legislator obviously planned to refer to such regulatory scheme when enacting Article 49(4) of Regulation 1107/2009. For it is always the same issue, i.e.: which kind of labelling is appropriate for advising the user on how a specific substance or product can be handled and used safely. Also, the introductory remarks of Annex V to Directive 91/414 assume that there shall be standard phrases in Directive 1999/45 in respect of safety.

⁶ A reference to a legal act within another may also be useless if the cited legal act no longer exists; which is not the case here, because Directive 1999/45 remains effective despite the issuance of the Regulation 1272/2008 (meaning preparation labelling can still be carried out in accordance with the Directive 1999/45 until 2015).

Even if one comes to the conclusion that Article 49(4) of Regulation 1107/2009 requires a labelling with standard phrases according to Directive 1999/45 (in conjunction with Directive 67/548) it is not yet decided under which preconditions and in which way such labelling requirements apply. As described above, Directives 1999/45 and 67/548 embody certain criteria for assigning a specific S-phrase to a specific substance or preparation, depending on the specific properties of the particular substance or preparation. The question is how this general rule has to be applied in the context of Article 49(4) of Regulation 1107/2009.

A **first option** would be to interpret the reference in Article 49(4) to the standard phrases **as being related to the corresponding plant protection product**. As presented above, plant protection products that are placed on the market must also be labelled according to Directive 1999/45, which includes a label with the respective S-phrases for the relevant preparation. The S-phrases used for the plant protection product could then also be used for the labelling of treated seeds. This seems, however, problematic due to the differences in the properties of plant protection products on the one side and seeds treated with plant protection products on the other. A plant protection product is considerably diluted after its application to seeds. On this basis, the risks caused by the treated seeds must be assessed differently due to the dilution factor, which could necessitate labelling with less/other phrases on safety issues. Thus, the assignment of the S-phrases of the plant protection product might be insofar misleading and counterproductive as this would, at least partly, demand the use of S-phrases which do not give the appropriate safety advices in respect of the treated seeds.

Moreover, the wording of Article 49(4) of Regulation 1107/2009 does not foresee the use of standard phrases which are assigned to a particular plant protection product. Article 49(4) just demands the use of “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” without referring to the plant protection product in this context. The wording thus differs from the reference in respect of risk mitigation measures which are to be declared if they are “*set out in the authorization for that product*”, i.e. the authorization of the plant protection product. Against this background, and especially with regard to the rationale of the labelling requirement, it is more convincing to rely on the properties of treated seeds when the phrases on safety aspects are to be assigned to treated seeds.

Then, the next question is how the scheme of standard phrases according to Directive 1999/45 (in conjunction with Directive 67/548) can be applied for treated seeds. A **second option** to interpret the reference in Article 49(4) to the standard phrases would be the following “**formal approach**”:

- Due to the citation of Directive 67/548 in Directive 1999/45, the S-phrases need to be assigned based on the criteria of Annex VI to Directive 67/548, and in addition according to the rules of Directive 1999/45.

- Due to the citation of Directive 67/548 in Directive 1999/45, only the S-phrases which are listed in Annex IV to Directive 67/548 can be used⁷; it is a general principle under Directives 67/548 and 1999/45 that S-phrases need to comply with the wording in Annex IV.

However, there are good arguments to oppose such formal approach which, for determining the relevant standard phrases for safety precautions for treated seeds, relies simply on the criteria of Annex VI to Directive 67/548 (and in addition the rules of Directive 1999/45); and which therefore would require a classification of the particular seeds according to parameters named in Annex VI to Directive 67/548 and, in this context, especially pursuant to the categories listed Article 2(2) of Directive 67/548.

First, it has to be noted that the wording of Article 49(4) of Regulation 1107/2009 does not specify the rules under which specific preconditions “*standard phrases for safety precautions*” are assigned to particular treated seeds. Article 49(4) simply states that treated seeds are labelled according to the standard phrases “*as provided for in Directive 1999/45/EC*”. This wording does not necessarily include a reference to the criteria of Directive 1999/45 in conjunction with Annex VI to Directive 67/548 under which S-phrases are assigned to dangerous preparations. At least, one has to admit that the wording of Article 49(4) is unclear in this respect.

Second, a formal adoption of the criteria of Directive 67/548 (especially its Annex VI) and Directive 1999/45 would not fit for the evaluation and classification of treated seeds, because those criteria were specifically designed for substances or preparations: A lot of the required testing methods (in particular animal testing) could no be applied in the case of treated seeds; at least some of the parameters for testing of substances and preparations would not fit for treated seeds (which, for example, will never be corrosive, because plant protection products were never be authorized in such case); seeds are often treated with two or several products (insecticides, fungicides ...) which, in practice, makes it not possible to evaluate each possible combination.

Third, a formal approach which only makes use of the S-phrases which are listed in Annex IV to Directive 67/548 would be problematic. Even though Article 49(4) of Regulation 1107/2009 refers to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” and, thus, directs towards the use of the S-phrases of Annex IV of Directive 67/548, there are two aspects which need to be taken into account: Annex IV contains several standard phrases which are clearly orientated at the handling and use of substances / preparations themselves. Due to this focus Annex IV

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Clearly not possible would be the use of the special standard phrases for safety precautions, which are provided in Annex V of Directive 91/414 for the labelling of plant protection products, because Article 49(4) of Regulation 1107/2009 in no way refers to Annex V to Directive 91/414.

does not contain any safety precautions which deal particularly with the handling of treated seeds.

In sum: The aforementioned (second) option to rely solely on the criteria of Directives 1999/45 and 67/548 for choosing the relevant standard phrases for safety precautions is neither clearly demanded by the wording of Article 49(4) of Regulation 1107/2009 nor does it seem as an appropriate approach from a practical standpoint. Furthermore, an approach which only relies on the S-phrases listed in Annex IV to Directive 67/548 seems problematic when one takes the specific features of the handling of seeds into account. Then, of course, the question arises which criteria shall be applied for a determination of the relevant standard phrases for safety precautions; and under which preconditions a derogation from the listing of Annex IV to Directive 67/548 is feasible.

Against this background, it shall be assessed if the seed industry has the right to choose an **alternative approach, by developing a generic set of standard phrases for safety precautions** which, in the experience of industry, shall depict “best practice”. This **third option** (of an understanding of Article 49(4) of Regulation 1107/2009) would contain an approach which would not evaluate and classify each treated seed, and assign particular S-phrases to the treated seed, only taken from Annex IV to Directive 67/548. Instead, industry would decide, based on a general evaluation and assessment of the possible risks and safety issues, which types of safety precautions are typically necessary for treated seeds and should therefore be chosen as respective standard phrases.

The first argument in favor of the feasibility of this approach is that Article 49(4) of Regulation 1107/2009, as described above, is not clear in its wording: Article 49(4), compared to the Directives 1999/45 and Directive 67/548, uses a different wording, especially not referring explicitly to the S-phrases of those Directives. Furthermore, Article 49(4) does not name the relevant criteria for assigning standard phrases for safety precautions.

A second argument is that already the existing EU legislation on chemical substances and preparations gives some leeway with regard to the labelling with S-phrases. Thus, the labelling with the appropriate safety advices is not regarded as a strict dogma. Rather derogations or modifications seem possible, at least to a certain degree. For example, pursuant to Annex VI No. 7.5.2., the choice of safety phrases is, as a general rule, limited to six s-phrases. As a consequence, S-phrases which are actually relevant, may be omitted. Also, Regulation 1272/2008 allows to omit precautionary statements if their selection is “clearly redundant or unnecessary given the specific substance, mixture or packaging” (cf. Article 28(1) of Regulation 1272/2008)⁸. If the EU

⁸ Furthermore Article 17(1)(g) of Regulation 1272/2008 demands “appropriate precautionary statements” only “where applicable”.

legislation on chemicals law allows modifications already for substances and preparations, this should apply for treated seeds *a fortiori*.

However, it must also be reminded that Article 49(4) of Regulation 1107/2009 does not clearly state that industry has the right to fulfill its labelling obligation by developing a generic set of standard phrases for safety precautions. Even though there are good arguments for this third option, there is always a risk that the competent authority will not accept such approach by industry and, instead, requires a labelling according to the other two approaches which were described above. If industry decides to follow the third option, a framework for developing the generic set of standard phrases for safety precautions needs to be developed. Relevant features of such framework are in our opinion:

- The approach of a generic set of standard phrases for safety precautions is only feasible if there is indeed a general standard of safety advices which, based on the current state of the art, has to be regarded as a common ground for all treated seeds.
- The choice of the generic set of standard phrases must be derived from objective grounds, mirroring the state of the art, and must be developed in a comprehensible procedure.
- For example: Taking the expertise of industry into account, is it correct that all treated seeds should be kept out of the reach of children, livestock and wildlife? If the question is answered with yes, there is an objective justification to use a respective standard phrase for safety precaution for all treated seeds. In the same way, it has to be examined if all relevant risks are covered by respective standard phrases for safety precautions. In this context, the S-phrases of Annex IV, even if the list is not exclusive in respect of safety issues for treated seeds, give an indication which safety advices should be considered. E.g.: Is there a scientific justification that the user of treated seeds should wear suitable gloves (cf. S-phrase S37), then such standard phrase must be adopted.
- The wording of the “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” should take into account: If the S-phrases of Annex IV to Directive 67/548 fit to describe the necessary safety precautions with regard to treated seeds, those S-phrases should be used in the way as provided by Annex IV to Directive 67/548 (e.g. “Keep out of reach of children”). This includes that S-phrases of Annex IV to Directive 67/548 should not be modified (“Keep out of reach of children, livestock and wildlife”). Instead, two separate standard phrases should be chosen, with the first taking the standard phrase directly from Annex IV (“Keep out of reach of children”) and the second creating an own standard phrase (“Keep out of reach of livestock and wildlife”).

- If particular safety issues in respect of treated seeds are not covered by Annex IV to Directive 67/548 (e.g. sowing of the respective material), a new standard phrase needs to be created (“Before sowing After sowing ...”). If seed industry develops new safety precautions which are not foreseen in Annex IV to Directive 67/548, this may be regarded as labelling on a voluntary basis, based on the argument that mandatory labelling is limited to the safety issues pursuant to Directive 1999/45 and Annex IV to Directive 67/548. Then, it would not fall under the scope of Article 49(4) of Regulation 1272/2009. However, the competent authorities may rely on a contrary view and argue: If the labelling with standard phrases for safety precautions is to be derived from objective grounds, such labelling should always be mandatory. This question is relevant for the issue whether safety precautions can be provided alternatively as label on seed bags or with the documents accompanying the treated seeds (see B.II.3.).
- Furthermore, it should be, in general, feasible to have a voluntary labelling, e.g. to use key message pictograms, although Article 49(4) does not contain any rules on hazard pictograms. As long as such symbols are not misleading (especially with respect to the danger symbols of Directive 67/548) and do not interfere with the prescribed labelling, this approach can be regarded as a voluntary labelling which does not fall under the scope of Article 49(4) of Regulation 1272/2009 and, furthermore, which is not prohibited by Article 49(4). There is no indication in Article 49(4) that this provision prohibits an extra labelling which strengthens the protection of the customer. The legal consequences for a voluntary labelling are described under B.II.2.

Overall, there are three options how the reference to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” in Article 49(4) of Regulation 1272/2009 can be interpreted: (i) that the labelling of treated seeds must contain the S-phrases which are assigned to the particular plant protection product which was used to treat the seeds; (ii) that the labelling of treated seeds must be strictly based on the criteria provided Directives 1999/45 and 67/548 and that the S-phrases which are listed in Annex IV to Directive 67/548 must be used. For the wording of Article 49(4) of Regulation 1272/2009 is not clear and the rationale of said provision does not indicate that option (i) or option (ii) are the correct interpretations: there are good arguments (although there is no certainty from a legal standpoint) that the seeds industry can apply an alternative option (iii) and develop, based on its experience, a generic set of standard phrases for safety precautions. Yet, industry is not free when developing such standard phrases, but has to comply with specific rules; e.g., the generic set of standard phrases must be derived from objective grounds, mirroring the state of the art, and the standards phrase, if possible, should be assigned like the S-phrases provided by Annex IV to Directive 67/548.

2. **The reference to “*risk mitigation measures set out in the authorisation for that product where appropriate*”**

Insofar as Article 49(4) of Regulation 1107/2009 refers to “*risk mitigation measures set out in the authorisation for that product*”, the provision refers to the authorisation of the plant protection product (and not the active substance). This results from the literal interpretation of Article 49(4), with the phrase “for that product” referring to the plant protection product which was used to treat the seeds. Also, Regulation 1107/2009 typically uses the term “products” when referring to plant protection products. Furthermore, under Regulation 1107/2009 active substances are subject of an approval, while plant protection products need to be authorized (by the Member States).

Within the authorisation of a plant protection product risk mitigation measures are a feasible condition of the product authorization. If the plant protection product is used for the treatment of seeds, specific risk mitigation measures may deal with seeds treated with the particular plant protection product. Therefore, risk mitigations measures set out in such authorization may be relevant for the treatment and the subsequent handling of treated seeds. In such case, the labelling requirement of Article 49(4) of Regulation 1107/2009 in respect of risk mitigation measures has to be considered “*appropriate*” in the meaning of that provision. As a consequence, the labelling does not have to include all risk mitigation measures set out in the authorization but only those which are relevant with regard to treated seeds.

3. **The reference to “*the label and documents accompanying the treated seeds shall include*”**

The question is then how the labelling requirement of Article 49(4) of Regulation 1107/2009 must be fulfilled with regard to risk mitigation measures and safety precautions.

Article 49(4) foresees that the particular information shall be included on “*the label and documents accompanying the treated seeds*”. Since Article 49(4) uses the word “*and*”, it contains the general principle that **the relevant information has to be given by both means**. If the European Legislator intended to implement a scheme which allows an alternative labelling, either with a label on the seed bag or in the documents accompanying the treated seeds the Legislator would have used a different wording. Even though the text of Article 49(4) of Regulation 1107/2009 is clear insofar that the particular information has to be given by both means, it seems fair to argue that the logic of this concept is hard to see. There are good arguments for the view that it would be sufficient for the protection of the user to provide the particular information in just one way.

The only starting point within the text of Article 49(4) to grant some discretion with regard to the labelling with **risk mitigation measures** might be the phrase “*where*”

appropriate” (in the German version: “*gegebenenfalls*”). In this respect it could be argued that the phrase “*where appropriate*” can be understood in a way that the labelling with risk mitigation measures is, at least to a certain degree, optional and gives the person who places the treated seeds on the market some room to decide on the design of the labelling; with the consequence that such person could decide to choose an differentiating approach, and to include the relevant risk mitigation measures only in the documents accompanying the treated seeds. Yet, it needs to be pointed out that there is a relatively high risk that the competent authorities would not agree with this approach and would argue that the phrase “*where appropriate*” only refers to the condition that the applicable risk mitigation measures have to be labelled; and, thus, that the authorities would demand a labelling with the relevant risk mitigation measures on the label of the seed bag as well as in the accompanying documents.

With regard to the **labelling with safety precautions** it can be distinguished as follows:

- Insofar as safety precautions which shall be provided are not required by Article 49(4) of Regulation 1107/2009, the obligation under Article 49(4) does not apply. In such case it is possible to choose whether the particular information shall be given on the label of the seed bag or in documents accompanying the treated seeds. For, in this case, the information would be provided on a voluntary basis. Then, the questions that remain are if such voluntary labelling of treated seeds is allowed under Regulation 1107/2009 and which kind of labelling with safety precautions is considered voluntary (cf. B.II.1., especially with regard to the aspect that the interpretation of Article 49(4) allowing the industry to develop generic safety phrases may narrow down the possibilities of voluntary labelling).
- As far as Article 49(4) of Regulation 1107/2009 contains a legal obligation to provide safety precautions by the means of labelling (cf. B.II.1.), the requirements of Article 49(4) with regard to the modalities of labeling have to be complied with; i.e.: the particular information has to be included on the label as well as in the documents accompanying the treated seeds. For Article 49(4) explicitly states that this information has to be given by both means. Article 49(4) does not leave any room to derogate from this obligation.
- Then, room to manoeuvre exists only insofar as the obligation to provide standard phrases for safety precautions is reduced or modified. In this context, it seems arguable to apply the concepts of the EU legislation on seeds *mutatis mutandis*. This follows from the necessity to have a coherent approach within EU legislation: As described above (B.I.4.), the placing on the market of seeds has to comply with the specific labelling requirements under the EU legislation on seeds, e.g. the labelling requirements of Directive 2002/55/EC, Directive 2002/57/EC, Directive 66/401/EEC or Directive 66/402/EEC. The labelling as

required by those Directives is additional to the labelling pursuant to Article 49(4) of Regulation 1107/2009. Thus, a person who places seeds treated with plant protection products on the market has to comply with the labelling requirements pursuant to Article 49(4) of Regulation 1107/2009 as well as with the labelling requirements of the EU legislation on seeds. Against this background the question arises: If the EU legislation on seeds foresees specific modalities of labelling for special kinds of packaging, do those modalities also apply for the labelling pursuant to Article 49(4)? For example, the EU legislation contains special rules for small size packaging to take the specifics of this form of supply into account. Although there are no special rules for small size packaging within Article 49(4) of Regulation 1107/2009, it could be argued that the respective rules of EU legislation on seeds (e.g. Article 32 of Directive 2002/55/EC) to the labelling requirement of Article 49(4) and, by that, establish a coherent approach. However, it is uncertain if the competent authorities would agree with such approach.

Finally, it shall be assessed how the term “*documents accompanying the treated seeds*” must be interpreted. The term is neither defined in Articles 3 and 49 of Regulation 1107/2009 nor in the rest of the text of that regulation⁹. The EU legislation on seeds stipulates, under specific preconditions, that documents which are affixed to or accompany the seed lot, have to be provided (e.g. Article 31 of Directive 2002/55/EC, Article 11a of Directive 66/401/EEC or Article 11a of Directive 66/402/EEC with regard to seed of a variety which has been genetically modified). Yet, those provisions do not contain a definition on the features of such documents. In absence of a definition under the respective EU Legislation there is, at least, some room for interpretation. However, there are also limits for such interpretation which result from the wording used in Article 49(4) of Regulation 1107/2009 and the rationale of this provision. The logic behind the provision is that the user shall be given information for his safety in a way that he can inform himself directly on the proper safety precautions and risk mitigations. This requires – as the wording “*accompanying*” demonstrates – that the relevant documents are provided physically and together with (but not necessarily affixed to) the treated seeds (e.g. by handing out a leaflet to the customer).

III. Interpretation of Article 80(6) of Regulation 1107/2009

The issue listed under A.5. deals with the question of whether Article 80(6) of Regulation 1107/2009 applies to seeds treated with plant protection products. Article 80(6) of Regulation 1107/2009 states:

⁹ A different type of “accompanying documents” are those referred to in Article 41(1) of Regulation 1107/2009 which deal with documents which shall accompany the application for an authorisation.

“Products labelled in accordance with Article 16 of Directive 91/414/EEC may continue to be placed on the market until 14 June 2015”.

Article 80(6) is part of the scheme of transitional measures enacted to enable a smooth transition from the old regime of Directive 91/414 to the new regime of Regulation 1107/2009. Therefore, Regulation 1107/2009 also foresees transitional measures regarding labelling. If seeds treated with plant protection products would fall under the scope of Article 80(6), this could result in more time for compliance with the labelling requirements for treated seeds.

Seeds treated with plant protection products would fall under the scope of Article 80(6) of Regulation 1107/2009 if they were to be regarded as “products” in the sense of this provision. It should first be noted that the wording of Article 80(6) (“product”) is not directly limited to plant protection products. Furthermore, the term “product” is not defined in the Regulation 1107/2009, especially not in Article 3 of the Regulation. From a literal perspective, plant protection products as well as seeds could be seen as “products”, although seeds are special in that they are agricultural products.

On the other hand, it should be taken into consideration that Regulation 1107/2009 refers to “products” in multiple places (cf., inter alia, Article 1(4)). Typically, the term “products” refers to plant protection products (cf. Article 2(1): “*These products are referred to as ‘plant protection products’.*”). This also applies to Article 49(4) of Regulation 1107/2009 („...*the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, ... set out in the authorisation for that product* “). There is therefore reason to believe that the European Legislator also intended to refer solely to plant protection products in Article 80(6) of Regulation 1107/2009.

This is further indicated by the referral in Article 80(6) to Article 16 of Directive 91/414 which – as previously mentioned – applies to the labelling of plant protection products, but not to treated seeds. If the temporary regulation provided by Article 80(6) were actually applicable to treated seeds, this would mean that the labelling would correspondingly be carried out in accordance with Article 16 of Directive 91/414. This would be problematic, because the specifications of Article 16 of Directive 91/414 are tailored to plant protection products and would not suit a treated seeds labelling.

The application of Article 80(6) to treated seeds also seems problematic with regard to the purpose and function of Article 80 of Regulation 1107/2009. In order to provide a transition from the old regime of Directive 91/414/EEG to the new regime of Regulation 1107/2009, as described by recital 59, “certain provisions of Directive 91/414/EEC should remain applicable during the transitional period”. This should also apply for the old labelling regime according to Article 16 in conjunction with Annexes IV, V of Directive 91/414, which will be replaced by the new labelling regime

according to Article 65 of Regulation 1107/2009 in conjunction with the new Regulation containing the requirements of the labelling of plant protection products. The labelling requirement according to Article 49(4) of Regulation 1107/2009 is, however, another matter: a universal labelling requirement is to be created that was previously nonexistent.

However – and this calls the aforesaid finding into question – it is evident that Regulation 1107/2009 does not contain any phase-in provisions for treated seeds (probably due to the fact that the provision for the special case of treated seeds in Article 49 was adopted late in the legislative process). There are, however, quite comparable interests regarding plant production products on the one side and treated seeds on the other. The provisions’ addressees must adjust to a new labelling system in both cases: in the case of plant protection products from Article 16 in conjunction with Annexes IV, V of Directive 91/414 to Article 65 of Regulation 1107/2009 in conjunction with the new Regulation, and in the case of treated seeds from a nonexistent labelling and information obligation to the labelling system according to Article 49(4) of Regulation 1107/2009.

Consequentially, it seems arguable that the European Legislator is not line with the principle of equal treatment by establishing transitional regulations in Regulation 1107/2009 solely for plant protection products and not for treated seeds. The principle of equal treatment, which is acknowledged as a general principle of European Law by the Court of Justice of the European Union and is guaranteed by Article 20 of the Charter of Fundamental Rights (“Everyone is equal before the law”), dictates that like cases should be treated alike; and that a different treatment of comparable situations is only allowed if there is an objective reason for doing so¹⁰. However, based on the fact that treated seeds have to be distinguished from plant protection products and the legal background is different for both, it seems fair to argue that, in the absence of “like cases” the principle of equal treatment is not infringed. Especially, this reasoning would apply if Article 80(6) of Regulation 1107/2009 were only to be considered as a sell-off period for plant protection products which have already been labelled according to Article 16 of Directive 91/414.

C. Conclusions

In respect of **labelling requirements for treated seeds** the following legal framework applies:

¹⁰ In respect of the recognition of the principle of equal treatment by the ECJ see, inter alia, the rulings in the cases 117/76 and 16/77 – *Ruckdeschel* [1977] ECR 1753 and Case C-292/97 – *Karlsson* [2000] ECR I-2737.

- Labelling requirements for seeds treated with plant protection products have to be distinguished from labelling requirements for plant protection products. In contrast to Directive 91/414, Regulation 1107/2009 contains in Article 49(4) specific labelling requirements for treated seeds. Moreover, requirements for the labelling of treated seed may be set out in the authorization of a particular active substance which lead to an Annex I inclusion under Directive 91/414.
- In our opinion, the labelling requirements under the EU legislation on chemical substances do not apply directly for treated seeds, because treated seeds can be considered neither as substances nor as preparations (mixtures) in the meaning of the EU legislation on chemical substances.
- In its legislation on seeds, the EU enacted specific labelling requirements under which any chemical treatment of seeds has to be noted on the label and on the package or inside it. This general requirement can be specified in the implementing national legislation with regard to plant protection products.

In respect of the interpretation of **Article 49(4) of Regulation 1107/2009**, the legal opinion reaches the following conclusions:

- Insofar as Article 49(4) of Regulation 1107/2009 refers to “*standard phrases for safety precautions as provided for in Directive 1999/45/EC*” it seems reasonable that the European Legislator meant to refer to the phrasing in respect of safety issues which was introduced by Directive 1999/45 in conjunction with Directive 67/548. There are three options how this reference can be interpreted: (i) that the labelling of treated seeds must contain the S-phrases which are assigned to the particular plant protection product which was used to treat the seeds; (ii) that the labelling of treated seeds must be strictly based on the criteria provided by Directives 1999/45 and 67/548 and that the S-phrases which are listed in Annex IV to Directive 67/548 must be used. For the wording of Article 49(4) of Regulation 1272/2009 is not clear and the rationale of said provision does not indicate that option (i) or option (ii) are the correct interpretations: there are good arguments (although there is no certainty from a legal standpoint) that the seeds industry can apply alternative option (iii) and develop, based on its experience, a generic set of standard phrases for safety precautions. Yet, industry is not free when developing such standard phrases, but has to comply with specific rules; e.g., the generic set of standard phrases must be derived from objective grounds, mirroring the state of the art, and the standards phrase, if possible, should be assigned like the S-phrases provided by Annex IV to Directive 67/548.
- Insofar as Article 49(4) of Regulation 1107/2009 refers to “*risk mitigation measures set out in the authorisation for that product where appropriate*”, the

provision refers to the authorisation of the plant protection product (and not the active substance). The labelling does not have to include all risk mitigation measures set out in the authorization but only those which are relevant with regard to treated seeds. Since Article 49(4) uses the word “*and*”, it contains the general principle that the risk mitigation measures have to be given on the label of the seed bag as well as in the documents accompanying the treated seeds. It could be argued that the phrase “*where appropriate*” can be understood in a way that the labelling with risk mitigation measures is, at least to a certain degree, optional and gives the person who places the treated seeds on the market some leeway to decide on the means of labelling (e.g. to include the relevant risk mitigation measures only in the documents accompanying the treated seeds). However, there is a relatively high risk that the competent authorities would not agree with this approach and line of argumentation.

- In case of a voluntary labelling with safety precautions the obligation pursuant to Article 49(4) does not apply. In such case it is possible to choose whether the particular information shall be given on the label of the seed bag or in documents accompanying the treated seeds. Yet, it has to be noted that the interpretation of Article 49(4) allowing the industry to develop generic safety phrases may narrow down the possibilities of voluntary labelling. As far as Article 49(4) of Regulation 1107/2009 contains a legal obligation to provide safety precautions by the means of labelling, the particular information has to be included on the label as well as in the documents accompanying the treated seeds. Leeway exists only insofar as the obligation to provide standard phrases for safety precautions is reduced or modified. In this context, it seems arguable to apply the concepts of the EU legislation on seeds *mutatis mutandis*. This follows from the necessity to have a coherent approach within EU legislation. One example would be a transfer of the special rules for small size packaging within EU legislation on seeds to Article 49(4) of Regulation 1107/2009. However, it is uncertain if the competent authorities would agree with such approach.
- The term “*documents accompanying the treated seeds*” is not defined in Regulation 1107/2009. While, in absence of a definition under the respective EU Legislation, there is some room for interpretation, it is required – as the wording “*accompanying*” and the rationale of the provision demonstrate – that the relevant documents are provided physically and together with (but not necessarily affixed to) the treated seeds.

In respect of the question if **Article 80(6) of Regulation 1107/2009** can be interpreted to include seeds treated with plant protection products there is reason to believe that the European Legislator, when choosing the wording “products” intended to refer solely to

plant protection products. This is further indicated by the referral in Article 80(6) to Article 16 of Directive 91/414 which only applies to the labelling of plant protection products, but not to treated seeds. Such view is probably not violating the principle of equal treatment.