ESA Comments on the Commission Discussion paper prepared for the stakeholder meeting of December 9, 2014

As explained in our cover letter, ESA European Seed Association supports the horizontal comments made and co-signed by several industry associations in a joint position paper a copy of which has also been provided to DG Environment by ESA. In addition to those horizontal points ESA however wishes to make a number of other comments which are rather of a sectorial nature but are of key importance for the European plant breeding sector.

Article 7:

Declaration of due diligence at the stage of research funding

- According to the ideas outlined in the Discussion Paper the moment when a declaration of due diligence would need to be made in case of receipt of research funding would be – at the latest - when the recipient obtains the genetic resources. However, it has to be noted that in some cases it may not be known at that moment if genetic resources falling under the scope of the Regulation will be utilised according to the definition of the EU Regulation in the project or not. For example in the case of a project related to pre-breeding hundreds of genetic resources may be accessed from collections (or from elsewhere) part of which may be under the scope of the Regulation and part of which may not. Since the first step will be to screen all the material to find out which are the ones to be used for breeding in the project it may happen that only material outside the scope of the Regulation will be utilised in the end. Therefore – to find a pragmatic way to avoid superfluous administrative burden – we propose that it should be indicated in the project proposal that only genetic resources that fall outside the scope of the EU Regulation or for which due diligence will be exercised would be used in the project and the due diligence declaration itself should be made at the end of the project when the final check is done and when there is full clarity and certainty regarding which genetic resources have been utilised.

- As also stated in the joint position paper referred to above, ESA is of the view that Article 7(1) should only apply to cases of public research funding. Should the Commission however decide otherwise, it is important to clarify what should be considered as private funding. During the stakeholder meeting it was clearly mentioned that this does not concern all private money. In our opinion, private funding should in any case not include resources such as:
    - Own resources of a company

- Payment to another company or institute as compensation for the performance of a specific service or project for the benefit of the paying company
- Tax benefits

Annex A:

- Question no. 2 requires recipient(s) of funding to provide information on their contact details. However it is not clear from the Discussion Paper and the Annex who are considered to be recipient(s). For the sake of clarity, simplicity and avoidance of superfluous administrative burden ESA proposes that it should be only the obligation of one and probably mostly the main applicant in the project to make the declaration.

- Question 3 (d) deals with the scenario where no internationally recognized certificate of compliance is available and none of the presumptions pursuant to Article 4(4) or 4(7) apply. However, even in such scenarios PIC and MAT are not always applicable. Therefore, a question or a box to allow users to indicate if PIC and MAT are applicable at all should be provided for before entering into the more detailed questions. Unless the Commission is of the opinion that no declaration has to be submitted, if no PIC and MAT were required. Such a position would have the support of ESA, since it limits the administrative burden.

- Regarding sub-point (viii) of question 3(d) ESA wishes to underline that for users in the plant breeding industry it is impossible to answer this question, if it is considered to apply also to the varieties that they commercialize. This is because in plant breeding when a plant variety is placed on the market it is freely available for others to be used in breeding activities. It is therefore impossible to know for the user who placed the variety on the market if and by whom the plant variety is further utilized for breeding. ESA therefore understands that this obligation is focused on the transfer of material in the form received. The Commission is asked to confirm this interpretation.

- In Part B of Annex A the possibility to tick a box to indicate that information is confidential is not provided for. As this information is not passed on to the ABS Clearing House, ESA supposes that the information is confidential and will be kept confidential. It would be helpful to indicate this directly in the form.

Declaration of due diligence at the stage of final development of a product

- The Regulation states in its Article 7(2) that users have to declare that they have exercised due diligence at the stage of final development of a product developed via the utilization of genetic resources, which final stage of development has to be elaborated sector by sector. In implementation of this provision the Discussion Paper proposes five different scenarios and recommends that the declaration is made at the moment when any of the five scenarios occur:

  - *market approval is sought for a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources;*
  - *a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources;*
  - *placing for the first time on the Union market a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources, for which no market approval or notification is required;*
  - *the result of the utilisation is sold or in any other form transferred to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);*
  - *the result of the utilisation is sold or in any other form transferred to a natural or legal person outside the Union.*

  We believe that the first three scenarios are mutually exclusive and it makes sense to have all three options to reflect the potential differences in how placing on the market is regulated in the different sectors where products developed via the utilization of genetic resources may be marketed. However, as also expressed in the joint position paper referred to above, we believe that the notion of « placing on the Union market for the first time » is defined in the Discussion Paper in a very broad manner and the situations it may cover can be very far reaching: for example it can cover situations where material is supplied to a third party for carrying out pre-commercial trials or for multiplication in which cases the material will go back to the original user.

  ESA realizes that this notion of “placing on the Union market for the first time” may cover different situations for the different sectors involved since product development has its

own particularities in every industry. Therefore, the Commission should explore individually with every sector concerned the situations that should be covered by this notion. ESA is currently working on this matter and will come up with a proposal to discuss with the Commission regarding the situation in the plant breeding sector.

In relation to point (e) it is noted that the Discussion Paper states that "*effective monitoring of user compliance within the Union must also address cases where the result of the utilisation is sold or in any other form transferred outside the Union without placing a product on the Union market. In order to ensure consistency of treatment of products placed on the Union market, the declaration should also be made when the development of a product has taken place outside the Union.*" Since these scenarios do not seem to be clear-cut included in the scope of the Regulation ESA suggests that equal treatment of products as a concern needs to be taken into account in this regard and would wish to understand better from the Commission (i) the reasons for the above outlined scenarios; (ii) the legal grounds on which they are based; and (iii) in particular the ways how the Commission envisages to implement these provisions in practice.

- Article 7(5) of the Regulation refers to the fact that confidentiality of information should be taken into account and accordingly several reference to confidential information are made in the Discussion Paper and its Annexes. However, there is no clarity as to how an indication by a user of confidentiality will be interpreted and by whom. For example in the declaration forms the user is required to indicate whether a piece of information is confidential or not and in case it is, the user has to provide the grounds on which such confidentiality is claimed. In the field of plant breeding ESA is of the view that at least the following information should enjoy confidential treatment: the purpose of the use or type of product; project parties; accession numbers; country or source where the genetic resource was accessed; information on pedigree (genetic composition) of plant varieties etc. These types of information fall in the category of business secrets and should be handled as confidential.

  There should be clear guidance from the Commission regarding the grounds on the basis of which confidentiality can be claimed and the type of information that may enjoy such status. This is essential for users to know before providing information in the declaration forms. A uniform interpretation throughout the Member States is important to provide users with legal certainty.

Annex C

- In addition to the comments made on Annex A (which are also relevant for Annex C) we are of the view that under question 3 the question whether the utilization has taken place outside the EU should not be asked since it has no relevance.

Article 8: Best Practices

- In addition to the remarks made on Article 8 in the joint industry position paper ESA wishes to lake the following additional comment: The Discussion Paper suggests that the Member State in which the applicant is established receives a copy of the application and is also involved in the procedure. However, no involvement in the procedure of the Member State in which the applicant is located is foreseen in Article 8 of the Regulation. ESA believes that involvement of such Member State in the procedure may be justified to check the legality of the establishment of the applicant but any involvement broader than that does not seem to be appropriate.