Preliminary Position Paper on the European Commission Proposal for a Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union COM (2012) 576 final

Speaking for their member companies the German Chemical Industry Association (Verband der Chemischen Industrie e.V.) and the German Biotechnology Industry Association (DIB) support the objectives of the Convention on Biological Diversity (CBD): The conservation and sustainable use of biological diversity as well as the fair and equitable sharing of benefits arising from utilization of genetic resources.

The chemical and biotechnology industry, hereinafter referred to as industry or the industry, fully supports the CBD underpinning the Protocol and stands ready to work with the German government and the EU on ensuring the Protocol's fair and balanced implementation in Germany and across the EU.

A key driver in that process must be to ensure legal certainty for potential users of genetic resources in the EU.

We welcome the general direction of the draft Regulation but have a number of concerns regarding some of its ambiguous language and, by association, its lack of legal certainty.

Our preliminary views are set out below. A detailed analysis is forthcoming.

<u>The Industry welcomes the fact that the draft Regulation:</u>

- Clarifies that its rules only apply to those genetic resources and traditional knowledge accessed after the entry into force of the Protocol in the European Union, and that the definition of "access" actually refers to the "acquisition" of a genetic resource, as this is key to ensuring legal certainty. [Reference 9 and Art. 3]
- Applies a due diligence obligation on users proportionate to the circumstances of each case, while acknowledging that this may in practice create uncertainty as to the precise scope of the obligation. [Article 4]
- The due diligence approach leaves users some flexibility to take measures that work best for their respective context, and also to develop sectoral best practices. This is an important aspect of a future regulation, because all industries creating value by means of biotechnological processes or products are affected either actually or potentially by the implementing provisions of the CBD. There can be no single answer to the question as to how far individual sectors of the industry are affected. In detail, this will depend particularly on the definition of their operative range and their position within the industrial value creation chain.

- The due diligence obligation should apply to all users irrespective of their size, including to micro-enterprises and small and medium-sized companies. Excluding these actors from the system would entirely undermine its effectiveness. It would also run against the international obligations of the Union under the Nagoya Protocol. However, the Regulation should offer a range of measures and tools to enable microenterprises and small and medium-sized companies to comply with their obligations at low cost and with high legal certainty. [Reference 15]
- Refers to the CBD and COP11 decisions to exclude human genetic resources [Reference 12]
- Recognises the valuable role that users' best practice guidance (such as the IFPMA Guidelines) can play in supporting implementation of the Protocol across the EU. [Reference 16, Article 8]
- Confirms that an ABS declaration made when requesting market approval should not be considered part of the approval procedure. [Reference 17]
- Takes particularly microenterprises, small and medium sized companies and academic research into account to ensure that they can fulfil future obligations and provisions without any added administrative input and costs and are thus not excluded from the system. [Reference 15, 19 and 24, Article 14]

Industry is still considering the full implications of the draft Regulation. Pending this detailed analysis, we set out below our initial key concerns about some of its provisions, followed by areas where further clarity would be helpful.

<u>Areas of concern</u>

- We question why declarations to the Competent Authorities relating to regulated products (which may never be commercialised) should be made earlier than nonregulated products. We would therefore suggest that references to market approvals be deleted from the draft Regulation. [(1) Preamble, paragraph 17; (2) Article 7]
- In this context, we also believe it is unfortunate that the pharmaceutical sector is specifically singled out in the Explanatory Memorandum. It sends out a disproportionate message regarding one sector's involvement in the debate.
- Industry would welcome an explicit recognition within the body of the Regulation of the need to protect business confidential information within the framework of the requirement to provide access to documentation.
- The draft Regulation should state that when an "internationally recognised certificate" - as defined in the draft - is not available, other legally acceptable forms of compliance would be considered sufficient proof that MATs and PIC have been established. [Reference 20 and Article 9(5)]

- The draft Regulation should exclude pathogens. Pathogens were not intended to be included within the scope of the CBD and the Nagoya Protocol - under Article 8(c) of the CBD, members are obliged to control or eradicate alien species which threaten ecosystems, habitats or species. [Article 2]
- Competent authorities should not have disproportionate powers to monitor compliance with the draft Regulation. Articles 9.1-4 should therefore be limited so that checks on user compliance would only be exercised if the authority is in possession of relevant information which raises a reasonable suspicion of non-compliance by the user with the Regulation. [Article 9]

In addition to the above concerns, there are a number of areas where we believe, on the basis of an initial reading of the draft Regulation, that further clarity may be needed.

Scope

- For completeness, industry believes the draft Regulation should explicitly refer to the WHO Pandemic Influenza Preparedness Framework as it does with the International Treaty on Plant Genetic Resources. [Reference 10]
- Commodities and material freely available in the normal channels of trade should be explicitly excluded from the draft Regulation. [Article 2]
- The draft Regulation will create obligations throughout the EU the sanction for breach of which will be “effective and dissuasive penalties”. Therefore, clarity as to when the obligations arise is needed. Consideration should in particular be given to whether the words “product developed on the basis of genetic resources or traditional knowledge associated with such resources” are sufficiently clear. [Article 7.2.]

Process and Terminology

- Industry would welcome the inclusion of some procedural safeguards, including rights of appeal and rights to receive notice / be notified.
- The Definitions section [Article 3] of the draft Regulation should refer to any understanding of traditional knowledge given in an ABS agreement. Possible wording might include “Where an ABD agreement defines traditional knowledge”, that definition should govern the obligations arising from the relationship”.
- We suggest that article 4 has a number of areas that require greater precision, whether through the elaboration of sector-specific provisions or changes in the text:

    - The draft Regulation will create due diligence obligations throughout the EU the

sanction for breach of which will be “effective and dissuasive penalties”. Therefore, clarity as to who would be concerned by the obligations is needed. Consideration should in particular be given to whether the words “users” and “genetic resources used” are sufficiently clear. [Article 4(1)]

- Similarly, clarity as to the scope and the practical implications of the obligations set out in article 4(2) is needed. [Article 4(2)]

- The draft Regulation should clarify the definition of “commercialization”. One possible suggestion could be “before the product is placed on the market”. [Article 7(2)]

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