International Platform of Insects for Food & Feed (IPIFF)

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INFO NOTE

EXTENSION OF COMMERCIAL RIGHTS/LICENSING PROCEDURES

- **Official procedures until July 2022**

1. Considering the former procedures for the extension of commercial rights (until July 2022), according to which a company with a granted data-protected Novel Food authorisation, when signing a commercial agreement with a different business operator would require the last (meaning the operator wishing to commercialise the data-protected product) to submit a separate authorisation application to the European Commission accompanied by the agreement made by the two parties (ceasing 'protected data' to a subsequent producer in the framework of a contractual agreement).

- **New simplified Procedures as of July 2022**

2. Taking into consideration the entry into force of the new simplified procedures (as of July 2022) for the extension of the commercialisation rights, a business operator with a commercial agreement with an authorised applicant of a Novel Food product no longer must submit a different application to the EC. The business operator can commercialise the product in question, based on the terms defined in the agreement signed between both parties.

- **Concerns from the business operators**

3. Taking into account the concerns expressed by the IPIFF members at the last IPIFF Working Group meeting on '*Food Safety & consumer Information*' held on the 6th of September, 2022, respecting the validation of the commercial agreements in question by the EU Member States (MS) competent National authorities;
4. The IPIFF Secretariat reached out to the European Commission Directorate-General on Health and Food Safety (DG SANTE) to address the raised concerns;
5. Taking note that such concerns were based on the experience of business operators when attempted to validate such commercial agreements and the EU MS respective National competent authorities demonstrated to not be well informed and in the capacity of providing such validation, especially when the mentioned commercial agreements were signed between business operators from different EU MS.

6. Acknowledging that such obstacles created on behalf of the EU MS National competent authorities resulted in the impediment of the business operators to commercialise the products to which were granted commercial rights, as it is their lawful right, as recognised by the European Commission, based on the existing legal framework.

- **The European Commission acknowledged and validated the concerns of the business operators**

7. The European Commission recognised the existing obstacles deriving from the MS competent national authorities' inability to validate the mentioned commercial agreements;
8. The European Commission acknowledged and demonstrated its support for the above-mentioned concerns, by taking the initiative to address the EU MS to urgently overcome the experienced obstacles by the business operators to lawful operate within the EU Internal Market.
9. The European Commission's DG SANTE, to further clarify and enable better enforcement on behalf of the EU MS national competent authorities proactively addressed the mentioned concerns to the EU MS.
10. On the DG SANTE's Working Group on Novel Foods meeting of the 21st of October 2022, where the EU MS respective National Competent Authorities are seated, the European Commission addressed the EU MS regarding these concerns, being included as part of the Meeting Agenda (item number 9 of Other Businesses-AOB).
11. At the mentioned meeting, the European Commission recalled the EU Member States that according to the new procedures, as of July 2022, a novel food authorised business operator to extend its commercialisation rights to another business operator, the second no longer needs to submit a separate application to the European Commission to be validated to commercialise the product in question. The current legal procedures are based exclusively on a celebrated commercial agreement signed by both parties.
12. The European Commission further recalled the EU MS that commercial agreements are not to be contemplated as part of the legal act once it is a purely commercial procedure between two business operators. If doubts persist on this matter, the European Commission offered its support to provide clarification on this matter, when needed.
13. The European Commission reinstated that EU Member States' competent national authorities must ensure that those commercial agreements are validated, according to the present legal framework to enable the proper functioning of the EU Internal Market. Therefore, any similar obstacles on behalf of the EU MS National competent authorities are unlawful. Therefore, EU MS were requested to take action to avoid any similar impediment in the future.
14. The European Commission also expressed its support to the business operators, by recommending those that experience similar impediments on behalf of the competent national authorities, namely when requesting additional information, to refer to the EU Official Controls Legislation (Regulation 2017/625) under Enforcement, article 12 on Documented Control Procedures, where clearly states that the only obligation on behalf of the business operator is to present the commercial agreement signed between both parties.

- **Recommendations on how business operators should proceed**

15. For enforcement purposes, the business operator seeking to validate the commercial agreement, is requested to submit it in the national language of the respective EU MS where it aims to commercialise a given authorised Novel food product to which commercial rights were granted.
16. Although there is no legal obligation associated with it, the business operators may also proactively advance to the recipient EU MS competent authority the list of business operators to which commercialisation rights are granted. This information can easily circulate amongst all EU MS competent authorities, within the DG SANTE Working Group on Novel Foods.

- **Recommendations on how EU MS National competent authorities can proceed**

17. The European Commission also instructed the Member States to inform their competent authorities to contact the other concerned EU MS competent authority (whenever the commercial agreement involves operators from different EU MS). The EU MS where the Novel food authorised business operator is located, can therefore contact the company in question, if there is a need for any additional confirmation.
18. On what concerns authorised business operators from countries outside the European Union, such as the case of the partially defeated house cricket (Vietnam) with foreseen authorisation in the near future, the same procedures are in place.
19. Nevertheless, when EU outside countries are involved, the European Commission can support establishing contact with the respective third country National competent authority and also the Novel Food authorisation holder in question.