Brussels, 10 November 2015

IPIFF Position Paper on the revision of the EU Novel Foods legislation

Introduction

In the context of world's ever expanding population, the United Nation FAO recently encouraged the exploration of insects as an important source of protein for human consumption: whereas insects are already part of the staple diet of around 2,5 billion people in large areas of the planet, the development of insects as new source of food production is expected to gain importance on currently 'undeveloped' markets, such as in Europe.

EU stakeholders and the general public have also started to realize the potential of the sector to upscale in Europe, and the EU legislator is today exploring options for better regulating the marketing of insects products for food consumption, (notably) through the revision of the EU Regulation on 'novel foods'[1].

IPIFF- the 'umbrella' organisation for the insect sector for food & feed at international level - would like to use this opportunity to bring its contribution to the ongoing reflection on the development & implementation of this new EU legal framework.

General remarks

- **IPIFF welcomes the EU legislator plans to harmonize & streamline the current EU rules on novel foods (NF)**, since the insect production sector primarily relies on a 'solid' & 'stable' EU regulatory framework to secure its production activities & investments plans.
- IPIFF emphasises the importance for EU authorities to establish **workable rules & to provide sufficient guidance for insect production companies** to implement the EU NF requirements & its associated authorisation procedures.
- Finally, the implementation of this new framework should **be accompanied with appropriate transitional measures** in order to enable the insect sector to adapt and conform to the new rules.

[1] Proposal for a Regulation of the European Parliament and of the Council on novel Foods. COM(2013) 894 final.

I. Establishing clear & 'realistic' EU rules is a key priority for the IPIFF members

- Under the current EU legislation[2], insects and/or food derived from insects are considered as 'novel food' (NF) provided that '*they have not hitherto been used for human consumption to a significant degree before 15 May 1997*': as a consequence, these products must be assessed and receive a European authorisation before they can be legally placed on the EU market.

- There is however legal uncertainty about whether 'whole insects & their preparations' are covered by the EU legislation, which results in diverging interpretations from one EU Member State to another[3].

> ➢ IPIFF pleads for the **harmonization of the EU Regulation on novel foods** & supports the EU legislator intentions **to better specify its legal scope in relation to insects & insect derived products**. Indeed:
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> - Insect producing companies capacities to invest & develop innovative food products for the EU market are facilitated if a 'clear' EU legal framework is in place;
>
> - The establishment of 'solid' EU harmonized rules will contribute to create a level playing field between insect producers across the EU.

- The current proposal for a revised legislation[4] considers '*whole insects and their parts*' as NF, which in concrete terms means that all types & forms of insects would in the future be subject to safety assessment & authorisation procedure, unless evidence can be provided that these have been consumed before 15 May 1997.

- According to article 10 of the draft text, the application for authorisation by the company marketing the product shall include *inter allia "scientific evidence demonstrating that the novel food does not pose a safety risk to human health"*.

[2] Regulation (EC) 258/97 concerning novel foods & novel foods ingredients

[3] E.g. Countries like UK consider that whole insects are outside the scope of the Novel Foods Legislation. Several countries (i.e. Netherlands, Belgium) have established lists of insects tolerated for human consumption.

[4] Text as adopted by the European Parliament on 28 October 2015.

- Whilst certain species of whole insects have already been authorised at national level and/or consumed within the EU for many years, the **companies selling these products have gathered substantial data** (i.e. through analysis performed in the framework of auto control measures, consumption data over several years) **demonstrating the safety of their products for human consumption**. This is notably the case of the following insect species: *Tenebrio Molitor, lesser mealworm, Black Soldier Fly, Common Grasshoppers & House cricket*.

- **The IPIFF Members are willing to share this information with the European Commission & the European Food Safety Authority (EFSA)**: the provision of this information should facilitate the examination & assessment of submitted application dossiers by these authorities.

II. IPIFF supports the EU legislator efforts to simplify the EU authorisation procedures but asks for guidance for dossier applicants

- The current proposal for a revised legislation introduces an EU centralised system for the authorisation of NF: all applications shall be directly transmitted to the European Commission prior to their submission to EFSA.

- The draft text also includes provisions aiming at streamlining the authorisation process, especially by introducing 'shortest' deadlines and workable adoption procedure – through 'implementing acts'.

- IPIFF **welcomes the efforts made by the EU legislator to simplify the 'procedural steps' under the EU NF Legislation**. We believe that these changes will contribute to speed-up the authorisation of insects products as NF. Indeed:

  - the workability & predictability of EU authorization procedures is key for insect producing companies, who invest substantially in research activities with the view to introduce innovative products on the EU market;

  - Composed in majority of start-ups, the capacities of the EU insect sector to bring new products on the EU market are therefore more hardly impacted by financial & administrative burden imposed by the EU legislator.

- The EU authorities (i.e. the European Commission & EFSA) are currently preparing the legal acts (the EC) & a guidance document (EFSA) detailing the content of applications for authorisation.

- **The provision of clear guidance concerning the content of NF applications is key for the insect sector.**

  - Insect producing companies require in particular assistance in identifying precisely the content of "*the scientific evidence needed by the EU authorities to demonstrate the safety of the product*" art. 10 2. e. (e.g. process books, results of analysis from auto control tests, compliance with Guides of Good Hygiene Practice, product & process certification)

  - The preparation of the EFSA Guidance document on the preparation & presentation of NF applications should give the opportunity to streamline and/or clarify the recommendations contained in the current EC recommendation/guideline document[5].

- **Efforts should also be made in order to reduce unnecessary administrative burden and/costs for applicants**

  - this concerns in particular the documentation to be included in the novel food dossiers (e.g. the clinical tests currently required as part of 'toxicological information' purposes may replaced by other types of evidence as long as these demonstrate the safety of the products in question)

  - the new rules should offer the option for applicants to file an authorisation dossier covering different applications under the same insect species (whenever the composition/properties of the product do not significantly differ), instead of building a dossier for each individual product.

III. IPIFF asks for appropriate transitional measures in order to ease the uptake of the new EU rules by the insect sector

- Article 35. 1 of the new proposed text provides that applications for NF Authorisation submitted before the new text applies but "*for which the final decision has not been taken before 2 years following its entry into force, shall be treated as an application under the new NF legislation*".

[5] See Commission Recommendation of 29 July 1997 (97/618/EC)

- **IPIFF asks for clarifications as to the procedural requirements which shall apply to 'early' applications**, in particular as regards the followings:

- whether application dossiers shall be assessed by national authorities or would the new EU centralized procedure directly apply;

- whether the criteria contained in the existing EC recommendation/guideline document[6] will continue to apply to these applications, instead of the future new guidance documents.

- Article 35.2 provides that products "*which were lawfully placed on the market*" before the entry into force of the new EU NF Legislation may not be withdrawn, provided that an application for authorisation has been submitted within a reasonable time after the entry of the new text (date to be specified through implementing acts).

- We regret that **the maximum period allocated for insect producing/distribution companies to submit an application in only two years**: for many insect producers, this timeline seems unrealistic to gather all the necessary documentation required in the NF application dossiers.

- the legal text should also make clear that producers who have submitted an application within the legal timeline (i.e. two years) **may continue to place their products on the market, until a final decision for authorisation has been taken by the EU institutions.**

- In order to ensure a level playing field between operators across the EU, **these transitional measures should benefit to all insects companies who have so far marketed their products on the EU market**.

[6] See Ibid