

Brussels, 29 November 2016

## IPIFF position paper - Implementation of EU Regulation 2015/2283 on 'novel foods'

### Introduction & General Remarks

On 25 November 2015, the EU legislator adopted [Regulation \(EU\) 2015/2283](#) on 'novel foods': the regulation introduces a new procedure for authorising 'Novel Foods' for commercialisation on the EU market. Replacing the current EU [Regulation \(EC\) 258/97](#) -, this new text will apply as from 1st January 2018.

The EU legislator clarified the legal status of insects and their derived products - *including for 'whole insects & their preparations'* (see recital 8 of the text) - which are now explicitly covered under the new Novel Foods (NF) legislation: consequently, insect products which have not been '*consumed to a significant degree within the European Union (EU) before 15 May 1997*' must be assessed and receive a European authorisation with the view to be legally placed on the EU market as from 2018.

IPIFF considers that the establishment of **harmonized rules for the marketing of insect products is a 'step in the right direction'**: while insects have the potential to become a major source of protein in Europe, insect producers primarily rely on a 'solid' & 'stable' EU regulatory framework to plan their investment & marketing activities throughout the continent.

IPIFF emphasises, however, the importance for EU authorities to **establish 'workable' rules & to provide guidance at implementation stage**. These principles, along with **appropriate transitional measures**, are notably relevant to facilitate the uptake of this new legislation by the insect producers.

### IPIFF welcome efforts towards the streamlining of authorization procedures

#### Simplification of authorisation procedures

All in all, IPIFF **welcomes the efforts made to simplify & harmonize the 'procedural steps'** under the new EU NF legislation: these improvements are notably materialized through the creation of an EU centralised authorisation system relying on the European Food Safety Authority (EFSA) as 'sole assessment body', or through the introduction of shortest deadlines during the authorisation procedure. We are confident that these changes will contribute to reduce application costs (i.e. EFSA does not charge application fee, expected shortened authorisation procedure) and 'create the conditions for a level playing field' between EU insect producers.

The '**timely' adoption of the implementing rules** - detailing the 'procedural steps' & the expected content of application dossiers - is now of the utmost importance, for insect businesses to anticipate their marketing strategy & decisions.

#### IPIFF recommendations:

- IPIFF calls on the European institutions to '**secure' the adoption of the implementing act** detailing the '*content, drafting & presentation of the application*' (see art. 13. A of the text) **at least a few months before the date of application of the new text** (i.e. 1<sup>st</sup> January 2018).

- Furthermore, operators should be given the **option to apply the ‘new’ EU NF legislation by ‘anticipation’** (i.e. before 1<sup>st</sup> January 2018) once the ‘necessary’ implementing rules of the text (art. 13 a.) have been adopted. Such option would give the possibility to overcome practical difficulties associated with the transition between the current EU NF ‘national procedure’ and the new EU procedure applying from 1<sup>st</sup> January 2018 (i.e. transfer of application to the EC & expected requests for additional information usually trigger ‘prolongations’). This option is even more relevant in situations where the applicant does not benefit from transitional measure for the submission of its application - *see below for further details*).

## Harmonized implementation of EU transitional measures

As outlined above, the predictability of new rules & authorisation procedures introduced in Regulation 2015/2283 is key for insect producers: in line with this ‘necessity’, **the EU Legislator has foreseen transitional measures** which provide that products ‘*lawfully placed on the market*’ can continue to be sold for at least two years following its entry into application’ (i.e. until 2 January 2020) (*see article 35.2 of the new text*).

This measure is particularly valuable for the insect sector, since it guarantees that operators are not ‘forced’ to discontinue their production process, whilst preparing a Novel Food application, in compliance with the provisions of the new text.

IPIFF fears, however, **that due to ‘restrictive interpretations’ of this provision by several EU national authorities** (i.e. several Member States are prone to consider that these products are currently not ‘lawfully placed on the market’), the transitional period of 2 years will be applied by a few countries only. These diverging interpretations will furthermore **create unfair competition between insect producers across the EU** because of these ‘differentiated treatments’.

### IPIFF recommendations

- At the very least, IPIFF calls on EU Member States to **clarify their position** as to whether operators selling insects on their national territory may **benefit from the 2 years’ transitional period**. ‘Legal clarity’ on this matter is indeed necessary for insect producers to determine their business decision & marketing strategy.
- In the event of ‘pending uncertainties’ and/or ‘misinterpretations’ of this provision by EU Member States, we believe that the **EU institutions should clarify the ‘legal status’ of producers selling ‘whole insect & their products’** within the EU: i.e. whether these products shall be considered as falling within the scope of the current NF Regulation (i.e. Regulation 258/97)

## Generic authorisation system & joint applications

While under Regulation 258/97 authorisations are only granted to the applicant, the new NF Regulation awards ‘generic’ authorisations to all those producing the NF product in question. However, the new text also opens the possibility to protect ‘*scientific evidence or scientific data supporting the application*’ for a 5-years period (see article 26). This provision prevents another operator from benefiting an ‘initial’ authorisation (e.g. in case the authorisation covers the same product) through access to ‘supporting data’.

**IPIFF greatly appreciates the shift towards a ‘generic authorisation system’**, since this should benefit SMEs & start-ups all along the production chain (i.e. no obligation to submit a separate dossier for the same product related product already authorized), while it will facilitate the broader dissemination of

insect products among EU consumers. **The 5 years' data protection period is a necessary buffer to protect 'authorisation initiatives'** and stimulate the investments towards innovative products by insect production businesses.

Finally, we are confident that the 'generic authorisation system' will **facilitate joint applications**, notably by groups of producers covering the same insect species.

IPIFF is however **asking for guidance** from the European Commission on the 'operational' aspects of **new EU authorisation system** (see recommendations below).

IPIFF recommendations:

IPIFF does seek to ensure that 'operational' aspects of the new NF text will be clarified - possibly through the implementing rules of the new text. Notably, IPIFF has flagged the following pending issues:

- the **conditions for applying data protection**, both in the context of 'individual' and 'joint' applications;
- eventual **procedures** required for **producers seeking to benefit 'previously authorised authorisation'** covering similar or related products (e.g. 'notification for equivalence');
- whether several insect species may be included in the same application dossier;
- determine 'scenarios' for which '**supplementary authorisation**' is required (e.g. cases in which the molecular structure of 'previously authorised ingredient' has been substantially transformed once incorporated into the final product).

## IPIFF pleads for workable rules & guidance at implementing stage

### Consistent & realistic authorisation requirements

All types & forms of insects will now be subject to EU safety assessment & pre-market authorisation. The applications for authorisation submitted by operators shall notably contain comprehensive information & '*scientific evidence demonstrating that the novel food does not pose a safety risk to human health*'.

The IPIFF members are **fully committed to provide EU authorities with all 'necessary' information supporting such applications**. Based on extensive experience in the implementation of safety standards & risk based procedures (e.g. through HACCP), the IPIFF company members have notably gathered safety evidence all along the production process (notably regarding methods of farming & processing or on the substrate used which are seen as 'critical points' by EFSA - *see EFSA's opinion from 8 October 2015*). These elements will be reflected in the NF applications which will be prepared and submitted by the IPIFF members from 2018 onward.

IPIFF recommendations:

The content of applications & scientific evidence supporting these applications shall notably demonstrate that producers **comply with all necessary hygienic conditions & procedures enabling them to control effectively any hazards along their production process** ('risk based approach' in line with HACCP procedure).

Along this line, **certain flexibility** should be given for operators to **single out the type of evidence & materials** in order to demonstrate the safety of the insect products in their applications. So, these remain consistent with the control methods which they apply on the ground (e.g. sampling results in the context of auto control measures), even if these may 'deviate' from the general 'scientific' requirements elaborated by EFSA (e.g. replacement of the 90 days oral feeding in rodents, which is required as part toxicity studies by other types of other studies/evidence demonstrating the safety of the products in question).

## Exchange of information & guidance

On 10 November 2016, EFSA published a guidance document which outlines the scientific data & other scientific requirements of NF applications. We understand that this document constitutes the standard according to which EFSA will form its opinion on application dossiers. On this basis, the European Commission will prepare implementing acts detailing the administrative 'content of the dossier' (see article 13 as mentioned above).

IPIFF highly values this document which provides 'baseline information' for its members to prepare their applications (see chapter 1 above). More generally IPIFF considers that close **collaboration between the industry & EU policy makers** - including the European Food Safety Authority - **shall continue during the process of preparation & submission of NF application**: these exchanges would indeed contribute to advance knowledge on the safety of insect products.

### IPIFF recommendations:

As EU umbrella organisations for insect producers, **IPIFF is committed to share with the EU public authorities any 'representative' data or evidence demonstrating the safety of insect products** (e.g. on issues related history of safe use, anticipated intake, nutritional, consumption data, toxicological & allergenicity).