Guidance for the risk assessment of additives produced with GM microorganisms

Input from industrial stakeholders

EFSA Info Session on Applications

Technical meeting with stakeholders on feed additives applications

14 and 15 July 2016

Management Center Europe, Brussels

EFSA has announced a Self-Task to develop a guidance document for the risk assessment of additives produced with GMMs

Who?

EFSA Feed Unit, FEEDAP Panel WG on GMMs involving experts from the CEF Panel

How and when?

- WG meetings during 2016
- Discussion and approval of draft revised guidance document end 2016 or beginning of 2017
- Public consultation during 8 weeks in March and April 2017
- Final adoption by the FEEDAP Panel during summer 2017
- Target completion end September 2017

amfep association of manufacturers & formulators of enzyme products

EuropaBio® The European Association for Bioindustries

fefana

FEFANA, AMFEP and EuropaBio welcome the initiative to develop a new guidance document for additives produced with GMMs

Since the current version from 2011:

- New technologies have emerged providing new possibilities to confirm safety of production strains
- We (industry, EU Commission, EFSA) have gained valuable experience

amfep association of manufacturers & formulators of enzyme products

EuropaBio® The European Association for Bioindustries

fefana

Overall industry objective of the development of the GMM guidance document

It is our hope that the guidance document remains:

- Operational and proportionate
- Risk and evidence based

Our associations have a strong wish:

- To be brought in as early as possible to share experiences and expectations
- To get the opportunity to have a scientific dialogue with EFSA - **prior to the planned public consultation**

Topics for discussion

As the GMM guidance document has a direct impact on how our industry operates we especially hope to be able to provide inputs to and discuss the following points (as also proposed by EFSA as priorities):

Technological advancements

How to reflect new technologies (e.g. ‘shotgun’ genome sequencing) in the guidance document?

rDNA measurements

Highly important to industry due to both a scientific and regulatory impact

Antibiotic resistance markers

Industry is phasing out production strains with antibiotic marker genes

As well as other points, such as: > demonstration of genetic stability; > risk assessment of chemically synthesized DNA etc.

amfep association of manufacturers & formulators of enzyme products

EuropaBio® The European Association for Bioindustries

fefana

Finally…..

FEFANA, AMFEP & EuropaBio would like to thank EFSA for this opportunity to express our interest in the development of the GMM Guidance document

We are looking forward to fruitful and constructive discussions throughout a clear and transparent procedure with stakeholder involvement

THANK YOU!