

Risk assessment of novel proteins regarding their potential capacity to cause celiac disease

Ad hoc meeting with industry representatives, 23-24 October, Parma



Current situation



Main aspects to highlight

- Real harmonisation between applicants
- Overall approach followed by applicants in line with EFSA 2017 allergenicity guidance
- EFSA respected transition period
- EFSA looking forward to advancing the tool increase trust on the assessments



Collaborative interaction with Stakeholders on achieving this major goal

Aspects requiring follow-up



Possible exclusion criteria (WoE approach)

Development of a database

HLA-DQ-peptide modelling

Possible exclusion criteria (WoE)



Additional considerations on amino acids flanking relevant motifs

- Specific position of individual amino acids
- Nature of amino acids _ size, charge,...
- Presence/absence of highly relevant amino acids (proline, glutamine, glutamic acid,...)
- Tool should be practical (stepwise/case-by-case approach)
- EFSA internally discussing potential means on:
 - how to address these and related points
 - how to provide additional considerations that can be used by the public at large

Development of a robust database



Key elements to be further advanced

Updates of current applicants' database are expected

A robust database will better frame what is the meaning we wish to allocate to the safety assessment



Database designed for risk assessment purposes within a defined context

Publicly available and curated regularly

Recognised inclusion criteria for the entrance of data into the database

Others...

HLA-DQ-peptide modelling



Re-launch of the EFSA procurement

Deadline for submission: 30th October 2019

https://www.efsa.europa.eu/en/procurement/tenders

Ongoing	Closed for offers			
Deadline		Reference	Title	Published
30/10/2019	14:30:59+01:00	OC/EFSA/GMO/2019/02	HLA-DQ Peptide Modelling Software	19/08/2019

RA novel proteins & celiac disease





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