Ad hoc meeting with industry association (AMFEP)

Joint Dossiers on Food Enzymes

AMFEP input

Topics

- Communication between EFSA and data holders
- Scientific gaps & Time frames
- EFSA opinions

AMFEP's main goal

Ensure that market is not disrupted and all the enzymes appear on the first positive list

- Keep the framework of the joint dossier
- Company specific data submission

To achieve this goal, resubmissions need to be done in a timeframe that is considered acceptable and feasible by EFSA/COM/Industry

Communication between EFSA and data holders

- AMFEP will ensure that all relevant information is shared with all JD members
  - Information from EFSA 16th March meeting
  - Supportive documents smoothening the data gathering and data submission for JD members
  - Any other relevant information
- Not all JD members are AMFEP members
- For each JD, AMFEP will provide an updated list of contacts

Communication between EFSA and data holders

- New submissions (microbial):
  - full dossier with all generic or incomplete elements replaced with company-specific data
- Proposal AMFEP:
  - Submission of company specific dossier directly to EFSA and not via AMFEP
  - Further communication on the company specific dossier between EFSA and individual companies
- Will EFSA formally communicate on dossiers' specific gaps?

Withdrawal from JD

Dossiers members will inform AMFEP, EFSA and EU Commission as soon as possible

Reasons could be :

- No longer interested in the specific enzymes for any reason (e.g. no longer producing)
- No data available
- Merging of companies

Timing

Analysis of scientific gaps & impact on submission timeline

Based on 3 main criteria

Study	Time	Resources	Costs	Total impact
pH curve	x	x	x	1
CoA	x	x	x	1
Allergenicity	x	xx	x	2
Exposure	?	x		2
QPS qualification	xx	x	xx	2
DNA	xx	x	xxx	3
WGS	xx	xxx	xx	3
Tox studies	xxx	xx	xxxx	4

?: will depend on the availability of FEIM models

One example : the tox studies

Current estimation:

- **40-45 new toxicity studies to be conducted**
- ***(for 56 new data packages – see next slide)***

Challenges

- Limited number of CROs can perform toxicity studies for food enzymes
- GLP analyses: transfer and validation enzyme essay time consuming
- Additional burden on top of compiling data on post 2015 and new enzymes
- Unexpected costs on especially low margin products
- Allow time to budget and spread costs

Timing (cont.)

Current estimation of expected number of new data packages

- based on the number of JD and number of members in each JD

No. of joint dossiers	Estimated no. of data packages
11 JD without tox requirements	65 • 24 of non-microbial origin • 41 QPS micro-organisms
7 JD with tox requirements	56
Total number of company specific data package	**121**

Fine tuning :

Possible withdrawals (Non-manufacturers, company strategy, burden…)

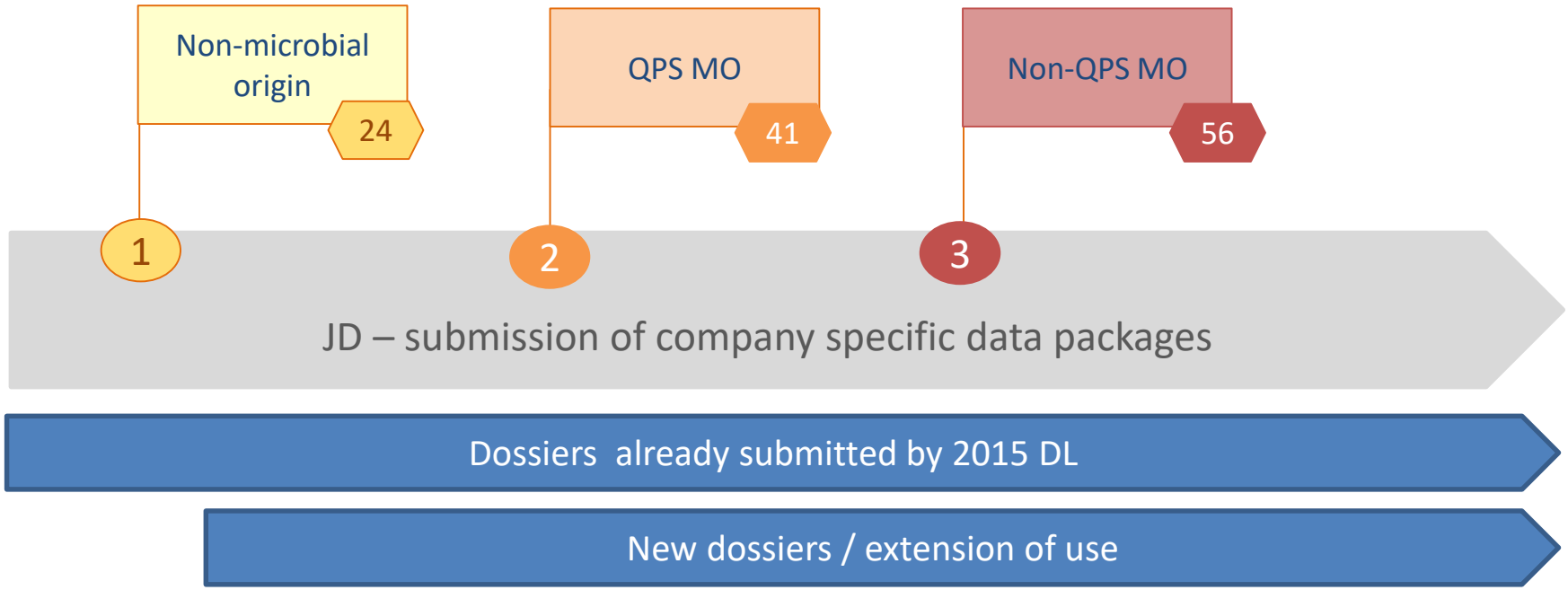
One company member of a JD can have several strains expressing the same enzyme (would lead to several new data pack/member)

This will come in addition to :

- the currently evaluated dossiers
- the new dossiers and extensions of use that will be submitted

Timing (cont.)

AMFEP proposal : Step-wise submission schedule, based on impact



- Responsibility of achieving (agreed) timelines lays with the individual companies.
- AMFEP will do everything in its power to facilitate timely submissions, but cannot give commitment on achieving timelines by individual companies.

Papain

- Produced from papaya (*Carica papaya*)- a fruit consumed throughout the world
- Papain is produced from the latex obtained from the green fruit as these contain high levels of papain
- Papaya latex has a long history of use including both food and pharma applications, a simple extraction process is used to obtain the pure commercial papain preparation from the latex

Papain

- Clarification is needed of EFSA requirements

- Industry suggests
  - Providing references showing the use of green papaya and papaya latex in food and pharma products

EFSA opinions

- Given the fact that strain specific data are being submitted, how will this be reflected in the EFSA opinion?

- Due to the use of state of the art taxonomic identification techniques, differences in taxonomy will appear. How will EFSA deal with that?

- Timing: how will different timing by companies to submit additional information during the dossier evaluation impact the finalization of the opinions?

Thank you for your attention!