General issues

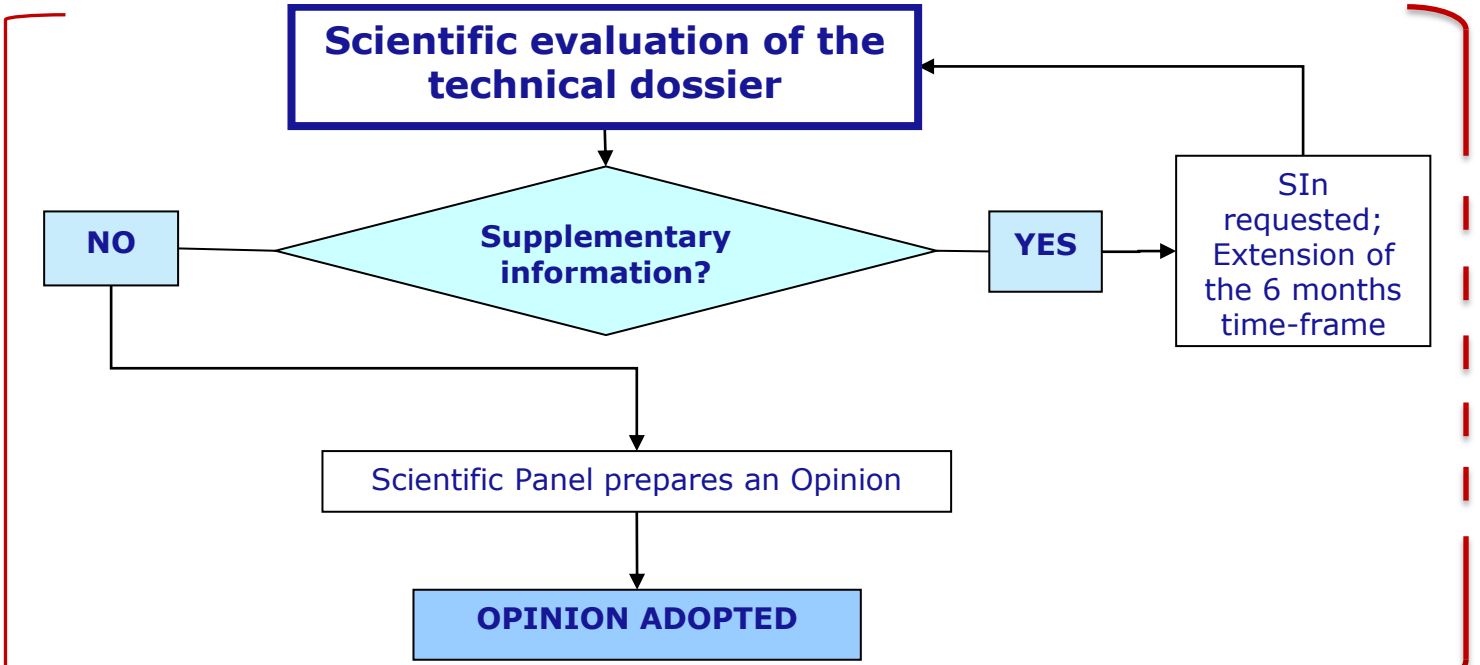
5 May 2015

OUTLINE

- Timelines
- Common issues with study acceptability
- Recent developments in the assessment
  - Duration piglet trials
  - Tolerance studies for trace elements
  - Assessment of phytases

TIMELINES

Process overview



6 Months

~ 15 months

6 + […] Months

INDICATIVE TIMELINES

EFSA Journal 2014;12(1):3553

- Streamline interaction EFSA/applicants
- Equal treatment on time limits
- Plan work Panel

- Extension of deadlines properly justified

Main issues

- Study design
- Study development
- Study reporting

Study design

- Test item
- Lack of adequate controls
- Treatment selection
- End-points measured
- Duration of studies
- Statistics:
  - Experimental unit
  - Replication
  - Statistical analysis

Study development

- Therapeutic/preventive treatments
- Morbidity/mortality
- Low performance
- Determination of active substance/agent in feed

Study reporting

- Limited reporting
- Missing essential information
- Raw data
- Statistical evaluation:
  - Experimental units
  - Only relevant treatments to be reported
  - EFSA Guidance on Statistical reporting (2014)

STUDY DURATION WITH PIGLETS

(Minutes of 99th Plenary – October 2013)

42 vs 35 days

A period of at least 35 days may be accepted if:

- Cumulative weight gain >17.5 kg/pig

For tolerance:

- Age < 35 days
- Adaptation period not included (basal diet)
- Body weight & feed intake measured 4 times
- Feed *ad libitum*

(Minutes of 103rd Plenary – April 2014)

Most sensitive species

"Where the application is for all animal species/categories tolerance data may be limited to one study in one target species or laboratory animal (the most sensitive in each case)."

- The identification of the "most sensitive animal" may become an issue in some cases.

- Sensitiveness of the test. Doses used, positive controls, selection of biomarkers and toxicological endpoints.

- The Panel provided a list of species for which the tolerance studies are considered equivalent.

EFFICACY ASSESSMENT PHYTASES (I)

(Minutes of 107th Plenary – October 2014)

Efficacy of phytases can be demonstrated with 3 short-term studies provided that digestibility of phytate/total P and partial (e.g., bone ash/P) or total P retention are included as end-points.

Studies in which the effect of a phytase is only measured as the digestibility of total phosphorus will not be accepted as proof of efficacy

EFFICACY ASSESSMENT PHYTASES (II)

(Minutes of 107th Plenary – October 2014)

Exception!

Considering ethical and technical reasons, the Panel may accept the study of the **faecal digestibility of total phosphorus in sows**

Note that,

Applications for gestating and lactating, **at least one study should be performed in lactating sows**

In **lactating sows**, the additive should be offered during the whole lactation period and the performance of the litter during the lactation should be reported

EFFICACY ASSESSMENT PHYTASES (III)

(Minutes of 107th Plenary – October 2014)

The Panel noted that the study of the effect of the additive in **laying hens** should consider the following:

The study of the phosphorus balance should include the study of **Phosphorus in excreta and in the egg**

The **laying intensity** of the hens should be recorded **before** (minimum two weeks) and **during** the balance period