Frequent deficiencies in applications

General

- Tables in all B sections shall be in an editable format
- All relevant endpoints shall be mentioned in the B section, a reference to EFSA LoEP is not sufficient
- Explanations and conclusions on the risk assessments shall be given in all B sections
- All B sections shall be adjusted to the Northern Zone. DEPA does not accept dRR's from the Central or Southern Zone
- The requirements in the Northern Zone guidance document and in the Danish Framework shall be fulfilled
- The application must comply with restrictions in the Commission Implementing Regulation for the active substance
- The application should comply with the data requirements in force at time of dossier submission
- Data gaps identified in the EFSA conclusion should be addressed
- Annex II and Annex III studies shall be submitted in a manageable format and shall include all studies used in the assessment. If Annex II studies have been submitted earlier and if the studies are still in a readable format (i.e. Caddy-xml), resubmission is not mandatory

Mammalian Toxicology (Section Part B6)

- Dermal absorption values shall be recalculated in accordance with EFSA Journal 2017;15(6):4873[1]
- If it is mandatory for the product to be in a tank-mix, this shall be clear in the B6 section and the tank mix shall be a part of the product evaluation
- Applications for mutual recognition shall comply with the Northern Zone guidance and Danish Framework
- In cases where the EFSA calculator cannot be used for exposure calculations, default values shall comply with EFSA Journal 2014;12(10):3874[1]

Physical and chemical properties (Section Part B 1,2,4)

- The requirement for the foam test shall be fulfilled
- If the product is to be sprayed, the spray pattern shall be demonstrated
- If the product forms aerosols during fx spraying or is on powder form, particle size distribution shall be measured and fraction < < 50 uM reported
- If the product is formulated in a bag, a stacking test shall be performed
- Test for explosive properties, oxidizing properties and corrosion shall be performed, unless a valid waiving is presented
- Two year stability test required before authorisation – packaging type and size must be covered

Analytical methods (Section Part B5)

- All analytical methods, both for active substance and impurities, shall be validated in accordance with SANCO/3030/99 rev.5[1] and the requirements shall be fulfilled and described

[1] or later rev. when available

Ecotoxicology (Section Part B9)

- If the PPP contains more than one active substance and formulation toxicity data are not available for certain endpoints, an assessment of the cumulative risk must be performed for the concerned non-target species cf. the EFSA guidance document for birds and mammals (EFSA Journal 2009; 7(12) 1438) and the Northern Zone Guidance document
- Risk assessments must be performed for all metabolites in the various compartments (soil, water, sediment)

Birds and mammals:

- Higher tier risk assessments must be performed according to the Northern Zone Guidance document
- An assessment of secondary poisoning for the active substance and metabolites must be performed when triggered

Aquatic organisms:

- Product endpoints (converted to active substance unit) must be used in the aquatic risk assessment
- Analytical methods must be addressed for the aquatic studies in section B5

Soil meso- and macrofauna:

- Endpoints must be corrected by a factor of 2 if the log Kow is greater than 2 and if the toxicity tests are performed with soil containing less organic matter than 10%, unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of organic carbon content in soil.
- Chronic toxicity studies and studies for other soil organisms than earthworms are required according to the data requirements set in Regulation (EC) 284/2013

Arthropods other than bees:

- If a higher tier risk assessment is triggered, studies on a sufficient number of species must be submitted according to the data requirements

Bees:

- Chronic toxicity studies for adult bees and larvae must be submitted according to the data requirements set in Regulation (EC) 284/2013. The risk assessment must be performed according to the Northern Zone Guidance document

Environmental fate (Section Part B8)

- All in-/output files for modelling must be submitted

Assessment of substances in soil:

- An assessment of persistency of active substance and metabolites in soil is required. For field studies, non-normalised DT_{50} values must be used in the persistency assessment
- PEC_{max} and PEC_{acc} must be reported for all active substances and metabolites

Assessment of substances in ground water and surface water:

- PEC_{sw} must always be available at Step 3
- PECgw national requirements must be fulfilled

Confidential information (Section Part C)

- Details on the complete (100 %) composition of co-formulants shall be submitted
- All relevant impurities in the product shall be addressed in section Part C