



Chemicals Regulation Division

Two Day Efficacy Workshop: Efficacy Requirements and Assessment under EC 1107/2009

Programme

September 2018

Time	DAY 1
9:30 – 10:00	Registration and coffee
10:00 – 10:15	Welcome and introductions to CRD
10:15 – 11:15	Efficacy overview of Legislation <ul style="list-style-type: none">• Active substance• What are the data requirements?• Requirements of zonal authorisations• Chemical composition changes and generic products• Zonal decision making
11:15 – 11:30	EPPO standards <ul style="list-style-type: none">• Use of EPPO and other standards
11:30 – 11:50	Refreshment break
11:50 – 12:00	dRR Sec 3.7: test facilities -OR/GEP certificates <ul style="list-style-type: none">• Brief overview of requirements
12:00 – 12:20	Major and minor crops and targets <ul style="list-style-type: none">• Why is it required• What is needed in the draft registration report (dRR)?• What information may be considered?• Extrapolations• UK Examples
12:20 – 12:50	Principles of data presentation

	<ul style="list-style-type: none"> • Summarising appropriately to address the data requirements • Relationship between the biological assessment dossier (BAD) and the dRR • Common Errors
12:50-13:00	Question and answer session
13:00 -13:50	Buffet Lunch – will be provided
13:50 –14:15	Draft registration report templates <ul style="list-style-type: none"> • The guidance • The template
14:15 – 14:30	dRR Section 3.2.1: Preliminary data <ul style="list-style-type: none"> • Importance • Supporting co-formulations
14:30- 14:45	Worked example: justifying co-formulations
14:45 - 15:05	Refreshment break
15:05 – 15:20	dRR Sec 3.2.2 Minimum effective dose tests <ul style="list-style-type: none"> • What data are needed and how to present them.
15:20 – 15:40	Worked example: minimum effective dose
15:40 – 16:10	dRR section 3.2.3: Efficacy tests – Overview <ul style="list-style-type: none"> • Key aspects • Zonal aspects of data presentation + zonal example • Examples • Data inclusion and exclusion • Extrapolations • Common errors
16:10 – 16:30	dRR section 3.2.3: Efficacy tests – herbicides
16:30 –17:00	Worked example: effectiveness - herbicides
17:00 –17:20	Round up of day 1 and questions and answers for afternoon session
	End of day 1
Time	DAY 2
8:45 – 9:00	Refreshments
9:00 – 9:10	Brief review of day 1 and Look forward to day 2
9:10 – 9:40	dRR section 3.2.3: Efficacy tests – fungicides <ul style="list-style-type: none"> • Key aspects • Zonal examples • Following the data through

	<ul style="list-style-type: none"> • UK claim levels + special cases • Extrapolations • Common errors
9:40 – 10:10	Worked example: effectiveness - fungicide
10:10 –10:40	dRR section 3.2.3: Efficacy tests – insecticides <ul style="list-style-type: none"> • Key aspects • Zonal aspects • Life cycle stage • UK claim levels + special cases • Extrapolations • Common Errors
10:40 – 11:00	Worked example: effectiveness - insecticide
11:00 – 11:20	Refreshment break
11:20 – 11:50	dRR 3.3 resistance <ul style="list-style-type: none"> • Key elements • Resistance risk assessment and management strategies • Using the information available appropriately • UK issues and guidance
11:50–12:30	dRR Sec 3.4 Adverse effects (phytotoxicity, yield, quality) <ul style="list-style-type: none"> • Key aspects • Crop safety and selectivity trials • Relationship between phytotoxicity and yield • Quality
12:30 –12:50	Worked example: effectiveness – adverse effects
12:50 – 13:00	Questions and answer on morning session
13:00 –13:50	Lunch
13:50 –14:00	dRR Sec 3.4 3-3.4.5 Adverse effects: propagation, taint and transformation processes <ul style="list-style-type: none"> • How to address with data and/or cases
14:00 –14:20	dRR Sec 3.5 Side effects: succeeding & adjacent crops <ul style="list-style-type: none"> • Calculating toxicity exposure ratios (TERs) • Tiered approaches and using field trials • Restrictions to manage risk • Common problems
14:20-14:30	dRR Sec 3.5.2 and 3.6 Other Studies <ul style="list-style-type: none"> • Residues in tank and tank washing procedures • Other studies
14:30 –14:50	Worked example: succeeding crops

14:50-15:10	Refreshments
15:10 – 15:35	UK national addenda
15:35 – 15:45	Article 43 Renewals
15:45 – 16:00	Final questions on day 2 sessions and any other questions
16:00	Depart

(We reserve the right to amend the content if appropriate)