EXAMPLE BUFFER ZONE ASSESSMENT FOR SPRAY DRIFT FOR A HORIZONTAL BOOM SPRAYER IN FIELD CROPS

1. Introduction

'Lerapo' is a fungicide product containing the active substance lerazole used on winter wheat and oilseed rape. Details of the good agricultural practice (GAP) for this product are shown below.

Table 1 Details of the GAP and uses of 'Lerapo'

Crop	Disease	Timing	Maximum individual dose g a.s./ha	No. of applications	Spray interval (days)	Maximum total dose g a.s/ha
Winter wheat:	Septoria	BBCH 41-61	1000	2	14 days	2000
Winter wheat:	Yellow rust	BBCH 31-69	500	2	14 days	1000
Oilseed rape	Light leaf spot	BBCH 21-69	1500	1	14 day	1500
Oilseed rape	Sclerotinia	BBCH 60-69	1250	2	14 days	2500

The buffer zone assessment for 'Lerapo' should be performed on **an individual crop basis** using the principles of the risk envelope approach. The key parameters influencing the entry into adjacent surface water via spray drift are: application rate, number of applications and interval between applications. For all field crops treated via typical horizontal boom spray equipment a single set of drift values are available irrespective of application timing (see Appendix 2). Additionally a calculator is provided on the CRD website which can be used to calculate the appropriate Predicted Environmental Concentration surface water (PECsw values). The field crop drift data provides an estimate of a 90th percentile drift event for single applications and an overall 90th percentile drift for multiple applications based on lower individual percentile drift events for each individual application. When estimating potential exposure levels arising from multiple applications, a single first order water phase dissipation DT50 value is required[1]. The choice of DT50 is generally the longest value from the available water/sediment systems.

[1] Note that dissipation is used to describe the process leading to the eventual disappearance of a substance from an environmental compartment. Dissipation does not differentiate between transfer processes and degradation processes and can therefore include partitioning to sediment and volatilisation as well as degradation.

An important issue arises from the use of lower spray drift values for individual applications in a multiple application scheme compared to the 90^{th} percentile spray drift value for a single application. **Dependent on the water phase DT50 and application interval, the use of the 90^{th} percentile drift value for a single application could give a higher Predicted Environmental Concentration surface water (PECsw) than the overall 90th percentile for multiple applications.** Thus it is always important with multiple application scenarios to initially conduct calculations for both a single application and multiple applications to determine which gives the highest PECsw. The highest PECsw should be used as the basis of all risk envelope decisions and subsequent aquatic risk assessments.

For the example above, of the two proposed uses on winter wheat, using the risk envelope approach the use against Septoria will represent the highest potential surface water exposure levels via drift, since of the two proposed winter wheat uses this represents both the highest individual and total dose and the application interval is 14 days for both uses. However both the single and multiple application pattern for the Septoria use should be assessed to ensure the highest PECsw is used for the aquatic risk assessment. This is shown in the worked example below.

For the proposed oilseed rape uses the risk envelope approach must also consider the single and multiple application patterns. Since dependant on the water DT50 the highest PECsw could arise from either the single application of 1500 g a.s./ha or the multiple application of 2 x 1250 g a.s./ha. This process is also further explained in the tables below.

2. Fate calculation of predicted environmental concentrations for surface water from spray drift for the active substance

An aquatic risk assessment for each crop is undertaken using which ever rate will generate the maximum predicted environmental concentration for surface water via spray drift. The product 'Lerapo' contains the active substance lerazole for which the longest single first order water phase dissipation DT50 agreed during the Annex I assessment[2] is 10 days (DT90 = 33.2 d).

[2] Applicants should be aware that the water phase dissipation DT50 values may not always be listed in the EU Review Report of EFSA conclusion, which may only report water, sediment or total system degradation DT50 values for the purposes of FOCUSsw modelling. Since dissipation values will often be significantly shorter than degradation values Applicants may need to derive appropriate values from the range of acceptable water/sediment studies considered at Annex I inclusion.

Table 2 Summary of drift PECsw values for the proposed use of 'Lerapo' on winter wheat

Distance (m)	PECsw (µg/l) following **single** applications of 1000 g a.s./ha based on 90^{th} percentile drift data	PECsw (µg/l) following **two applications** of 1000 g a.s./ha at 14 d intervals based on 82nd percentile drift data
1	9.233	**10.940**
5	1.900	**2.160**
6	1.600	**1.793**

In this example it can be seen that the multiple application pattern resulted in higher PECsw values at every distance. This will generally be the case when the water phase DT90 is longer than the application interval since significant residues will be carried over between applications. However this can sometimes be quite complex and further difficulties can arise if application rates and/or intervals change across the proposed GAP. It is therefore always advisable to perform a quantitative assessment of single and multiple application GAPs to ensure the correct PECsw is used in the risk assessment. Note that in the above example there was no need to formally consider the 500 g a.s./ha rate against yellow rust on winter wheat since this will always result in lower PECsw values than the 1000 g a.s./ha rate against Septoria.

Table 3 Summary of drift PECsw values for the proposed use of 'Lerapo' on oilseed rape

Distance (m)	PECsw (µg/l) following **single** applications of 1500 g a.s./ha based on 90^{th} percentile drift data	PECsw (µg/l) following **two applications** of 1250 g a.s./ha at 14 d intervals based on 82nd percentile drift data
1	**13.850**	13.674
5	**2.850**	2.700
6	**2.400**	2.241
7	**2.050**	1.953
8	**1.800**	1.666

In this example it can be seen that the single application pattern at 1500 g a.s./ha resulted in higher PECsw values than the multiple application pattern of 2 x 1250 g a.s./ha at every distance. Note that in this example there was no need to formally assess a single application of 1250 g a.s./ha since this would always result in lower PECsw values than the single 1500 g a.s./ha rate.

The implications of the different PECsw values for each crop are discussed below.

3. Aquatic risk assessment for the active substance

All toxicity endpoints for the product data were converted into units of active substance for comparison with the active substance endpoints to see whether the active substance or formulation was more toxic. **In fact in this case the active substance was more toxic than the formulation so it is the active substance endpoints which are relevant for the aquatic assessment.** There are two separate approaches that can be used in to assess the aquatic risk for the product 'Lerapo'. These are described below, it should be noted that it is only necessary to undertake one of these approaches, so you can choose which you want to use. The toxicity data are as follows:

Table 4: Toxicity data for 'Lerapo' (the active substance lerazole was more toxic than the formulation)

Organism	Time scale	Endpoint µg a.s./L
Fish	Acute	LC50:400
Aquatic invertebrate	Acute	EC50:310
Fish	Chronic	NOEC: 21.6
Aquatic invertebrate	Chronic	NOEC: 55
Algae	Chronic	EbC50: 1500

3.1 The toxicity exposure ratio approach (TER)

Either a standard TER approach is used and each aquatic organism and crop is considered in turn or a regulatory acceptable concentration (RAC) approach can be considered (see 3.2 below). In determining the PECsw value which will give an acceptable risk the regulatory acceptable concentration (RAC) can be considered. Full details are given at 3.2 below and this shows that the PECsw must be ≤ 2.16 µg a.s./L for the chronic risk for fish (which is driving the risk assessment) to be acceptable. Looking at the PECsw tables (Tables 2 and 3) it can be seen that this occurs at exactly 5m for wheat but for oilseed rape a buffer zone of 7 m is required.

Table 5: TERs for ‘Lerapo’ for aquatic organisms

Wheat					
Organism	Time scale	Endpoint µg a.s./L	PECsw 5m µg a.s./L	TER (5m)	Annex VI trigger value
Fish	Acute	LC50:400	2.16	185.2	100
Aquatic invertebrate	Acute	EC50:310	2.16	143.5	100
Fish	Chronic	NOEC: 21.6	2.16	10.0	10
Aquatic invertebrate	Chronic	NOEC: 55	2.16	25.5	10
Algae	Chronic	EbC50: 1500	2.16	694.4	10
Oilseed rape					
Organism	Time scale	Endpoint µg a.s./L	PECsw 7m µg a.s./L	TER (7m)	Annex VI trigger value
Fish	Acute	LC50:400	2.050	195.1	100
Aquatic invertebrate	Acute	EC50:310	2.050	151.2	100
Fish	Chronic	NOEC: 21.6	2.050	10.5	10
Aquatic invertebrate	Chronic	NOEC: 55	2.050	26.8	10
Algae	Chronic	EbC50: 1500	2.050	731.7	10

3.2 The Regulatory Acceptable Concentration (RAC) approach

Alternatively the regulatory acceptable concentration (RAC) for each group of organisms is derived as shown in the table below. The RAC is simply the toxicity endpoint divided by the appropriate Annex VI trigger value for that organism. It can be seen that the lowest RAC is obtained using the chronic toxicity data for fish. Therefore an assessment covering the chronic risk to fish will also ensure that the risk to all other groups of aquatic organisms is acceptable. The lowest RAC is compared with the maximum PECsw for each of the proposed crops; the risk is acceptable where the PECsw is ≤ 2.16 µg a.s./L. Scanning the PECsw tables (Tables 2 and 3) it can be seen that this occurs at exactly 5m for wheat but for oilseed rape a buffer zone of 7 m is required.

Table 6: Regulatory acceptable concentrations for 'Lerapo' (all endpoints in terms of active substance)

Organism	Time scale	Endpoint µg a.s./L	Annex VI trigger value	Regulatory acceptable concentrations µg a.s./L
Fish	Acute	LC50:400	100	4.0
Aquatic invertebrate	Acute	EC50:310	100	3.1
Fish	Chronic	NOEC: 21.6	10	**2.16**
Aquatic invertebrate	Chronic	NOEC: 55	10	5.5
Algae	Chronic	EbC50: 1500	10	150

(NB the regulatory acceptable concentration is simply the toxicity endpoint divided by the Annex VI trigger value).

Table 7: Comparison of the PECsw with the RAC to determine if a buffer distance is required and if so the distance needed

Crop	Lowest RAC µg a.s./L	PECsw µg a.s./L	Buffer distance (m)
Wheat	Chronic fish RAC: 2.16	2.16	5
Oilseed rape	‘’	2.050	7

Some people are less familiar with the concept of ensuring that the PECsw is ≤ the regulatory acceptable concentration therefore it is also shown what this means in terms of a toxicity exposure ratio (TER) (in this example only the TER for the chronic toxicity for fish is examined as this will cover all the other aquatic organisms). It should be noted that Table 8 is purely provided here for illustrative purposes and is not required to be submitted.

Table 8: This shows how an acceptable RAC also results in an acceptable TER

Organism with lowest RAC	Endpoint µg a.s./L	Crop	PECsw µg a.s./L	TER	Annex VI trigger
Chronic fish	21.6	Wheat	2.16 at 5m	10	10
‘’	‘’	Oilseed rape	2.050 at 7m	10.5	10

3.3 Buffer zone requirements

This example shows that a buffer zone of 5 metres is required for wheat and 7 metres for oilseed rape.

4. Metabolites

The active substance lerazole has only one relevant metabolite, lerazole acid and a risk assessment also needs to be undertaken for this.

4.1 Fate calculation of predicted environmental concentrations for the metabolite in surface water from spray drift

For metabolites the PECsw can be calculated based on the active substance application rate adjusted for maximum observed metabolite formation in the water/sediment studies and further corrected for molecular weight differences as appropriate. Due to the uncertainty over peak formation of metabolite levels following multiple application GAPs, the simple first tier approach recommended in the UK for multiple applications is to use the maximum total dose of the active substance (corrected for peak metabolite occurrence and molecular weight) and to combine this with the appropriate overall 90th percentile spray drift value i.e. if the GAP specifies two applications the 82nd percentile drift data should be used for the metabolite calculations e.g. 2.38% at 1m, 0.47% at 5m etc. This method can be used to calculate a simple conservative peak metabolite concentration for the purposes of a first tier risk assessment. More refined methods that take into account the pattern of formation and decline may be applied if this simple first tier approach does not result in an acceptable risk assessment.

The metabolite lerazole acid only occurred in significant amounts in the water phase of the available water sediment studies (peak occurrence of 25% of parent applied). The parent molecular weight is 350 g/mol and the metabolite molecular weight is 277 g/mol. For the winter wheat use, the maximum total dose proposed is 2000 g a.s./ha. This can be converted to metabolite equivalents using the peak occurrence and molecular weight differences i.e. 2000 g a.s./ha * 25% * 277/350 = 395.7 g lerazole acid / ha. This value can be combined with the appropriate overall 90th percentile spray drift value and in this case since the total dose arises from two applications, the 82nd percentile drift data should be used. This results in a metabolite PECsw value of **3.14 µg/l** at 1m for the wheat use.

For the oilseed rape use, the maximum total dose proposed is 2500 g a.s./ha. This can again be converted to metabolite equivalents using the peak occurrence and molecular weight differences i.e. 2500 g a.s./ha * 25% * 277/350 = 494.6 g lerazole acid / ha. This value can be combined with the appropriate overall 90th percentile spray drift value and in this case since the total dose again arises from two applications, the 82nd percentile drift data should be used. This results in a metabolite PECsw value of **3.92 µg/l** at 1m for the oilseed rape use.

4.2 Aquatic risk assessment for the metabolite

The toxicity data for lerazole acid are shown in the table below.

Table 9 Toxicity data for lerazole acid

Organism	Time scale	Endpoint µg a.s./L	RAC µg a.s./L
Fish	Acute	LC50:>2000	>20
Aquatic invertebrate	Acute	EC50:>2000	>20
Fish	Chronic	NOEC: 1000	100
Aquatic invertebrate	Chronic	NOEC: 1000	100
Algae	Chronic	EbC50: >2000	>200

4.2.1 TER approach

Either the toxicity endpoints for the metabolite are compared with the PECsw for the metabolite for wheat and oilseed rape or the RAC approach at 4.2.2 is used. The TER results are shown in the table below.

Table 10 TERs for the metabolite lerazole acid for aquatic organisms from use on wheat and oilseed rape.

Wheat					
Organism	Time scale	Endpoint µg metabolite/L	PECsw 1m µg metabolite/L	TER (1m)	Annex VI trigger value
Fish	Acute	LC50:>2000	3.14	>636.9	100
Aquatic invertebrate	Acute	EC50:>2000	3.14	>636.9	100
Fish	Chronic	NOEC: 1000	3.14	318.5	10
Aquatic invertebrate	Chronic	NOEC: 1000	3.14	318.5	10
Algae	Chronic	EbC50: >2000	3.14	>636.9	10
Oilseed rape					
Organism	Time scale	Endpoint µg metabolite/L	PECsw Xm µg metabolite/L	TER (Xm)	Annex VI trigger value
Fish	Acute	LC50:>2000	3.92	510.2	100
Aquatic invertebrate	Acute	EC50:>2000	3.92	510.2	100
Fish	Chronic	NOEC: 1000	3.92	255.1	10
Aquatic	Chronic	NOEC: 1000	3.92	255.1	10

invertebrate					
Algae	Chronic	EbC50: >2000	3.92	510.2	10

4.2.2 The RAC approach

The lowest RAC is selected and in this example there are several organisms with the same lowest RAC of >20 µg a.s./L. For the risk to be acceptable the PECsw needs to be ≤20 µg a.s./L. Examining the PECsw it can be seen that these are both below 20 µg a.s./L for each crop and so the metabolite risk is acceptable with no buffer zone.

Table 10 Comparison of the metabolite lerazole acid PECsw with its RAC to determine if a buffer distance is required

Lowest RAC µg metabolite/L	Crop	PECsw µg metabolite/L
Acute fish, acute aquatic invertebrate and algae: >20	Wheat	3.14
‘’	Oilseed rape	3.92

4.2.3 Conclusion

No buffer zone is required in either wheat or oilseed rape to manage the risk of the metabolite lerazole acid.

5. Overall conclusion of aquatic risk assessment

The risk assessment shows that the following buffer zones are required to manage the risk for ‘Lerapo’. The risk to aquatic organisms will therefore be managed by specifying the required buffer distance and adding appropriate labelling to the product.

Table 12 Summary of the buffer zone requirements and label phrases for 'Lerapo'

Crop	Buffer zone required (metres)	Label phrase required.
Wheat	5	SPe3: To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements. DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body]*. Aim spray away from water. * if hand-held uses are permitted
Oilseed rape	7m	SPe3: To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements. DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within the distance specified for the crop to the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body.]* Aim spray away from water. THIS PRODUCT IS NOT ELIGIBLE FOR BUFFER ZONE

Crop	Buffer zone required (metres)	Label phrase required.
		REDUCTION UNDER THE LERAP HORIZONTAL BOOM SPRAYERS SCHEME * if hand-held uses are permitted

APPENDIX 1: EXAMPLE SHOWING HOW THE AQUATIC RISK IS ASSESSED WHEN THE FORMULATION IS MORE TOXIC THAN THE ACTIVE SUBSTANCE

1. Introduction

The product 'Buffero' is a fungicide containing the active substance bufferzole for Septoria control on winter wheat only. Formulation data show that the formulation is more toxic than the active substance and therefore in addition to undertaking a risk assessment for the active substance a risk assessment is also required for the formulation. **This example only focuses on the formulation aspect of the risk assessment as an example is already provided to show how to address the risk from an active substance.** There are no metabolites of the active substance bufferzole. The good agricultural practice (GAP) for 'Buffero' is shown in Table A1.

Table A1 <u>The GAP for 'Buffero'</u>

Crop	Disease	Timing	Maximum individual dose g formulation/ha[1]	No. of applications	Spray interval (days)	Maximum total dose g formulation /ha
Winter wheat:	Septoria	BBCH 41-61	500	2	14 days	1000

[1] This equates to 250 g a.s./ha.

2. Fate calculation of predicted environmental concentrations for surface water from spray drift for the active substance

When calculating the potential for surface water exposure via spray drift for the formulation it is only necessary to consider a single application at the maximum individual dose rate along with the spray drift data for a single application (e.g. the 90^{th} percentile spray drift data). A single peak PECsw need only be calculated. This is because it is assumed that exposure to the intact formulation will only occur immediately after an individual spray event and that the individual components of the formulation will have dissipated in the water body by the time of any subsequent applications. Therefore for the product 'Buffero' a single application of 500 g formulation/ha should be considered and results are shown in Table A2 below.

Table A2 <u>Summary of formulation spray drift PECsw values for the proposed use of 'Buffero' on winter wheat</u>

Distance (m)	PECsw (µg/l) following **single** application of 500 g

	formulation/ha based on 90th percentile drift data
1	**4.62**
5	**0.95**

3. Aquatic risk assessment for the active substance

In the same way as for the active substance there are two separate approaches that can be used in to assess the aquatic risk for the product 'Lerapo'. These are described below, it should be noted that it is only necessary to undertake one of these approaches, so you can choose which you want to use.
The toxicity data for 'Buffero' are as follows:

Table A3: Toxicity data for 'Buffero' (the formulation was more toxic than the active substance)

Organism	Time scale	Endpoint µg formulation/L	Annex VI trigger value	RAC µg formulation/L
Fish	Acute	LC_{50}:500	100	5.0
Aquatic invertebrate	Acute	EC_{50}:480	100	4.8
Algae	Chronic	EbC_{50}: 1500	10	150

3.1 The toxicity exposure ratio approach (TER)

The standard TER approach can be used and the toxicity end point for each organism is compared with the formulation PECsw.

Table A4: TERs for 'Buffero' for aquatic organisms for wheat

Organism	Time scale	Endpoint µg formulation/L	Formulation PECsw µg formulation/L at 1 m	TER (1m)	Annex VI trigger value
Fish	Acute	LC_{50}:500	4.62	108.2	100
Aquatic invertebrate	Acute	EC_{50}:480	4.62	103.9	100
Algae	Chronic	EbC_{50}: 1500	4.62	324.7	10

No buffer zone is required to manage the formulation risk.

3.2 The Regulatory Acceptable Concentration (RAC) approach

Alternatively the regulatory acceptable concentration (RAC) for each group of organisms is derived by simply dividing the toxicity endpoint by the appropriate Annex VI trigger value for that organism. This is shown in the table above. It can be seen that the lowest RAC is obtained using the acute toxicity data for aquatic invertebrates. Therefore if an assessment is done to cover the acute risk to aquatic invertebrates then this will also cover the formulation risk to all other groups of aquatic organisms is also acceptable. The lowest RAC is then compared with the maximum formulation PECsw for the proposed crop the risk is acceptable where the PECsw is ≤ 4.8 µg formulation/L. From the table of PECsw for the formulation (see Table A2 above) it can be seen that this occurs at 1m for wheat. This is shown in the table below.

Table A5: Comparison of the formulation PECsw with the formulation RAC to determine if a buffer distance is required

Crop	Lowest RAC µg a.s./L	PECsw µg formulation/L
Wheat	Acute aquatic invertebrates RAC: 4.8	4.62 (at 1m)

No buffer zone is required to manage the formulation risk.

5. Overall conclusion of the formulation aquatic risk assessment

The risk assessment shows that the no buffer zone is required to manage the formulation risk for ‘Buffero’. The formulation risk to aquatic organisms does not therefore require a buffer zone to mitigate it.

It is important to note that it is also necessary to undertake a risk assessment for the active substance since for instance it could be the chronic risk to fish which is pivotal to the risk assessment i.e. which ultimately determines if the risk is acceptable and any buffer zone required. This is not shown here again as an example of an active substance risk assessment has already been provided.

APPENDIX 2: SPRAY DRIFT VALUES FOR HORIZONTAL BOOM SPRAYERS FOR 1 TO 8 (AND ABOVE) APPLICATIONS AT DISTANCES UP TO 20 METRES

Rautmann Drift Values

Field Crops

Source: https://www.julius-kuehn.de/at/ab/abdrift-und-risikominderung/abdrifteckwerte/

(>Abdrifteckwerte > Tabelle der Abdrifteckwerte.xls)

Basic drift power curve y = axb

Parameter values

Power parameters	No of applications							
	1	2	3	4	5	6	7	8 and more
a	2.7705	2.3816	2.0093	1.8542	1.7488	1.6429	1.6111	1.5222
b	-0.9787	-1.005	-0.9922	-0.9907	-0.9885	-0.9843	-0.9847	-0.9817

Calculated Basic Drift Values

Distance	**No of applications**							
[m]	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8 and more**
	90th centile	**82nd centile**	**77th centile**	**74th centile**	**72nd centile**	**70th centile**	**69th centile**	**67th centile**
1	2.77	2.38	2.01	1.85	1.75	1.64	1.61	1.52
5	0.57	0.47	0.41	0.38	0.36	0.34	0.33	0.31

6	0.48	0.39	0.34	0.31	0.3	0.28	0.28	0.26
7	0.41	0.34	0.29	0.27	0.26	0.24	0.24	0.23
8	0.36	0.29	0.26	0.24	0.22	0.21	0.21	0.2
9	0.32	0.26	0.23	0.21	0.2	0.19	0.19	0.18
10	0.29	0.24	0.2	0.19	0.18	0.17	0.17	0.16
11	0.27	0.21	0.19	0.17	0.16	0.16	0.15	0.14
12	0.24	0.2	0.17	0.16	0.15	0.14	0.14	0.13
13	0.23	0.18	0.16	0.15	0.14	0.13	0.13	0.12
14	0.21	0.17	0.15	0.14	0.13	0.12	0.12	0.11
15	0.2	0.16	0.14	0.13	0.12	0.11	0.11	0.11
16	0.18	0.15	0.13	0.12	0.11	0.11	0.11	0.1
17	0.17	0.14	0.12	0.11	0.11	0.1	0.1	0.09
18	0.16	0.13	0.11	0.11	0.1	0.1	0.09	0.09
19	0.16	0.12	0.11	0.1	0.1	0.09	0.09	0.08
20	0.15	0.12	0.1	0.1	0.09	0.09	0.08	0.08