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SID 5 Research Project Final Report

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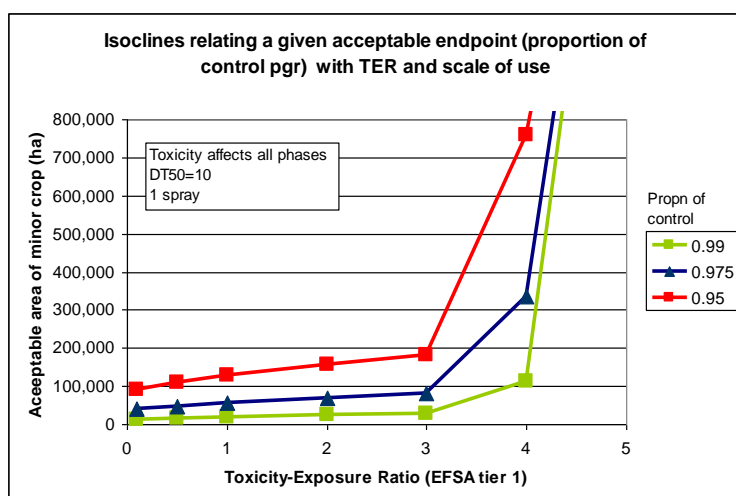
Executive Summary

7. The executive summary must not exceed 2 sides in total of A4 and should be understandable to the intelligent non-scientist. It should cover the main objectives, methods and findings of the research, together with any other significant events and options for new work.

1. Current approaches to assessing the risks from pesticides to wild birds and mammals are based on estimates of exposure for animals that are visiting pesticide-treated crops. This assesses the risk for that part of the population that visits treated crops. It does not take account of the scale of use of the pesticide, which determines what proportion of the total population is exposed. This project considered practical ways to take account of scale of use in acute and reproductive risk assessments for birds and mammals.
2. The implication is that the acceptability of a risk is influenced by its spatial extent as well as its magnitude. In order to take account of this, it is necessary to replace or augment current measures of risk (e.g. toxicity exposure ratio, TER) with new measures of risk that reflect the scale of use in an appropriate way and with new criteria for decision-making.
3. The project therefore undertook a preliminary assessment of the potential ecological (population) consequences of different levels of the new risk measures, to assist the authorities in establishing appropriate criteria. As part of the project, a workshop was held (February, 2010) to discuss the results of the research with CRD, additional experts and stakeholders.
4. The most pressing problem faced by CRD in this context is the authorisation of pesticides when the TER for use on major crops poses an acceptable risk but breaches the trigger value for use on minor crops. The regulator then needs to decide whether the small area likely to be treated can count in mitigation for the product's authorisation for use on a minor crop.
5. Discussion at the workshop led to three practical suggestions Extrapolation, Rule of thumb and Isoclines
6. Extrapolation. If the minor crop is similar in key respects to the major crop it may be possible to adopt the arguments used in refining the risk assessment for the major crop in the service of the minor crop. The validity of the extrapolation will to some extent be uncertain. But because the minor crop occupies a smaller area than the major crop we may be prepared to accept some uncertainty.
7. Rule of thumb. A simple measure of this type would be the number of hectares where the TER indicates a potential risk (e.g. TER<10 for acute or < 5 reproductive risk assessments). The decision could take the form of a rule of thumb in which the risk manager would authorise a scale of use that would affect less than, say 1%, of arable land. This has the advantage of using the familiar TER measure, but is not readily interpretable in terms of actual impacts (i.e. the frequency of mortality and reproductive effects).
8. Isoclines. If a pesticide falls below the TER threshold, then it is likely to be non-negligible effects on wildlife and it behoves risk assessors to estimate what these effects might be. By making explicit estimates of the consequences of pesticides on wildlife mortality and reproduction we can use isoclines to show what is the quantitative trade-off between TER and acceptable area of the pesticide

use on crops. This means going beyond TERs to consider pesticide effects on mortality and reproductive success.

9. In the current scale of use project we have built on the broods-at-risk spreadsheet to estimate the consequences for breeding success of a range of different pesticide toxicities and spray dates. For each of the TERs shown we took the worst-case spray date and asked how the associated reduction in breeding success would affect the general population growth rate if this reduction manifested itself on all crops grown below a given area.
10. For example, for a pesticide with an EFSA tier 1 TER of 3, the worst-case scenario is assumed to occur on 2nd June resulting in 1.45 successfully reared chicks per breeding pair. This breeding productivity is then incorporated into population growth rate using standard mortality data for skylarks, and we calculate what acreage of pesticide treated crop would result in *pgrs* of 99%, 97.5% and 95% of the control scenario *pgr* (where no pesticide is used). Each isocline links points of equivalent effect on population growth rate averaged over all cropped land for a sensitive bird species. For example, if it were considered acceptable that pesticides on minor crops reduce *pgr* by no more than 5% compared to control crops where no pesticide was used, then a pesticide with a TER of 3 could be approved for use on minor crops grown on no more than 183,000ha, whereas a pesticide with TER of 0.1 would have the same effect on *pgr* if it were approved for use on minor crops grown on no more than 90,000ha.



Project Report to Defra

8. As a guide this report should be no longer than 20 sides of A4. This report is to provide Defra with details of the outputs of the research project for internal purposes; to meet the terms of the contract; and to allow Defra to publish details of the outputs to meet Environmental Information Regulation or Freedom of Information obligations. This short report to Defra does not preclude contractors from also seeking to publish a full, formal scientific report/paper in an appropriate scientific or other journal/publication. Indeed, Defra actively encourages such publications as part of the contract terms. The report to Defra should include:
 - the scientific objectives as set out in the contract;
 - the extent to which the objectives set out in the contract have been met;
 - details of methods used and the results obtained, including statistical analysis (if appropriate);
 - a discussion of the results and their reliability;
 - the main implications of the findings;
 - possible future work; and
 - any action resulting from the research (e.g. IP, Knowledge Transfer).

Scale of use workshop held at Fera 11th –12th Feb 2010

Currently UK pesticide regulators assess the risks to birds and mammals of a new plant protection product by comparing its toxicity with the potential exposure of representative wildlife species. According to EU legislation (91/414), if a product has an acute Toxicity-Exposure Ratio (TER) of less than 10 for acute assessments or less than 5 for reproductive assessments, then it should not be authorised for use without further justification. Therefore, if a product was intended for use on winter wheat and the risk assessment for, say, skylarks indicated a TER>10 then it would likely receive authorisation.

Often however manufacturers would also like authorisation to use their products on minor crops (e.g. Rye, Linseed) as well as major crops like wheat. It sometimes happens that the risk assessment for a product on a major crop appears acceptable but the same product used on a minor crop gives rise to a TER < trigger value (10 or 5). The regulator then needs to decide whether the small area likely to be treated can count in mitigation for the product's authorisation for use on a minor crop.

Therefore we convened a workshop to consider how best to assess the risks to wildlife posed by pesticides that are approved for wide scale use on major crops but which fail the standard risk assessment criteria for use on minor crops. The "Scale of Use workshop" was held at Fera, Sand Hutton on 11th and 12th February 2010 and was attended by 16 invited experts from a range of backgrounds in government, industry and academia.

Name	Institute
Richard Sibly	University of Reading
Chris Topping	Aarhus University, Denmark
Pernille Thorbek	Syngenta
Nigel Boatman	Food and Environment research Agency
Andy Hart	Food and Environment research Agency
Joe Crocker	Food and Environment research Agency
Julie Ewald	Game Conservancy Trust
Gavin Siriwardena	British Trust for Ornithology
Alastair Burn	Natural England
Mark Clook	Chemicals Regulation Directorate
Melissa Reed	Chemicals Regulation Directorate
Rachel Sharp	Chemicals Regulation Directorate
Adrian Dixon	Chemicals Regulation Directorate
Julie Howarth	Chemicals Regulation Directorate
Christian Wolf	RifCon, Germany
Jan-Dieter Ludwigs	RifCon, Germany

Table 1. List of participants at the workshop

Participants received an invitation with background briefing and a case study was circulated before the workshop. Presentations were made at the workshop by Mark Clook, Joe Crocker, Andy Hart, Pernille Thorbek and Chris Topping.

The resulting discussion led to 3 suggestions.

1. Extrapolation from major crop
2. Rule of thumb
3. Isoclines

1. Extrapolation from major crop.

For Chemicals Regulation Directorate (CRD) the crux of the problem with minor crops is that few or no data are usually available to carry out anything beyond a very simple and conservative Tier 1 risk assessment: it would be very unlikely for example that radio-tracking information about time spent in crop (PT) or measurement of pesticides residue half-life on the crop would be available. But the risk assessment for a major crop that fails the first Tier is likely to be able to draw upon other more realistic data that bring the Toxicity Exposure Ratio (TER) within acceptable levels (ie >10 for acute, > 5 for reproductive assessments.). Would it be reasonable to extrapolate from the data and arguments used in the risk assessment refinement for the major crop, to make similar refinements to the minor crop assessment?

For example, if during a more refined risk assessment, detailed field work found that residue half-life on the major crop was much lower than that suggested by Tier 1 default values and that this brought TER to acceptable levels, then (if the minor crop structure rather similar) one might substitute the major crop DT50 in risk calculation for the minor crop.

Extrapolation of major crop refinements to minor crop may be more defensible if:

- a. **Tier 1 risk assessment.** If the Tier 1 risk assessment for the minor crop was similar or less risky than that for the major crop ie
 $\text{Tier 1 TER}_{\text{major}} \leq \text{Tier 1 TER}_{\text{minor}}$
- b. **Good Agricultural Practice** is similar between major and minor crops. The pesticide application rate and number of sprays on the minor crop were the same or less than the major crop. The interval between sprays on the minor should be the same or more than the major crop. The half-life (DT_{50}) of residues on the minor crop should be less than or equal to that on the major crop.
 - i. $\text{Application Rate}_{\text{major}} \geq \text{Application Rate}_{\text{minor}}$
 - ii. $n \text{ sprays}_{\text{major}} \geq n \text{ sprays}_{\text{minor}}$
 - iii. $\text{Interval between sprays}_{\text{major}} \leq \text{Interval}_{\text{minor}}$
- c. **Half-life.** If there were no reason to think that residues would persist longer on the minor compared to the major crop ie
 $\text{DT50}_{\text{major}} > \text{DT50}_{\text{minor}}$
- d. **Structure** of minor crop is similar to major. If major crop were wheat then it may be legitimate to extrapolate to other minor cereals (rye, triticale) and perhaps other monocots (such as maize). If minor crop were broadleaf then so should major crop?
- e. **Attractiveness** of minor crop to wildlife is similar to the major crop¹. No evidence that minor crop is more attractive to focal species than major crop (ie PT unlikely to be greater in minor crop). For example woodpigeons have strong preference for OSR in autumn & winter. Need to check bird census data for other minor crop preferences.
- f. **Aggregation.** Minor crop distributed evenly through agricultural landscape rather than clumped in only a few locations

It is unlikely that all of the above caveats will be met. And the more divergences, the more doubtful the legitimacy of the extrapolation. Even if all caveats were met, the risks posed by a pesticide different crop scenario will never be identical. The extrapolation will always be uncertain to some extent. It is because the minor crop occupies a smaller area than the major crop that we are prepared to accept greater uncertainty. The question for the risk manager is how small? What is the trade off between crop area and the uncertainty of extrapolation?

It is possible to devise a more or less credible exchange rate² but it is likely to be more or less problematic. The key problem in extrapolating from one scenario to another is that TERs give us no clear idea about the consequences to wildlife in either scenario.

¹ CRD project PS2328 has explored differences in attractiveness to wildlife between minor and major crops.

² Suppose, for example, that the Tier 1 assessment for the a.s. on wheat gave a TER of 7 but that further refinement indicated a TER of 20 was a more realistic outcome. In this case the ratio of refined/Tier 1

2. Rule of thumb.

Would it be possible to devise a simple rule of thumb that brings the scale of pesticide use into the risk assessment? For example could we say that if the TER for a major crop was acceptable then a product could be approved for use on a minor crop if its area was less than 1000ha (or 5000 or 10,000ha)?

If such a rule could be settled on, then the acceptability of a pesticide's use on a minor crop (despite breaching the TER trigger value(s)) will follow explicitly from the fact that it is being applied to a relatively small area. This being so, it would seem reasonable for other pesticide manufacturers claim similar mitigation for their own minor crop uses. In other words, if it was felt that a particular plant protection product could be used on a minor crop because that crop was only grown on, say, 5000ha, then it may be necessary to assume that all crops grown at or less than this acreage should benefit from the same mitigation. In which case, a special dispensation to allow a pesticide use on a minor crop of 5000ha would lead to a similar dispensation for all crops grown on ≤ 5000 ha, equivalent to 39000ha in total or 0.86% of arable land (see Table 2).

is 2.9. Could we legitimately extrapolate from the refined/Tier 1 ratio for wheat and apply it to Tier 1 result for a minor crop? For example if the minor crop had a Tier 1 TER of 5 then the extrapolation factor of 2.9 would bring the refined TER to >10 and therefore acceptable, whereas a Tier 1 TER of 3 would still be unacceptable even when refined assessment on the major crop was taken into account.

Crop	GB ha	Cum. ha	Cumulative %
Gooseberry	142	142	0.003%
Blackcurrant - mkt	145	287	0.006%
Culinary apples (others)	157	444	0.010%
Hybrid berry	162	606	0.013%
Red/white	166	772	0.017%
Blueberry	221	993	0.021%
Blackberry	245	1,238	0.027%
Other top fruit (inc nuts)	410	1,648	0.036%
Cherries	457	2,105	0.046%
Vine	856	2,961	0.064%
Plums	1,288	4,249	0.092%
Hops	1,358	5,607	0.121%
Sweet corn	1,371	6,978	0.151%
Raspberry	1,469	8,447	0.183%
Pears	1,959	10,406	0.225%
Cucurbits	1,964	12,370	0.268%
Other root veg	2,058	14,428	0.312%
Blackcurrant - proc	2,338	16,766	0.363%
Culinary apples (Bramley)	2,596	19,362	0.419%
Root crucifers	2,891	22,253	0.482%
Dessert apples (others)	3,348	25,601	0.554%
Dessert apples (Cox)	3,618	29,219	0.633%
Strawberry	4,480	33,699	0.730%
Rye	4,954	38,653	0.837%
Cider apples & perry pears	5,967	44,620	0.966%
Lettuce	6,032	50,652	1.097%
Other vegetables	6,952	57,604	1.247%
Fodder beet & mangolds	7,495	65,099	1.409%
Kale cabbage & rape	10,266	75,365	1.632%
Onions	12,118	87,483	1.894%
Turnips & swedes	13,001	100,484	2.175%
Seed potatoes	14,588	115,072	2.491%
Carrots	15,380	130,452	2.824%
Linseed	16,258	146,710	3.176%
Triticale	17,252	163,962	3.550%
Stubble turnips & catch crops	23,944	187,906	4.068%
Brassicas	27,969	215,875	4.673%
Peas	29,876	245,751	5.320%
Other crops for stockfeeding	33,860	279,611	6.053%
Peas	41,376	320,987	6.949%
Beans	118,462	439,449	9.514%
Sugar beet	119,653	559,102	12.104%
Potatoes	126,766	685,868	14.848%
Maize	128,513	814,381	17.631%
Oats	132,604	946,985	20.501%
Winter barley	410,263	1,357,248	29.383%
Spring barley	596,077	1,953,325	42.288%
Oilseed rape	597,706	2,551,031	55.227%
Wheat	2,068,104	4,619,135	100.000%

28 crops < 10,000ha totalling 1.41% of overall cropped area

24 crops < 5,000ha totalling 0.86% of overall cropped area

Key

- Hops
- Soft fruit
- Top fruit
- Outdoor veg
- Fodder crops
- Arable

Table 2 UK crops in ascending order of land area devoted to them/

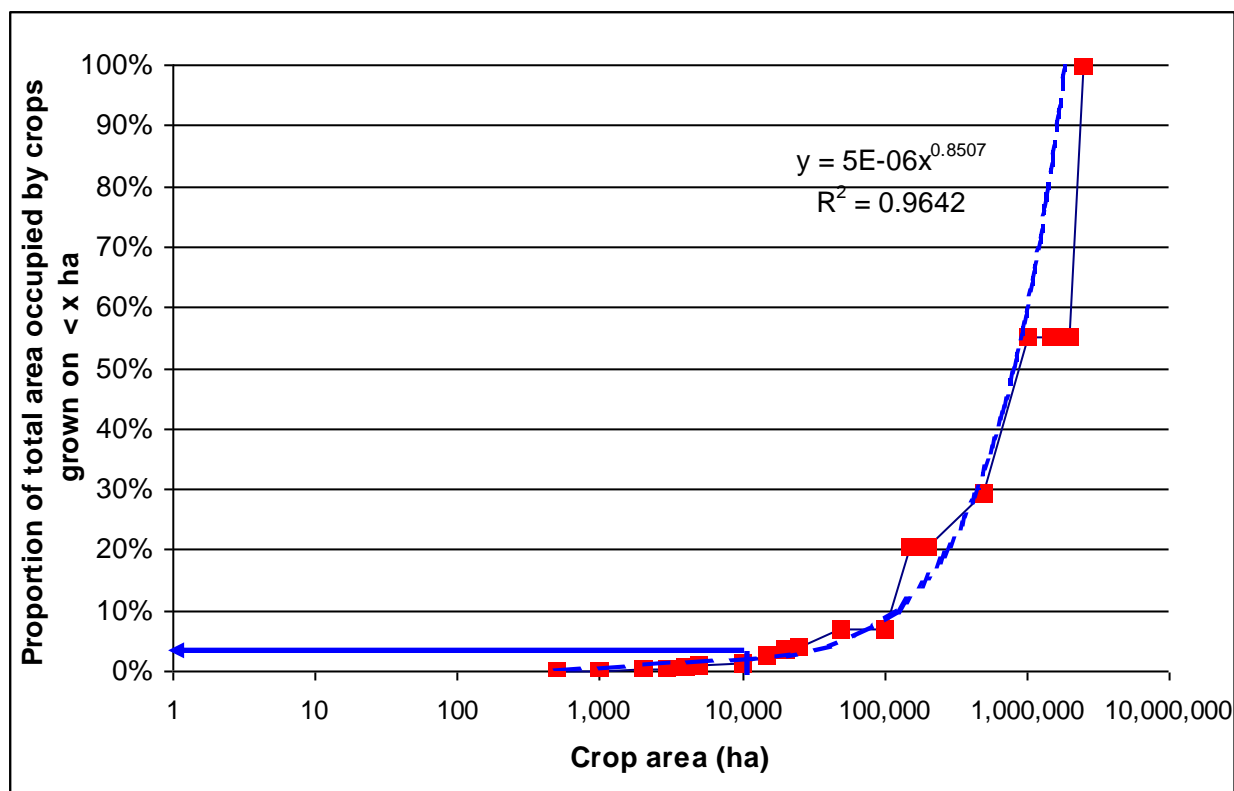


Figure 1. Relationship between area occupied by minor crops and total area of cropped land. For example crops grown on less than 10,000 ha account for about 1.5% of total cropped area. Blue dashed line shows a fitted relationship

We can see from Table 2 and Figure 1 that crops that are grown on 10,000 hectares or less account for 1.4% of the overall cropped area in Great Britain. Whatever the consequences of falling below the relevant TER trigger value, these consequences would affect 1.4% of agricultural land as it is currently used³. If the consequences were considered acceptable then the product could be approved for the 28 crops above Kale listed in Table 2 (red arrow). Similarly, crops grown on less than 5000ha occupy 0.86% of total cropped land. A rule of thumb approving minor crop uses of less than 5000ha would allow approval on the 24 crops above cider apples in Table 2 (blue arrow).

Extreme worst-case

The difficulty in establishing a rule of thumb is estimating the consequences of falling below the standard trigger values for a pesticide on minor crops. If we assumed for example, as a worst-case, that acute TERs of <10 killed all birds using the crop and that reproductive TERs of < 5 prevented all breeding, then the effect of allowing pesticide use on crops with less than 10,000 ha grown would be to reduce the total carrying capacity of arable land by 1.4%,⁴ Whether this were acceptable in terms of achieving Biodiversity Action Plan targets or Government Public Service Agreements would depend on population trends on major crops. It may be that conservation measures such as Entry Level Stewardship establishment may more than compensate for increased risk on minor crops. The RSPB, for example, have more

³ Lawrence (2010) similarly argues that although the TER for a particular seed treatment falls below the standard trigger value, the proportion of farmed bird habitat exposed to these low TERs is very small (worst-case 5% of cropped habitat)

⁴ This makes a simplifying assumption that all arable land carries the same density of birds. How misleading the assumption is will depend on the species and the crops of concern.

than doubled the number of skylark breeding territories in cereals at their experimental Hope farm, by introducing simple measures such as skylark plots – small areas of bare ground in which birds may forage.

We also need to remember however, that although the effect of the minor crop pesticide may be acceptable at the wider population level, it may be unacceptable at the local level. In the worst-case example just mentioned it would be unlikely that death or failure to breed of all birds in minor crops having an area < 10,000ha would be considered acceptable. On the other hand if it were concluded that a reduction by 1.4% of the total carrying capacity on arable land was tolerable then the research focus could turn to estimating the level of local effects rather than on population modelling. If, for example, a minor crop tended to be concentrated over a small area, would birds have sufficient alternative habitat available to them, or would the effects of the pesticide be unacceptably conspicuous in that locality?

3. Realistic worst-case: Isoclines

In reality if a pesticide falls below the TER threshold of 10 for acute effects (or 5 for reproductive effects), it is unlikely that all birds will die (acute risk) or that all birds will fail to reproduce. Our estimate of the effects of allowing the use of these sub-threshold pesticides on minor crops will be more realistic if we can estimate the actual consequences of their use for wildlife populations. This means going beyond TERs to consider pesticide effects on mortality and reproductive success. These have been considered in three previous CRD projects. Pesticide effects on mortality were explored in the WEBFRAM projects (PS2303, PS2331) and reproductive effects in the broods at risk project (PS2346)

It is a common concern at CRD that pesticides that can be approved for use on the basis of their acute risk, can fail because of the assessment of their reproductive risks. Therefore, in the remainder of this report we will focus on scale-of-use in relation to reproductive effects.

The Broods-at-Risk project focused on a single wildlife scenario of skylarks breeding by arable fields. It used data collected by the British Trust for Ornithology over a 10 year period to summarize typical timing of skylark nesting behaviour. For any given spray date it was possible to say what proportion of broods were at any particular phase (eg incubation, nestling) and depending on the nature of the pesticide toxicity, what proportion would be at risk from toxic effects. In this project we went further and estimated pesticide effects on the breeding success of a typical pair of skylarks. The advantage of estimating breeding success rather than simple broods-at-risk is that the former is a vital rate that can be used in estimates of the population effects of a pesticide. To calculate population effects we need to know, for each breeding pair, how many offspring they are likely to successfully raise in a given year. We were therefore able to compare skylark population growth rates with and without pesticide use and so estimate any subsequent reduction in *pgr* caused by pesticide.

A useful graphical tool for risk assessors might allow them to calculate TER in the customary way and then to read off from the graph over what area such a pesticide might be used with out exceeding an acceptable effect. (This of course requires an agreement on what constitutes an acceptable effect). **Error! Reference source not found.** sketches a hypothetical relationship between acute TER and acceptable minor crop area. Suppose the effect we were concerned about was population growth rate. We might agree⁵ that a reduction in *pgr* compared to control of $\leq 1\%$ is acceptable. For this level of effect we can plot its equivalence for different TERs and scales of use. For example, a $\leq 1\%$ depression in *pgr* on arable land might occur when acute TER is 1 and scale of use is 10,000ha, but would also occur when TER is 3 and scale of use is 40,000ha or when TER is 5 and area is 400,000 ha. In this way we might calculate the TER of a given pesticide application and use the isocline relationship to find what area the pesticide use would not exceed the acceptable negative effect.

⁵ Arriving at such an agreement will likely call for a broader discussion of wildlife population targets, and the degree to which pesticide effects may be offset by mitigating practices (eg game strips etc).

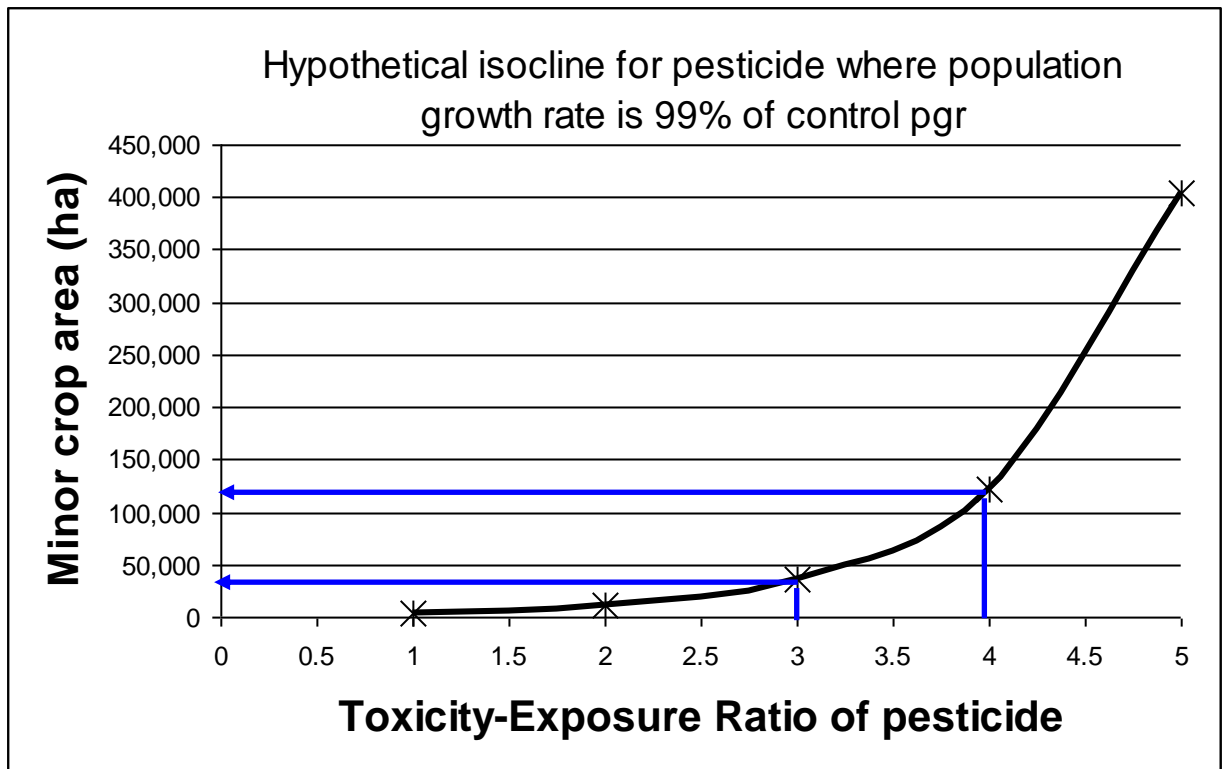


Figure 2. Example of hypothetical isocline. If it were agreed that pesticides should not reduce overall population growth rate by more 1%, the graph shows how the area on minor crops using the pesticide could vary according to TER. In this hypothetical relationship a pesticide with an acute TER of 4 used on minor crops grown on no more than 120,000 ha would have an equivalent effect on *pgr* as a pesticide with an acute TER of 3 applied to minor crops grown on no more than 40,000 ha.

There are some challenges in implementing the isocline approach

- a) Acute or Reproductive TER? If the target measure of acceptable effect is the population growth rate or some derivative thereof then, because it is affected by both acute and reproductive toxicity, there are 2 possible x axes, one showing acute and one showing reproductive TERs. If the isocline approach were to proceed further then it may be advisable to calculate isoclines showing the effects of varying both acute and reproductive toxicity. In remainder of this document we will assume for simplicity that reproductive toxicity is the more critical factor (which it usually is for CRD problems with minor crops), plotting reproductive TER on the x axis and assuming that acute toxicity has negligible consequences for *pgr*
- b) Different toxic effects. Different pesticides that may have the same tier 1 TER and yet have different consequences on breeding productivity depending on whether they affect copulation, laying, incubation or nestling phases. Exploration of the broods-at-risk model suggests that pesticides which affect later stages of the breeding cycle are more damaging to breeding productivity than pesticides affecting only early stages. In general pesticides that reduce adult body mass are the most damaging because they can cause brood abandonment at late stages and because they can affect adults even when they are between breeding attempts (Crocker 2009), increasing the recovery time before breeding can be resumed. (See Figure 3) As a worst-case we could assume, as in standard guidance, that the lowest reproductive NOEL for the pesticide applies to all reproductive toxicity endpoints.

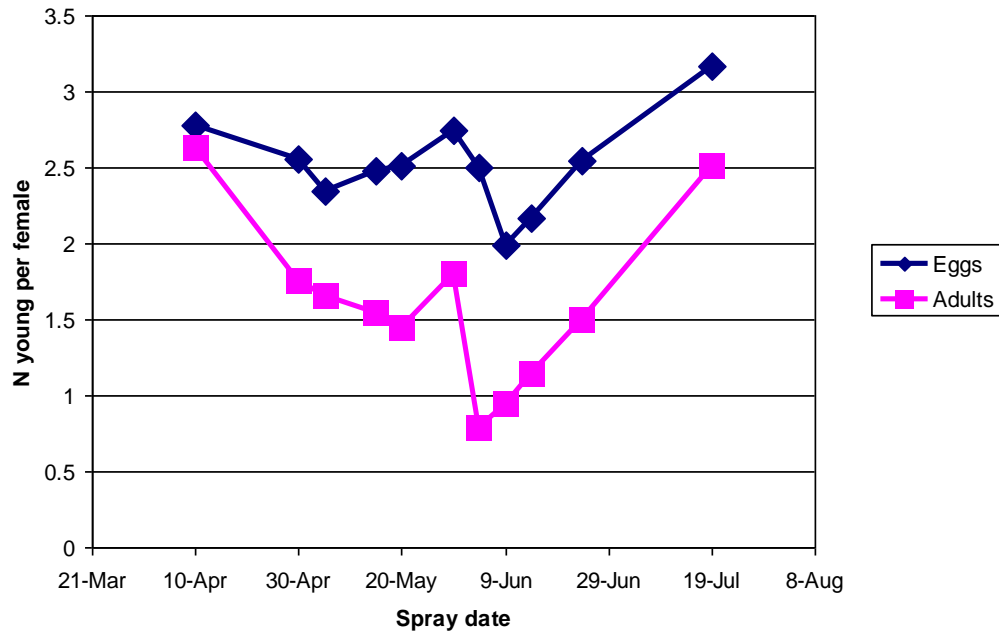


Figure 3. Comparison of effects on breeding productivity of spraying date for two pesticides, one of which affects mainly the eggs (blue) and the other affecting adult bodyweight (pink). Otherwise pesticides have the same NOEL and are both sprayed 3 times at 7 day intervals. The spraying date on the x axis thus indicates the first date of a series of 3 sprays. For both pesticides the effect on breeding productivity (as estimated by the brood-at-risk model) worsens with spraying date until the point where the third spray falls later than the last date that birds can begin a breeding attempt.

- c) Spray date. Another factor to consider is the timing of the spray relative to breeding season of the exposed wildlife species. Again, pesticides with the same TER may have different consequences for breeding productivity depending on when they are sprayed. In general the brood-at-risk model suggests that failure later in the season is more costly than earlier failures (because earlier failure can be compensated by later success). If we wish to develop a realistic worst-case we should assume a worst-case spray date (eg late May, early June in Figure 3).

In considering worst-case spraying date we need also to investigate the effects of

- *Number of sprays and spraying intervals.* Related to spraying date is the number of sprays and the interval between them. The date that results in the biggest reduction in breeding productivity for a single spray will not be the same as that for say, 3 sprays with a seven day interval between sprays. We therefore need to assume a worst-case spraying number and interval. Or show how isoclines vary under different assumptions about spraying number and interval.
- *DT50.* Pesticides with longer half-lives will generally have worse effects on breeding productivity, especially when they are sprayed several times with short intervals between them. Longer DT50s will result in earlier worst-case spray dates.
- *Toxicity.* Toxicity will also combine with DT50 and spray date to affect breeding productivity. Figure 4 shows that as TER decreases (and toxicity increases) so does breeding productivity and so does the spray date that results in the greatest reduction of breeding productivity.

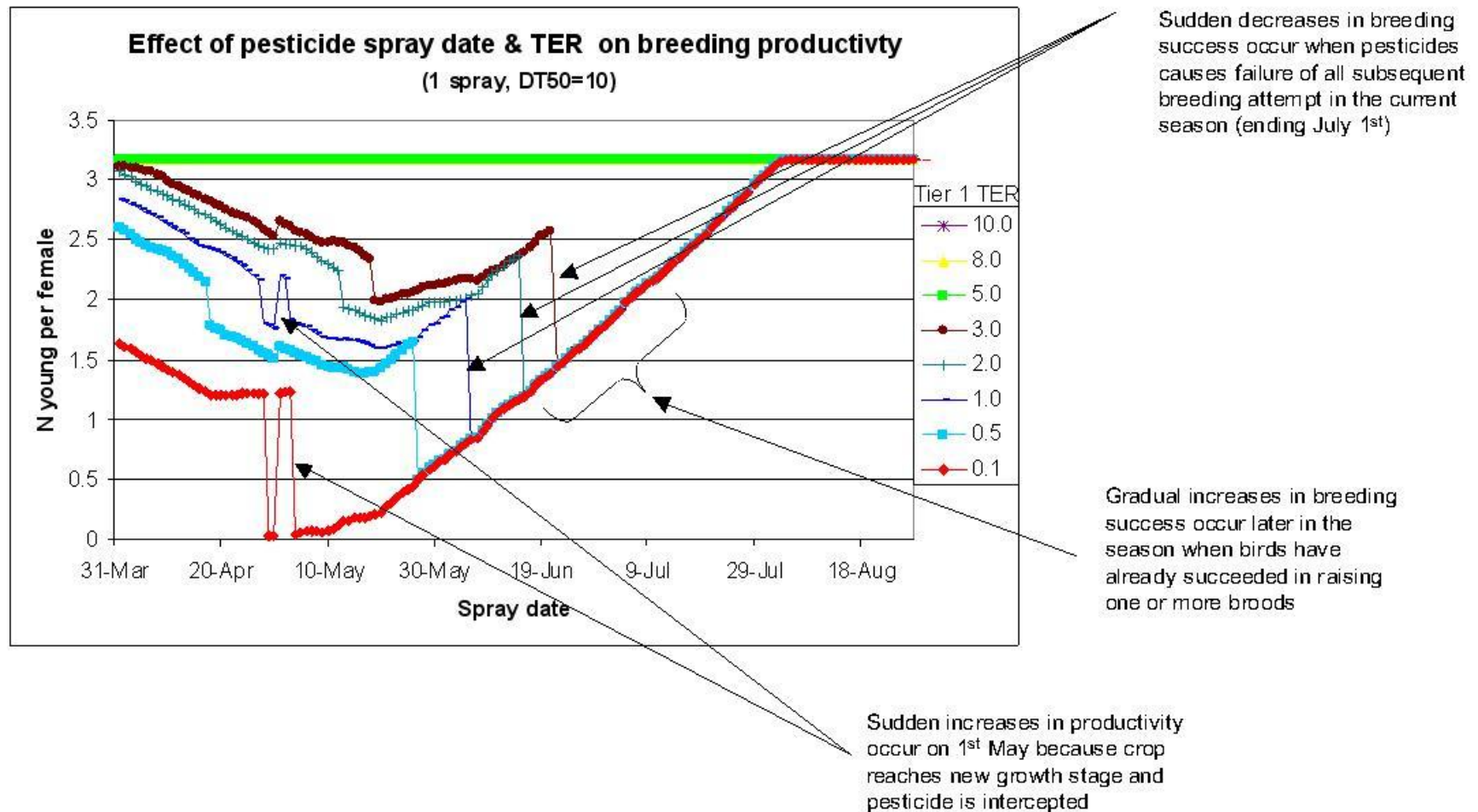


Figure 4. Each point on the graph represents an outcome from the brood-at-risk model for a particular spray day in relation to skylarks in cereal fields. Pesticides applied early or late in the breeding season cause less reduction in breeding productivity. As pesticide toxicity increases (indicated by decreasing TERs), breeding productivity decreases, and the spray date that results in greatest reduction of breeding productivity occurs earlier in the season.

Sudden changes in productivity are to some degree attributable to the deterministic nature of the model eg all new breeding attempts cease on July 1st, wheat growth stage changes abruptly on May 1st. Smoother changes would be expected under more realistic probabilistic modelling. The very large declines in breeding productivity seen over the course of a single day occur when the spraying regime (3 sprays with 7 day intervals between them) prevents birds from making another breeding attempt in the current breeding season. Breeding productivity gradually improves after this low point as more breeding attempts are completed before the 3 spray regime begins and later sprays occur after the end of the normal breeding calendar). In this model for skylarks in cereals a typical breeding attempt takes 37 days..

Results: An example of the Isocline approach

Mindful of these issues, I have constructed a set of isoclines showing how, for a fixed reduction in *pgr* caused by pesticide spray, TER relates to scale of use. I have as far as possible tried to follow the latest EFSA Tier 1 guidance (2009) on pesticide risk assessment for birds and mammals and have incorporated the appropriate Multiple Application Factors.

Annex 1 of the guidance provides a table (Table 1.2, p126) of different species/crop scenarios with a so-called “shortcut RUD value” for each scenario. This value is based on a more detailed calculation of species’ food intake rate and bodyweight and on empirical data of pesticide residues on crops and arthropods. Multiplying the shortcut RUD value by the application rate (kg/ha) provides an estimate of the initial exposure (mg as per kg bodyweight). Two RUD shortcuts are provided, a mean value suitable for calculations involving of reproductive toxicity and 90th centile value used for acute risks.

The following assumptions are made

- The pesticide is sprayed on cereals and exposure data are taken from EFSA guidance for a generic focal species “small omnivorous lark”.
- Data on breeding phenology are for skylarks in UK arable landscape supplied by the British Trust for Ornithology.
- The pesticide affects population growth rate only by reducing breeding productivity. Effects of acute toxicity causing adult deaths are assumed to be negligible (ie that acute TER > trigger value).
- The toxicity of pesticide is assumed to have its effect when TER falls below 5. Under the standard brood-at-risk model we follow the methods developed by Bennett et al 2005, assuming that toxic effects occur when ingested pesticide exceeds the lowest No Observable Effect Level. If we applied the standard model to the normal risk assessment process then all pesticides with a TER > 1 would be acceptable because no reproductive impairment would occur. The point of using a TER of 5 in risk assessment is to add a safety or extrapolation factor to allow, among other things, for the fact that species vary in their sensitivity to toxins and the landscape where the pesticide is used may contain sensitive species. Therefore, we have modified the broods-at-risk model so that toxic effect occur whenever TER is < 5 rather than 1. The resulting figures and isoclines should therefore be interpreted as relating to a conservative scenario, one for example in which the focal species that is particularly sensitive to the pesticide
- Data from the BTO suggests that in the UK Skylarks’ first eggs rarely appear before April. And according to the HGCA Barley growth guide, Winter Barley in the UK reaches growth stage 30 by the beginning of April. Consulting Annex 1 of the EFSA guidance suggests that we should use shortcut value of 5.4 in April. As the barley grows, so, for a given application rate the pesticide residues fall and therefore in May and later months a shortcut value of 3.6 is indicated. However, EFSA guidance (EFSA Appendix J, Table 1, Appendix R, Table 1) also provides examples of exposure based on chick food intake and bodyweight ratios. These suggest a short cut value of 3.78⁶ and therefore we used this value in later months as being worst-case scenario.
- The RUD shortcut value multiplied by the application rate gives an estimate of initial exposure (Daily Dietary Dose) of individuals to a single spray. When several sprays are delivered then exposure will depend on the half-life (DT50) of the residues on food, the number of sprays and the interval between sprays. For most examples shown here we have assumed that barley is sprayed 3 times at 7 day intervals with a DT50 of 10days. The brood-at-risk program assumes that residues decay as a first order process⁷ and compares the resulting Daily Dietary Dose with the appropriate toxicity endpoint each day. In each of the brood-at-risk manipulations shown below we arbitrarily set the initial TER at 10, 8, 5, 3,

⁶ This value assumes a worst case Food Intake Ratio/Bodyweight for chicks of 1.08 (see EFSA Appendix J, Table 1), which when multiplied by a mean RUD of 3.5 (Appendix A, line 24 “Ground dwelling invertebrates with interception) giving a shortcut RUD values of 3.78.

⁷ Specifically, the concentration of residues on food is assumed to follow

$$C_t = C_o * (1 - e^{-kt})$$

Where

C_t = concentration of residue at time t

C_o = Initial concentration of residue

K = velocity constant (ln2/DT50)

t = time since spraying.

In previous guidance (SANCO2002) it was assumed that this formula was valid only for residues on vegetation. However, the new EFSA guidance reviews recent evidence and concludes that the same first order kinetics formula may be used on arthropod foods (EFSA Appendix H).

2, 1 and 0.5. On the graphs these values have been divided by the appropriate Multiple Application Factor (MAF) to give the Tier 1 TER calculated in the EFSA guidance. Because different scenarios lead to different MAFs the values of the Tier 1 TERs also differ between different brood-at-risk graphs.

- The brood-at-risk spreadsheet also calculates appropriate phase specific Time-Weighted Average (TWA) exposures following the formula in EFSA guidance Appendix H. (The Tier 1 TERs shown in the graphs assume short term toxic effects with no TWA)

Using the above values the brood-at-risk model was run for a range of different toxicities and in each it was determined which spray date had the greatest effect on breeding productivity). We then took the lowest breeding productivity (n of young per female) for each TER and calculated population growth rate using these worst-case values.

At its simplest population growth rate can be expressed as follows:

Equation 1

$$\lambda = \frac{N_{(t+1)}}{N_{(t)}}$$

where

λ = population growth rate (*pgr*)

$N_{(t)}$ = population at time *t*

$N_{(t+1)}$ = population at time *t+1* (eg 1year later)

If we take a single pair of breeding birds then the population at the start of the current breeding season.

$$N_{(t)}=2_{(adults)}$$

At the end of the breeding season there will be some successfully raised juvenile birds. Not all of these juveniles and adults will survive the winter, so by the start of the next breeding season there will be

Equation 2

$$N_{t=1} = 2_{adults} \cdot p(\text{winter survival}) + N_{juveniles} \cdot p(\text{winter survival})$$

The broods-at-risk spreadsheet allows us to calculate how many young a pair will successfully raise in a breeding season, and therefore gives us $N_{(juveniles)}$ in Equation 2. We assume that the probability of surviving the winter until the next breeding season is the same for adults and juveniles and that acute effects of the pesticide are negligible. We have used a value of 0.66 (Wolfenden & Peach ,2001) for the probability of over-winter survival. Depending on the effect of pesticides on breeding productivity *pgr* (or λ)

$$\lambda = \frac{(2 \cdot 0.66 + N_{juveniles} \cdot 0.66)}{2}$$

Scale of use was incorporated by assuming that if the pesticide were permitted for use on a particular minor crop then, eventually, pesticides with the same TER and GAP would be permitted on all crops grown on equivalent or smaller areas. Population growth rate on the remaining major crops was assumed to be unaffected by pesticide. We used the relationship shown in Figure 1 between the size of a minor crop and the proportion that it, and all smaller crops, represented of the total cropped area of the UK. ie

Equation 3

$$\text{Proprn UKcroppedarea} = 0.000006 \cdot \text{minor crop area}^{0.8507}$$

For example minor crops grown on 10,000ha or less represented about 1.5% of all the UK cropped area. For any given pesticide toxicity we can use the broods-at-risk model to calculate a population growth rate (and compare this with the control *pgr* with without the use of the pesticide). Assuming that the exposure remains the same for different toxicities we can then relate TER to *pgr* and without use For a given reduction in overall *pgr* for birds on cropped land then the acceptable area of minor crop is given by

Equation 4

$$\text{Acceptable minor crop area} = \sqrt[0.8507]{\frac{(1-P)}{(1-\lambda_p/\lambda_c)}} \cdot 0.000006$$

where

constants 0.8507 and 0.000006 come from Equation 3

P= proportion of the control population growth rate that would be acceptable if the pesticide were allowed on minor crops. In the majority of figures we have explored the effects of P at 0.99, 0.975 and 0.95.

λ_c = population growth rate estimated by broods-at-risk model when the pesticide is not used

λ_p = population growth rate estimated by broods-at-risk model if the pesticide is used. Each different λ_p value is associated with a particular TER value allowing us to show the relationship between TER and acceptable area of minor crop use.

In Equation 4, the term (1-P) may be interpreted as the acceptable proportion reduction in pgr , while the term $(1 - \lambda_p / \lambda_c)$ is the actual proportion reduction in pgr caused by the pesticide. Therefore if $\lambda_p = \lambda_c$, the pesticide has no effect on pgr , the actual reduction in $pgr = 0$, and since $(1-P)/0$ is infinitely large, then the pesticide may be used on all crops. When $\lambda_p = 0$, then the pesticide causes complete failure of population growth, the actual proportion reduction is 1, and therefore pesticide should be used only on those crops grown on area, small enough that even if all birds fail to breed, then this would not exceed the acceptable pgr reduction (1-P). If for example it was agreed that a pesticide should not cause more than 0.1% reduction in pgr then Equation 4 would suggest that a pesticide that prevented all reproduction could be sanctioned on minor crops grown on no more than 409ha.

Three isoclines are shown in Figure 5(b). Each line links points of equivalent effect on population growth rate averaged over all cropped land for a sensitive bird species. For example, if it were considered acceptable that pesticides on minor crops reduce pgr on cropped land by no more than 5% compared to control crops where no pesticide was used, then a pesticide with a TER of 3 could be approved for use on minor crops grown on no more than 183,000ha, whereas a pesticide with TER of 0.1 would have the same effect on pgr if it were approved for use on minor crops grown on no more than 90,000ha. Similarly, if we would accept no more than a 1% reduction in pgr then a pesticide with TER of 3 might be used on minor crops grown on no more than 28,000ha or with a TER of 0.1 on 14,000ha.

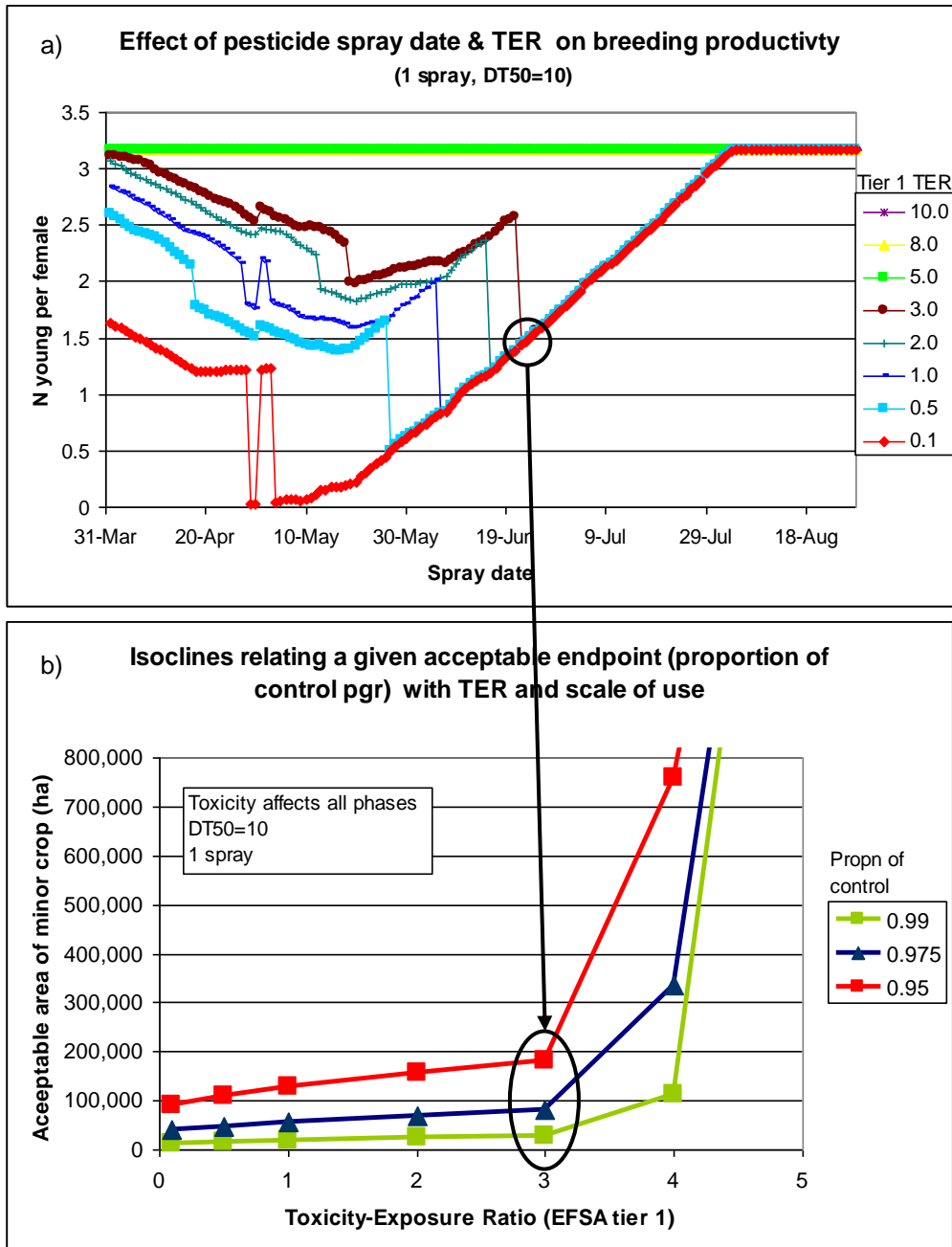


Figure 5 (a) Output from broods at risk model showing the effect on breeding productivity of different TERs and different spray dates and **(b)** three isoclines showing how the area on which pesticide might be used with acceptable effects on population growth rate decreases with decreasing TER. For example, if it were considered acceptable that the pesticide caused a reduction of *pgr* of 5% (compared to unsprayed control scenario) then pesticides with an EFSA tier 1 TER of 3 could be used on minor crops grown on less than 200,000ha.

Annotations to the graph show how the brood-at-risk output translates to an isocline, For example, in **Figure 5 a**, for a pesticide with an EFSA tier 1 TER of 3, the worst-case scenario is assumed with a spray date of 22nd June resulting in an 1.45 successfully reared young per female. This breeding productivity is then incorporated into population growth rate using standard mortality data for skylarks, and we calculate what acreage of pesticide treated crop would result in *pgr*s on cropped land of 99%, 97.5% and 95% of the control scenario *pgr* where the pesticide is not used.

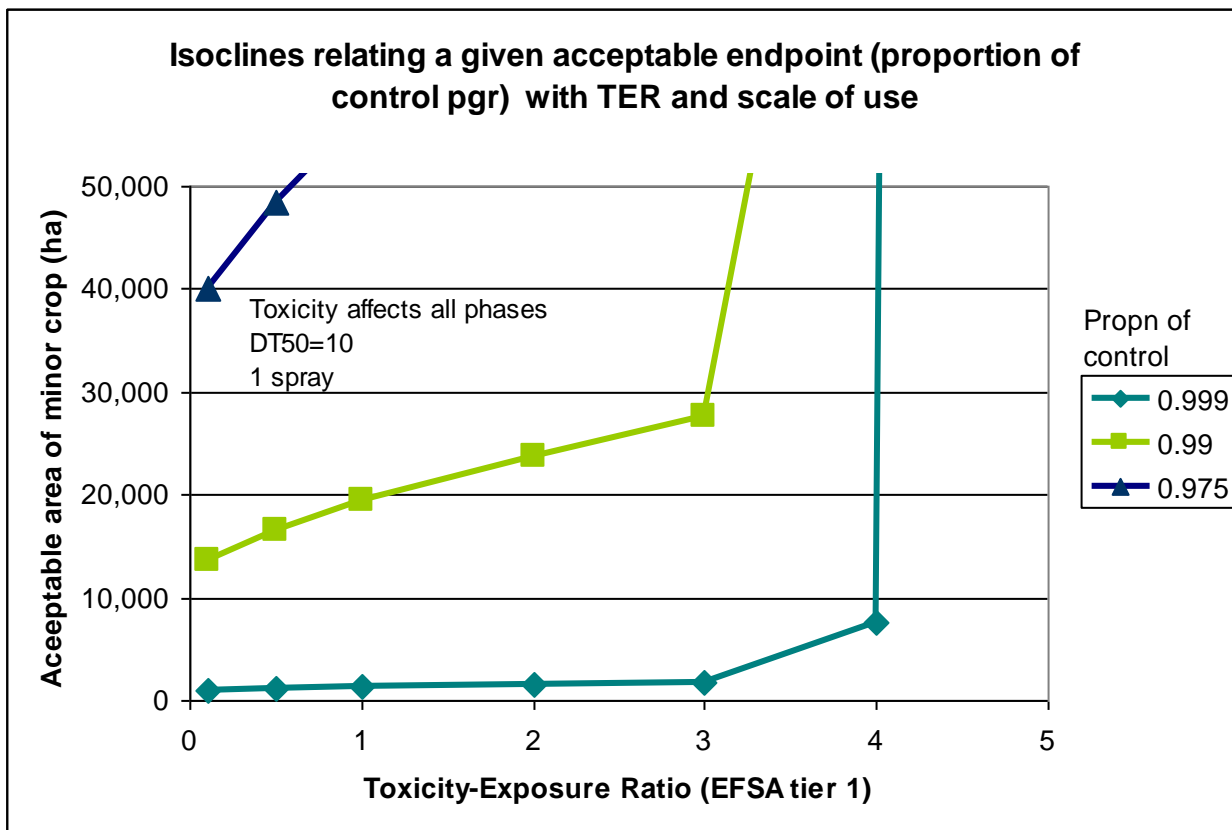
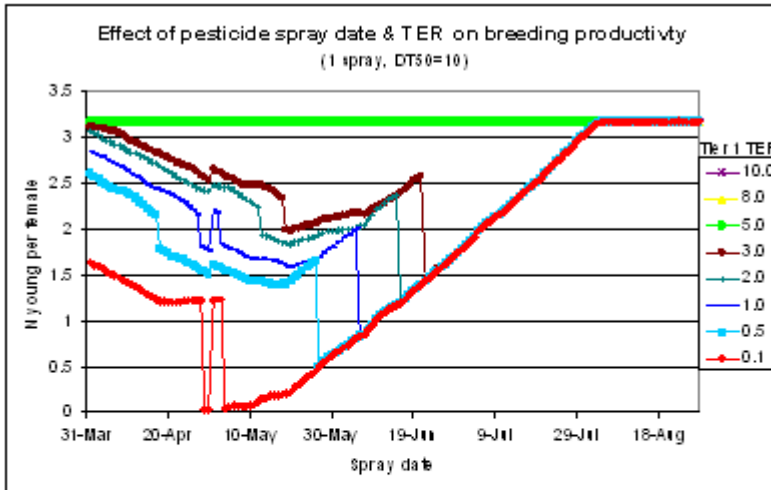


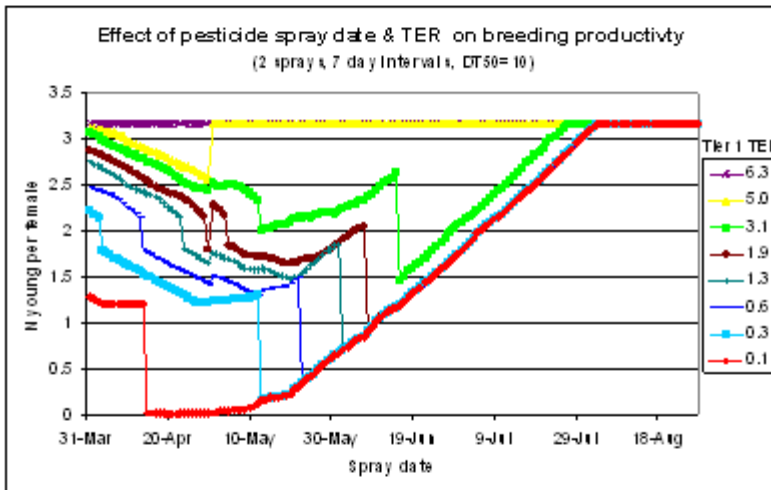
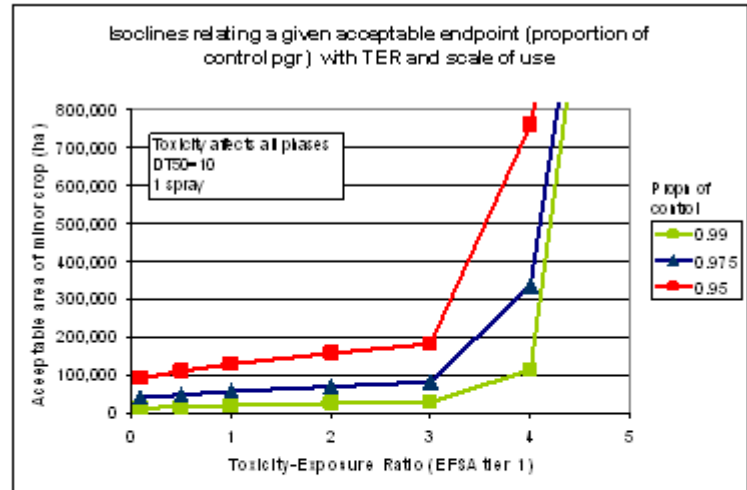
Figure 6. Data are the same as for Figure 5 (b) but the y-axis has been rescaled to show smaller minor crop areas and another isocline has been added for 0.999 of the control *pgr* ie a 0.1% reduction in *pgr*.

Breeding productivity and spray date

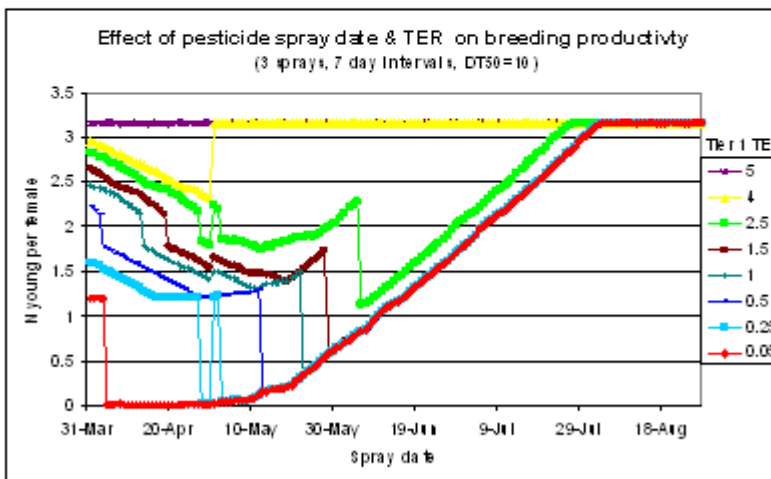
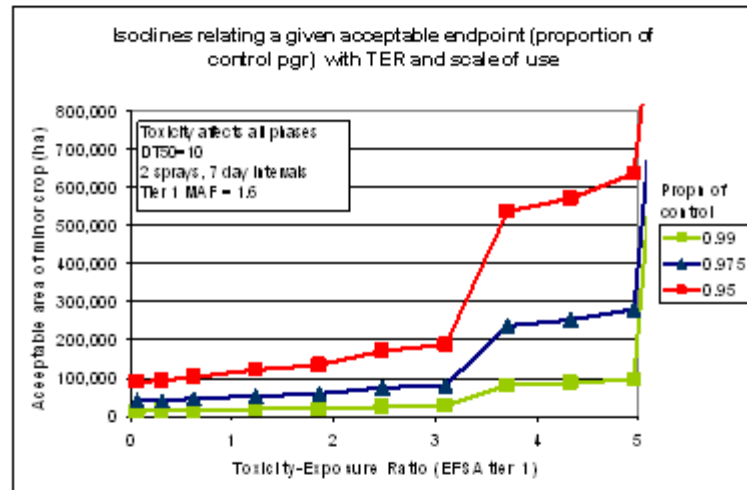


1 spray

Scale of use isoclines



2 sprays



3 sprays

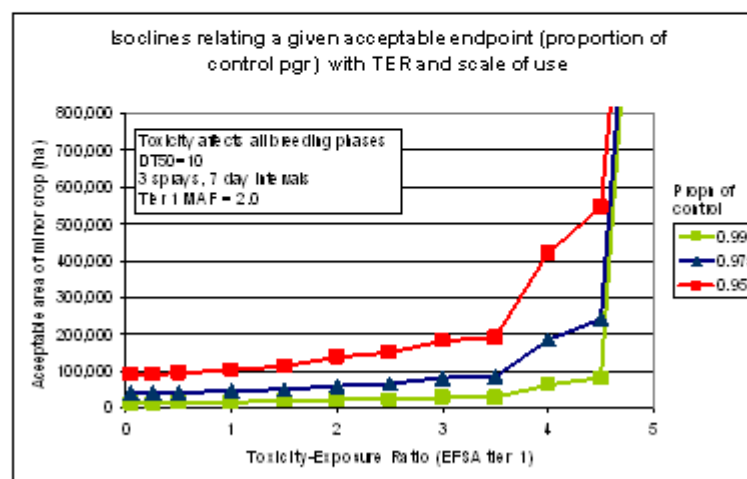
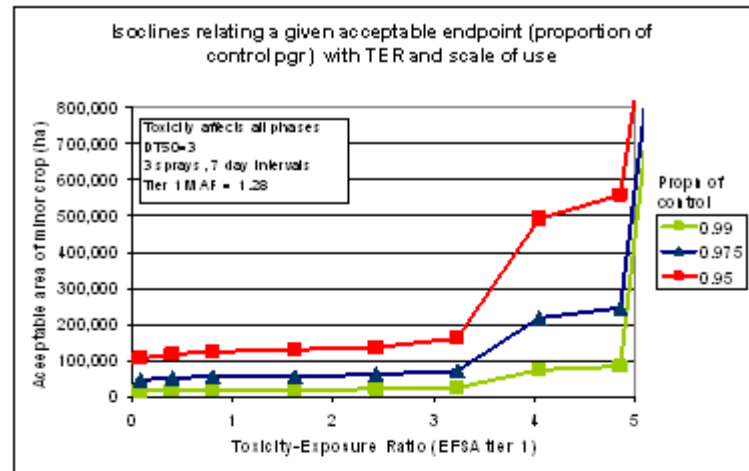
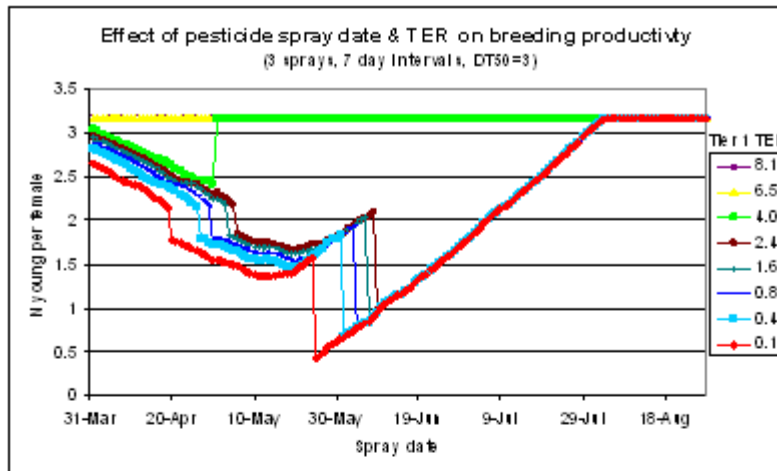


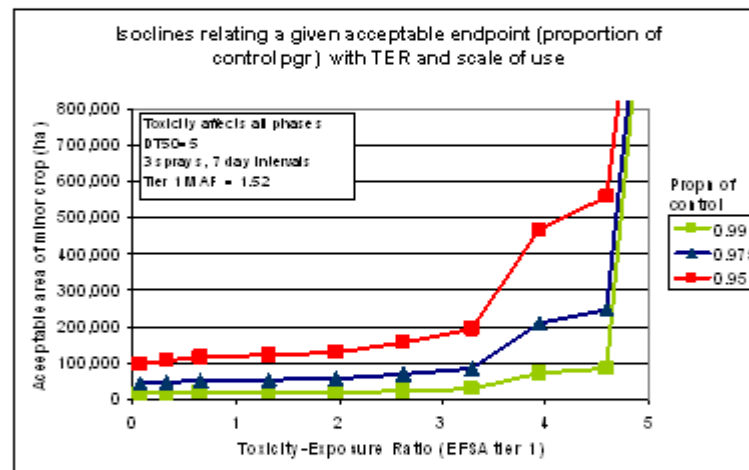
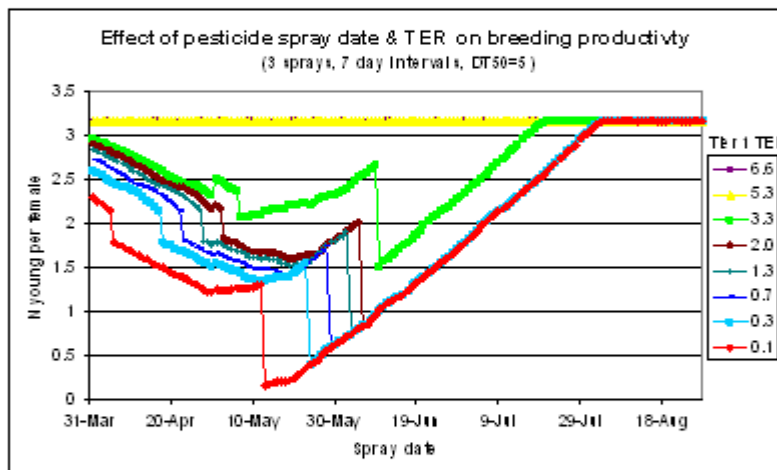
Figure 7. Effect of number of sprays on breeding productivity and on acceptable scale of use. TERs are those calculated using standard EFSA guidance including a Multiple Application Factor (MAF) based on n sprays, DT50 (= 10 days) and interval between sprays (= 7 days).

Breeding productivity and spray date

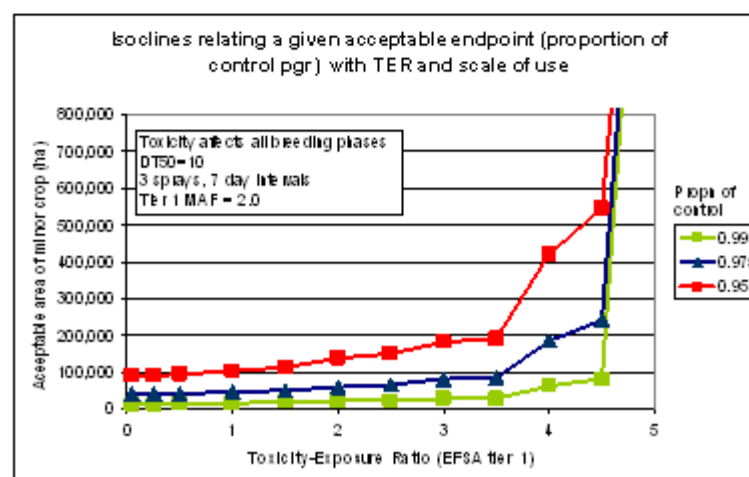
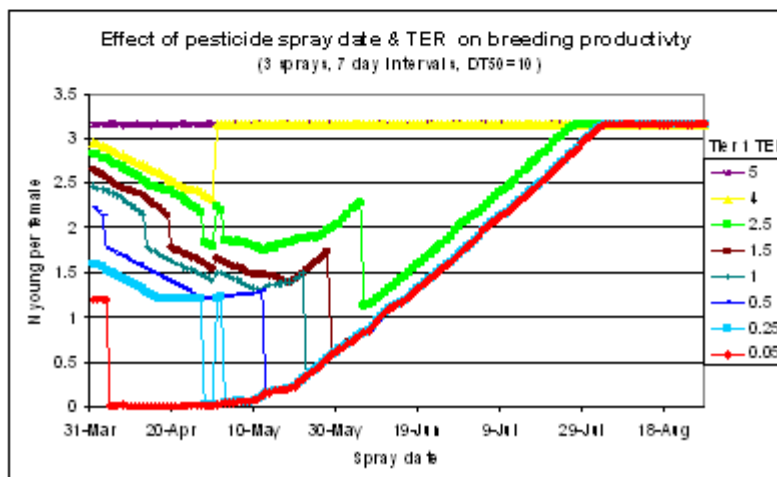
Scale of use isoclines



DT50 = 3 days



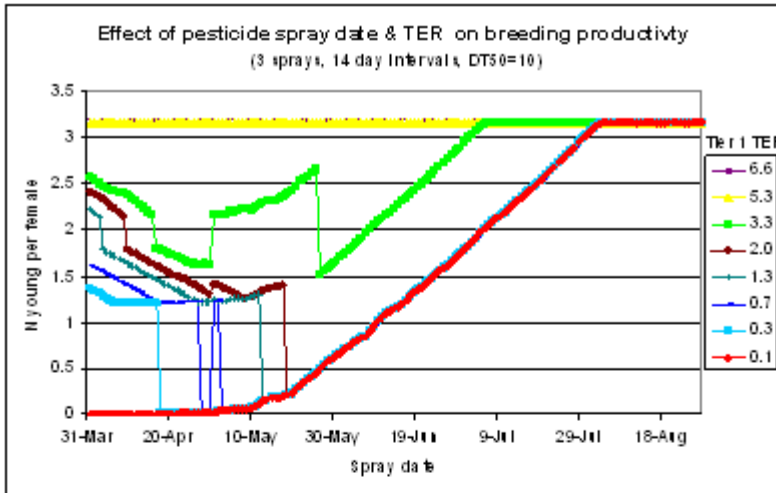
DT50 = 5 days



DT50 = 10 days

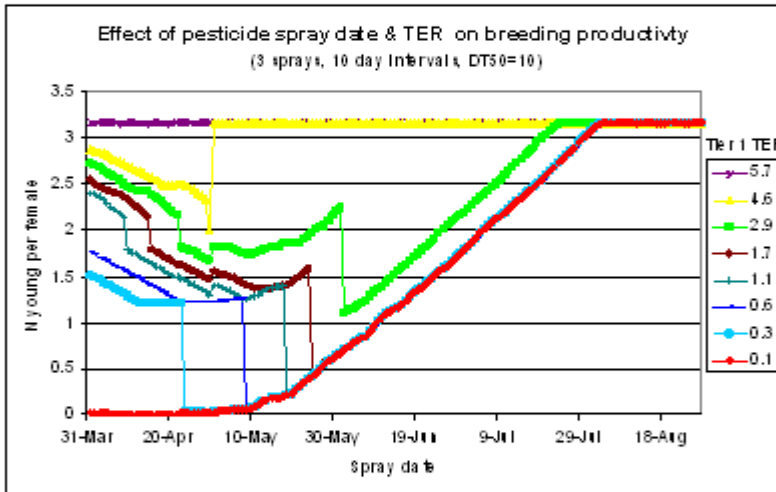
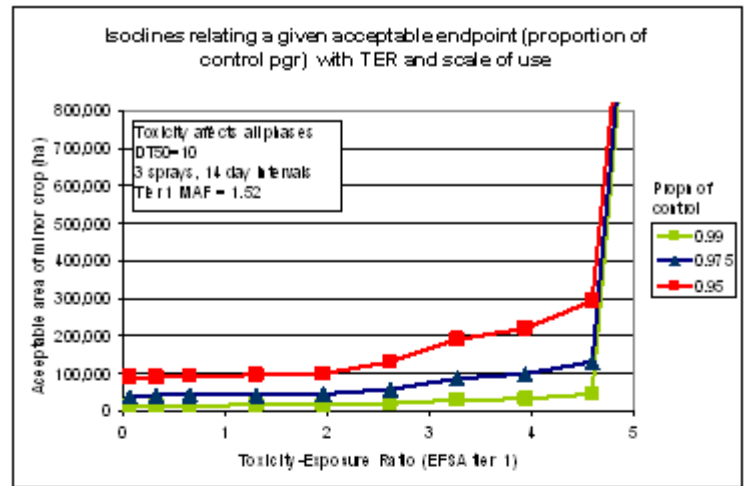
Figure 8. Effect of DT50 on sprays on breeding productivity and on acceptable scale of use. TERs are those calculated using standard EFSA guidance including a Multiple Application Factor (MAF) based on n sprays (3), DT50 and interval between sprays (= 7 days).

Breeding productivity and spray date

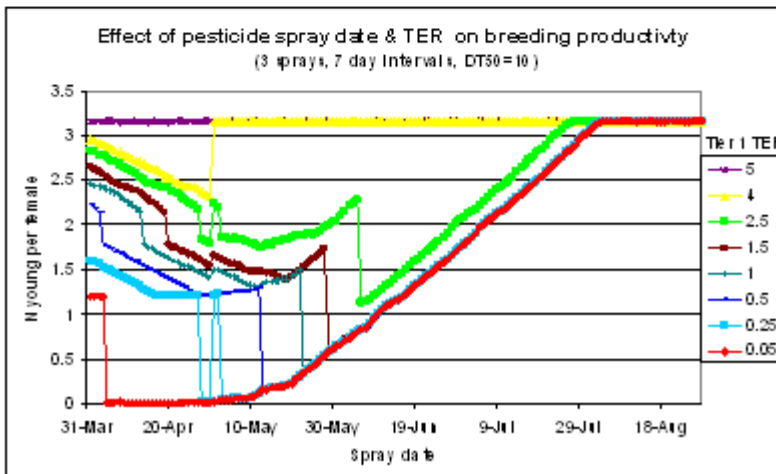
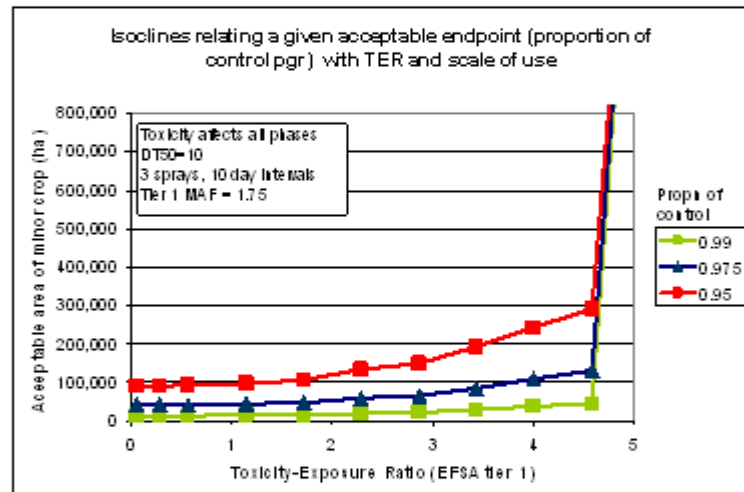


Spraying interval = 14 days

Scale of use isoclines



Spraying interval = 10 days



Spraying interval = 7 days

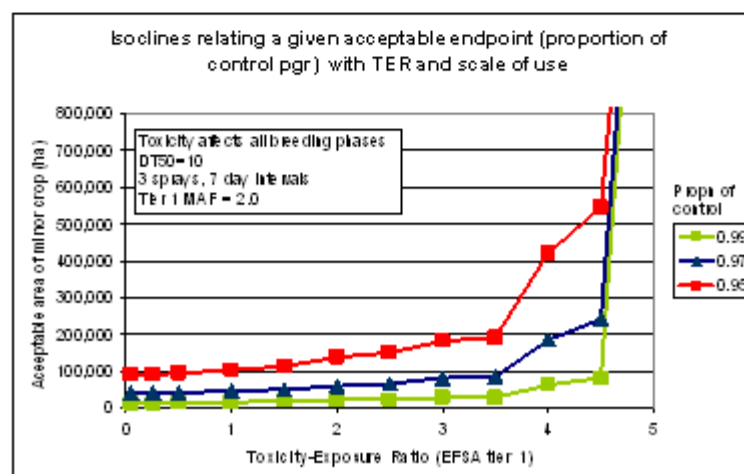
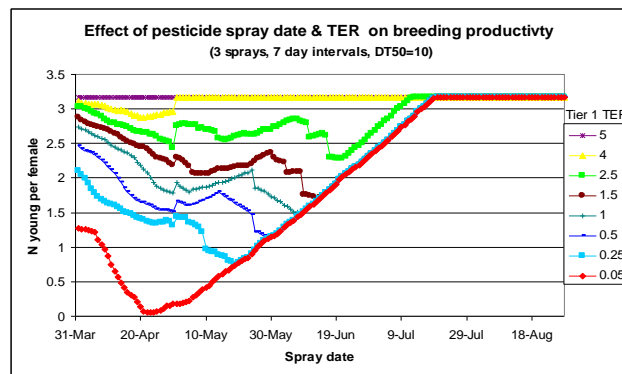
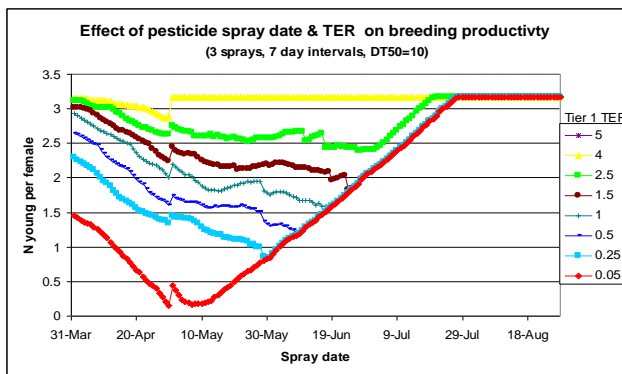
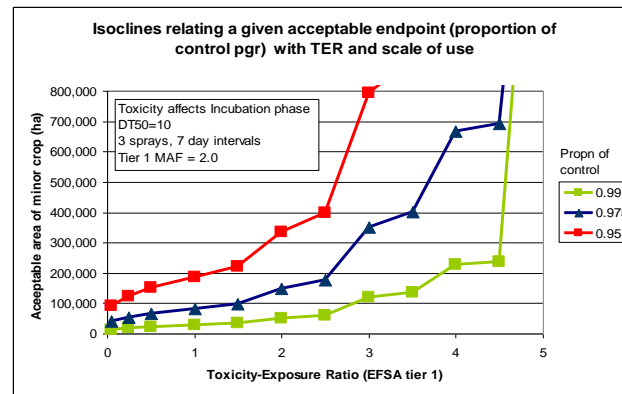
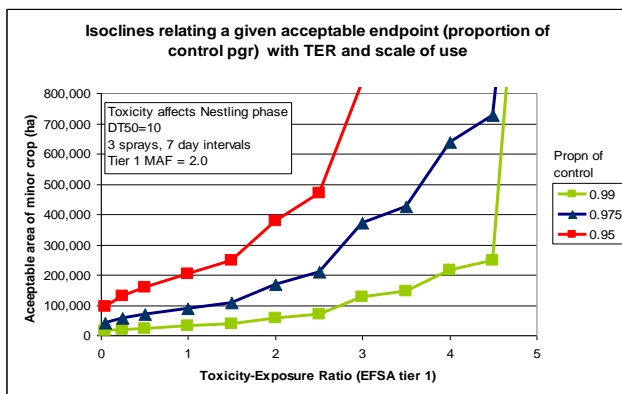


Figure 9. Effect of interval between sprays on breeding productivity and on acceptable scale of use. TERs are those calculated using standard EFSA guidance including a Multiple Application Factor (MAF) based on n sprays (=3), DT50 (=10 days) and interval between sprays

Breeding productivity and



Scale of use isoclines

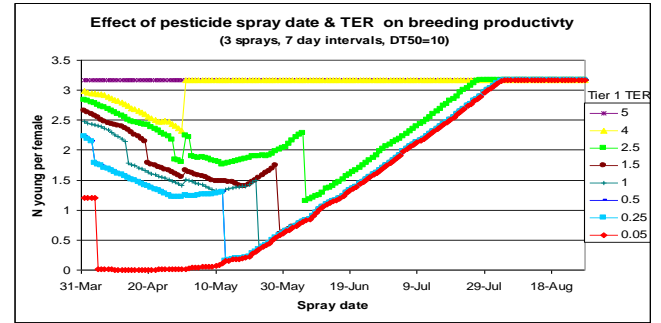
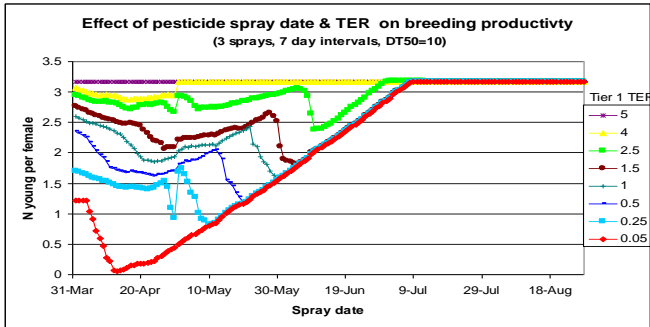


Nestling phase

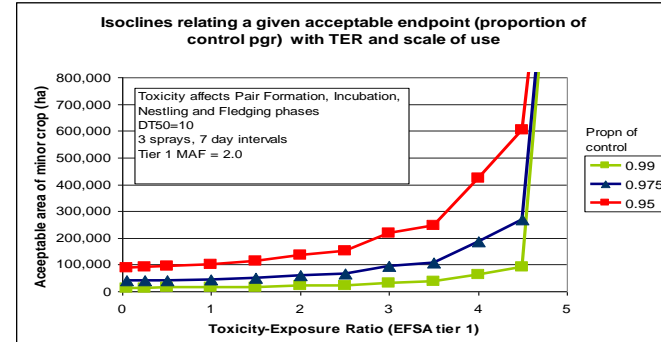
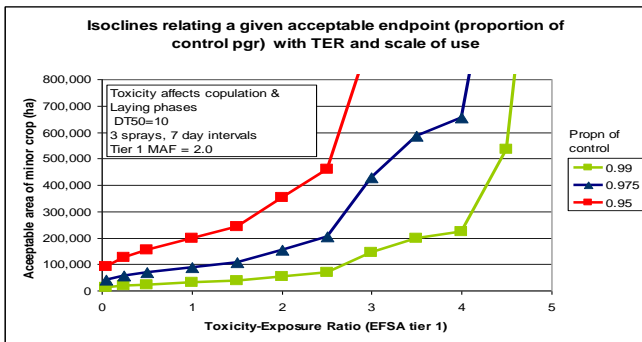
Incubation

Figure 10. Effect of pesticide on breeding productivity and on acceptable scale of use when toxic effect is on different phases of the breeding cycle. Nestling phase is affected when pesticide reduces chick survival to 14 days or when effects are seen in 5 day juvenile dietary toxicity test. Incubation phase is affected when the pesticide reduces % eggs that hatch. TERs are those calculated using standard EFSA guidance including a Multiple Application Factor (MAF) based on number of sprays (=3), DT50 (= 10 days) and interval between sprays (= 7 days).

Breeding productivity



Scale of use



Copulation & Laying phases

Pair formation, incubation, nestling & fledgling

Figure 11 Effect of pesticide on breeding productivity and on acceptable scale of use when toxic effect is on different phases of the breeding cycle. Copulation & Laying phases are affected when pesticide reduces N eggs laid, eggshell thickness or egg fertility. Pair formation, Incubation, nestling and fledgling phases are affected by adult exposure to $> 1/10$ LD50. TERs are those calculated using standard EFSA guidance including a Multiple Application Factor (MAF) based on number of sprays (=3), DT50 (= 10 days) and interval between sprays (= 7 days)

In Figure 7 to **Figure 11** we manipulate parameters of the spray regime to investigate the effects on breeding productivity and on acceptable area of minor crop showing these effects. The effect of increasing the number of sprays from 1 to 3 (Figure 7) is to reduce breeding success and to bring forward the worst-case spraying dates. Similarly isoclines show that the area on which a pesticide may be used with acceptable effects on *pgr* becomes smaller with increasing number of sprays. In general the isoclines are flat at TERs below 3 or 4 and show a steep increase (from left to right) as TERs approach the trigger value of 5. When the level of acceptable effect on *pgr* is set more stringently (say 99% of control – green isocline, rather than 95% red isocline) the relationship between TER and acceptable area becomes more hockey stick shaped ie flatter at lower TERs and more steeply increasing as the TER approaches the trigger value. In other words (and from right to left in the figures) when the TER breaches the value at which toxic effects begin to happen there is a steep fall in the acceptable area of minor crop on which the product might find acceptable use. The decline flattens off as TER becomes smaller. This pattern is more pronounced when we are less prepared to tolerate pesticide effects on *pgr* (green 99% vs red 95% isoclines)

Decreasing the half-life (DT50) of the pesticide residues from 10 to 5 to 3 (**Figure 8**) days has a similar effect to decreasing the number of sprays – breeding success is increased and the worst effects occur later in the season.

Increasing the time between sprays from 7 to 10 to 14 days also seems to exacerbate pesticide effects (**Figure 9**). The effects are less damaging if they are concentrated closer together in time (but this result will in turn also depend on the particular values chosen for DT50 (10 days) and number of sprays (3)).

When the birds are exposed to $>1/10^{\text{th}}$ adult LD50 then multiple breeding phases (pair formation, incubation, nestling and fledgling phases) are assumed to be affected and the reduction of breeding success is greater than when only incubation, nestling, or copulation and laying phases are affected (Figure 10 and **Figure 11**)

Ideally for any given wildlife scenario it would be helpful to have a single isocline relationship between TER and acceptable area of minor crop. In this way, so long as the risk assessors are clear that say a 1% reduction in *pgr* of a given species is acceptable then all they need do is calculate the TER for pesticide in question using the standard EFSA tier 1 formula and they can read off from the isocline a value for the acceptable minor crop area. If the registrant is proposing use on a minor crop of a greater area then the pesticide should not be authorised. However, as we have seen in Figure 7 to **Figure 11**, the isocline relationships will vary with particular toxic effect of the pesticide on particular breeding phases and on other characteristics of the spray regime. Opting for a single isocline implies choosing the worst-case parameter combination such as multiple sprays (3 or 4?) with long half-lives (DT50=10days) affecting several breeding phases. If it was felt that this degree of worst-case assumption was invidious then it is possible to customise the risk assessment using the brood-at-risk spreadsheet.

For any pesticide with known reproductive toxicity, DT50, number of sprays and spray interval, then the brood-at-risk spreadsheet⁸ will show how breeding success will vary with the timing of spraying. The risk assessor can use these results to consider whether the impairment of breeding success in exposed birds is acceptable; they might for example consider restricting the pesticide use to before or after the peak breeding period. Having settled on a level of damage to reproductive success that is acceptable, it is simple, if mortality rates are also known, to proceed to calculate the consequences for the local population growth rate. And if we know the area on which the pesticide is likely to be used, then we can ask what contribution it will make to the general population growth rate for all birds of that species on farmland. In answering this question we assume that the mitigating argument -- that the small acreage on which the pesticide is used can offset its non-negligible toxic effects -- also applies to all other crops grown on similar or smaller acreages; ie we assume that the pesticide (or something like it) will be applied to all crops below a give area.

Isoclines and ALMaSS

At the scale of use workshop in February Chris Topping (Aarhus University, Denmark) offered to investigate the possibility of creating isoclines within the ALMaSS agent based modelling system. Fuller details of the system and results are described in Appendix 3. In essence ALMaSS is a computer simulation of a 10*10km parcel of the Danish farming landscape, complete with populations of several wildlife species. Each individual within a population negotiates its virtual world in a manner intended to mirror a real skylark (or vole or beetle) looking for food and mates. Following a basic set of rules for living

⁸ Currently only for skylarks nesting on farmland, but in principal the model can be adapted to any species for which we have good data on timing of breeding in farmland.

the virtual agents move, feed, interact and respond to changes in the environment (weather, vegetation, farming practices such as spray regimes.)

In the simulation reported here, a herbicide was applied to spring barley. The pesticide was applied at the 2 leaf growth stage and after an interval of 7 days was applied again.

Spring barley typically makes up 40% of the Danish farmed landscape area. In order to get an idea of the effects of scale of use, simulations were made in which pesticide was applied to between 0% and 100% of barley (0 to 40% of the landscape). Toxicity of the pesticide was also varied.

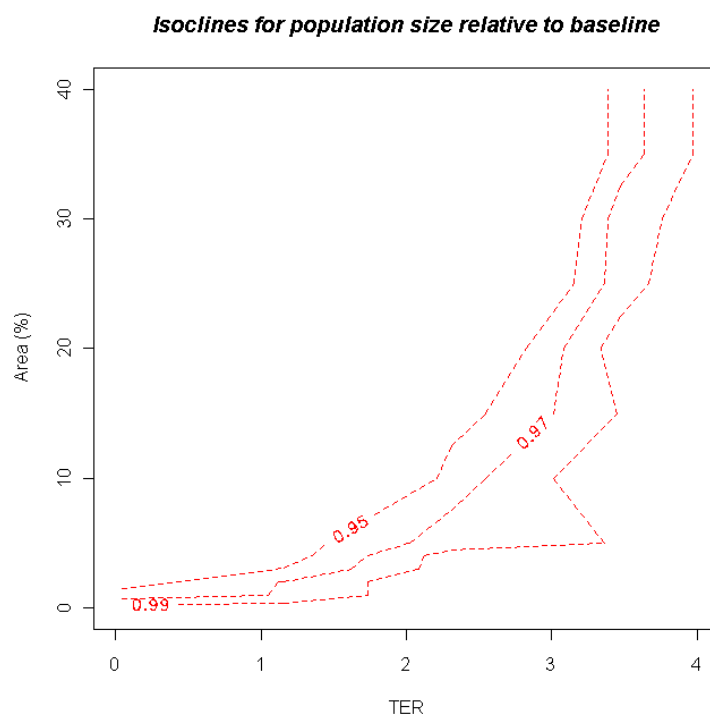


Figure 12 Isoclines fitted to simulations result for population size relative to baseline with changing area of application and TER. Three isoclines have been fitted to the mean population effect over 10 years of pesticide treatment, where the population receiving pesticide is reduced to 99%, 07.5% or 95% of the baseline, untreated, population. [Note TERs in this figure have been rescaled (multiplied by 5 compared to the Figures in Appendix 3) to simulate conservative scenario in which toxic pesticide effects are seen at TERs <5]

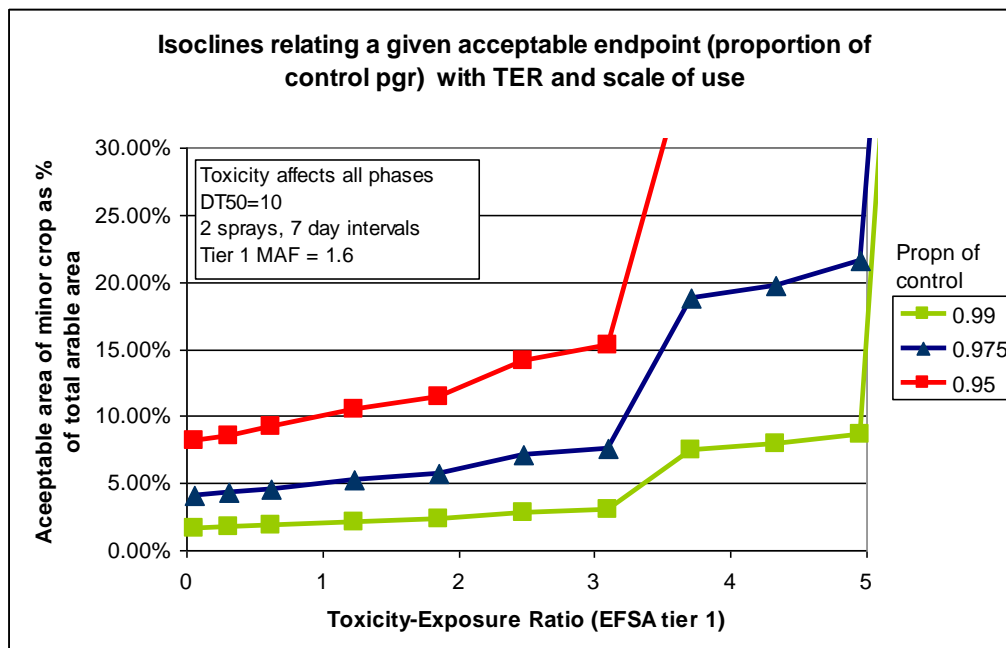


Figure 13. Isoclines from Figure 7, (2 sprays separated by 7 days with DT50 of 10days) rescaled so that the ALMaSS and Broods-at-models can be compared. The y-axis represents % of arable land on which the pesticide could acceptably be used given a TER value and an acceptable level of *pgr* reduction (99%, 97.5% or 95% of untreated control)

Comparison of the ALMaSS (Figure 12) with the Fera isoclines suggests a broadly similar pattern. From right to left, as TER increases, the relationship with acceptable area increases gradually until we approach the trigger value TER when the pesticide quickly becomes acceptable on much larger areas. Again, the hockey stick shape is more pronounced when we less willing to accept larger population losses (eg for 99% isocline compared to 95% of baseline population).

The ALMaSS model differs from the Fera model in many ways, the most obvious being that they describe different outcomes. The output of ALMaSS is the steady population size under a given set of conditions (eg with pesticide applied). This is usually expressed as percentage of the baseline population size (eg without pesticide). The Fera model output is not population, but population *growth rate*, again expressed as a percentage of the *pgr* expected without pesticide use. Although related, population and *pgr* are different things. Population is the total number of individuals, whereas *pgr* (estimated in the absence of density dependent constraints) may be seen as a measure how strong is the engine for growth without other constraints. Given this and other differences⁹ between the models it is perhaps surprising that as well as showing a similar isocline shapes their results are also alike quantitatively. (Compare Figure 12 and Figure 13)

The y-axes in the Fera isoclines express the area in hectares of crops on which the pesticide might acceptably be used. (The area is a cumulative value which assumes that the pesticide will be used on all crops grown at or less than the specified area.). If we rescale the y-axis so that it represents the % of total arable land on which the pesticide might be acceptably used, then we get the relationship seen in Figure 13. For example taking the 99% isocline and the closest matching scenario (2 spray 7 day interval in Figure 7) then for a TER of 3 the acceptable area of minor crop is 26,000 ha. The fitted relationship in Figure 1 suggests that crops grown over this acreage or less account for 3% of the total. In the ALMaSS model the 99% isocline at TER=3 suggests an acceptable area of 4 - 5%.

Conclusions

- i. Extrapolation from major to minor crop. If a refined risk assessment for a pesticide use on a major crop generates evidence that brings the Tier 1 TER from a value in breach of the trigger value, to an acceptable value, then we may be able to use the same evidence to modify the risk assessment of the minor crop

⁹ Another, probably important, difference is that ALMaSS spraying dates are dictated by behavioural rules of the simulated farmers who spray the herbicide when a particular crop growth stage is reached: and depending on the weather this may vary from year to year. The Fera model looks at the effect of spraying on all days in the breeding season and picks the day on which the spray will have the worst effects.

Advantages.

- Requires the least change to current practice.
- Keeps within current risk assessment practice, calculating TERs, but includes a reasoned argument about the circumstances under which an unacceptable TER may be mitigated by considering scale of use
- Could be used a part of a weight of evidence approach to decision making.

Disadvantages.

- More likely to be limited to minor crops where the spray regime, toxicity characteristics and crop structure are similar to the authorised use on the major crop.
- More likely to be a qualitative argument. Scale-of-use is used as an argument in mitigation of a pesticide that breaches the normal rules. But it is not clear what should be the trade-off between added risk of authorising use of a pesticide with a low TER and the lesser consequences on wildlife populations because of the smaller area of its use.

- ii. Rule of thumb. For a proposed pesticide use on a minor crop we can consult agricultural statistics and asks how many hectares are, or what proportion of arable land is, likely to suffer from TERs < 10 (acute risk) or < 5 (reproductive risk). If we make a worst-case assumption that low TERs will lead to complete loss of local population on the fields where the pesticide is used, we might try to settle on a maximum minor crop area – a rule of thumb -- that would have a negligible effect on the general populations.

Advantages.

- Simple to apply.
- Incorporates scale of use in a quantitative way

Disadvantages.

- Unrealistic “worst-case”. Not all individuals exposed to a pesticide with a low TER will die or fail to breed.
- Rule of thumb demands agreement on what counts as acceptable effects at the general population level.
- If pesticide effects on the general population are acceptable, then the worst-case effects may not be acceptable at the local level. We need more realistic estimates so that we can consider what would be acceptable.
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- iii. Isoclines attempt to predict realistic worst-case effects of a pesticide on mortality and breeding success and to place these local effects into a broader context, predicting effects at the population level

Advantages.

- Incorporates scale of use in a quantitative way.
- Simple to use (once set up). For any scenario of interest (eg skylark on arable land), risk assessor can calculate standard Tier 1 TER, select a level of acceptable effect, and look-up the acceptable area of minor crop that leads to that effect.
- Because actual consequences of pesticide on wildlife mortality and reproduction are estimated at the field scale and at the landscape level, then the risk manager is more able to consider the acceptability of these effects are acceptable

Disadvantages.

- Requires that risk assessors can agree on an acceptable degree of pesticide effect at the local field level and at the general landscape level

- Relatively complex to set up. Needs detailed information on breeding phenology of the focal wildlife species.

Extrapolation to a minor crop using evidence gathered for a major crop is the simplest remedy but is more difficult to justify when the minor crop pesticide spray regime diverges from the major crop. Extrapolation from the major crop is essentially a qualitative argument. Settling on a rule of thumb that defines a maximum acceptable area of minor crop in which TER falls below the trigger value is difficult because it is not clear what are the consequences of falling below the trigger value.

When a pesticide is used in circumstances where $TER > \text{trigger value}$ then it is implied that it will have negligible consequences for wildlife. Conversely a product with $TER < \text{trigger}$ may have, by definition, non-negligible effects. And if the effects are non-negligible then it behoves risk assessors to estimate what these effects might be. By making explicit estimates of the consequences of pesticides on wildlife mortality and reproduction we can use isoclines to show what is the quantitative trade-off between TER and acceptable area of the pesticide use on crops.

Next Steps

If scale of use is to become a standard feature of pesticide risk assessment then risk managers need to be able to agree on the answers to these questions

1. **What is an acceptable pesticide effect on the local population exposed on fields where pesticide is used?**

The EFSA 2008 opinion (Figure 14) makes it clear that products passing first tier risk assessments should not result in visible mortality. "Visible mortality" is taken to mean animals dying in public places or in noticeable numbers, and it is therefore a social or political criterion, rather than an ecological one. (EFSA guidance Appendix C). The EFSA protection goals seem to imply that some mortality may be acceptable. But they don't say how much.

3. Level of protection provided by proposed first-tier assessment procedures

Risk management information

The purpose of this section is to document the basis for the first-tier procedures proposed in the opinion and, in particular, the level of protection they provide.

It is assumed (for reasons explained below) that the risk management criterion is that an active substance may be authorised if it is *clearly established* that the proposed use will cause *no visible mortality and no long-term repercussions for abundance and diversity of non-target species*.

The EFSA Journal (2008) 734, 25-181

Figure 14. Protection goals outlined in EFSA 2008 opinion.

EFSA guidance Appendix C concludes from the review of field studies (reported in CRD project PS2331) that

Pesticide uses with TERs between 0.1 and 10 caused detectable mortality in some of the field studies but not others, while those with $TER < 0.1$ caused detectable mortality in a high proportion of field studies. It is difficult to assess how often this mortality would reach a sufficient level to be 'visible'. It seems clear, however, that uses with TERs below 10 cannot be regarded as achieving the surrogate protection goal of any mortality being unlikely.

Neither does EFSA advise what is an acceptable local effect on *reproductive* health, as distinct from mortality. Presumably the same social criteria apply: if a pesticide does not give rise to a noticeable fall in local wildlife breeding success and it does not affect the larger population, it is acceptable?

2. **What is an acceptable pesticide effect on larger wildlife populations in the general farming landscape?**

Annex VI C.1, Number 5 to Directive 91/414/EEC specifies that Member States "... shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species". But, as EFSA guidance Appendix C notes,

... this still does not precisely define the protection goal. For example, it does not define the temporal scale (how long is long-term?) nor the spatial scale (local, regional, etc.) on which changes in abundance and diversity should be assessed. This is important because it makes it uncertain what level of short-term impacts on mortality or reproduction can be tolerated without threatening the long-term population goal. Furthermore, the directive does not state explicitly whether short-term effects can be unacceptable in themselves.

Regardless of the precision of EEC levels of protection there are other population goals that may guide decisions on acceptability. In particular we have Government Public Service Agreements (PSA) It is stated policy of Defra for example to "Reverse the decline in farmland birds". The favoured measure of success or failure is the BTO's farmland bird index, which considers the demographic health of 19 common and widespread farmland birds. We also have Biodiversity Action Plans for various farmland bird species that set specific targets to be reached by specific dates. For example for the skylark, the targets are to

1. Increase the Breeding Birds Survey index to 115% of the 2003 level by 2015 and to 130% of the 2003 level by 2020 (for UK, England, NI and Scotland). Maintain current (2003) levels in Wales.
2. Maintain the percentage of occupied British Breeding Survey squares at the 2003 levels.

The Biodiversity Action Plan contains targets both for abundance and distribution of bird species. The skylark BAP could not be achieved if population increased while the range of the bird decreased.

The "Scale of Use" project estimates the degree to which a pesticide might reduce population growth rate of a sensitive species but it makes no explicit calculations about how pesticide use might reduce the probability of achieving government targets. A next step might be to consider the likely consequences of pesticides on particular government population targets and consider how these consequences mitigated by particular conservation measures such as the creation of skylark foraging plots within crop. (It is at least possible that small negative effects of pesticide on use minor crops could be mitigated by positive effects of conservation measures)

If risk managers can in principle resolve the questions of pesticide acceptability at both local and landscape levels, and it is felt that "scale of use" is an important factor in pesticide risk assessment than some practical next steps follow.

- The "scale-of-use" model, and the "broods-at-risk" model on which it depends, explore only the single example of skylarks on arable land. A broader range of species/crop scenarios needs to be elaborated.
- The models need to be available in a user-friendly format. The "broods-at-risk" model exists in spreadsheet format but no special effort has been made to ensure that it answers the needs of the risk manager. The "broods at risk spreadsheet could be extended so that scale of use was incorporated and isocline graphs automatically generated enabling the risk manager to read off from standard TER calculations an acceptable scale of pesticide use.

References

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References to published material

9. This section should be used to record links (hypertext links where possible) or references to other published material generated by, or relating to this project.

