

Revised assessment of the impact on crop protection in the UK of the ‘cut-off criteria’ and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market

This assessment has been prepared as a supplement to the regulatory impact assessment for this proposal. It has been revised in light of the 2nd reading amendments agreed by the European Parliament’s Environment, Public Health and Food Safety Committee

This assessment examines the impact of various sets of provisions reflecting stages in the EC negotiation process. However, the process is ongoing and it cannot therefore reflect the latest position in the negotiations

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Contents

Executive summary

1. Objective
2. Background
3. Approval criteria
4. Methodology
5. Disclaimer
6. Overview
7. Implications for conventional crop protection in the UK

Glossary

Annex 1 List of active substances assessed

Annex 2 A Substances that may not be approved according to the Council common position (endocrine disruptor definition based on the previous UK assessment from May 2008 assuming 'may cause adverse effect' is interpreted in a broad way)

Annex 2 B Substances that may not be approved according to the Council common position (assuming assessment using the ENVI Committee proposal to define endocrine potential endocrine disruptors as substances which are for example R3)

Annex 2 C Substances that may not be approved according to the Council common position (assuming assessment using the Swedish criteria assessment (potential endocrine disruptors which are R2 or 3 and C3, or substances classified as R2 or 3 which have toxic effects on endocrine organs))

Annex 3 Additional substances that may not be approved according to the ENVI Committee amended criteria.

Executive summary

This assessment revises that published by PSD in May 2008 and considers the impact of the provisions in the common position of the Council adopted in September 2008 and the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee's second reading report adopted in early November 2008. In the case of endocrine disruptors, the potential impact of a definition used in Sweden's recent impact assessment is also analysed.

The 286 substances considered in May have again been reviewed. Eight of these have since not been included in Annex I of Directive 91/414 so the total number has fallen slightly. The reasons for not extending the assessment to List 4 substances and pending new actives substances are set out in paragraph 4.1, although they will again be considered in the agronomic impact where relevant.

Some impacts remain difficult to assess because the criteria are not fully defined.

No meaningful benefits to public health protection from any criteria, beyond those delivered by the existing risk assessment arrangements, have been demonstrated.

The common position could remove up to 14% of the substances assessed, a total very similar to the 15% estimated for the Commission's original proposal. However, it remains difficult to estimate the impact for endocrine disruptors given the lack of a definition in the common position. This impact assessment notes that the common position provides a derogation whereby certain substances might be retained for a period in certain circumstances. Additionally, the date at which particular substances would be subject to these new criteria is indicated in the relevant Annexes.

The European Parliament's ENVI Committee's proposals to amend the Council common position could result in the loss of around 14 to 23 % of substances assessed. If endocrine disruptors were defined as R3, rather than as an example, these figures would fall to 9 to 21%. This compares to the loss of 85% of conventional chemical substances estimated on the basis of the Parliament's first reading proposals. However, the ENVI Committee's proposals include two criteria - on developmental neurotoxicity and immunotoxicity – which are particularly difficult to assess. We had previously assumed that no substances would be affected by these criteria because the other criteria were assessed to have such a broad impact. However, with the proposed changes from the ENVI Committee, these criteria have potentially become more significant and a more detailed consideration is required. It seems clear that the main impact of the developmental neurotoxicity criterion would fall to insecticides as indicated in Annex 3. The uncertainty over the definition of endocrine disruptors is also a factor in assessing the ENVI Committee's proposals.

The loss of active substances from the Common Position as previously identified in PSD's previous assessment would have serious implications in both agriculture and horticulture. Notably the potential loss of triazole compounds would remove the foundation-stone of control programmes on wheat against Septoria with potential for substantive yield losses. Loss of some herbicides would seriously affect weed control in some crops such as carrots, parsnips and onions. With a more specific definition of endocrine disrupter substances along the lines of that proposed by the European Parliament or that suggested by Sweden these impacts are substantially ameliorated, although certain important herbicides are still lost. However introduction of a cut off criteria for developmental neurotoxicity as proposed by the European Parliament, with the potential significant impact on the availability of insecticides, could lead to significant control issues in some circumstances.

1. **Objective**

To update the indicative impact for crop protection in the UK of the 'cut-off criteria' for plant protection products published in May 2008. This assessment considers the revised proposals in the common position agreed by the Council and the second reading amendments proposed by the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee. A third possible provision on endocrine disruptors, based on criteria used in a recent Swedish impact assessment, is also considered.

2. **Background**

Since the impact assessment of May 2008 was published two things have happened which require significant changes to the assessment. In September the Council adopted a common position on the proposal and on 5 November the ENVI Committee voted on its second reading amendments.

The assessment of the impact of the cut off criteria has been revised in light of these changes.

Candidates for substitution have not been revisited because:

- The ENVI Committee no longer propose to change the criteria for identifying candidates for substitution.
- The ENVI Committee have clarified that it was not their intention that approval for candidates for substitution should not be renewable.

3. **Approval criteria**

3.1 The following is a summary of the key criteria in the Council common position and key changes from the Commission proposal:

- no category 1 or 2 mutagens
- no category 1 or 2 carcinogen or reproductive toxin unless exposure is 'negligible';
- no endocrine disruptor which may cause adverse effects unless exposure is 'negligible';
- no POPs;
- no PBT;
- no vPvB.

In addition the Council added a derogation at Article 4(7) allowing approval of active substances for a period of five years where it is necessary to 'control a serious danger to plant health which cannot be contained by other means' even it does not satisfy the requirements on carcinogenic or reproductive toxicity category 2 or endocrine disruptors. The Commission indicated in the Council that they would expect this derogation to be used only exceptionally.

3.2 The following is a summary of the amendments proposed by the ENVI Committee to the criteria for approval in addition to the Council common position:

- addition of an example (category 3 reproductive toxins) for what might be considered an adverse effect in humans for endocrine disruptors. Further criteria are to be adopted 18 months after entry into force of the Regulation;
- no substances considered to cause a significant risk of developmental neurotoxic or immunotoxic properties (affecting one in one million) in humans, unless exposure is 'negligible';
- extension of PBT and vPvB criteria to transformation products and residues;
- exposure to bees is either negligible or established through a risk assessment to have no unacceptable effects;
- no substances on priority hazardous list for water in the Water Framework Directive 2000/60/EC.

The ENVI Committee propose to retain the derogation with some tightening of conditions including a four year approval period and the additional exclusion of category 2 carcinogens without a threshold.

4. Methodology

4.1 The 286 substances that were examined in the May 2008 assessment have been reconsidered and substances which have not been included in Annex I to Directive 91/414/EEC have been identified in Annex 1. The number of substances considered has thus reduced slightly to 278. However it should be noted that substances which were voluntarily withdrawn under Commission Regulation 1095/2007 were done so on the basis that they would be resubmitted and gain Annex I inclusion after that resubmission. They have therefore been retained within the scope of the analysis.

PSD's May 2008 assessment has been criticised for being an 'arbitrary' selection of substances. However the selection was in fact made

carefully and covered the majority of the conventional chemical substances available. List 4 review substances were not included in the main assessment but were considered in the agronomic assessment where it was noted that:

'The analysis conducted does not consider the impact on substances in list 4 of the current review programme. This list includes some compounds that can provide a useful contribution to pest control, particularly in the insecticide arena, with substances such as Bacillus thuringiensis, nicotine fatty acids and pyrethrins. There are also insecticidal substances such as pheromones for moth control and fungi for aphid control. However they generally do not deliver the level, persistence or consistency of control delivered by conventional chemistry. As such they are commonly used in conjunction with conventional chemistry (to ensure populations are reduced sufficiently) or in partnership with biological control agents in protected situations (where control by introduction of parasites and predators can be more reliable due to the more consistent environmental conditions). Whilst an increase in frequency of their use might lead to higher levels of control of some pests, this would lead to increased problems with resistance, present already for many of these substances. In the herbicide and fungicide area, the diversity of list 4 compounds is much more limited and (with the exception of sulphuric acid widely used for potato haulm desiccation and ethylene as a PGR) they only provide a small contribution to the control of weeds and diseases, or have very specific and limited application.'

Likewise new substances pending consideration for approval under Directive 91/414/EEC were not included in the main assessment. They were, however, considered in the agronomic assessment where they have provisional authorisation in the UK and offered an alternative to substances that might be lost. It is also clear that the majority of pending new substances are not new classes of chemistry but variations on existing substances. New substances would need to be in development now to be available as replacements for substances which might be lost over the next ten years. Furthermore given the broad nature of the Parliament's first reading amendments it was probable that new substances would be equally likely to fail the criteria.

Finally it is clear that it is not simply the percentage or absolute numbers of substances that might be lost which is the most important factor, but the particular substances concerned. As before an agronomic assessment of impacts is therefore being made.

Additional information is also provided for those substances which may fail the approval criteria regarding the date at which the approval criteria would become applicable for the substance (and they would have to be withdrawn) and whether the derogation in Article 4(7) would be applicable.

A full list of the substances analysed is provided in Annex 1.

- 4.2 With respect to each of the criteria, the following assessment has been made.
- 4.2.1 CMR – based on either agreed classification, EFSA conclusions, EFSA peer review expert meeting reports or the DAR.
- 4.2.2 Endocrine disruption. As was stated in May this criterion is very difficult to assess, given that no study guidelines or assessment criteria have been agreed. The Council common position excludes substances ‘which may cause adverse effects in humans’. The May assessment identified substances identified with endocrine disrupting properties in the Commission sponsored reports for the Community strategy on endocrine disruptors¹, all triazole fungicides and prochloraz based on a report published by the Danish Ministry of Environment² and in one case information from a DAR. DARs were not been systematically examined for these effects, because the reporting is very variable given the lack of guidelines. We made it clear that it was possible that, when the study guidelines and assessment criteria were developed, other substances may meet this criterion or that substances identified here would not.

Subsequent to the publication of the May impact assessment Sweden published their own interpretation and impact assessment³. The endocrine assessment was based on substances which are either category 3 carcinogens and category 2 or 3 reproductive toxins or are category 2 or 3 reproductive toxins and have toxic effects on the endocrine organs. A slightly different group of substances was considered to that in the UK assessment. The Swedish approach has been included in the analysis described below. The ENVI Committee in their second reading amendments propose to define endocrine disruptors as, for example, those which are category 3 reproductive toxins.

This assessment identifies three different scenarios for the endocrine disruptor definition:

¹ http://ec.europa.eu/environment/endocrine/documents/bkh_report.pdf#page=1
http://ec.europa.eu/environment/docum/pdf/bkh_main.pdf

²

<http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-538-1/html/default.htm>

³ Interpretation in Sweden of the impact of the “cut-off” criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)
http://www.kemi.se/upload/Bekampningsmedel/Docs_eng/SE_positionpapper_annenII_sep08.pdf

- Annex 2 A based on the previous UK assessment from May 2008 assuming 'may cause adverse effect' is interpreted in a broad way
- Annex 2B. Substances that may not be approved according to the Council common position (assuming assessment using the ENVI Committee proposal to define endocrine potential endocrine disruptors as substances which are for example R3). However unless this example is adopted as a precise definition, rather than an example, we believe the broader definition followed in Annex 2A would still apply.
- Annex 2 C active substances that may not be approved according to the criteria used in the Swedish assessment (potential endocrine disruptors which are R2 or R3 and C3, or substances classified as R2 or 3 which have toxic effects on endocrine organs)

To re-inforce the uncertainty that applies to this criteria it is noted that the Swedish assessment identifies four substances as endocrine disruptors (molinate, tralkoxydim, tepraloxym and thiacloprid) which are included in this assessment but were not identified as endocrine disruptors using the methodologies we used to establish Annexes 2A, 2B and 2C.

- 4.2.4 POP, PBT and vPvB criteria remain difficult to assess without the full guidance in place. It is notable that the OECD Working Group Pesticides is to develop guidance on evaluation of PBT substances. Data for this assessment have again been taken from Commission review reports, EFSA conclusions, end points in peer review or the DAR. We have not assessed the likely impact of the extension of the PBT and vPvB criteria proposed by the ENVI Committee to include transformation products and residues because of lack of relevant information
- 4.2.5 Developmental neurotoxic or immunotoxic properties are also particularly difficult to assess, but these criteria could have wide implications. In the May 2008 assessment it was assumed that no substances would be affected. This was partly because of the difficulty in establishing which substances might be affected when decision making criteria do not exist for this criterion but mainly because the majority of substances were caught by other criteria anyway. However now that the proposal is to change the other criteria the developmental neurotoxic or immunotoxic criteria are potentially much more significant. As one possible starting point in relation to developmental

neurotoxicity the Pesticides Action Network (PAN) have previously circulated a note⁴ in which they make the following statement:

'To make an estimate of how many of the chemicals after testing will be banned or restricted, a similar testing regime in the USA is taken as a basis. In 1996 the USA created the Food Quality Protection Act to protect children against pesticides with neurodevelopmental effects. After the testing programme <10% of the pesticides demonstrated severe neurodevelopmental effects. The 10% is therefore taken as an estimate of what could be the result of creating 'cut-off' criteria in the EU pesticides harmonisation regulation.'

An alternative approach would be to assume that the classes of substances identified in a recently published paper⁵ would be vulnerable to this criteria. These would include organophosphates, carbamates, pyrethroids, ethylenebisdithiocarbamates and chlorophenoxy herbicides. These substances are identified in Annex 3 and amount to 12 % of the substances assessed, not a widely dissimilar figure to that identified by PAN. We note that the ENVI Committee propose a standard of significant risk as affecting one in one million citizens. Such quantitative approaches are not used routinely in the human health assessments of pesticides and we cannot make any judgement on the implications of this.

We have been unable to find a realistic basis on which the impact of the criteria on immunotoxicity could be assessed at this stage.

- 4.2.6 Effects on bees. The ENVI Committee has amended its position on the use of the hazard quotient value as a cut off criteria to a requirement for a risk assessment. This criterion is likely to have no greater impact than the risk assessment approach taken currently.

5. Disclaimer

This assessment is intended to provide an indicative assessment of the impact of these proposals on crop protection in the UK. **It is not intended to be a definitive list of substances that will be affected by these criteria and this analysis is not a substitute for thorough evaluation using, where appropriate, new guideline studies and assessment criteria.** As can be seen in Section 4 above some of these criteria are not well defined and it is inevitable that, in analysing nearly 20 different criteria for nearly 300 substances, there is scope for different interpretations.

⁴ How many active substances will disappear from the market as a result of the European harmonisation and the use of "cut-off" criteria; what is the impact on agriculture?

⁵ Bjorling-Poulsen *et al*, Potential developmental neurotoxicity of pesticides used in Europe, Environmental Health 2008, 7:50

6. Overview

The potential impact on individual substances is set out in Annexes 2 A, B and C and 3:

- Annex 2 A Substances that may not be approved according to the Council common position (endocrine disruptor definition based on the previous UK assessment from May 2008 assuming 'may cause adverse effect' is interpreted in a broad way)
- Annex 2 B Substances that may not be approved according to the Council common position (assuming assessment using the ENVI Committee proposal to define endocrine potential endocrine disruptors as substances which are for example R3)
- Annex 2 C Substances that may not be approved according to the Council common position (assuming assessment using the Swedish criteria assessment (potential endocrine disruptors which are R2 or 3 and C3, or substances classified as R2 or 3 which have toxic effects on endocrine organs))
- Annex 3 Additional substances that may not be approved according to ENVI Committee amended criteria.

The potential impact in terms of the percentage reductions in available active substances are summarised below.

The common position could remove up to 14% of the substances assessed. However, it remains difficult to estimate the impact for endocrine disruptors given the lack of a definition in the common position. The Article 4(7) derogation could apply to a number, but not all, affected substances and the point at which these new criteria would become applicable is indicated in the Annex 2 A.

The European Parliament's ENVI Committee's proposals to amend the Council common position could result in the loss of around 14 to 23 % of substances assessed. If endocrine disruptors were defined as R3, rather than as an example, these figures would fall to 9 to 21%. This compares to the loss of 85% of conventional chemical substances estimated on the basis of the Parliament's first reading proposals. However, the ENVI Committee's proposals include two criteria - on developmental neurotoxicity and immunotoxicity – which are particularly difficult to assess. We had previously assumed that no substances would be affected by these criteria because the other criteria were assessed to have such a broad impact. However, with the

proposed changes from the ENVI Committee, these criteria have potentially become more significant and a more detailed consideration is required. It seems clear that the main impact of the developmental neurotoxicity criterion would fall to insecticides as indicated in Annex 3. The uncertainty over the definition of endocrine disruptors is also a factor in assessing the ENVI Committee's proposals. The Article 4(7) derogation would not apply to the substances in Annex 3.

7. Implications for conventional crop protection in the UK

The following section identifies key areas where the impact of loss of the actives identified under the different criteria, as identified in annexes 2 A, B and C, and 3, will affect UK agriculture and horticulture. It is noted that substances will be impacted by the agreed criteria at various dates over the next ten years as set out in the Annexes. Later dates clearly allow more time for the development of alternatives although it should also be noted that new chemical substances have a long lead in time to market and would need to be in development now to be available. It is noted an exemption is available from some, but not all, of the criteria in cases of a serious danger to plant health. Again the details are given in the Annexes. It is unclear how this derogation would be used and the Commission have been clear that they see its use as an exceptional measure.

Summary

The loss of active substances from the Common Position, as detailed in Annex 2A, as previously identified (PSD 2008) would have serious implications in both agriculture and horticulture. Notably the potential loss of triazole compounds would remove the foundation-stone of control programmes on wheat against Septoria with potential for substantive yield losses. Similarly, on oilseed rape the removal of a range of fungicides would not leave any fully effective compounds for the major diseases of rape. There were significant implications for minor crops such as carrots, parsnips and onions because the majority of currently approved herbicides may no longer be available. There was potential for up to 100% yield loss on carrots. Insecticide losses are of limited impact.

Annexes 2B and 2C: Endocrine disruptor criterion

With revision to the ED criterion under both annex 2B and 2C criteria, the impact on cereals from loss of triazoles is substantively ameliorated and several fungicides that provide useful control of a range of diseases remain available. This amelioration is dependent on the retention of prothioconazole which, as a new active substance, has not been covered in the impact assessment. Epoxiconazole would be lost according to the proposals and if prothioconazole were also to fail the criterion, annual yield losses of around to 5-20% are possible,

depending on the varieties involved and the weather conditions. On horticultural crops and potatoes, the loss of mancozeb (under all the Annex 2 scenarios) will impact seriously on resistance management. Mancozeb has shown resilience to resistance and its loss will increase resistance pressure on existing alternatives or alternatives would need to be developed. In addition loss of some important triazoles (e.g. tebuconazole) would potentially seriously affect disease control on many crops. Possible alternative compounds may well exist although substantial costs in gaining authorisation across a wide range of minor crops would be encountered (due to residue data requirements).

In the herbicide area, there is some amelioration in terms of the active substances available with some significant products being retained. However, the substantive impact across both cereal crops and many minor crops, where pendimethalin and linuron are very important, will not be changed.

Insecticide losses are of minimal impact and marginally ameliorated by these definitions of ED.

Annex 3: Developmental neurotoxicity and other criteria.

There is potential for increased impact from loss of herbicides in cereals and in rotational horticultural crops, as well as increased cost of weed control in grassland. However, the most significant impact is the loss of several groups of insecticides, notably the pyrethroids, carbamates and organophosphorous (OP) compounds. For some targets such as nematodes there are no alternative treatments. This will have profound consequences for the production of potatoes and also carrots and onions. The loss of major groups of insecticides will remove control options for many serious pests, particularly virus vectors. The majority of control will be forced to rely on mainly neonicotinoid insecticides and some other aphicides. The increased resistance risk associated with the loss of these compounds in major aphid species that have already shown a propensity for resistance development is a significant concern. This would particularly apply if new modes of action are not developed in the medium term. Finally the possible loss of methiocarb one of the two major active ingredients used for the control of slugs is a concern. Slugs are one of the most intractable problems facing UK agriculture and horticulture.

Impact of loss of substances under the different annexes.

Annex 2 A (Substances that may not be approved according to the Council common position (endocrine disruptor definition based on the previous UK assessment from May 2008 assuming 'may cause adverse effect' is interpreted in a broad way)

Agronomic implications are as previously identified in the PSD impact assessment published May 2008. Key points are as follows;

Insecticides

Of the 6 active substances that could be lost, four are approved in the UK. Three of these are pyrethroids (bifenthrin, esfenvalerate, deltamethrin), and the other is the OP dimethoate. The three pyrethroids have a wide range of uses but the availability of other pyrethroids and neonicotinoids that can be used in their place minimises any impact. The caveat remains that increased use of the latter group continues to raise the resistance pressure. The key dimethoate use with the biggest impact of its withdrawal is the control of wheat bulb fly where it is used in an integrated programme with seed treatments and foliar applications of chlorpyrifos. The overall impact of insecticide losses will be relatively minor from the common position.

Fungicides

Under Annex 2A the loss of the triazoles, especially the few remaining ones with activity against *Septoria tritici* is likely to have a significant effect on wheat yields with regular reductions in yield of 10-20%. In oilseed rape there is a risk that there would be no effective products for the control of either stem canker and light leaf spot, both of which have the potential to halve yields in the UK.

The loss of mancozeb would have considerable significance as this active is an important component in resistance management strategies in potatoes and a wide range of minor crops. There may be some situations where other dithiocarbamates, such as thiram, or newer compounds originally developed for potato late blight control may be able to replace mancozeb. But this would be costly and may not be practical in all situations. Where resistance does develop and products cease to be effective there may be no fall back product allowing crop production to continue while new treatments are developed. For example, in onions, downy mildew is a serious disease that can halve yields and all current products for its control contain mancozeb.

Overall, for minor pesticide uses, although alternatives to products likely to be withdrawn do exist, the time and costs involved in developing alternatives make it likely that new products will not become available for all situations.

Herbicides

Under Annex 2A there are 10 herbicides that would no longer be available. The most important of these are linuron, pendimethalin and ioxynil. The loss of these active substances has significant implications for minor crops such as carrots, parsnips and onions because the majority of currently approved herbicides will no longer be available. There will also be a significant effect on broad-acre crops. Pendimethalin is the cornerstone (together with flufenacet) of pre-

emergence black-grass control in cereals. Black-grass is the major grass weed species in England and the loss of pendimethalin will jeopardise its control, leading to yield losses, and placing increased pressure and risk of resistance on remaining active substances.

Annex 2 B (Substances that may not be approved according to the Council common position (assuming assessment using the ENVI Committee proposal to define potential endocrine disruptors as substances which are, for example, R3)

Insecticides

Under Annex 2B, dimethoate is no longer listed. The already minor impact is therefore further reduced with this active being available as part of the control programme for wheat bulb fly in cereals.

Fungicides

Under Annex 2B the impact on cereals from the loss of the triazoles is substantially ameliorated. A number of important fungicides, particularly epoxiconazole, are still expected to be lost. But several fungicides that provide useful control of a range of diseases remain available. Prothioconazole, a new substance not included in this assessment might be retained. If this is the case then the effect on cereal production is likely to be minor. If prothioconazole is also lost then, in the absence of effective new chemistry, annual yield losses of around to 5-20% are possible, depending on the varieties involved and the weather conditions. In both 2007 and 2008, for example, the wet summers have resulted in high disease pressure with yield responses of up to 40% from fungicide uses compared to untreated crop.

On oilseed rape a range of effective compounds such as propiconazole and difenoconazole would continue to be available under these proposals. The greatest effect would be from the loss of triazoles with growth regulatory properties. However, these could be replaced by the use of additional plant growth regulators. If the additional compounds listed in annex 3 were lost this would include thiram, a useful seed treatment, the loss of which may make the establishment of oilseed rape crops more difficult in some years.

Tebuconazole is also widely used in horticulture, and might be eliminated by these proposals. Again, for many of its uses it may be possible to substitute other similar triazole compounds that are not affected by the proposals but this would require substantial investment. Mancozeb would also be lost under this annex with the potential consequences described above.

Finally, a number of fungicides such as iprodione and thiram. remain under Annex 2B. These would be very valuable in minor crops and

thiram may offer some potential to replace mancozeb where resistance is an issue, although it is unlikely to be suitable or as effective for all uses.

Herbicides

Annex 2B includes the same active substances as Annex 2A except that 2, 4-D, picloram and triflurosulfuron will be retained, all of which have significant uses. 2, 4-D is a broad-leaved herbicide approved for use in cereals, amenity grassland and aquatic areas. In cereals a key problem is control of grass weeds and 2, 4-D would have little impact in this context. 2, 4-D is also unsuitable for use in the minor crops that are hardest hit by the proposals. However, the continued availability of 2, 4-D would benefit weed control in amenity and grassland sectors. It would also be a benefit in aquatic environments where increasingly the only available herbicide is glyphosate. . Picloram is currently approved for use in the UK on land not intended for cropping and in oilseed rape. In the original impact assessment oilseed rape was not identified as one of those crops where the impacts would be most severe. However, oilseed rape growers do not have many herbicides available and picloram is useful in the herbicide armoury in that it controls cleavers. . Additionally the focus of the original impact assessment was agriculture/horticulture. However, picloram is also used in the control of invasive species such as Japanese Knotweed. and other pernicious weeds Triflurosulfuron is approved for use in sugar beet for the control of a range of broad-leaved weeds. Although the sugar beet crop was relatively little affected by the Council common position under Annex 2A this would still be of benefit.

Agronomic implications of loss of substances listed in Annex 2 C (Substances that may not be approved according to the Council common position (assuming assessment using the Swedish criteria assessment (potential endocrine disruptors which are R2 or 3 and C3, or substances classified as R2 or 3 which have toxic effects on endocrine organs))

Insecticides

This list no longer includes the pyrethroid deltamethrin, further reducing the minimal impact.

Fungicides

One additional fungicide would be retained under this annex but overall there is likely to be relatively little difference in potential impacts.

Herbicides

The list of active substances in Annex 2C is identical to that in Annex 2B except that metribuzin is not included. Metribuzin is approved for use in potatoes and its continued availability will have some benefit.

Agronomic implications of loss of substances listed in Annex 3 (Additional substances that may not be approved according to ENVI Committee amended criteria.)

There is considerable uncertainty about which substances will be affected by the ENVI Committee proposals. This assessment is made on the basis of the analysis in Annex 3 but could be substantially altered if further substances were lost or, alternatively, if those in Annex 3 were not.

Insecticides

The actives provisionally included here would result in the greatest impact on insect control. They fall into three groups of organophosphorous (OPs), carbamates, and pyrethroids. In this respect, many of the specific examples discussed in our previous assessment from May 2008 with respect to the Parliament's first reading criteria remain relevant. Key points for the loss of each group are:

- OP's and carbamates – chlorpyrifos still has some key uses such as wheat bulb fly control in cereals, and is considered a more IPM compatible option in many horticultural crops. Pirimicarb is a key aphicide in both arable and horticultural crops with both contact and fumigant action enabling it to control aphids which may not be directly contacted by a spray application. Its loss, combined with pyrethroids, would impact on many crops such as brassicas, lettuce, and require wider neonicotinoid use with consequent rise in resistance risk. For certain crops (particularly horticultural) other modes of action will still be available (e.g. pymetrozine), although it is important to retain a diversity of modes of action for resistance management.

The loss of oxamyl and fosthiazate leaves no chemical control options for PCN control in potatoes, or free living nematodes in carrots, potatoes and onions. As previously described in the original impact paper this may result in significant yield losses (figures around 6 t/ha costing £15 million per year), shortage of PCN-free land, and use of longer crop rotations. The loss of methiocarb could be very significant for slug control in arable and horticultural crops. The future impact if lost can not be fully determined however until the outcome of the review of

metalddehyde (which currently has been voluntarily withdrawn from the review process) is known. The worst case situation would be the loss of both actives, leaving only ferric phosphate as a chemical control option (a newly approved product), a possible need for re-drilling when plant losses at establishment are high, and use of longer crop rotations. In horticultural crops there could be significant loss of quality (and crop rejection) in seasons favourable to slug activity.

- Pyrethroids (impact on control measures) - the actives listed include both foliar and seed treatments. If seed treatments become unavailable, this would result in failure to control many soil dwelling pests which can be particularly damaging. Foliar applications of pyrethroids are extensively used in arable and horticultural crops, where they provide a key component in the overall treatment programmes, including of some virus vector aphids. In some crops, such as peas and beans, and OSR, they control a range of key pests, including pea moth where high levels of control are required to avoid crop rejection. Their loss would mean neonicotinoids usually being the remaining broad spectrum insecticide option. Their loss will be particularly relevant in those situations where their initial speed of activity, superior to virtually all alternatives at present including neonicotinoids, makes them the product of choice. This particularly relates to their use against pests which are vectors of viruses that cause disease. The quick 'knock down' provided by pyrethroids stops the pest feeding, and therefore transmitting the virus to the plant (and through the crop). In a crop such as seed potatoes, the production of disease free tubers is essential.
- Resistance management -Two of the key modifiers in reducing resistance risk is limiting the number of applications, and alternating modes of action. The loss of pyrethroids, OP's and carbamates would have consequences for resistance management in both of these areas. Alternation may become more difficult in certain crops. As mentioned above, there may be an increased resistance pressure on the existing actives if there is a need to use a greater number of foliar applications. Some changes in the sensitivity of aphids to pirimicarb and OPs have occurred recently in *Myzus persicae*. However, the possible loss of both these groups further undermines potential for resistance management of a range of aphid pests, which have shown ability to develop resistance to most active substances to which they have been exposed. Should resistance problems make aphid control in, for example sugar beet, ineffective yield losses of around 20% are likely and up to 50% are possible. Retaining options for use in future management strategies is important in attempts to combat changing populations of aphids.

In summary, the potential losses under these criteria can be divided into two areas. Firstly, there are a limited number of specific situations where the loss of these actives will result in significant control issues and subsequent impacts on yield. However, for many situations there are generally alternative insecticides available. These are based around usually the broad spectrum neonicotinoids, and a number of more specialised actives with niche markets in vegetables, fruit and protected crops. The other more general area of concern would be the loss of the pyrethroid, OP and carbamate groups as available modes of action used in resistance programmes. The ability to implement a resistance management strategy, based around limiting the use of a class of actives and alternating different modes of action, will be restricted (particularly when also considering the loss of pirimicarb). This will be combined with increased demand particularly of neonicotinoids, which are already widely used as seed and foliar treatments. In the absence of the development of new active groups, this may lead to an increased resistance risk on this group, which has already replaced older chemistry no longer available or is used where instances of resistance has developed to other actives.

If the nicotinoid insecticides were also affected by the neurotox criteria, consequences of their loss would be extremely significant removing the majority of broader spectrum insecticides.

Fungicides

The main effect of the proposals set out in Annex 3 on fungicides is the removal of all dithiocarbamates, including compounds that may offer some limited replacement for mancozeb, such as thiram. As stated previously these are important both as resistance management partners and as useful 'reserve' products that can be used when more effective compounds become ineffective due to resistance. Thiram is also an important seed treatment in a range of crops, including oilseed rape where its loss could make the establishment of crops difficult in some years where the weather favours seedling diseases.

Herbicides

Annex 3 includes the chlorophenoxy herbicides and this effectively means the loss of the 'hormone type' herbicides such as 2, 4-D, mecoprop-p, MCPA etc. These herbicides are approved for use in a wide range of crops, both in the agricultural and amenity sectors. Mecoprop-p is used in winter cereals as a critical component of strategies to avoid target site resistance to ALS inhibitor herbicides in broad-leaved weeds. In addition, where cereals form part of a rotation with horticultural crops the loss of mecoprop-p would cause significant problems in the following horticultural crop. The only real alternatives are the sulphonyl urea herbicides (SU) but these are likely to cause crop damage in following horticultural crops. Horticultural crops already

face significant challenges from the loss of trifluralin and other herbicides such as pendimethalin and linuron. In grassland the loss of 2, 4-D and MCPA would be significant but triclopyr or dicamba could be used as substitutes. This would, however, increase the cost of weed control in grassland. The loss of MCPB and MCPA would also have further impact on weed control in peas, already significantly affected by the loss of pendimethalin, trifluralin, terbutryn and cyanazine. Since active substances included in this group are approved across a range of situations the loss of the whole group would be highly significant.

Glossary

ACCase	acetyl-coenzyme A carboxylase
ADI	acceptable daily intake (for consumers)
ALS	acetolactate synthase
AOEL	acceptable operator exposure level
ARfD	acute reference dose
BYDV	barley yellow dwarf virus
C	carcinogenic
CMR	carcinogenic, mutagenic or toxic to reproduction
DAR	draft assessment report
EC	European Community
ECJ	European Court of Justice
EFSA	European Food Safety Authority
ENVI	European Parliament's Environment, Public Health and Food Safety Committee
ha	hectare
IPM	integrated pest management
M	mutagenic
NGO	non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
PAN	Pesticides Action Network
PBT	persistent, bioaccumulating, toxic
PCN	potato cyst nematode
PGR	plant growth regulator
POP	persistent organic pollutant
PPP	plant protection product
R	toxic to reproduction
vPvB	very persistent, very bioaccumulating
WRAG	Weed Resistance Action Group

Annex 1 List of substances assessed

Grey highlighting indicates those substances which have not been, or are no longer, included in Annex I as of 27 November 2008.

Substance	Status#	Approved in UK	Function*
1-methylcyclopropene	AI	y	PGR
2,4-D	AI	y	H
2,4-DB	AI	y	H
abamectin	AI	y	I
acetamiprid	AI	y	I
acetochlor	list 3 vw	n	H
acibenzolar-s-methyl	AI	y	?
aclonifen	AI	n	H
acrinathrin	list 3 vw	n	I
alpha cypermethrin	AI	y	I
aluminium phosphide	AI	y	I
amidosulfuron	AI	y	H
amitrole	AI	y	H
ampelomyces quisqualis	AI	n	F
asulam	list 3 vw	y	H
azimsulfuron	AI	n	H
azoxystrobin	AI	y	F
bacillus subtilis	AI	n	F
beflutamid	AI	n	H
benalaxyl	AI	y	F
benfluralin	AI	n	H
bensulfuron	list 3	n	H
bentazone	AI	y	H
benzoic acid	AI	y	disinfect
beta-cyfluthrin	AI	y	I
bifenazate	AI	y	I
bifenox	AI	y	H
bifenthrin	list 3	y	I
bitertanol	list 3 vw	y	F
bromoxynil	AI	y	H
bromuconazole	list 3	y	F
bupirimate	list 3 vw	y	F
buprofezin	list 3	y	I
calcium phosphide	AI	n	R
captan	AI	y	F
carbendazim	AI	y	F
carbetamide	list 3 vw	y	H
carboxin	list 3 vw	y	H

carfentrazone ethyl	Al	y	H
chlorate	list 3	n	H
chloridazon	Al	y	H
chlormequat	list 3	y	PGR
chloropicrin	list 3 vw	y	F
chlorothalonil	Al	y	F
chlorotoluron	Al	y	H
chlorpropham	Al	y	PGR
chlorpyrifos	Al	y	I
chlorpyrifos methyl	Al	y	I
chlorsulfuron	list 3	n	H
cinidon ethyl	Al	y	H
clethodim	list 3 vw	n	H
clodinafop	Al	y	H
clofentezine	Al	y	I
clomazone	Al	y	H
clopyralid	Al	y	H
clothianidin	Al	y	I
coniothyrium minitans	Al	y	F
copper compounds	list 3	y	F
cyazofamid	Al	y	F
cyclanilide	Al	n	PGR
cycloxydim	list 3 vw	y	H
cyfluthrin	Al	y	I
cyhalofop butyl	Al	n	H
cymoxanil	Al	y	F
cypermethrin	Al	y	I
cyproconazole	list 3 vw	y	F
cyprodinil	Al	y	F
cyromazine	list 3	n	I
daminozide	Al	y	PGR
dazomet	list 3 vw	y	SS
deltamethrin	Al	y	I
desmedipham	Al	y	H
dicamba	Al	y	H
dichlorobenzoic acid methylester	Al	n	PGR
dichlorprop p	Al	y	H
diethfencarb	list 3 vw	n	F
difenoconazole	Al	y	F
diflubenzuron	Al	y	I
diflufenican	Al	y	H
dimethachlor	list 3	n	H
dimethanamid -p	Al	y	H
dimethoate	Al	y	I

dimethomorph	Al	y	F
dimoxystrobin	Al	y	F
dinocap	Al	n	F
diphenylamine	list 3	n	?
diquat	Al	y	H
dithianon	list 3 vw	y	F
dodemorph	Al	n	F
dodine	list 3 vw	y	F
epoxiconazole	Al	y	F
esfenvalerate	Al	y	I
ethalfluralin	list 3 vw	n	H
ethephon	Al	y	PGR
ethofumesate	Al	y	H
ethoxysulfuron	Al	n	H
ethprophos	Al	y	I
etofenprox	list 3	n	I
etoxazole	Al	n	I
etridiazole	list 3 vw	n	F
famoxadone	Al	y	F
fenamidone	Al	y	F
fenamiphos	Al	n	I
fenarimol	Al	y	F
fenazaquin	list 3 vw	y	I
fenbuconazole	list 3 vw	y	F
fenbutatin oxide	list 3 vw	n	I
fenhexamid	Al	y	F
fenoxaprop p	Al	y	H
fenoxycarb	list 3 vw	y	I
fenpropidin	Al	y	F
fenpropimorph	Al	y	F
fenpyroximate	Al	y	I
ferric phosphate	Al	y	M
fipronil	Al	n	I
flazasulfuron	Al	y	H
florasulam	Al	y	H
fluazifop-p	list 3 vw	y	H
fluazinam	Al	y	F
fludioxonil	Al	y	F
flufenacet	Al	y	H
flufenoxuron	list 3 vw	n	I
flumioxazine	Al	y	H
fluometuron	list 3 vw	n	H
flupyrsulfuron methyl	Al	y	H
fluquinconazole	list 3 vw	y	F

flurochloridone	list 3 vw	n	H
fluroxypyr	Al	y	H
flurprimidol	list 3	n	PGR
flurtamone	Al	y	H
flusilazole	Al	y	F
flutolanil	Al	y	F
folpet	Al	n	F
foramsulfuron	Al	n	H
forchlorfenuron	Al	n	PGR
formetanate	Al	n	I
fostetyl	Al	y	F
fosthiazate	Al	y	I
fuberidazole	Al	y	F
gliocaldium catenulatum	Al	n	F
glufosinate	Al	y	H
glyphosate	Al	y	H
guazatine	list 3 vw	y	F
hexythiazox	list 3 vw	n	I
hymexazol	list 3 vw	y	F
imazalil	Al	y	F
imazamox	Al	y	H
imazaquin	Al	y	PGR
imazosulfuron	Al	n	H
imidacloprid	Al	y	I
indoxacarb	Al	y	I
iodosulfuron	Al	y	H
ioxynil	Al	y	H
iprodione	Al	y	F
iprovalicarb	Al	n	F
isoproturon	Al	y	H
isoxaben	list 3 vw	y	H
isoxaflutole	Al	y	H
kresoxim methyl	Al	y	F
lambda cyhalothrin	Al	y	I
laminarin	Al	y	?
lenacil	Al	y	H
linuron	Al	y	H
lufenuron	list 3	n	I
magnesium phosphide	Al	y	I
maleic hydrazide	Al	y	PGR
mancozeb	Al	y	F
maneb	Al	y	F
MCPA	Al	y	H
MCPB	Al	y	H

mecoprop	Al	n	H
mecoprop-p	Al	y	H
mepanipyrim	Al	y	F
mepiquat	Al	y	H
mesosulfuron	Al	y	H
mesotrione	Al	y	H
metalaxyl-M	Al	y	F
metaldehyde	list 3 vw	y	M
metam	list 3	y	SS
metamitron	Al	y	H
metazachlor	Al	y	H
metconazole	Al	y	F
methamidophos	Al	n	I
methiocarb	Al	y	I
methoxyfenozide	Al	y	I
metiram	Al	y	F
metosulam	list 3 vw	y	H
metrafenone	Al	y	F
metribuzin	Al	y	H
metsulfuron methyl	Al	y	H
milbemectin	Al	n	I
molinate	Al	n	H
myclobutanil	list 3 vw	y	F
napropamide	list 3	y	H
nicosulfuron	Al	y	H
oryzalin	list 3 vw	n	H
oxadiargyl	Al	n	H
oxadiazon	Al	y	H
oxamyl	Al	y	I
oxasulfuron	Al	n	H
oxyfluorfen	list 3 vw	n	H
paclobutrazol	list 3 vw	y	H
paecilomyces fumosoroseus	Al	n	I
penconazole	list 3	y	F
pencycuron	list 3 vw	y	F
pendimethalin	Al	y	H
pethoxamid	Al	n	H
phenmedipham	Al	y	H
phosmet	Al	n	I
picloram	Al	y	H
picolinafen	Al	y	H
picoxystrobin	Al	y	F
pirimicarb	Al	y	I
pirimiphos-methyl	Al	y	I

prochloraz	list 3 vw	y	F
procymidone	Al	n	F
prohexadione calcium	Al	y	PGR
propachlor	list 3	y	H
propamocarb	Al	y	F
propanil	list 3	n	H
propaquizafop	list 3	y	H
propargite	list 3 vw	n	I
propiconazole	Al	y	F
propineb	Al	n	F
propoxycarbazone	Al	y	H
propyzamide	Al	y	H
prosulfocarb	Al	y	H
prosulfuron	Al	y	H
Pseudomonas chlororaphis	Al	n	F
pymetrozine	Al	y	I
pyraclostrobin	Al	y	F
pyraflufen ethyl	Al	y	H
pyridaben	list 3 vw	n	I
pyridate	Al	n	H
pyrimethanil	Al	y	F
pyriproxyfen	Al	n	I
quinmerac	list 3 vw	y	H
quinoclamine	Al	n	H
quinoxifen	Al	y	F
quizalofop-p-ethyl	list 3	y	H
quizalofop-p-tefuryl	list 3	y	H
rimsulfuron	Al	y	H
silthiofam	Al	y	F
sintofen	list 3 vw	n	HA
s-metolachlor	Al	n	H
sodium 5 nitroguaiacolate	list 3	n	PGR
sodium o nitrophenolate	list 3	n	PGR
sodium p nitrophenolate	list 3	n	PGR
spinosad	Al	y	I
spiroxamine	Al	y	F
spodotera exigua	Al	n	I
sulcotrione	Al	n	H
sulfosulfuron	Al	y	H
tau fluvalinate	list 3 vw	y	I
tebuconazole	Al	y	F
tebufenozone	list 3 vw	n	I
tebufenpyrad	list 3	y	I
teflubenzuron	list 3	y	I

tepraloxydim	AI	y	H
terbutylazine	list 3 vw	y	H
tetraconazole	list 3	y	F
thiabendazole	AI	y	F
thiacloprid	AI	y	I
thifensulfuron methyl	AI	y	H
thimethoxam	AI	y	I
thiobencarb	list 3 vw	n	H
thiophanate methyl	AI	y	F
thiram	AI	y	F
tolclofos methyl	AI	y	F
tralkoxydim	AI	y	H
triadimenol	AI	y	F
triallate	list 3	y	H
triasulfuron	AI	y	H
triazoxide	list 3	y	F
tribenuron	AI	y	H
triclopyr	AI	y	H
trifloxystrobin	AI	y	F
triflumuron	list 3	n	I
triflusulfuron	list 3	y	H
trinexapac	AI	y	PGR
triticonazole	AI	y	F
warfarin	AI	y	R
zeta-cypermethrin	list 3	y	I
ziram	AI	y	F
zoxamide	AI	y	F

Status

AI – included in Annex I to Directive 91/414/EEC

List 3 – under review as part of the third stage of the EC review programme

List 3 vw – voluntary withdrawal (these substances are likely to be re-submitted under Directive 91/414/EEC and for the purpose of this assessment it is assumed that they secure inclusion in Annex I in 2010)

* Function

I - insecticide

F - fungicide

H - herbicide

PGR – plant growth regulator

SS – soil sterilant

M - molluscicide

? – other functions

Annex 2 A Substances that may not be approved according to the Council Common Position (endocrine disruptor definition based on the previous UK assessment from May 2008 assuming 'may cause adverse effect' is interpreted in a broad way)

Insecticides

Substance	Status	Approved in UK	Criteria failed	Date of expiry Annex I#	Article 4(7) derogation may apply
bifenthrin	list 3	y	PBT/ vPvB + Endocrine?	2018	n
esfenvalerate	AI	y	PBT	2011	n
flufenoxuron	list 3 vw	n	C2/ PBT	2020	n
lufenuron	list 3	n	PBT/ vPvB	2018	n

deltamethrin	AI	y	Endocrine?	2013	y
dimethoate	AI	y	Endocrine?	2016	y

Fungicides

bitertanol	list 3 vw	y	R2+ Endocrine?	2020	y
carbendazim	AI	y	M2/ R2 + Endocrine?	2009	n
dinocap	AI	n	R2	2009	y
flusilazole	AI	y	R2 + Endocrine?	Deadline suspended by ECJ	y
quinoxifen	AI	y	vPvB	2014	n

cyproconazole	list 3 vw	y	Endocrine?	2020	y
difenoconazole	AI	y	Endocrine?	2018	y
epoxiconazole	AI	y	Endocrine?	2018	y
fenbuconazole	list 3 vw	y	Endocrine?	2020	y
fluquinconazole	list 3 vw	y	Endocrine?	2020	y
iprodione	AI	y	Endocrine?	2013	y
mancozeb	AI	y	Endocrine?	2016	y
maneb	AI	y	Endocrine?	2016	y
metconazole	AI	y	Endocrine?	2017	y
metiram	AI	y	Endocrine?	2015	y
myclobutanil	list 3 vw	y	Endocrine?	2020	y

penconazole	list 3	y	Endocrine?	2018	y
prochloraz	list 3 vw	y	Endocrine?	2020	y
propiconazole	AI	y	Endocrine?	2013	y
tebuconazole	AI	y	Endocrine?	2019	y
tetraconazole	list 3	y	Endocrine?	2018	y
thiram	AI	y	Endocrine?	2013	y
triticonazole	AI	y	Endocrine?	2017	y
triademenol	AI	y	Endocrine?	2018	y

Herbicides

flumioxazine	AI	y	R2	2012	y
glufosinate	AI	y	R2	2017	y
linuron	AI	y	R2 + Endocrine?	2013	y
pendimethalin	AI	y	PBT	2013	n

2,4-D	AI	y	Endocrine?	2011	y
amitrole	AI	y	Endocrine?	2011	y
ioxynil	AI	y	Endocrine?	2015	y
metribuzin	AI	y	Endocrine?	2017	y
picloram	AI	y	Endocrine?	2018	y
triflusalufuron	list 3	y	Endocrine?	2018	y

In addition the following substance is classified but may be expected to have 'negligible' exposure.

Rodenticides

warfarin	AI	y	R1	2016	n
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- assuming Annex I inclusion for substances not yet included

Annex 2 B Substances that may not be approved according to the Council common position (assuming assessment using the ENVI Committee proposal to define endocrine potential endocrine disruptors as substances which are for example R3)

Insecticides

Substance	Status	Approved in UK	Criteria failed	Date of expiry Annex I#	Article 4(7) derogation may apply
bifenthrin	list 3	y	PBT/ vPvB + Endocrine?	2018	n
esfenvalerate	AI	y	PBT	2011	n
flufenoxuron	list 3 vw	n	C2/ PBT	2020	n
lufenuron	list 3	n	PBT/ vPvB	2018	n

deltamethrin	AI	y	Endocrine?	2013	y
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Fungicides

bitertanol	list 3 vw	y	R2+ Endocrine?	2020	y
carbendazim	AI	y	M2/ R2 + Endocrine?	2009	n
dinocap	AI	n	R2	2009	y
flusilazole	AI	y	R2 + Endocrine?	Deadline suspended by ECJ	y
quinoxifen	AI	y	vPvB	2014	n

cyproconazole	list 3 vw	y	Endocrine?	2020	y
epoxiconazole	AI	y	Endocrine?	2018	y
fenbuconazole	list 3 vw	y	Endocrine?	2020	y
mancozeb	AI	y	Endocrine?	2016	y
maneb	AI	y	Endocrine?	2016	y
metconazole	AI	y	Endocrine?	2017	y
myclobutanil	list 3 vw	y	Endocrine?	2020	y
tebuconazole	AI	y	Endocrine?	2019	y

Herbicides

flumioxazine	AI	y	R2	2012	y
glufosinate	AI	y	R2	2017	y
linuron	AI	y	R2 +	2013	y

			Endocrine?		
pendimethalin	AI	y	PBT	2013	n

amitrole	AI	y	Endocrine?	2011	y
ioxynil	AI	y	Endocrine?	2015	y
metribuzin	AI	y	Endocrine?	2017	y

In addition the following substances is classified but may be expected to have 'negligible' exposure.

Rodenticides

warfarin	AI	y	R1	2016	n
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- assuming Annex I inclusion for substances not yet included

Annex 2 C Substances that may not be approved according to the Council common position (assuming assessment using the Swedish criteria assessment (potential endocrine disruptors which are R2 or 3 and C3, or substances classified as R2 or 3 which have toxic effects on endocrine organs))

Insecticides

Substance	Status	Approved in UK	Criteria failed	Date of expiry Annex I#	Article 4(7) derogation may apply
bifenthrin	list 3	y	PBT/ vPvB + Endocrine?	2018	n
esfenvalerate	AI	y	PBT	2011	n
flufenoxuron	list 3 vw	n	C2/ PBT	2020	n
lufenuron	list 3	n	PBT/ vPvB	2018	n

Fungicides

bitertanol	list 3 vw	y	R2+ Endocrine?	2020	y
carbendazim	AI	y	M2/ R2 + Endocrine?	2009	n
dinocap	AI	n	R2	2009	y
flusilazole	AI	y	R2 + Endocrine?	Deadline suspended by ECJ	y
quinoxifen	AI	y	vPvB	2014	n

cyproconazole	list 3 vw	y	R3 C3 Triazole Not assessed by Sweden	2020	y
epoxiconazole	AI	y	C3 R3 In Swedish assessment as ED	2018	y
fenbuconazole	list 3 vw	y	R3 Triazole Not assessed by Sweden	2020	y
mancozeb	AI	y	R3 Ovarian hypertrophy In Swedish	2016	y

			assessment as ED		
maneb	AI	y	R3 Decrease thyroid hormone synthesis In Swedish assessment as ED	2016	y
metconazole	AI	y	R3 Triazole In Swedish assessment as ED	2017	y
tebuconazole	AI	y	R3 Gestational length, maternal progesterone levels, masculinised female offspring, feminisation of male offspring doocrine organ effects In Swedish assessment as ED	2019	y

Herbicides

flumioxazine	AI	y	R2	2012	y
glufosinate	AI	y	R2	2017	y
linuron	AI	y	R2 + Endocrine?	2013	y
pendimethalin	AI	y	PBT	2013	n

amitrole	AI	y	R3 Decrease hormone synthesis In Swedish assessment	2011	y
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			as ED		
ioxynil	AI	y	R3 Reduced bw gain, liver hypertrophy and enzyme induction, thyroid hyperactivity In Swedish assessment as ED	2015	y

In addition the following substances are classified but may be expected to have 'negligible' exposure.

Rodenticides

warfarin	AI	y	R1	2016	n
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- assuming Annex I inclusion for substances not yet included

Annex 3 Additional substances that may not be approved according to the ENVI Committee amended criteria.

No substances currently authorised in plant protection products are identified as priority hazardous substances.

The following substances could be vulnerable to the developmental neurotoxicity criterion (does not include substances which may fail other criteria in the ENVI Committee criteria (Annex 2B).

Insecticides

Substance	Status#	Approved in UK	Function*	Date of expiry Annex I#	Article 4(7) derogation may apply
acrinathrin	list 3 vw	n	I	2020	n
alpha cypermethrin	AI	y	I	2015	n
beta-cyfluthrin	AI	y	I	2013	n
chlorpyrifos	AI	y	I	2016	n
chlorpyrifos methyl	AI	y	I	2016	n
cyfluthrin	AI	y	I	2013	n
cypermethrin	AI	y	I	2016	n
dimethoate	AI	y	I	2017	n
ethprophos	AI	y	I	2017	n
etofenprox	list 3	n	I	2018	n
fenamiphos	AI	n	I	2017	n
formetanate	AI	n	I	2017	n
fosthiazate	AI	y	I	2013	n
lambda cyhalothrin	AI	y	I	2011	n
methamidophos	AI	n	I	2017	n
methiocarb	AI	y	I	2017	n
oxamyl	AI	y	I	2016	n
phosmet	AI	n	I	2017	n
pirimicarb	AI	y	I	2017	n
pirimiphos-methyl	AI	y	I	2017	n
tau fluvalinate	list 3 vw	y	I	2020	n
tefluthrin	list 3 vw	y	I	2020	n
zeta-cypermethrin	list 3	y	I	2018	n

Fungicides

metiram	AI	y	F	2016	n
thiram	AI	y	F	2014	n
ziram	AI	y	F	2014	n

Herbicides

2,4-D	AI	y	H	2012	n
2,4-DB	AI	y	H	2013	n
dichlorprop p	AI	y	H	2017	n
MCPA	AI	y	H	2016	n
MCPB	AI	y	H	2016	n
mecoprop	AI	n	H	2014	n
mecoprop-p	AI	y	H	2014	n

Other

metam	list 3	y	SS	2018	n
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- assuming Annex I inclusion for substances not yet included

We do not expect the criteria for bees to affect additional substances.

We have not assessed the likely impact of the extension of the PBT and vPvB criteria to include transformation products and residues because of lack of relevant information.

We have been unable to find a realistic basis on which the impact of the criteria on immunotoxicity could be assessed at this stage.