It is always necessary to acquire experience through using a product in practice

Q1: Do you have any comments on these proposed definitions?

Bayer

significantly safer: will this be based on tox profile or other aspects eg consumer safety. Will one aspect of safety override another. Similar effect: use may be for 'off label pests' and advice on importance should be sought from agronomists and growers.

agree with the proposed definitions and with proposed restriction to data, data plus or major change routes. Ask that an EAMU is not considered an amendment to authorisation and there be definition of a new product in the proposed definition of the benefits of a product. Suggest when submitting a new product or new use applicant be given the option of derogation from CA. Propose the derogation can be used for new products and for major changes to authorised products - including new uses

What does significant economic or practical disadvantages mean? Who will decide if it is significant or not. Whoever makes the decision will need to be advised by practical agronomists. There is a similar issue about who decides whether an active has significantly higher human or environmental effect. Those making the decision need advice from independent experts

agree with the proposed working definitions and with proposed restriction to data, data plus or major change routes. Welcome practical working definitions. The real test will come with having actual products with which to make comparisons. Welcome the consequences for minor use authorisations to be taken into account. Understand this will incorporate any EAMU

Fresh Produce consortium

agree but suggest there is some quantifiable measure applied (such as a $/lower risk

Supports proposed working definition of significantly safer. This must be a demonstrable improvement to human health or the environment based on empirical evidence and not a marginal decision which could be a factor of error or variance. The working definition of similar effect is the only reasonable definition. A substitution should only be considered if the effect was comparable if not greater. Also agree with the type of application that requires CA

Hutchinsons

Agree. Any potential benefit in sharing resources likely to be minimal and the need for a process of consultation would probably eradicate any saving in resources. May be advantageous to review the potential for work sharing at the time as the zonal approaches to authorisations are bedded in. Support stepwise approach allowing termination at any stage where a conclusion can be reached. Assume minor uses will be a key priority area for assessing need to retain a PTP containing a candidate for substitution.

Agree applicants should have the opportunity to present a case to authorities for retention of their product, but CA must be carried out objectively by CRD. Other sources of relevant information: growers and representatives of potential practical or economic disadvantages of alternatives. Applicants may not have access to the detailed information on a competitors product or non-chemical alternatives required to complete a full comparison.

NFU

Q2: What are your views of the possibility of work-sharing between member states?

Would be sensible to share workload and reduce duplication, but recognise different agronomics may result in differing conclusions between MS

Information should be shared, but different authorisations may mean that work sharing would be difficult. Important to collaborate between MS due to impact on small MS with large market potential for a product that could be commercially non-viable if substituted in larger MS.

agree limited scope for work sharing. Request CA assessment is a separate section of the national addenda to the draft Registration report (eg to Part A)

Zonal harmonisation being introduced and actively reviewed on a zonal basis, but CA being done on a National basis. Can a MS require that a product NOT be substituted when other countries in the zone say it should be? What process is envisaged?

agree limited scope for work sharing.

Agree applicants should have the opportunity to present their own case for evaluation in an application that includes a comparative assessment?

Yes applicants should present their own case

Yes especially for minor uses and specialty crops to take account of all crops, soil types, Cultivars and field scale application techniques

yes - need to fully understand the benefits of a product. Suggest when submitting a new product or new use applicant be given the option of derogation from CA. Propose the derogation can be used for new products and for major changes to authorised products - including new uses

yes - need to fully understand the context of identifying an evaluating potential extension of uses to minor crops. Noted that CA must be carried out at the stage of any amendment to authorisation

yes there should always be practical experience

yes to fully ascertain their value in crop production and what opportunity may exist for mitigation. Particularly when a new product delivers the active in a new way which mitigates the risks previously associated with other uses of actives

AIC

broadly agree for chemical methods. Difficult to compare chemical and non-chemical. Concern about varying interpretations of regulation. Difficult to compare labels during transition to CLP labelling (to 2015).

Q3: Should applicants present their own case for evaluation in an application that includes a comparative assessment?

Agree - but not applicants for EAMUs. Suggest estimated time required is significant underestimate.

Yes for their own products, but unbiased assessment needed of alternatives

agree but it should be optional rather than mandatory. Request guidance on how CRD want a comparative assessment to be conducted.

agree but it should be optional rather than mandatory.

Yes applicants should present their own case

AHDIB

Q4: Is it always necessary to acquire experience first through using a product in practice?

Yes. Allow assessment in practice over several seasons including tank mixing, and variable pest pressures

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yes because PPP authorisations and CA are both member state specific accept that at this stage there is limited opportunity for joint working between MS. Opportunities should be considered in future once experience is built up on the process and MS using similar definitions and with similar use profiles can then consider joint-working particularly within the zonal registration structure.

Comparative assessment and substitution is a member state responsibility, but CRD will continue to work with colleagues in other MS in central zone as the harmonisation of authorisations across the central zone progresses. Can a MS require that a product NOT be substituted when other countries in the zone say it should be?

agree limited scope for work sharing. Request CA assessment is a separate section of the national addenda to the draft Registration report (eg to Part A)

Adopt the proposed working definitions for significantly safer and similar effect. Once we have experience consider the need for a 'quantifiable' measure. Note the desire for a working definition of 'new product' and 'significant economic or practical disadvantages'. Note the suggestion for advice from independent experts

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yes to fully ascertain their value in crop production and what opportunity may exist for mitigation. Particularly when a new product delivers the active in a new way which mitigates the risks previously associated with other uses of actives

AIC
Q5 Can circumstances be specified where it is considered necessary to acquire experience of the product in use?

Mobile pests, new threats identified in the Plant Health risk register; diversity of pest populations resulting in variation of efficacy in practice

See Q4 request the 5 year period for all new products

Q6 Should the derogation from comparative assessment for new products be offered to applicants as an option?

Yes. For both products containing new active and new combinations of actives

Important to know what is meant by new. Is a new formulation of a well established active new?

See Q4

Q7 Are there other options that could also be used in reaching a rapid conclusion to a comparative assessment by considering the suitability of substitution?

1. resistance management is important. As suggested in EPPO guidance if at least 4 alternative modes of action not available do not substitute. 2. This requirement should also apply to minor uses. 3. No opinion

1. resistance management is important. As suggested in EPPO guidance if at least 4 alternative modes of action not available do not substitute. 2. As suggested in EPPO guidance if at least 4 alternative modes of action not available do not substitute. 3. Consideration of resistance strategies and consequences on minor uses are potential tools for shortening the process. By pre-evaluating some of the non-chemical methods there may be a possibility they can be discounted as being a viable alternative e.g. a flame thrower for weed control in field crops, in such circumstances it would then not be required to be considered for individual horticultural crops.

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Alternative methods requiring additional passes and thus additional fuel costs and greenhouse gas emissions could be discounted from being a viable alternative automatically. Once viable alternatives identified one reason alone should be sufficient to stop CA and consideration of other points would not then need to be presented or evaluated. Further opportunity for applicants to add other reasons should be made available in the case CRD do not agree.

Q8 CRD would favour completing a general comparative assessment for minor uses thus restricting a detailed consideration of potential comparative assessment and substitution major uses only. What are your views?

1. Agree this would reduce workload and COSHH would identify safety option available. Any active in and EAMU should be considered a minor use and CA cease. Such products allowed by organic production protocols should be considered minor uses even if on major crops.

It would seem appropriate that applicants are asked to comment on importance for minor uses or specialty crops in their comparative assessment cases. Important that major uses continue to ensure economically feasible to produce products for each MS - see also 2.

CRD is supportive of the need to maintain minor uses which would mean that active whose major use was vulnerable could be protected from substitution because of the impact on associated minor use. It is unclear how a group comparative assessment would work for minor uses and clear guidance is required. Risks that some uses might be accidentally overbroaded or considered unimportant. This would need some sort of appeals process to allow industry to respond to decisions and get them reviewed.

CRD would seek clarification from the Commission about the possible exclusion of minor uses, including products used in organic agriculture. If not legally possible, CRD will take account of the suggested information sources (here and below) to consider a general assessment. Clearly provision would be required for updating.

Q9 Is there information that could be readily made available to assist such a group comparative assessment?

Work done by the growers liaison group may help. No knowledge Do not believe CA of minor uses is required. Do not believe CA of minor uses is required. Don’t believe CA of minor uses is required. See above.

CRD’s preliminary impact assessment at the time of introduction of the regulation. Additional work was carried out by Cranfield University and ADAS. These could provide a starting point. SCEPTRE project assessing efficacy and viability of certain crop protection products and non-chemical treatments. Anticipated work will continue via HDC.
Q10 Do you consider it is appropriate to require a higher number of alternative modes of action to be available before a substitution is made in order to maintain sufficient security in resistance risk management given the unpredictable loss of UK products at re-registration?

Yes. Other additional threats to availability include EU wide regulation (eg neonicotinoids), water framework directive and drinking water directive. Weather pattern changes may change susceptibility to introduce new pests. Commercial viability of candidates for substitution may lead to commercial withdrawal

Q11 Do you have any suggestions as to what would be an appropriate margin?

No, but concern about the classification of Candidates for substitution and the impact of the order of consideration. Could be dependent on individual organism and the number of alternatives. See Q10

Q12 CRD would favour completing a general comparative assessment for home garden products, Do you agree that the current UK policy for home garden products means that there is no advantage to be gained by requiring them to be subject to individual comparative assessment?

Agree comparative assessment for home garden not necessary. Yes lower volumes of uses and factors considered in the evaluation make this a low risk area.

Q13 Is there information that could be readily made available to assist such a group comparative assessment?

Nothing, only a few actives used in this area so it may be appropriate to reconsider and consult again once the list of Candidates for Substitution is finalised.

Q14 Does this approach offer scope to reduce the resources required to complete comparative assessments? (ie main claims considered first and lesser claims considered based on results of primary CA)

At face value sounds sensible. However not all pests are on the label and some uses against ‘off-label pests’ are important, and can impact on total pesticide use.

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<th>AIC</th>
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Agree it would be sensible to consider main claims first. If these indicate a possible substitution it will be important to consider the lesser claims as these may not have alternatives.

**Agree it would be sensible to consider main claims first. If these indicate a possible substitution it will be important to consider the lesser claims as these may not have alternatives.**

Growers need a suite of crop protection products to avoid build up of resistance. Products that offer additional control albeit as lesser claims can offer viable alternatives in a crop protection programme. It seems logical to assess the main claims first but not to forget the importance of some of these lesser claims for horticultural crops.

**Agrees with the proposal to consider main claims first and only consider lesser claims if necessary based on initial CA. Important to note sometimes partial control can be important as a combinational control eg black grass control and in cereal fungicides where a number of actives offer limited control but in combination provide effective control and extend the life of actives.**

**Agree it is sensible to assess main claims first, but if a possible substitution is identified the lesser claims must also be considered as there may be no suitable alternatives.**
| Q15 Are there any disadvantages you can see? | See Q14 |
| Q16 Are applicants in a position to identify appropriate ‘lead’ products based on their knowledge of the industry sector and an examination of the authorised products list? | Probability but not always. Care needed re: co-formulations (particularly if only co-formulations available). All label uses should be reflected in the ‘lead’ selected to prevent uses being overlooked. |

**Minor uses and specialty crops** are often not included on the label and EAMUs may not include all target pests. Important to have an appeals process so agronomists and growers can consider any that appear to fail.  

Don’t consider applicants should be expected to identify ‘lead’ products. Applicants have expertise in their own products and are not necessarily in a position to evaluate alternatives. Don’t believe applicants should be expected to provide information on ‘differences in risk’ between candidate and alternatives. Hazard classification risk and safety phrases shouldn’t be used as the regulation 1107/2009 specifies risks and benefits not hazards. It may be appropriate to use PPE, exclusion times, buffer zones, restrictions on times of application in CA as these are results of a risk assessment. However comparisons may not be accurate as all products will not have been assessed using the current procedures.

A risk envelope approach involves taking highest application rate, max no. treatments, shortest interval to demonstrate that the highest risk will pass regulatory triggers. This differs significantly to deriving the product with the lowest risk, so don’t think risk envelope approach is useful for CA-ag buffer zone uses do not mean a like for like comparison has been conducted, higher tier studies are provided to reduce uncertainty and unless similar types of studies used the level of risk determination will not be comparable.

Concerns have been identified about the potential for commercial bias, the lack of applicant expertise in products other than their own and the need to ensure important uses are not overlooked. It has been suggested that a database be compiled to avoid repetition. CRD will consider how best to ensure that the information referred to in Regulation 1107/2009 can be gathered and compared in the light of these comments.
Q17 Is it an acceptable possibility that a substitution could be overlooked at this stage by only asking for detailed information on ‘lead’ products? NB in all cases risk assessments will have been compiled and found acceptable prior to authorisation of all products including those not examined in a comparative risk assessment at this stage.

Maybe see 16

Yes para 6.1 regulation 1107/2009 requires a significant difference in risk to be identified. If lead products that are obviously safer can be identified the possibility of substitution being overlooked is minimal. Intention of 1107/2009 to reduce MS workload by requiring renewal for actives to be extended to 15 years is completely undermined by listing 30% actives as Candidates for Substitution with renewal interval of 7 years. 30% actives translates to >50% products - again undermining the 1107/2009 principles.

Yes para 6.1 regulation 1107/2009 requires a significant difference in risk to be identified. If lead products that are obviously safer can be identified the possibility of substitution being overlooked is minimal.

Concerns the list of Candidates for Substitution will be treated as a ‘black list’ of products by pressure groups and potentially retailers who will seek to avoid such products being used in their supply chain. This could undermine public confidence, implying that many products that have undergone a robust and thorough independent assessment are potentially not safe for use.

CRD is aware of the concerns raised about potential negative impacts of the list of Candidates for Substitution and of comparative assessment. The legislation requires member states to inform the authorisation holder if they intend to withdraw or amend an authorisation and to allow the authorisation to submit comments or further information. Thus there will be an opportunity to appeal if a substitution is identified to be inappropriate. As usual for R&D, CRD will make available their recent research on non-chemical alternatives available in the UK. The options to re-manufacture a product need to include the full range of application types to take account of emergency situations, reinstatements after a very short period of time and re-instatements many years later following significant further review activity. UK will continue to work towards greater harmonisation of PPP authorisations across the Member States.

A large list of actives in Candidates for Substitution will be misinterpreted, turned into a black list by retailers, and seen by public as indicative that the regulatory system lacks rigour and is failing to protect the environment and the public. Ask regulators to ensure the list is a focused as possible on a few main actives and that communication of the process and the list is made very clear by regulators.
How are the environmental and other potential hazards from non-chemical controls to be evaluated? (e.g. how are the relative risks of a skylark being affected by an agrochemical or having its nest obliterated by a hoe to be judged?) Who is assessing the impacts on non-chemical methods? Similar issues apply when comparing pesticides to biological control agents.

Concern about timing. Understands CA will take place when products come up for re-registration, meaning it is not possible to take account of relative effects of other actives controlling the same pest from a scientifically valid comparative database. As a consequence a product with average toxicity could be substituted in an early round, yet it may later become clear that it would have been better to keep that one in preference to a more damaging/less useful product reviewed in a later evaluation. An overall assessment of an active's contribution to the management of the target species should be done before substitution.

Some initial work was carried out by Cranfield University to assess impact of potential loss of certain crop protection products on a crop by crop basis. This initial assessment could be reviewed and updated to assist understanding of “significant practical and economic disadvantages”. The horticultural industry as well as the applicant should be engaged in this process.

Concerned there is a risk of inconsistency across MS, and the process threatens to undermine the work done to get consistency and harmonisation across the EU. Would like to understand how the UK government intends to avoid this and ensure harmonisation of CA within the zonal system.

Concerned that 1107/2009 is very onerous, unnecessarily complicated and continues to increase the barriers to innovation in the EU. This results in EU farmers and growers being at a fundamental disadvantage due to barriers on technologies, making it harder for growers to manage volatility pest control and food safety. Believes the European Commission must take the opportunity to review 1107/2009 in 2014.

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