EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Safety of the food chain
Chemicals, contaminants, pesticides

SANCO/10055/2013 Rev. 4
3 October 2013

Applicable from 3 April 2014

GUIDANCE DOCUMENT ON THE EFFICACY COMPOSITION OF CORE DOSSIER AND NATIONAL ADDENDA SUBMITTED TO SUPPORT THE AUTHORIZATION OF PLANT PROTECTION PRODUCTS UNDER REGULATION (EC) NO 1107/2009 OF THE EU PARLIAMENT AND COUNCIL ON PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

SANCO E3 WORKING DOCUMENT DOES NOT NECESSARILY REPRESENT THE COMMISSION'S VIEWS

This document has been conceived as a working document of the Commission Services which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation 1107/2009 nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

1. Background

Regulation EC 1107/2009 specifies that the assessment of plant protection products should be conducted on a zonal basis, with a nominated zonal rapporteur Member State (zRMS) assessing the application on behalf of all other Member States (MS) to which an application has been made (the concerned Member States or cMS). The application should include the Biological Assessment Dossier (BAD), which is summarised in Part B section 7 of the draft registration report (dRR), and any national addenda to address specific MS issues, as described in SANCO/6896/2009[1]. Regulation 1107/2009 also includes provisions for Mutual Recognition (MR) of authorizations, whether from other Member States within a zone, or from different zones. Once again, the Mutual Recognition application may be accompanied by national addenda.

The purpose of this guidance is to indicate areas of the efficacy data requirements that should be considered as part of the core zonal dossier, and what relevant issues may need to be addressed under national addenda

2. General principles on the relationship between zonal core submissions and National addenda

a) Core Zonal Product Submission

Guidance document SANCO/13169/2010[2] describes the requirements and procedures for zonal evaluations and mutual recognition under 1107/2009. This notes that applicants should consider the use of a 'risk envelope' approach to the core dossier. This is to minimize the number of individual uses assessed by the zRMS in relation to the various areas of the risk assessment. The concept is based on the fact that within a group of similar uses for the proposed product there will be an identified '*worst case situation'* (GAP) for each area of the risk assessment that will then cover less critical GAPs. The efficacy assessment differs in that its' basis is consideration of all the proposed uses, of which there may be several crop/pest combinations. However, similar principles can be applied, to the extent of trying to have

[1] Guidance document on a process for intra &inter-zonal work-sharing to facilitate the registration and re-registration of plant protection products following inclusion of an active substance in annex i of council directive 91/414/EEC

[2] Guidance document on zonal evaluation and mutual recognition under Regulation. (EC) No 1107/2009

simplified, common proposed uses/targets, doses, timings (to both crop and target), and extrapolating from major to minor uses, where appropriate to do so. A risk envelope approach can be utilised for some areas of efficacy assessment, particularly those relating to adverse effects, such as identifying 'worst case' scenarios for adjacent und succeeding crops. In terms of the intended targets, however, the 'critical' use may vary depending on the data requirement. For example, the key target in addressing dose justification may not be the same as that for resistance management. The principle of minimum effective dose is fundamental to the efficacy assessment, and it is not always appropriate to extrapolate between crops or between target organisms. The efficacy assessment therefore needs to review all individual proposed uses/targets on every proposed crop/situation in order to identify and assess the key uses in relation to each data requirement.

As part of the zonal and mutual recognition process (MR), cMS only have 120 days to consider the zRMS assessment, or zonal authorization for which MR is sought. It is important, therefore, that as much as possible of the efficacy evaluation should be conducted by the zRMS, to minimize the number of uses considered in national addenda. The core dossier should include where possible all intended target species. In addition it may include, for information, data covering early developmental formulations that were tested in the trials. Guidance on the criteria applicable to formulation (chemical composition) changes, and the efficacy trials package that may be required to support such changes, is still under development by EPPO. ((SANCO/12638/2011 (20/11/2012 rev.2[3]) provides general guidance on changes to the chemical composition of products.

b) <u>National Addenda</u>

National addenda should include very limited additional data, addressing either specific individual MS requirements, or possibly supporting a specific localized use or target (see below). Any specific national risk management measures should also be presented here.
There is no requirement to submit a national addendum, but if one is being submitted it can provide a very useful format to also provide, if required, additional background information or explanation for the cMS on how the proposed National uses relate to the core dossier. For example in explaining how national labels (if relevant) are derived and supported by the core

[3] Guidance Document on changing the chemical composition of authorised Plant Protection Products (PPPs)

dossier, and highlighting any amendments/deviations (Where a National addenda is not being submitted, the applicant should still consider providing such explanations, if appropriate).
There may in practice be a very limited number of specific MS national requirements associated with efficacy related issues. They could particularly apply, however, where there is currently no EPPO (or other) standard guidance to follow. Examples might be national label claims for 'rainfastness', or support for convenience tank mixtures. MS are encouraged to provide further information on any such requirements.

National addenda may be used to seek authorization for specific recommendations in individual MS. Two different situations are described in more depth below. It is important to remember that if these uses represent the 'worst case' for any area of the risk assessment then they must be presented in the core submission.

- Specific dose(s) for a given use in a single MS (or a limited number of MS) in the zone concerned. For example;

    - A specific lower dose may be required because of national risk mitigation measures. This may result in having to accept lower (but still beneficial) levels of control in an individual MS. As such the data might be available in the core dossier (as part of dose justification), but equally specific additional data may have to be generated and presented for the relevant national targets in national addenda.

    - A specific dose is proposed for a particular target (unless 'worst case' and should be in core) due to differences in conditions encountered in the individual MS that impact on effectiveness/crop safety e.g. pest pressure, soil type, or environmental factors. EPPO 1/278 'Principles of zonal data production and evaluation' requires that the zonal data package should encompass the conditions encountered in the area where authorization is sought. By testing the product under the range of conditions, it avoids having to generate data in each MS. Therefore careful consideration should be given when proposing specific doses in national addenda, because the conditions encountered, and proposed dose, may be relevant to several other MS. (Under those circumstances it would be appropriate to consider as part of the core

dossier). It is very important that the applicant provides a justification as to why the required dose differs from that considered in the core dossier. If different doses are proposed in the zone for a particular use, the dose proposed for the majority of MS in the zone, or the dose concerning the largest production area of the crop in question, is presented in the core dossier.

- Specific use, or uses concerning specific crops, in a single MS or a limited number of MS in the zone concerned. For example;

    - Cases of specific uses/targets, or uses on specific crops, in one or (a small number) of Member States of the zone may be covered by the core dossier or national addendum, at the notifier's discretion or in conjunction with the MS. Where there is a national target species on a crop included in the core dossier (on other uses) it may be relevant to also refer to the information provided in the core dossier on crop safety. (There may also be effectiveness data in the core dossier on related species, which again might be referred to as supporting evidence). The applicant may not have to address all of the efficacy data requirements again in the national addenda, and should consider which aspects of the core dossier (and therefore the zRMS evaluation) are relevant. In the case of resistance, any proposed national target use should still form part of the information provided in the core dossier when conducting a resistance risk analysis and proposals for resistance management strategy.

3. Presentation of information in the Core Dossier and National addenda

a) Introduction in the Core Dossier and associated National addenda

The core BAD and the dRR must start with an introduction/overview describing the common proposed uses. This should include a clear explanation of the strategy behind the proposed doses/rates, particularly any proposed variations in dose (or timing and number of applications) in individual MS. The rationale should be explained e.g. differences in target pressure, or identified differences in performance related to the conditions under which the trials were conducted. It is important that the efficacy zRMS maintains an overview; it would not be appropriate, for example, to only consider one dose on a particular use in the core dossier, and then propose many different variations in individual MS national addenda.

Whichever approach is being taken, it must clearly be supported by the submitted data (whether in the core dossier or national addenda, as discussed previously).

The national addenda can usefully provide the cMS with an introduction/background explaining how the proposed individual MS uses have been derived from the core dossier. If there are any significant deviations from what has been considered under the zonal assessment, this should be highlighted and justified by reasoned case and reference to the relevant sections of the core dossier or (if required) by submission of additional data. It may also be necessary to provide further argumentation on the relevance of the data to particular circumstances in the individual MS. This includes addressing the relevance of the proposed targets to the individual MS, in accordance with Uniform Principles (546/2011[4]) requirements to consider whether the target is harmful/causes damage. Where the product is already authorized in a MS (and now a new target and/or crop is being proposed, or a change in existing conditions of use), the applicant should highlight this and potentially further justify the new/amended uses. In some cases, the core dossier may address certain aspects of the data requirements by general statements referring to the long term use of the active and existing products. Where this approach is taken, it is reliant on data access to such information. Therefore further explanation and justification may be required in the national addenda, with specific reference to existing authorized products in that MS.

b) Directions for use in the Core Dossier, and relationship to National Product labels (submitted with National Addenda)

Under the 1107/2009 process, there is no submission of a 'zonal label' as part of the core application for authorization of a plant protection product. The proposed uses are detailed in the GAP table, which does include some information on the pests controlled. This information can be relatively limited in terms of listing all individual target species and their specific recommendations for use. Furthermore, 'directions for use' sections on national labels often include much more detailed instructions than available in the GAP tables. For example they provide information on how to use the product in relation to a particular target/use. These instructions help in understanding the interaction between product

[4] Commission Regulation (EU) No 546/2011 of 10 June 2011implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of plant protection products valuation and authorization of plant protection products

performance and target biology. They also assist in determining the validity of both the trials conduct and the relevance of the generated data. The type of information being referred to here could include a description of the most susceptible life stages, references to local thresholds and advice on optimal conditions for product performance. (Specific descriptions for levels of control on product labels will reflect individual Member State requirements. Appendix 1 does include however a commonly agreed scale to describe levels of weed control, for the purposes of the core evaluation). Appendix 2 has provided some typical examples of the type of advice often included on product labels to assist growers. The importance and use of this information is discussed in more depth in EPPO standard 1/278 'Principles for zonal data production and evaluation'. This refers to the concept of the 'master label', defined as '*recommendations and directions for use*' (but it is not a 'product' label with all risk and safety phrases).

In considering their own draft national labels, it is important that MS can compare as much as possible the proposed national recommendations with the data considered under the zonal assessment. This will ensure that relevant claims/instructions have been supported appropriately. MS also need to consider whether the directions for use on the label are appropriate, or require further clarification/amendment to adjust to local conditions (e.g. references to local thresholds). It would therefore be very helpful, as part of the efficacy core zonal dossier, to include the proposed label text for each of the relevant uses. The most convenient way to do this is to include the proposed text in the relevant section of the BAD/dRR.

Any national labels should principally be derived from this core dossier but may require some amendment, as discussed above.

The national addenda and any draft label should take account of existing MS requirements for expressing levels of control, and how groups of targets may be specified (e.g. German terms for 'biting/chewing' insects). In addition there may also be individual MS schemes for specifying crop groupings and crop hierarchies, and those need to be reflected on national labels.

In the case of use on 3 dimensional crops (e.g. orchards) there may be different MS methods used for dose expression (on national labels). It may therefore be necessary to convert the

dose expression used in the core dossier to national schemes. In all cases, the trials must record all relevant parameters of orchard structure, and the information should include the amount of product/ha leaf wall area, and the amount of product/ha. Reference: EPPO standard PP 1/239(2) 'Dose expression for plant protection products'). In the case of differences in dose expression among the MS for a particular use, the doses should be converted into the same unit within the core dossier to ensure legibility and comparability of the doses applied in the trials. This conversion must be placed in advance in the core dossier. If the doses are similar, they should be included in the core dossier. If not, the result will be several different doses, which will require creation of an addendum (see 2b).

4. Data requirements

It is important to emphasize that Regulation 1107/2009 has introduced a fundamental change in the way that efficacy assessments will be conducted. Under 91/414, data were generated to meet specific national requirements on numbers of trials, which were based on the relative importance of crops and targets in that MS. Under 1107/2009, the zonal assessment must be based on a data package than encompasses and is representative of the range of conditions encountered in the areas for which authorization is sought. Consideration must therefore be given to the range of main targets, differences in target pressure, resistance status, agronomic practices, recommendations for use with an adjuvant etc when designing and evaluating zonal data packages. This is explained more fully in EPPO Standard 1/278 'Principles for zonal data production and evaluation'. EPPO is looking to develop further zonal guidance on specific target/crops and applicants should take account of all available EPPO guidance and plan their trials programme and protocols accordingly (information is updated on the EPPO website under 'Zonal Efficacy Assessment')

Trials must be conducted and reported in accordance with all the relevant EPPO Standards, including those for the claimed use (where available), or with standards satisfying at least the requirements of the corresponding EPPO standard. The efficacy data requirements are specified in EU Regulation 284/2013[5].

[5] COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Preliminary tests (6.1)

- The types of data considered to be 'preliminary' include a range of laboratory/greenhouse studies on the following; Mode of action and range of activity, e.g. screening data indicating the level of insecticidal, fungicidal or herbicidal activity, and range of target activity. These studies may be reported either under this section, or under the relevant data requirement. Such data can be used to form reasoned cases in lieu of data to address various aspects of the data requirements (e.g. may be able to address transformation processes by demonstrating the active substance has no significant fungicidal activity); preliminary dose justification work (including to support the justification of the ratio of actives in a mixture formulation; and/or safener/synergist, adjuvant substances in the product formulation)
- Studies that may aid in understanding the impact of environmental conditions (e.g indoor and outdoor uses, pH, temperature, soil type, humidity) on the a.s and/or formulation

In the case where field studies have been performed to provide preliminary information on the appropriate dose then this could also be considered as core and would then be further validated in the efficacy tests. Preliminary tests providing the type of information described above performed in the laboratory/glasshouse and/or any field tests may come from any location (including non-EU). Further justification/explanation may be required on the location of trial, particularly field trials and if generated outside the area where authorization is sought. All preliminary data should be submitted and assessed in the core dossier.

Preliminary Data: National addenda

Preliminary data may be submitted if relevant to a specific use or dose being supported in the national addenda

Testing Effectiveness (6.2)

EPPO Standard 1/278 'Principles for zonal data production and evaluation' should be referred to when considering generating data for a zonal authorization. Where there are common pests across the zone where authorization is sought, then these data should be considered as core. Data should reflect the range of conditions, including variability in target pressure, application

timing, which will inform decisions on supporting the appropriate dose (see below). However, greater emphasis should be given to those data generated in regions of the zone considered representative of typical growing regions for the particular crop (if the target is crop specific). In these areas target pressure is more likely to develop to appropriately challenging levels. Data may also be relevant from EPPO regions outside the zone where authorization is sought, with an appropriate case justifying their relevance.

The efficacy trials are generally distributed throughout the entire crop production area in the zones concerned (or may be a more limited distribution when authorization is sought in only a few Member States within a regulatory zone). Accordingly, it would be very helpful to have a map of the zone in order to explain and justify the distribution of the trials, by including:

- distribution of crops related to the claims,
- presence/absence of targeted pests and possibly their damage potential
- where necessary, the diversity of farming practices (connected with the pest or use),
- where necessary, soil and climate diversity (connected with the pest or use),
- distribution of the trials

When providing information on the distribution of crops, it may be more accurate and practical to refer to current EUROSTAT.

Effectiveness: National addenda

There may be additional specific targets that pose a significant problem at national level. These claims would be included on individual national labels, and addressed in the national addenda. Evidence would need to be provided using specific national trials data, or it may be possible to address by extrapolation if an appropriate level of evidence was available (and can be cross-referenced from the core dossier). (Specific national data may also be required where there are local resistance issues, in order to provide an indication on the level of effectiveness that may be achieved). A specific dose may also be proposed for an individual Member State (as described in 2b).

The national addenda, with the proposed national label, should refer to the core dossier particularly where deviations from the considered core uses are proposed. Consideration and further justification may be required on the relevance/economic importance of the target species. It should also take account of the issues discussed above, in particular differences in

dose expression.

Minimum effective dose tests **(**also included under 6.2**)**

This should largely be addressed in the core dossier, with the evidence of dose response provided for at least the ,most important key target species, taking into account the spectrum of activity of the substance and biological parameters of the target pests (see EPPO standard PP 1/225 'Minimum Effective Dose'). As explained above, it needs to be made clear what doses are being proposed, and whether there are any significant differences between what is presented in the core dossier, and any National addenda. . For products containing more than one active substance, it is necessary to provide further justification/explanation for the co-formulation ratio and the benefit over the individual active substances, in addition to a justification of the product dose. Consideration should be given to providing evidence that will incorporate what are considered to be the major targets/crops within the zone. The zRMS will assess whether these data indicate reduced effectiveness at the lower doses, and as such the zRMS can conclude whether appropriate evidence has been provided for the principal uses. It is important that the core dossier provides an explanation and an overview to the zRMS of what the intended proposed rates will be for the individual MS (accepting that some variation may be required (see below)). A summary table of the national GAP's, may be useful, but should include information on individual targets, particularly where a different dose is proposed in individual MS for the same target. This explanation should include the rationale for e.g. supporting one dose on a target across the zone or varying doses (whether by target, crop, or growth stage of either).

The determination on whether minimum effective dose has been satisfactorily addressed on the major target/uses will be made by the zRMS, including indicating whether there is a dose response demonstrated.

Minimum Effective Dose: National addenda

Dose justification is based on providing evidence for the major targets/uses and/or highest doses. The major target in a particular crop may vary in individual member states (or across regions), as could the major crop/use. As such, the applicant needs to consider whether data are available to support what will be the identified as the relevant major uses/targets on that national label. (Furthermore differences in population pressures across a zone may mean that differences in applied rates are appropriate). The applicant should explain in the National

addenda how the data presented in the core dossier relates to the proposed national label. (If necessary provide a limited amount of additional data in the national addenda). Further data may also be needed where the national addenda include specific doses or uses, for which dose justification presented in the core dossier, are not relevant.

Information on the occurrence or possible occurrence of the development of resistance (6.3)

Consideration of resistance is a staged process and is outlined in EPPO Standard PP1/213 (3) 'Resistance risk analysis'. The resistance risk analysis considers the mode of action, resistance history of the intended targets and active substance, and the proposed pattern of use. If the risk is considered to be unacceptable then the second stage, for identified medium/high risk situations, is to consider a range of modifiers as part of an appropriate resistance management strategy. There is also a requirement for sensitivity data to be provided (if there is a common shared resistance status of the principal species, and samples are collected across the zone). The resistance risk analysis should be able to identify inherent risk factors in the core dossier. For new actives with new MOA, it is considered that most if not all of the resistance risk analysis should be included in the core dossier. For existing actives in products where resistance/shifts in sensitivity may have already occurred, this may require more consideration in national addenda (although all information on resistance development is relevant and should be included in the core resistance risk analysis). The need for, and type of, resistance management strategy must be addressed as part of the core dossier, including any proposed general label wording. Developing an appropriate resistance management strategy, including the use of modifiers such as limiting the number of applications, is very much dependent on local conditions in terms of: the resistance status of the pest; how many applications are required for effective control during the season; what doses are proposed at a national level; and availability of alternative control methods (whether chemical or non-chemical). It would be useful if in the core dossier the applicant lists any adaptations/changes to this resistance management strategy that are being proposed in the national addenda. This then allows both the zRMS and individual MS (where an application is being made) to have a clear understanding both of the overall management strategy, as well as how this may differ on a regional basis. By doing so, it may assist individual MS to reach a conclusion on the suitability of any proposed management strategy in the national addenda by, for example, being able to compare it with what is proposed in other areas considered

directly relevant to them. Included in this may be information on any national statutory restrictions, again this may be useful for other MS to be aware of.

The relevance of this strategy may need to be explained further in the national addenda, particularly where proposals are made to adapt to any local concerns. The national addenda, and proposed label, must also reflect any national statutory restrictions relating to resistance, and any national advisory information (e.g. resistance action groups). Information from the various industry 'resistance action committees' can be useful, but may need to take account of the more tailored individual member state advice.

Where there are resistance concerns on a particular target such that effectiveness trials need to be conducted in specific regions/individual member states, this would need to be taken into account in the location of the trials programme.

This section should provide, where possible/relevant, a map indicating incidents of confirmed resistance and an inventory for the entire zone prepared from known sources, from monitoring data or feedback from the field. The sensitivity for existing substances and baseline sensitivity for new active substances should be established on more than one sampled population. The extent of sampling will vary depending on the proposed use, taking account of factors such as the major growing areas of the intended crop, the resistance history of the intended target and active substance, and target pressure/relative importance within a region. It is envisaged that sampling will be more on a regional basis rather than within each individual MS. The higher the resistance risk of the target, the more advisable it would be to sample a wider range of populations. For existing active substances it is not possible to conduct baseline sensitivity testing. However, sensitivity testing is important to gauge any shifts in resistance over time. Cross resistance between different modes of action chemical groups should be addressed in the core dossier.

Strategies for communicating any resistance management measures should be described in general terms in the core dossier. However the techniques adopted in each MS may be very much dependent on local conditions. Therefore the relevance of any communication strategy will need to be explained if necessary in the National addenda, adapted to any local concerns.

Plans for monitoring and reporting resistance development should be outlined as part of the core dossier.

Resistance risk and management : National addenda

Generally, for the reasons described above, resistance risk analysis should be considered in the core dossier because of the importance of employing consistent management practices across the region where authorisation is sought. It may be useful to provide further explanation and give further consideration to the relevance of the management strategy to local conditions, and to explain which of the modifiers/strategy are particularly relevant. For example, limiting the number of applications is a commonly used tool, but this would need to be balanced against the number of applications needed overall in the treatment programme. Alternating modes of action is another common 'tool', but not all MS may have suitable alternatives. This also applies to considering the suitability of cultural control methods. Any national restrictions need to be applied, along with consideration of any national 'Resistance Action Group' advice. All of this needs to be clearly communicated on any national label.

Adverse Effects on treated crops (6.4)

6.4.1 Phytotoxicity to target plants (including different cultivars), or to target plant products

EPPO standard PP 1/135 'Phytotoxicity assessment' should be followed, in association with relevant specific standard for the claimed use (where available). Data to address phytotoxicity should be considered in the core dossier, provided an appropriate range of crops/cultivars are tested across the range of conditions. Again a 'worst case' approach can be taken where there are a proposed range of doses, number of applications, or application timing on the same crop. National addenda may be required if there are specific sensitive major crop varieties (or specific new uses) not included in the core dossier, or a significant difference in use pattern (e.g. higher doses, greater number of applications). There may be the possibility of using reasoned cases where new crops/cultivars are proposed in national addenda (although this may not be appropriate for herbicides or plant growth regulators). It will be dependent on the extent of the available data in the core dossier. In other words, if an appropriate range of sensitive species have been covered in the core dossier, there is no need for further consideration in national addenda. The core dossier should provide an appropriate reasoned argument.

The selectivity trials are generally allocated throughout the entire crop production area in the concerned zone (or may be a more limited distribution when authorization is sought in only a few MS within a regulatory zone). Accordingly, it would be very helpful to have a map of the zone, in order to explain and justify the distribution of the trials, by including:

- distribution of crops related to the claims,
- where necessary, the diversity of farming practices (connected with the pest or use),
- where necessary, soil and climate diversity (connected with the pest or use),
- distribution of the tests

(Please see 6.2).

When providing information on the distribution of crops, it may be more accurate and practical to refer to current EUROSTAT.

Phytotoxicity: National addenda

Where a specific use/crop is proposed in national addenda further data may be required. There may also be national requirements for specific testing on specific widely grown crop varieties . However, it may also be able to make a case based on the range of sensitive crops and varieties tested in the core dossier.

6.4.2 Effects on the yield of treated plants or plant products

This specifically relates to the examination of potential adverse crop effects. EPPO standards 1/135 'Phytotoxicity assessments' and 1/226 'Number of efficacy trials' detail the requirements for the extent of yield assessments. Where more than one dose is recommended on relevant crops, data from the highest dose may be considered in the core dossier, providing all other conditions of use are the same. For herbicides, the impact on yield at key application timings should be assessed (e.g. pre-emergence, 3 true leaves in autumn, and late tillering in spring for a cereal herbicide).

Consideration and information must be provided on the range of crop varieties tested. Specific national addenda may only be required where either a) a different crop is proposed for a specific use or b) the main local crop variety is particularly sensitive. In these cases, it

may still be possible to address via a reasoned case, depending on the extent of the data submitted in the core dossier

(It should be noted that any yield data generated in effectiveness trials (unless target pressure is low) is demonstrating the potential benefit of the treatment. Such data should be summarized under 6.2).

Yield (quantity): National addenda

Where a specific use/crop is proposed in national addenda further data may be required. There may also be national requirements for specific testing on specific widely grown crop varieties (However, it may also be able to make a case based on the range of sensitive crops and varieties tested in the core dossier).

6.4.3 Effects on the quality of treated plants or plant products

Data to address the impact on the quality of plant and plant products may be considered in the core dossier, provided that the proposed conditions of use (or 'worst case' GAP) are encompassed on an appropriate range of crops/cultivars. National addenda would only need to address any specific additional uses where relevant quality assessments may not be available in the core dossier or where there are major national crop varieties known to be specifically sensitive. There may be a possibility of a reasoned case based on extrapolation, depending on the extent of data in the core dossier

For certain types of uses it may be necessary to provide evidence that the use of the product does not give an unpleasant taste or smell ('taint') to the harvested or processed crop product. Where appropriate, taint data should be provided as part of the core dossier, and again where more than one dose is recommended on the same relevant crop, data from the 'worst case' (i.e highest rate and number of applications) will be sufficient. Taint data should only be submitted in national addenda to support any specific additional crops (or proposed higher doses on crops considered in the core dossier). EPPO standard 1/242 'Taint tests' provides guidance on when testing may be required, as well as methodology.

Effects on yield (quality): National addenda

Taint data may be required to support relevant additional national addenda uses

6.4.4 Effects on Transformation processes

Transformation processes are those that rely on biological activity (e.g. the action of yeast in brewing, wine-making or baking, and are potentially sensitive to residues of plant protection products. Data (or reasoned cases) to address transformation processes may be considered in the core dossier. National addenda would only need to address any specific additional relevant crops, or significant difference in use pattern (e.g. higher doses, greater number of applications, application timing, and/or crop growth stage), on crops considered in the core dossier. EPPO standard 1/243 'Effects of plant protection products on transformation processes' should be followed. (EPPO standard 1/268 'Studies of unintentional effects of plant protection products on fermentation processes and characteristics of wine' may also be relevant).

Effects on transformation processes: National addenda

Transformation data may be required to support relevant additional national addenda uses

6.4.5 Impact on treated plants or plant products to be used for propagation

This should be considered as part of the core dossier, with reference to EPPO standard PP1/135 which defines when data may be required. National addenda may only be required for any additional relevant proposed crops not considered in the core dossier, or significant difference in use pattern (e.g. higher doses, greater number of applications, application timing and/or crop growth stage). (EPPO PP 1/135 includes a decision making scheme indicating where further data may be required).

Plant parts for propagation: National addenda.

Specific data may be required for relevant uses, where EPPO PP1/135 indicates the product type/use requires it.

Observations on other undesirable or unintended side-effects (6.5)

These aspects are largely considered to be properties of the active substance, and therefore having established the lack of adverse effects in 'worst case' use patterns, there is scope for extrapolation between uses, and for different product formulations. (Although may require some further consideration at product level for different formulations, particularly herbicides)

6.5.1 Impact on succeeding crops

A step-wise approach should be taken following EPPO standard PP1/207, starting with the pre-emergence herbicidal activity of the active substance and glasshouse pre-emergence screening studies. This is usually sufficient for fungicides and insecticides, but further laboratory and field data may be required for herbicides/plant growth regulators. For the latter it may be necessary to conduct specific following crop 'replanting' trials using risk mitigation measures such as different cultivation techniques. . These data may be considered as core, but must encompass the relevant conditions including appropriate crops, and typical crop rotations found within the zone. National addenda may be required to include a consideration of whether potential effects are acceptable and requirements for possible management practices (including label wording) to reduce the risk to rotational/replacement crops. Having established an appropriate risk assessment, this may be utilized in future applications for different uses, product formulations, provided there are no significant changes impacting on the original risk assessment.

Succeeding crops: National addenda

It may be necessary to provide further justification on the relevance of the succeeding crop risk assessment to local circumstances (e.g. typical crop rotations , planting intervals), and support any proposed label restrictions. Particularly if these deviate from those considered in the core dossier.

6.5.2 Impact on other plants, including adjacent crops

Again, a step wise approach should be taken, following EPPO standard PP1/256, and should form part of the core dossier, starting with the post-emergence herbicidal activity of the active

substance and glasshouse post-emergence screening studies. It is important to consider all crops which are likely to be present as adjacent crops (either emerged or yet to emerge) across the zone where authorization is being sought . Data from other parts of the submission (e.g ecotoxicology – non target pre- and post-emergence data) can be included or cross-referenced. In addition, besides the importance of formulation type on leaf penetration (especially for herbicides) the volatility of the active substance (and if known the formulated product) should be considered as this may affect adjacent crops. Alternatively, for fungicides and insecticides, data from either post-emergence screening or observations in the effectiveness trials (provided this encompassed an appropriate wide variety of crops) will usually be sufficient. National addenda may only be required where additional crops are proposed that cannot be adequately addressed by reference to the data presented and assessed in the core dossier.

It is also a requirement that '*Sufficient data shall be submitted to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops'*. Tank cleaning should be considered as part of the core dossier, with any individual national labels reflecting the proposed procedure outlined in the core dossier and assessment. A step wise approach should be taken, with reference to data described under adjacent crops. For highly active herbicides, further testing may be necessary with a requirement for specific washing instructions. Cross-reference may be made to other relevant parts of the submission e.g. physical/chemical properties. For insecticides and fungicides it is anticipated that a reasoned case based on demonstrated crop safety will suffice

Adjacent crops: National addenda

There may be a requirement to address specific national labelling requirements for the inclusion of tank washing procedures, and the relevance of the core dossier to any proposed instructions. It may also be necessary to provide further justification/support on the relevance of the adjacent crop assessment, especially for herbicides.

6.5.3 Effects on beneficial and other non-target organisms

Any observations in the effectiveness trials of adverse effects on beneficial organisms should be recorded as core data. Otherwise, a reference to the Ecotoxicology section of the core dossier will be sufficient.

Effects on beneficial and non-target organisms: National addenda

If specific label claims are made relating to compatibility with IPM programmes (or information on named species), further data may be required. This particularly applies to insecticides, acaricides and fungicides used in situations where IPM is actively practiced (e.g. glasshouses, fruit and vineyards, or organic production systems).

In addition, the Sustainable Use Directive (2009/128/EC) requires Member States to establish or support the establishment of the necessary conditions for the implementation of Integrated Pest Management (IPM). Applicants should refer to the relevant MS National Action plans for any individual Member State requirements in this regard, and may need to provide further information and/or data in the national addenda, including national labeling polices.

Other Special Studies

There may be other additional studies to address specific issues, for example claims for 'rainfastness' or support for convenience tank mixtures. These will be subject to individual Member State requirements (and National labeling policies). The data can either be presented in the core dossier (if requirements are relevant to several MS), or should be presented in National addenda.

Summary

A brief summary of all data and information submitted in the core dossier must be provided, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimize adverse effects.

APPENDIX 1: Common EU scale for describing levels of weed control in the zonal BAD and dRR

There are many different approaches in individual Member States for describing levels of pest/weed/disease control on national labels. When a zRMS refers to the herbicide performance, it is therefore currently difficult to have a common term or understanding of that description. Therefore, ratherthan each of these appearing under the effectiveness section of the BAD and dRR it is considered more efficient to use a single EU scale as part of the evaluation. (NB – this does not replace individual MS systems for expressing control on national labels, but allows zRMS and cMS to share a common understanding).

To this end the following scale is proposed for use in the zonal BAD and dRR for the description of effectiveness against weeds;

Highly Susceptible (HS)	95-100 %
Susceptible (S)	85-94.9 %
Moderately Susceptible (MS)	70-84.9%
Moderately Tolerant (MT)	50-69.9%
Tolerant (T)	0-49.9 %

National labels, where appropriate, should be submitted as part of the national addenda. This should include an introduction explaining how the national label has been derived from the core dossier and should take account of existing member state requirements for expressing levels of control, and how groups of targets may be specified (e.g. German terms for 'biting/chewing' insects).
(There may also be existing Member State schemes relating to levels of fungicide/insecticide control, applicants are advised to consult the relevant regulatory authority)

APPENDIX 2 – Examples of the types of recommendations/additional advice that commonly appear on National product labels.

Sections 3 and 4 of this guidance document indicate that there is no requirement for a 'zonal label' to be submitted as part of an application for authorization of a product. However the BAD should include a draft 'directions for use' section for each of the relevant uses. Examples are provided below:

a) Insecticide - BYDV aphid vectors

Timing in high risk areas: for crops sown in September, optimal spraying time is in mid-October. For crops sown in October onwards, follow the low risk area timing.
Timing in low risk areas: only spray when risk is high, based on monitoring and local specialist advice.
Note – crops which follow closely a grass ley or weed stubble, where there is a direct risk of aphid migration into the crop, should be considered as a high risk.

b) Residual pre-emergence Herbicide

For optimal weed control, soils must be sufficiently moist at, or shortly after application, to ensure adequate uptake of active ingredient by the weed root systems. Cultivation after spraying will encourage weed germination and reduce residual activity of the herbicide. Activity may be reduced on soils with high organic matter.

c) Cereal Fungicide

A systemic fungicide with protectant and curative properties, apply at the start of foliar disease attack. For optimal effect against eyespot, apply between leaf sheaths erect and second node detectable stages of the crop. For protection against Fusarium, apply during ear emergence. For control of Septoria, apply normally after third node detectable stage, when the disease is present and conditions favour disease development,