Network on Pesticide Steering meeting on methodology for assessing Art.4(7) applications Minutes

Held on 10 March 2016, Parma

(Agreed on 21 April 2016)[1]

Participants

- **Network Representatives of Member States (including EFTA Countries):**

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[1] The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.
[2] Indicate first full name and them surname (John Smith) all throughout the document

Animal and Plant Health Unit (Ioannis KOUFAKIS, Plant Health team)

- **EFSA Working Group on Flumioxazin**

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1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from UK. The Chair referred to the scope and objective of the meeting. The European Commission (EC) requested EFSA to provide scientific assistance as regards data on evidence that the application of an active substance is necessary to control a serious danger to plant health that cannot be contained by other available means, including non-chemical methods (derogation under Article 4(7)). The purpose of the meeting is to have an in-depth discussion following the comments received from the MSs on the draft prepared by the EFSA Working Group, and getting agreement between the experts of the EFSA Working Group (WG) on Flumioxazin and the Member States experts regarding the methodology to be used in these assessments. EFSA and EC agreed on the need for risk management decisions supported by fit-for-purpose risk assessment.

2. Adoption of agenda

The agenda was adopted without changes.

3. Presentation by European Commission on the scope and legal background of the Art.4(7) applications

The EC representative thanked EFSA for the organisation of the meeting which brings together experts from Member States (MS) in the Plant Health area. The moment is critical to discuss the way forward due to the concerns from Member States, industry, NGOs and other stakeholders about how and when Article 4(7) would be applied to support approval of active substances.
The EC presented the scope and applicability of Article 4(7) of Regulation (EC) No 1107/2009 highlighting the difficulties in the interpretation of the Article.

According to Article 4(7) of Regulation (EC) No 1107/2009, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. This derogation shall not apply to active substances which are or have to be classified

in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.
Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

The EC commented that the Article was added at a late stage during the negotiations on Regulation (EC) No 1107/2009 at the request of MSs (COM(2008) 578 final). This derogation from the standard approval criteria was introduced to allow for consideration of approval of substances which are so essential but that may be non-approved based on the hazard based 'cut-off' criteria alone, even if there is an acceptable risk assessment showing that the substance could be used without harm to human health or the environment. If the risk assessment failed (i.e. no safe use can be demonstrated) the Article 4(7) provision is not applicable.

The Article can only be applied when one or more of the criteria in Annex II, points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 are not satisfied based on harmonised or proposed classifications (not when the substances are or have to be classified as C1A, R1A or C1B without threshold) and when an acceptable risk assessment is demonstrated. It was stressed that the Article is not designed to override deficient data packages or failing risk assessments. Maximum residue levels must be established for the uses so that consumers are always protected.

There are two situations when Article 4(7) may be triggered; this impacts the process to be followed:

- When a substance already has harmonised classification that triggers one or more of the Annex II, points 3.6.3, 3.6.4, 3.6.5, 3.8.2 criteria not being satisfied
- When the peer review proposes a substance classification in accordance with the provisions of Regulation (EC) No 1272/2008 that triggers one or more of the Annex II, points 3.6.3, 3.6.4, 3.6.5, 3.8.2 criteria not being satisfied

The currently ongoing cases under Article 4(7) are flumioxazin (R1B harmonised), flupyrsulfuron-methyl (endocrine disrupting properties following the interim criteria based on peer review proposal) and pymetrozine (endocrine disrupting properties following the interim criteria based on peer review proposal and harmonised classification).

To date no approval has been granted under the provisions of Article 4(7). The EC clarified that the approval would be limited to specific crop/ pest combinations meaning only those identified during the evaluation by MSs and EFSA. The approvals will be limited to maximum of five years (renewable) and would include mitigation measures and a need for a MS specific phase-out report. It was stressed that the approval will be very restricted and with no means a 'backdoor' to normal approval.

It was noted that this is a new area for all stakeholders and there is a need for clarity on how assessments should be carried out and who is involved. When classification is already harmonised, a submission should be made in the original application (e.g. flumioxazin) and no specific mandate should be sent to EFSA.

The EC and EFSA created a process for handling the submissions when made after the EFSA Conclusion is available (i.e. in cases where classification was proposed during peer review) e.g. pymetrozine. A general mandate has been sent to EFSA for these cases. In the first case (when classification is already harmonised triggering the cut-off criteria) the Rapporteur Member State (RMS) should evaluate the applicant's submission in the Renewal Assessment Report (RAR) (flumioxazin was exceptional as it was the first case and the RMS did not include the assessment in the RAR as there was no clear instruction at the time on how to handle such cases).

In the second case (when classification is proposed during the peer review), EC requests information from the applicant and asks RMS to consider the information provided. As a following step RMS asks all MSs to confirm that the uses are indeed authorised and that the use is considered essential to control the serious danger, giving **clear justification** for each use that is considered as critical. Also MS should provide a complete list of registered active substances in the MS to control the specific danger to plant health and finally perform an evaluation of the technical possibility (excluding economic evaluation) to use alternative non-chemical methods to control the serious danger. MSs are key actors in the process in order to assure that accurate information has been provided on their country specific situation and explain why there are no alternatives. EFSA acts as the co-ordinator of the process and ensures methodology is applied consistently.

The exact meaning of "serious danger to plant health" in this context was questioned. In a strict sense weeds do not directly pose a threat to plant health, but rather compete with crop plants for light/water/nutrients and thus affecting crop performance. Herbicides are important means for controlling weeds. It was generally agreed that the indirect effect of weeds on crop yield is qualified as "serious danger to plant health". Setting a measure or defined threshold e.g. in terms of yield reduction is not feasible, a case by case consideration based on information and evidence provided was proposed. Especially for herbicides it can be difficult to set a threshold as a herbicide is targeting a range of weeds and not a single weed species. Even with a single weed species it will be impossible to set a fixed percentage, as many factors are affecting the level of yield reduction. It was generally agreed that the weed control can be considered as "plant health issue". However, the definition of the threshold is still up to the risk managers.

The case of neighbouring countries that are not claiming for the use of an active substance for the same crops/uses for which the claims were raised by other countries was discussed. The possible use of alternative methods was raised. Examples of crops, uses, countries for which the applicant claimed the irreplaceability of flumioxazin were mentioned. The EC clarified that although it may make sense from a theoretical perspective, such examples of availability of alternatives in other MSs cannot be examined since Article 4(7) refers to other available means and therefore solutions in other MS cannot be considered in the frame of this Article. In addition, potential alternative PPP might be authorised in

a country, without however being registered for the specific crop. A plant protection product might not be authorised in a MS due to political, economic reasons, or if a substance is candidate for substitution.

It was noted that the full population of Plant Protection Products in Plant Protection Products Application Management System (PPPAMS) which is currently under development by the EC (plant protection product database, providing details on national registrations, including crops, application timing, weed spectrum) will help accessing necessary information in the future. Also EFSA's report might indicate other solutions if known, to help Member States in finding alternatives and prepare a phase out plan.

The role and weighting of non-chemical alternatives was discussed. Non-chemical alternatives are often technically possible in weed control and applied in organic agricultural systems. The EC commented that the reference to the non-chemical alternatives should be specific and evidence based and not simply a general assumption e.g. a specific piece of machinery, not a simple reference to crop rotations or agronomic practice. In case of specific uses (i.e. hop trimming) it was argued that the use may probably not be considered as serious danger but just a crop practice. Need for case by case consideration was stressed. The risk of resistance is also qualified as important in the evaluation. It was argued that from purely agronomic point of view, when you refer to a practice such as "crop rotation", you cannot be so specific. It was also agreed that if you have to control a "summer weed/flora", introducing a winter crop in the rotation you will improve the overall weed management strategy.

The level of detail in the assessment was questioned. Very specific cases e.g. the control of volunteer potatoes in vining peas, could be a sufficient reason to justify the maintenance of the use, as approval would be limited to uses identified. The report would identify for each MS considered, the specific cases where the a.s. is essential based on evidence and information provided by the MS. Minor uses should also be considered. Finally it was clarified that the consideration of the need for the substance under Article 4(7) is distinct from the comparative assessment under the Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009. In the case of Article 4(7), the substances, if approved, would be subject to specific restrictions for specific crop/pest uses and Member States would have no alternatives (taking into account risk for resistance), hence comparative assessment wouldn't be relevant. If a new PPP had become available in the meantime then the MS would need to consider that as an alternative.

The EC stressed that consideration of each substance would need to be on a case by case basis, taking into account information and justifications provided by the applicants and Member States.

The EC also reminded delegates that in cases of emergency, Article 53 of Regulation 1107/2009 allowed Member States the possibility of considering limited authorisation of plant protection products, including those containing non-approved active substances.

4. Presentation by the EFSA Working Group on Flumioxazin on the methodology applied for the flumioxazin Art.4(7) assessment

EFSA (ALPHA Unit) presented the methodology proposed by the WG on Flumioxazin for the flumioxazin Art.4(7) assessment.

Flumioxazin was approved as a herbicide for pre-emergence control or suppression of annual dicots weeds and annual grassweeds. The active substance (a.s.) destroys weeds during germination phase. In some situations flumioxazin can also be applied as early post-emergence herbicide. In accordance with Article 16 of Commission Regulation (EU) No 1141/2010, EFSA presented the conclusion on the peer review for flumioxazin in June 2014, proposing a classification as toxic for reproduction category 1B (H360D) and M=1000 for Aquatic Chronic 1. The harmonised classification was also proposed by ECHA Risk Assessment Committee (RAC). As a result of this proposed classification the Commission proposed a non-approval. In March 2015 the RMS made available to Commission and MS, integrative data provided by the applicant, in the form of an addendum to the Draft Renewal Assessment Report (DRAR) to support the necessity of flumioxazin to control serious danger to plant health. EFSA received an official mandate from DG SANTE for providing scientific assistance as regards data on evidence that the application of flumioxazin is necessary to control a serious danger to plant health including non-chemical methods. An ad hoc WG was then established to support the evaluation. The evaluation was based on the information contained in the addendum to the RAR of flumioxazin and additional information and data provided by MS following EFSA request. In this respect, EFSA organised a round of commenting inviting those MSs claiming essential uses to provide a complete list of registered herbicide a.s. for the relevant crops/uses and some further clarifications. An in depth analysis of the claims raised by the MSs supporting the request for renewal of flumioxazin was done. To perform an objective analysis of the "necessity of the application of flumioxazin to control a serious danger to plant health", the list of registered herbicides a.s. for all the uses listed in the claims (crops/uses X MS) was requested to MSs. A methodology was developed for conducting the evaluation of the alternative to flumioxazin, taking into consideration the management of the "risk of resistance". The WG agreed that, in case of weeds, indirect effects on plants/crops, caused mainly by the competition with weeds for light/water/nutrients, are qualified as "serious danger to plant health" due to indirect effect on crop yield. The WG considered that some weed species may have negative impacts on aspects other than crop yields like human health in the case of volunteer potato in vining peas in UK, or impacts on natural ecosystems. It was questioned if less stringent criteria should be used in the evaluation of such specific cases. The WG considered possible alternatives a.s. in a particular crop and in a particular MS. Evaluation of similarities between the evaluated a.s. and the alternatives was based on the following (broad) categories: annual or perennial weed control, monocots or dicots weed control, herbicide application time (pre, post, etc.).

The stepwise methodology initially used by the WG was explained and discussed.

- For each Member State and for the crops listed in the claim and/or added in a later stage by the Member State, chemical alternatives were listed, including all the herbicide a.s. registered for these crops as submitted by the respective Member State.
- The a.s. were classified according to HRAC groups, chemical families, type of treatment, entry site, weeds controlled and risk of resistance. The risk

of resistance of an a.s. was classified in four categories (low, moderate, high, very high) according to the number of unique cases reported in the International Survey of Herbicide Resistant Weeds (Heap, 2015)[3].

- From this list, only the a.s. that have the same time of application (pre-emergence, or early post-emergence) and spectrum of weed control (annual, perennial, broadleaved, grasses, etc.) as flumioxazin, were retained in a shortlist. The number of possible alternatives and their risk of resistance were used as criteria for evaluating the irreplaceability of flumioxazin.

In addition it was highlighted that in some cases non-chemical methods could be applied for weed management, depending on crop type (permanent crops, row crops, etc.), weed flora, soil and climate conditions, agronomic skills. It was noted however that the evaluation of non-chemical alternatives (including other curative and cultural control) is particularly complex and should rely also on information and supporting evidences provided by MSs.

MS commented on the lack of a harmonised database of all registered products/crops/uses. Some MSs reported that they have their own database for national registrations.

MSs stressed the importance of evaluating the a.s. against specific weed species and not against broad weed categories. This is important in view of the efficacy. The relevance of national resistant risk was highlighted; EFSA will rely on MS's information at national level for resistance and efficacy. MS argued that in some specific local conditions the application of non-chemical methods is not feasible. MS argued that a lot of resources are needed to handle these applications (including preparation of phase-out plan), stressing that the a.s. will be approved only for 5 years.

5. Methodologies applied by Member States Authorities

MSs presented their methodologies.

Austria (AT) based its proposal on EPPO PP 1/271(2) *Guidance on comparative assessment,* EPPO PP 1/213(4) *Resistance risk analysis* and on Rotteveel et al[4]. AT presented in a tabular form the assessment of alternatives for the candidate of Article 4(7). The question was whether alternatives (chemical and non-chemical, if frequently and successfully used in the respective MS) exist for controlling the target organism in the target crops of the candidate for Art. 4(7). The tabular form comprises the registered alternative Mode of Action (MoA) (including HRAC and the registered active substances) as well as non-chemical alternatives in the MS against the target pest. The list can include the same MoA as the candidate for Art. 4(7) as well as different MoAs authorized for use against the target pest. The "Combined Inherent risk" assessment of target pest, target a.s. and alternatives in the MS is measured (low, medium or high inherent resistance risk).

[3] Heap, I. 2015. The International Survey of Herbicide Resistant Weeds. Online. Internet. Thursday, October 1, 2015. Available www.weedscience.org

[4] Rotteveel T, Jorgensen LN and Heimbach U (2011): Resistance management in Europe: a preliminary proposal for the determination of a minimum number of active substances necessary to manage resistance. EPPO Bulletin 45, 388-391

In assessing and interpreting results and in the question how many active substances must be left and what is the minimum number of MoAs required to slow down resistance development to an acceptable level, AT proposed that if the combined inherent risk of the candidate of Article 4(7) is low, at least two alternative MoA are necessary, of which at least one should be of low inherent risk. If the combined inherent risk of the candidate of Article 4(7) is medium, at least three alternative MoAs are necessary, of which at least one should be of low inherent risk; the two further alternatives have to be less or equal to medium risk. Finally if the combined inherent risk of the candidate of Article 4(7) is high, at least four alternative MoAs are necessary; all alternatives have to be less or equal to medium risk. A question is whether the pest already developed resistance to the target MoA as well as to alternative MoA at national level in the MS (confirmed cases). Final question is whether the risk of resistance would increase to unacceptable levels (and therefore leading to possibly unsustainable control of target pest/disease/weed) if the candidate for Art. 4(7) would be removed. It should be indicated whether the removal of the candidate for Art. 4(7) would fasten and increase the resistance development at national level.

The non-chemical alternatives were evaluated on the basis of the existence of consolidated practices within the MS.

Denmark (DK) presented the methodology applied in Denmark. In general fewer a.s. are available in DK compared to other European countries due to specific issues on protection of groundwater (metabolites, leaching). Only few 'candidates for substitution' are authorised in DK. DK expects that the conclusion of assessments for derogation will consider "necessity" of several a.s. due to increasing problems with resistance, critically low number of available modes of action in relation to resistance risk management, and many minor use registrations. Flumioxazin is not authorized in DK. For flupyrsulfuron the authorised uses in DK includes autumn control of ALOMY, APESV and broadleaved weeds in winter wheat, triticale, winter rye and winter barley. The claims on flupyrsulfuron comprise blackgrass control in cereals and in forage grass crops. DK reported that the number of alternative a.s. with different modes of action authorised for the same use are less than the ones proposed by EFSA. Regarding non-chemical alternatives, some effects can be obtained by delayed sowing, change of crop rotation (more spring sown crops), competitive cultivars, increased crop density however, overall they are more expensive and not possible to apply to all fields. Non-chemical alternatives are more dependent on climatic conditions and have high variability in effects. DK concluded that there are no effective herbicides for the control of ALOMY in winter barley in the autumn, and in general there are reduced options for resistance risk management (critical low number of modes of action) and controlling ALOMY and other grasses.

According to **Hungary (HU)**, the efficacy of flumioxazin in HU was considered differently than in EFSA report. Flumioxazin does not control common barnyard grass (ECHCG), or foxtail grasses (SETSS) which are important weeds in row crops. Flumioxazin is essential in resistance management and works effectively under dry weather conditions (compared to other pre-emergence herbicides). HU evaluation is based on timing, weed spectrum, application method (pri, pre, post), and resistance management. In HU evaluation, in young forestry only pendimethalin is registered which has monocotyledonous weed spectrum. No

other authorised product is available against annual dicotyledonous weeds (glyphosate is authorised only in spruce and pine plantations). In stone-fruits no alternative active substances are available against dicotyledonous weeds with long term effect. Sorghum is a minor crop in HU, no other product is effective for pre-emergence usage against dicotyledonous. Therefore, for these uses there is no available alternative herbicide. Flumioxazin is essential in resistance management and works effectively under dry weather conditions.

The Netherlands (NL) presented its approach. The authorised Plant Protection Products (PPPs) based on a.s. authorised in NL are listed. The next step is to check for which uses are these PPPs authorised (crop/pest), whether there is danger/damage if the pest can not be controlled, and whether there are authorised alternative PPPs and non-chemical methods/measures and alternative PPPs with same mode of action/application (registered in the NL database). In case there are alternatives, these should be checked if they have comparable efficacy. Other parameters to be checked is the risk resistence management and the importance of the product for phytosanitary measures. The conclusion would be whether the package of alternative PPPs and non-chemical methods is or is not sufficient to control the pest without the product based on the a.s. under discussion.

In **Slovakia (SK)** important broadleaved weeds controlled by flumioxazin are: *Chenopodium album, Chenopodium hybridum, Datura stramonium, Solanum hybridum, Iva xanthifolia, Xanthium strumarium, Ambrosia artemisifolia, Amaranthus spp.* Active substances dimethenamid-p, linuron and pendimethalin can be applied up to 3 days after sowing when soil moisture is sufficient. Therefore these a.s. are not used for post- emergence application time in SK, only for pre - emergence application. Flumioxazin is the only a.s which can be applied post-emergence in sunflower after more days after sowing (up to BBCH 12-14) to secure sufficient regulation of important weeds. In practice flumioxazin is considered to be irreplaceable for growers in situations when pre- emergence application fails. In SK the methodology applied is checking of current authorised uses of flumioxazin, completing list of the a.s. which have the same use as flumioxazin. Furthermore, also the following points are taken into account: crop, target weeds, growth stages, time of application, mode of action (HRAC). In general, this methodology is partly similar to the comparative assessment.

Spain (ES) presented its approach. ES stressed that the exceptionality of the derogation must be adequately justified in the application. Regarding the identification of alternatives ES mentioned that only registered PPP for the same crop/pest, with efficiency proved under uniform principles (UP) should be considered as chemical alternatives. For non-chemical alternatives, a clear description of the availability of the non-chemical alternatives along with their efficiency, broadly applicable, must be given (from IPM, literature review, research projects..). Regarding the risk for appearance of resistances, the EPPO guidance requires at least 4 modes of action. Compatibility with IPM programs should be checked. Points to be considered for the application were identified: Crops in which the active substance is registered, target weed/pest/diseases on which the effectiveness of the active substance has been proved, mode of action of the active substance, application (mode of application; number of applications; time of application), efficiency of risk mitigation measures and their applicability, the socio / economic impact.

The United Kingdom (UK) had prepared a presentation which was not given due to absence of UK's representative in the meeting. In the UK the flumioxazin case was primarily based on resistance management in blackgrass and control of volunteer potatoes in vining peas. Generally, a similar approach is adopted to insecticides (pymetrozine). Issues relating to minor uses (potentially many as some key insect pests have a wide range of hosts) or compatibility with IPM can be of higher importance and greater complexity in insecticide cases. UK suggested that any methodology adopted should be compatible with the EPPO standards required for use in PPP authorisation.

One MS referred that in depth details of efficacy are listed in the registration reports at MS level. One MS commented that the approval of some alternative a.s. could be at stake in the future and thus candidates with only one or two alternatives in a specific crop could be of possible issue.

6. Discussion on a harmonised methodology to be applied for the assessment of the Art.4(7) applications: using the Art.4(7) applications for flumioxazin and flupyrsulfuron-methyl as case studies to support the discussion

It was stressed the inconsistency between Article 4(7) and plant health legislation. The EC welcomed the draft scientific report on flumioxazin. The methodology applied by the WG in the first draft report for the evaluation of data concerning the necessity of flumioxazin was generally agreed. The basic issue in the evaluation is the selection of the real alternatives in MSs based on crop/pest combination and the specific conditions in each MS. Some of the conditions selected by the WG were questioned as really suitable either because of environmental conditions or other restrictions applied in MSs. National databases in English with crop/pest combination would be useful to the WG, however these are only available in few MSs (i.e. Greece, Denmark). The MSs should transparently present in their assessment the **full list** of the active substances registered for the crops and then justify why some alternatives are not suitable, (e.g. an 'alternative' substance on the same crop may not have specific activity against a specific target), the **evidence** supporting these justifications should be provided when available and, then, will be peer-reviewed by EFSA. Finally the **short-list** of suitable alternatives would be assessed. A MS questioned the usefulness of the national databases; since the coding system is not based on international agreed system (i.e. EPPO) but serves national purposes. EFSA will verify the information provided by MSs if verifiable data supporting the justification is provided. If EFSA cannot verify the information in the course of peer review, the information will be transparently presented as MS evaluation not assessed by EFSA (all justification reports provided by MSs will be published as a background document to the EFSA output).

EFSA clarified that efficacy is evaluated during national authorisations and thus EFSA is not involved and does not have access to the information. Results of efficacy trials are reported in the registration reports of plant protection products at national level that are available in CIRCABC. EFSA will rely on efficacy evaluation reported by MSs; no other evaluation will be made. EFSA will also consider without assessing any specific restrictions applied at MS level if they are legally binding.

A MS commented that the role of the MSs in supporting uses might be crucial in case of minor uses.

Non-chemical alternatives are also considered at national level. MS should indicate if there are non-chemical alternatives in their territory and include the information in their evaluation. The integration to the weed management strategy is also considered at national level. According to the directive on Sustainable use of pesticides, sustainable, biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control. In their national programs MSs might have included some active substances that can be used in the Integrated Pests Management (IPM) strategy for specific crop. These cases could also support national uses and should be considered by the WG.

Regarding the risk of resistance, it was discussed and agreed that the information on **resistance** that can be verified by the WG (i.e. information in the HRAC database) will be included in the assessment. Information based on specific knowledge on local resistance should be transparently reported, however, it cannot be verified by EFSA.

It was agreed that any methodology adopted should be compatible with the EPPO standards required for use in PPP authorisations.

The derogation would be applicable to a specific crop/pest combination in the MS. The derogation will be applicable for 5 years; this practically means that in 2 years the applicant should submit an application for renewal. As critical conditions vary between countries, MSs have a key role in the assessment. Information provided by MSs will be transparently presented in the EFSA reports. Clarification should be given whether derogation would be granted for specific MSs or for specific conditions. EC will further consider this when progressing any subsequent approvals under the provisions of Article 4(7).

The methodology presented by the EFSA WG on flumioxazin (herbicides) was generally agreed. Discrepancies were identified in the short-list of pesticides due to the differences in the national /local conditions. The justification for exclusion of some a.s. should be provided by MSs, however, the WG will be able to assess the information and the justification only when fully supported by evidence.

The table proposed by AT was considered suitable to be used for a harmonised presentation of the assessment and the a.s. proposed for comparison. WG will revise the table where appropriate. For the non-chemical alternatives, the WG will rely on the MS's assessment.

In general the procedure applied for flumioxazin will be followed. Following applicant submission, RMS will launch a MS consultation on the uses proposed as necessary by the applicant. MSs with authorised products to confirm which proposed uses they consider as necessary to control a serious danger to plant health which cannot be retained by other available means and to provide justification why the use is critical. In case MS did report uses for which there is no alternative, the RMS prepares an addendum that is submitted to EFSA for peer review. The EFSA output will be circulated to MSs for comments (as it is always the case in peer review). If needed, ad-hoc teleconferences and/or expert meetings involving MS experts might be organised.

MSs requested to extend the timeline for collating the information and preparing the addendum by the RMS (six weeks in the recent procedure). The EC will check this request.

The EC clarified that socio-economic considerations are not specifically part of the Art.4(7) mandate.

It was agreed that similar methodology would be applicable for insecticides/fungicides. The WG will adapt the methodology where appropriate.

Action points agreed:

- EC to clarify whether derogation would be granted for specific MS or for specific conditions (pest/crop combination). In the first case a MS not listed might use the active substance only in emergency situations (Article 53).
- EC to clarify whether the MS can provide assessment in case applicant does not support a use.
- EC will check the timelines for collating comments and preparing the addendum by the RMS.
- WG to meet and conclude on the methodology and information that should be submitted by MSs supported by evidence. Meeting to be held in April 2016. A template will be developed with the information that should be submitted. The table presented by AT could be explored as a basis for populating the template. Refinements could be implemented.
- A MS consultation will be organised on the agreed methodology and the kind of information to be provided by MSs. MS consultation on agreed methodology is foreseen by May 2016.
- Following the agreement on the methodology and template, MSs will be invited to submit their justifications and supporting data (a.s. registered, shortlisted, etc.) regarding the necessity of flumioxazin and flupyrsylfuron-methyl.
- The methodology for evaluation of data concerning the necessity of fungicides/insecticides will be developed after agreement on the methodology for herbicides.
- The Pesticide Member State Competent Authorities contact points will be used for any relevant communication. MS Authorities to liaise internally in order to make sure the correct persons are consulted.

NOTE: Documents and presentations distributed during the meeting are considered documents under discussion and thus cannot be disclosed to third parties except MSs and the EC.