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**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**

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1 LEGAL STATUS

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 Annex II, III and VI of Council Directive 91/414/EEC, 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.

2 INTRODUCTION & BACKGROUND

This document proposes a procedure for the submission and assessment of applications for registration and re-registration following Annex I inclusion of an active substance under Directive 91/414/EEC. This procedure is compatible with the proposed new format for the Registration Report, and complements existing informal work-sharing arrangements. The procedures herein should be applied from 2 October 2009 (date of noting by the Standing Committee on the Food Chain and Animal Health).

Context and note on the new Regulation to replace Directive 91/414/EEC

It is noted that the work-sharing provisions in this document will eventually be replaced by the zonal authorisation process in the new Regulation to replace Directive 91/414/EEC. It should be noted however that new product applications ongoing at the time of application of the new Regulation to replace Directive 91/414/EEC, and re-registration applications for all existing products will fall outside the new Regulation, and should be assessed using the procedures in this document. See Article 80.5 of the new Regulation for details of transitional arrangements.

Wherever possible, the procedures in this document have been aligned with those in the new Regulation, to allow a smooth transition between the two processes.

What is the intra & inter-zonal work-sharing program?

The aim is to reduce duplication of work for both applicants and competent authorities, and in particular to facilitate the evaluation of the large number of product re-registrations expected in the next few years in all MS. Establishing a procedure for submission of applications will help to organise the work between MS.

It is an initiative developed on a voluntary basis between competent authorities of Member States in the three zones (as defined in the new Regulation):

- Northern zone (DK, EE, LV, LT, FI, SE),
- Central zone (BE, CZ, DE, IE, LU, HU, NL, AT, PL, RO, SI, SK, UK).
- Southern zone (BU, GR, ES, FR, IT, CY, MT, PT)

In summary, the process is as follows:

- the applicant submits to all MS where they wish to gain/maintain authorisation (the 'concerned' MS)
- one lead MS in each zone – the zonal RMS (ZRMS) - will complete the evaluation of a core assessment for the whole zone on behalf of and in advance of assessment by other MS in the zone,
- the ZRMS will then make this assessment available to all other MS in the zone via circa. Other MS then complete their national assessments based on the ZRMS core assessment.

Key elements

There are three key aspects fundamental to the work-sharing process are

- the **standardisation** of the **core** assessment
- use of the **risk envelope** approach in the core assessment to minimise the number of individual uses assessed, and maximise the value and relevance of the core assessment to all MS
- the **acceptance** of that core assessment by all MS who then use it (building upon it as necessary to address national issues) to prepare national authorisations

Each of the above is addressed below.

What does the core assessment look like?

The core assessment prepared by the ZRMS will be used by other MS in the zone as a basis for national regulatory decisions. The core assessment is summarised in Part B of the Registration Report.

The core assessment must reflect a Uniform Principle assessment for a product and its uses, and should cover all the uses required in the zone (see section on risk envelope below). The risk assessment should reflect current technical SANCO guidance documents. Assessments must be supported by appropriate data.

Where any MS have specific national assessment requirements (which differ from or extend the core assessment), then those MS should complete national addenda to Part B of the Registration Reports.

The Part B core assessments (and national addenda where necessary) are then used to determine national risk mitigation measures and other restrictions or conditions adapted to the national conditions in that MS (reported in Part A of the Registration Report).

What types of products can be evaluated through this procedure?

The procedure can be used to obtain authorisation for new products or to re-register existing products (or a combination of the two – e.g. an existing product re-registered in the ZRMS may then be launched as a new product in another MS). These procedures apply to products containing new and/or existing active substances included on Annex I of Directive 91/414/EEC. They may also be applied for products

containing active substances provisionally authorised in accordance with Article 8.1 of Directive 91/414/EEC.

Based on the transitional measures in the new Regulation to replace Directive 91/414/EEC, all products to be re-registered containing active substances included on Annex I of Directive 91/414/EEC, and new products where applications were submitted before the date of application of the new Regulation, should be considered under the procedure in this document.

It should be noted that when the new Regulation becomes binding for new products, that submission and assessment should follow the procedures relating to zonal authorisations .

Can the principles of work-sharing be applied *between* the zones?

Yes. There are some areas of the assessment which clearly apply to all MS, irrespective of the zone (e.g. physical chemical properties and formulation toxicity). There are also some types of uses (e.g. greenhouses, products to be applied in storage areas) where the *same* assessment will apply across the whole EU.

Where products are authorised (or submitted for authorisation) across more than one zone, the applicant should highlight that *inter*-zonal work sharing may be possible when they notify the zones of their intended submission.

ZRMS in each zone should then co-ordinate work (via bi/tri-lateral discussions) to ensure that there is minimal duplication of work.

Who will choose the ZRMS?

Whilst the applicants' preference for choice of ZRMS may be taken into consideration, the decision on ZRMS allocation should take into account the:

- identity of the original RMS for the Annex I consideration (noting that it will not always be possible to allocate the work to the original RMS),
- 'concerned' MS where authorisation is sought ,
- relevance/importance of the products in each MS,
- impact of mixed active products, and
- resource availability in each MS.

The decision will be made by the zone members via informal zonal steering groups.

What are the zonal steering groups?

These will be formed from representatives (usually the re-registration contacts) of the competent authorities of each MS in the zone. Their role will be to

- facilitate communication in work-sharing matters,
- co-ordinate work-sharing activities within and between zones,
- organise the allocation of work to ZRMS, and
- discuss and solve any general issues relating to the efficiency of the system.

These steering groups are informal and can be organised as the zonal members prefer. This may be via regular meetings, or via conference calls. It is suggested that these groups should 'meet' at least every three months, to ensure regular updates on the progress of work.

It will be particularly important that the ZRMS communicates well with others in the zone (or in other zones), to alert them at an early stage of any difficulties with the core assessment, particularly if they might lead to late delivery or refusal.

Who should industry contact in each MS?

Within each zone there is at least one re-registration contact in each MS, as defined in the [EU contacts list](#) on the SANCO website. Until the ZRMS is allocated applicants should use this list to contact each MS, making it clear in their e mail message or letter that it relates to proposed work-sharing.

Who will peer review the core assessment?

Because the content and format of the core assessment has been standardised (via draft registration report), it is hoped that the need for peer review of the core assessment will diminish with increasing experience of other MS assessments. However it is recognised that in particular with regard to higher tier assessments, that there may be a need for peer review (or bilateral discussions) to ensure acceptance of that core assessment (at least in the short term).

Peer review procedures may be established as preferred in each zone (eg standard commenting period, commenting tables) but it should be recognised that any peer review should be accommodated in the time scales allowed to complete the ZRMS evaluation (one year from acceptance of submission).

It should be noted that detailed peer review of *every* part of *every* assessment may be counterproductive in terms of resource inputs from each MS. Peer review within zonal groups should ideally focus on key areas (eg higher tier assessments, or where there is known to be a degree of difference between individuals MS' interpretation).

The ZRMS should complete the core assessment considering all comments, but where the MS in the zone (or outside the zone) cannot agree to the ZRMS interpretation of the assessment, then that MS should take the issues forward during their national assessment.

Note that the new Regulation requires that the zonal MS shall provide a period of comment.

What is the risk envelope approach and how shall it be used in the context of zonal submissions?

The risk envelope is a concept which exploits the idea that within a group of products and uses, there will be certain uses which represent the *worst-case situation* in each area of assessment/compartments. This can be different for the various specialist areas. The assessment of this worst-case product/use will cover all other situations

where the GAP is less critical or the same. By establishing the risk envelope, it is possible to minimise the number of individual product/use assessments that need to be completed.

The concept of risk envelope can be applied:

- within products (eg use on apples at 2N rate will cover use on pears at N rate in certain risk assessment areas),
- within a group of products (eg use of '*Product 100EC*' will cover use of '*Product 50 EC*' where the in-use rates are the same), and
- across the zone (e.g. the use of Product X on cereals at 100g/ha in DE will cover the use of Product X on cereals at 80 g/ha in UK in some areas of the risk assessment).

Notifiers are required, in the context of the work sharing framework, to propose the use which establishes the zonal risk envelope in each area of the assessment (whilst also highlighting *all* the uses authorised/required within the zone). Assessors should consider the proposal to establish the risk envelope as part of their assessment.

It should be noted that it may not be possible to define a risk envelope for all areas of the assessment (e.g. for fate and ecotoxicology there are many national assessment requirements which mean that it is not possible to define a risk envelope relevant to the zone. In this case the applicant should explain why the risk envelope approach is not applicable.

Is a completeness check required?

A completeness check is a useful tool to ensure that the company has provided all the required information (it would be inappropriate to accept an incomplete submission which compromised the ZRMS ability to complete the assessment within the required timescales). However the completeness check should take into account the new submission format of the draft Registration Report. If the application is not complete, and the application is not accepted then all concerned MS should be informed.

Can additional data/information be considered during the assessment?

During the assessment it is not uncommon to have issues to resolve with the applicant. This can be simple clarification or may involve the submission and assessment of new data. Whilst both are acceptable the ZRMS should specify a maximum time period of six months for the clarification of these issues/submission of new data by the applicant. In such cases the initial year assessment period may be extended by the additional period granted by the ZRMS. All affected MS should be kept informed of such changes to proposed completion dates by the ZRMS.

What language should be used?

The working language for the preparation and assessment of core zonal registration reports is English.

It is recognised that some MS may wish to prepare Part A and national addenda (Part B) in their own language, although this should be translated to English to allow the most flexible use of this assessment by other MS. The national authorisations (issued on completion of the assessment) will be prepared in national language.

3. PROCEDURES

Determination of workloads and ZRMS

At least six months before the Step 2 submission 'deadline' (or the proposed application date for new products) the applicant should submit to each 'concerned' MS in the zone a summary of the products for which re-registration will be sought, detailing in which MSs the authorisation will be required (see Appendix 1 for details of proposed form).

Applicants should consider standardising GAPs and products as far as possible across the EU, remembering that they will be required to fully support those required GAPs/formulations with appropriate data. If submissions can be made early (i.e. before the Step 2 submission deadline) this should be made clear. Where there is scope for inter-zonal co-operation (i.e. applications for identical products in more than one zone) this should also be highlighted.

The zonal steering group will decide who will act as ZRMS, which will be fed back to the applicant via the chosen ZRMS.

Where inter-zonal worksharing is a possibility, the ZRMS within each zone should coordinate who will assess each area and define timelines for the review.

Submission to all MS

By the Step 2 submission deadline (or proposed submission date for new products) at the latest, the applicant should submit to the all MS where authorisation is to be requested/maintained the following:

- Covering letter (see example attached at Appendix 2),
- Draft Registration Report for each product (see SANCO guidance 6895/2009 for details)
- Data underlying the core assessment (and national assessment if required), and
- Other national requirements (application forms etc) relevant to the receiving MS.

Note that the covering letter to those MS other than the ZRMS should highlight that the MS are to refrain from working on the national submission until such time as the ZRMS core assessment is completed.

Assessment by the ZRMS

Within one year of submission, the ZRMS should:

- determine completeness of the submission,
- complete their evaluation of the core assessment (and specific national assessment if required),
- give opportunity to other MS to comment on that core assessment and take account of those comments where appropriate,
- inform the applicant they have completed the core assessment, and
- make this available to all relevant MS in the zone by placing Parts A & B of the Registration Report onto circa. Part C should be made available to MS on request.

The zones may set standard internal milestones if preferred.

The ZRMS may issue their national authorisation as soon as their assessment is complete (note that under the new Regulation to replace Directive 91/414/EEC, the ZRMS authorisation should be issued within the one year deadline).

Timelines may be extended if additional clarification/new data are required, up to a maximum of 6 months (see section Can additional data/information be considered during the assessment?)

Trigger to start national assessments in other MS in zone

As soon as the core assessment has been completed by the ZRMS they should highlight to each concerned MS that the core assessment is complete and available on circa, which should trigger the start of the assessment in MS other than the ZRMS. See example notification at Appendix III.

Assessment by the other MS

By the final commission deadline for re-registration (approx one year from completion of the core assessment, the concerned MS shall complete their assessments taking into account the core assessment, any national assessment and national risk management, and issue authorisations as appropriate.

Please note that under the new Regulation to replace Directive 91/414/EEC, the timeline for MS assessments and issue of authorisation following completion of the zonal assessment is 120 days.

Appendix 1

Form to notify zones of intended re-registration/new product – send to [all MS](#) where authorisation is required

Active substance:

Applicant:

Summary of products and uses – please complete table overleaf.

Within each zone, please detail which MS authorisation represents the critical GAP – and thus can be used to establish the risk envelope. Please give *brief* details

For mixed active products, please highlight which MS in the zone has re-registered the other active(s) (if any)

Please highlight if the same product is authorised across more than one zone, since this could offer options for inter-zonal worksharing.

If the ZRMS submission can be made before the Step 2 submission deadline, please indicate the likely date of submission (otherwise assume submission at the deadline)

Appendix 1

MS	Trade Name in that MS ¹	Type of formulation	Content of a.s. (name all actives)	Authorisation holder	Authorisation number ²	Authorised uses/Intended uses (brief summary)	Comments

¹ Please highlight where identical formulations are marketed in different MS

² For new products not yet authorised only the relevant fields will be completed

Dear competent authority in [*northern/central/southern*] zone

Please find enclosed an application for [*insert product name*], containing [*active substance(s)*] for use as [*brief description of field of use*].

It has been previously agreed that [*chosen ZRMS*] will act as zonal assessor for this product and its uses, on behalf of the other MS in the zone where authorisation is required [*list affected MS*]. Full details of the intended uses for each MS in the zone are attached.

In order to facilitate the work-sharing process we have prepared a draft Registration Report, reflecting a Uniform Principle assessment of an appropriate data package, using current technical guidance where appropriate. The draft Registration Report (core and national addenda) and the supporting data are enclosed (using electronic format where appropriate).

Please note that we have considered the risk envelope approach, providing justification why the uses examined represents the worst-case use in the zone in each specialist area.

It has been agreed that [*ZRMS*] will complete the assessment within one year of acceptance of this application and in line with the SANCO guidance on worksharing (tbc/2009) it is advised that all other MS should not start work on their national assessments until the [*ZRMS*] core assessment is complete. [*ZRMS*] will alert you when the core assessment is complete and work can begin.

Appendix 3 – e-mail alert to all MS

Dear colleague

Please note that we have now completed the zonal core assessment for [*Product name*], containing [*active substance*] and the Registration Report has been placed on circa. In line with the SANCO guidance on worksharing (tbc/2009) all MS where a submission has been made may now start work on their national assessments, using the core assessment as a basis.