Report of the Workshop on Harmonized Classification and Labelling (CLH) of Active Substances in Plant Protection Products Held in Berlin on 12 and 13 April 2011

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Additional information is available at the end of the chapter

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1. Introduction

For approval of active substances Regulation (EC) No 1107/2009 (here referred to as PPP Regulation) provides in Annex II "Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II" that, amongst other things, active substances, safeners and synergists (here referred to as active substances) cannot be approved if they are classified or have to be classified for carcinogenicity, mutagenicity or reproductive toxicity (CMR), category 1A or 1B hazard classes in accordance with the Classification Labelling and Packaging (CLP) Regulation, unless exposure is negligible (for C and R, 1A or 1B). The PPP Regulation specifies in the approval procedures that the applicant shall submit a dossier to the Rapporteur Member State (RMS), who shall assess the dossier and present the results of that assessment in the draft assessment report (DAR). The RMS shall submit its DAR to the Commission and the European Food Safety Authority (EFSA). EFSA is required to make the DAR available within 30 days to the other Member States for a 60-day commenting period. In parallel, the DAR is also made publicly available by EFSA. EFSA have to adopt a conclusion within 120-150 days of the end of the commenting period on whether the active substance can be expected to meet the approval criteria and send this to the Commission and Member States. The Commission then has to present a review report and a draft regulation (proposed decision) to the Standing Committee on the Food Chain and Animal Health within 6 months of receipt of the conclusion.

For classification of active substances Regulation (EC) No 1272/2008 (here referred to as CLP Regulation), requires that proposals for Harmonized Classification and Labelling (C&L) of

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active substances in PPP should be submitted to the European Chemicals Agency (ECHA). The proposals follow an agreed procedure with an initial accordance check which is followed by a public consultation process and subsequent consideration of the proposal by the Committee for Risk Assessment (RAC). The legislation requires the RAC to adopt an opinion on the proposal.

The comments received during public consultation may have an impact on the subsequent steps of the process. In a dialogue between the dossier submitter, RAC rapporteurs and ECHA secretariat the best way to proceed will be decided in cases where substantial comments and/or new information are received during the public consultation. In certain cases this may lead to the withdrawal of the dossier and the submission of a revised version by the Member State or to another public consultation on a re-submitted dossier based on the RAC opinion. In other cases the RAC may indicate that the submitted information is insufficient and that it does not allow an opinion to be issued on the classification and labelling.[1]

The legislation requires the RAC to adopt an opinion on the proposal within 18 months. The opinion is forwarded by ECHA to the Commission for a final decision on the harmonized classification and labelling of the substance to be taken via comitology.

While the underlying database supporting a specific substance's assessment presented in the DAR and CLH proposal can be assumed to be broadly similar, the nature (i.e., the level of detail reported/presentation of study results) may differ as a result of the differing guidance and objectives of the two processes. The judgments made in relation to a particular piece of information may differ when considered under the hazard-based CLH process compared with the risk-based authorization process. Therefore, the DAR for approval and the CLH dossier for classification and labelling decisions may require different preparation and presentation of the underlying data, and not all data will be equally relevant for both decision-making procedures. To meet the regulatory objectives efficiently, both procedures require dossier formats specifically tailored to the different regulatory processes. The PPP Regulation requires a specific dossier structure and the CADDY electronic format system is used, whereas under the CLP Regulation there is a legal requirement for use of IUCLID (IUCLID 5 being the current version) which is a quite different electronic submission system using structured files.

A close linkage between these two processes is therefore highly desirable, especially for new active substances without existing, legally binding CLH in Annex VI of the CLP Regulation, or for active substances already classified which have to be re-evaluated in the light of new data that may necessitate revision of the existing classification and labelling.

The classification and labelling of active substances for human health endpoints is not only a principal criterion for the approval of active substances, safeners and synergists, but also the main basis for decisions on other regulatory categories and criteria established in the PPP Regulation namely:

[1] ECHA conclusions CLH Workshop 16 February 2011, ECHA

- consideration as low-risk active substances;
- identification as candidates for substitution;
- decisions on the interim criteria for endocrine disrupting properties that may cause adverse effects in humans;
- decisions on the relevance of metabolites that can occur in groundwater;
- decisions on toxicity with regard to defined persistence, bioaccumulation and toxicity (PBT) properties;
- setting risk mitigation measures for operators, workers, bystanders and residents in the procedure of national authorization of PPPs.

Therefore, a finalized harmonized C&L for active substances is, in many cases, a prerequisite for the harmonized authorization of PPP and mutual recognition according to the PPP Regulation. Furthermore, a final classification and labelling of the active substance is also essential for comparable decisions on approval of active substances in plant protection products under the PPP Regulation and biocidal products under the new Biocidal Products Regulation which will be published in 2012. Although the new Biocidal Products Regulation was not the subject of the workshop, part of the workshop results could have a positive impact on the classification procedure of biocides since the new Regulation will include cut-off criteria comparable to the PPP Regulation.

2. Workshop results

The main objectives of the workshop were to discuss options on how the two processes can most efficiently be aligned at the level of Member State authorities, EFSA and ECHA in the plenary session and in two main breakout group topics:

i. streamlining and integration of the review procedures for active substances in PPP for approval under the PPP Regulation and for classification and labelling under the CLP Regulation.
ii. scientific and practical issues in the interpretation of carcinogenicity, mutagenicity and reproductive toxicity studies and reporting regarding the criteria and practicalities in preparation of dossiers under both legislative frameworks.

The workshop started with a plenary session with lectures to introduce the two regulatory frameworks and provide technical information on the individual processes before entering into detailed discussions in two breakout groups. The presentations given in this first plenary session are available in Annex III of the workshop report which is published on the European Commission website:

(http://ec.europa.eu/food/plant/protection/evaluation/docs/report_berlin_april2011_en.pdf).

3. Streamlining and integration of the review procedures

Before the workshop, EFSA and ECHA had already started an exchange of information in order to identify practical solutions for processing proposals for CLH (especially for the

CMR hazard classes) concerning active substances in PPP quickly and efficiently and, as far as possible, within the same timeline as that of the risk assessment procedure. Based on a discussion paper prepared in February 2010 by ECHA on the cooperation between ECHA and EFSA in the assessment of hazard properties of active substances in PPP under the CLP and PPP Regulations, and a discussion at the meeting in June 2010 of EFSA's Network with the Member State authorities in the area of pesticides, the Pesticide Steering Committee, **the following scope was proposed as a starting point for the discussion in breakout group 1:**

- Streamlining and integration of the review procedures for active substances in PPP for approval under the PPP Regulation and for classification and labelling under the CLP Regulation.

The main goals of breakout group 1 were

1. to inform the discussion on **how the two processes could most efficiently be aligned** between Rapporteur Member States (RMS), EFSA and ECHA;
2. to consider the **anticipated workloads** stemming from the PPP active substance programmes in relation to the capacity of the **EFSA/ECHA process** with a view to ensuring that appropriate planning, management and prioritization procedures can be established;
3. to **raise awareness in Member States** (i.e., Competent Authorities (CAs) responsible for the evaluation of active substances in PPP and for their classification and labelling, respectively) and to communicate the importance of the issue and possible solutions;
4. to provide feedback on **a draft working document on processes** "Cooperation between CAs in Member States, ECHA and EFSA in the assessment of CMR properties of active substances in PPP under Regulations (EC) No 1107/2009 and 1272/2008" (based on the ECHA discussion paper from February 2011 regarding the preparation of the CLH report and the cooperation of the dossier submitter with RAC).

3.1. How the two processes could be aligned

Based on discussions held during the workshop, the following practical solutions were identified for new or existing active substances without existing legal C&L or for substances with legal C&L which have to be re-evaluated in consideration of new data for C&L:

- The Rapporteur Member State for the active substance should identify as early as possible in the evaluation process for approval or renewal of approval (preferably at the end of the completeness check) the need for an initiation of the CLH procedure under the CLP Regulation and should make a notification of intention for the CLH procedure to ECHA at an early stage. The notifier should be encouraged to indicate the classification and labelling in the PPP dossier.
- Specific issues, such as substance ID, for both approval under the PPP Regulation and inclusion under Annex VI of the CLP Regulation, should be solved as soon as possible by direct contact between the RMS and EFSA/ECHA.
- The RMS for the active substance could prepare in parallel:

  - the DAR for EFSA for developing conclusions on possible fulfilment of the approval criteria to be sent to the Commission
  - a proposal for harmonized classification and labelling for ECHA in accordance with the CLP Regulation, as well as ECHA's guidance and format requirements for developing a RAC opinion on classification and labelling
  - Ideally, the CLH report should be ready and submitted one month before the DAR in order to allow time for the accordance check.
- EFSA and ECHA should aim to conduct their public consultations at the same time (EFSA for 60 days and ECHA for 45 days) to streamline the processes.
- The time schedule in EFSA for adopting the conclusions on fulfilment of the approval criteria is 120-150 days from the end of the commenting process, after which the Commission has 6 months for preparing its review report and a draft regulation.
- ECHA and EFSA will follow closely and potentially participate in the deliberations during each other's review process. To avoid duplication of work, leading actors of both processes will keep each other informed on the progress, identify critical issues as early as possible and, if necessary, organize joint discussions in dedicated ad hoc groups assembling capable experts for the issue under consideration from both processes.
- RAC will start the consideration for agreement on the opinion as early as possible Although RAC formally has 18 months for providing their opinion, the scheduled procedure should allow the adoption of the opinion on adequate classification well before expiry of the 6 month period in which the Commission develops its review report and draft regulation after receiving EFSA's conclusion on whether the active substance is expected to fulfil the approval criteria in the PPP Regulation.

The above mentioned parallel, and partly joint, processing of the proposals – conclusion on expected fulfilment of the approval criteria by EFSA and on harmonized classification and labelling by ECHA – would assure that the RAC's opinion on fulfilment of the classification criteria (in particular for the CMR hazard classes) is delivered in time for the Commission to develop its review report and draft regulation (i.e., within 6 months of receiving EFSA's conclusions).

3.2. Workloads from the PPP programmes in relation to the capacity of the ECHA

In order to ensure that any agreed aligned processes can deliver conclusions on harmonized C&L in an efficient and timely manner there was also a need to consider:

- the anticipated workloads stemming from the PPP active substance process and
- the capacity of the ECHA process to deliver conclusions taking into account available resources and other demands on those resources.

Proposals for harmonized classification of PPP active substances may be submitted from the following EFSA work programmes:

- new active substances: it is possible that a considerable number of new active substance/ safener and synergist applications will be submitted each year;

- renewal programme for existing active substances: this programme will start in 2013 (R2) and continue with substance assessments being delivered in 2015 (R3), and each year thereafter for the foreseeable future;
- review of safeners and synergists: likely to be low numbers of assessments submitted to EFSA from 2016 or beyond.

In addition, it is possible that limited numbers of requests may arise on an ad hoc basis as part of the Commission obligations to establish, by 14 December 2013, a list of (approved) substances that satisfy the criteria for candidates for substitution.

A proportion of the existing substances will already have harmonized classifications (i.e., mainly in the renewal programme for existing active substances). However, the use of hazard classification, as part of the criteria for approval and in relation to other areas (e.g., candidates for substitution/interim endocrine disruption criteria), may result in the generation of further studies to support updates/revision of existing proposals. The demands from the existing substance 'renewal' programme and priorities could be estimated at an early stage based on pre-submission information (updating statements). Initial information on priority for CLH consideration for new active substances could be gathered in the pre-submission process.

Therefore, consideration should be given to the establishment of agreed procedures for the management and prioritization of PPP active substances entering the process together with transparent procedures for monitoring their progress and the delivery of conclusions. The need for linkages between the annual planning and resource management processes within EFSA and ECHA should also be taken into account.

3.3. Raise awareness in Member States

The need for communication of the importance of a harmonized classification process in the approval process for PPP active substances was emphasized in the workshop. It was noted that it might be challenging to establish communication structures between the two processes at the national level due to the number of and coordination among involved governmental ministries and agencies.

However, the role of existing structures within the PPP assessment and decision-making processes in communication and raising awareness should be considered.

In particular, the roles and responsibilities of the following in communicating/planning/ disseminating information should be considered, as well as the linkages between them:

- the Pesticide Steering Committee;
- the Standing Committee on the Food Chain and Animal Health;
- the Committee for Risk Assessment (RAC);
- the Competent Authorities for REACH and CLP (CARACAL, to advise the European Commission and ECHA on questions related to REACH and CLP).

There is a need to identify ways to facilitate continuous cooperation/scientific knowledge exchange at the national level among experts from different concerned authorities.

A critical element for ensuring a proper coordination is a full understanding of the different procedures according to the PPP and CLP Regulations and cooperation of the Member State acting as rapporteur under the EFSA process and dossier submitter under the ECHA process.

The RAC procedures are based on the full involvement of the dossier submitter, which does not end with the submission of the dossier. The dossier submitter is involved in the assessment of the comments received during the public consultation and should facilitate the RAC discussion by providing clarifications if needed.

CARACAL is composed of representatives from Member State competent authorities for REACH and CLP, representatives from competent authorities of EEA-EFTA countries, as well as a number of observers from non-EU countries, international organizations and stakeholders. The EUROPEAN COMMISSION (DG Enterprise and Industry and DG Environment) will prepare a proposal to adapt the CLH in Annex VI to the CLP Regulation to technical progress every year based on the opinions received from ECHA's RAC for harmonized classification and labelling.

ECHA is currently updating the process and cooperation between RAC and the MS as dossier submitters based on the outcome of the workshop "On the Way to CLH" held in February 2011.

The discussions at this workshop covered issues and procedural changes such as:

- changes in the Registry of Intentions;
- accordance check streamlining;
- facilitation of communication between dossier submitters, ECHA and RAC;
- dealing with comments received during public consultation;
- withdrawal and resubmission procedures in the case of receipt of new crucial information during public consultation or even at a later stage.

The Member State acting as rapporteur under the EFSA process and dossier submitter under the ECHA process should be fully familiar with the RAC process. ECHA will provide information if required. A full internal coordination among the MS experts and CAs is particularly essential when there is more than one CA involved in the process.

3.4. Finalize a draft working document on processes

During the workshop the working procedures were discussed intensively. The outcomes of the discussions are reported in the presentations as included in the report published on the Commission website: **http://ec.europa.eu/food/plant/protection/evaluation/docs/report_berlin_april2011_en.pdf.**

The workshop did not conclude on a draft working procedure, however, to keep up the momentum, the workshop Organizing Committee took the initiative to develop a draft working document on processes which will serve as a basis for the first projects in the

parallel processing of dossiers and which has been presented to Member States' competent authorities.

4. Scientific and practical issues in the interpretation of studies and reporting

Based on the criteria for the approval of active substances in PPP under the PPP Regulation and the classification criteria regarding "Health hazards" under the CLP Regulation, the following scope was proposed as a starting point for the discussion in breakout group 2:

- scientific and practical issues in the assessment and interpretation of carcinogenicity, mutagenicity and reproductive toxicity (CMR) studies, and requirements concerning adequate preparation of dossiers (with respect to scientific content and formatting according to the PPP Regulation and the CLP Regulation).

The main goals of breakout group 2 were:

1. to **recommend solutions regarding formatting problems** with documents/dossiers (e.g., how to facilitate compilation of CLH dossiers by the Rapporteur Member Stat, how to integrate additional relevant documents from the pesticide process in these dossiers, possibility of profits for CLH dossiers based on experience with previous pesticide assessments);
2. to discuss possibilities and **practicalities for submission of IUCLID 5 dossiers** in addition to the dossiers for active substances under the PPP Regulation to facilitate the preparation of dossiers for classification and labelling, as well as possible assistance for approval;
3. to **improve harmonized interpretation and reporting** of carcinogenicity, mutagenicity and reproductive toxicity studies, discuss scientific principles of interpretation of relevant studies. This shall contribute to avoiding conflicting interpretations and different reporting of the same studies under the two processes.

4.1. Recommended solutions regarding formatting problems

The workshop participants recognized that although in the current DARs the purpose of the substance evaluation is mainly to derive a basis for risk assessment (i.e., deriving NOAELs/LOAELs and setting reference doses) this issue requires reconsideration due to the new cut-off criteria settled in the PPP Regulation. The main intention of the CLH report is hazard identification (i.e., assessment of the nature and severity of effects and the dose response relationship to be compared with a defined set of criteria) including the specific comparison of the available evidence with the CLP classification criteria.

Currently the structure of the DAR is under discussion and will be revised in the next few years. A proposal for this revision was presented the break out group session.

For CMR substances, the DAR under the PPP Regulation would require a similar assessment (hazard identification and comparison with the criteria) to that required for the

CLP report, and therefore, the same document can cover both assessments. For other hazard classes, the DAR should also be the basis for the CLH proposal, and therefore, it seems logical to integrate this information as well.

The workshop participants considered that for a better common scientific understanding, it is essential to implement the same structure in the reporting and formatting of the DAR and CLH reports. In fact, the proposed solution is to incorporate the weight of evidence and comparison with the CLP criteria to be included in the CLH report as one of the chapters/documents/elements of the new DAR structure. Additional considerations are needed for facilitating the description of the key studies results in a way that could cover the needs for the DAR and for the CLH report. The structure of the CLH report is defined in the legislation (reference to Chemical Safety Assessment and Report under REACH) and described further in the CLP guidance, which allows the required flexibility to accommodate the dossier's specific needs. It should be kept in mind that the CLH process also applies to biocides and industrial chemicals, that some substances have several uses and that the CLH structure must be similar for all types of chemicals. However, as the structure and level of detail of the CLH report will be periodically updated based on RAC experience when processing the CLH dossiers, the specific input gained during the discussions of the new DAR format can be used in the periodic revisions of the CLH report format. In addition, specific guidance for preparing the CLH report as the hazard identification chapter of the DAR for PPP active substances is required.

As an outcome of the ECHA workshop "On the way to CLH", RAC, with the support of the ECHA secretariat, is currently revising the structure of its opinions and particularly of the background document presenting the detailed justification of the RAC opinion. The background document is based on the original CLH report. On the other hand, the PPP experts are currently discussing possible improvements to the structure of the DAR and dossier. It was considered that ECHA and EFSA should be in close contact during these developments in order to ensure mutual feedback and coordination between both processes.

To complement the proposal mentioned above, it was also recommended that when drafting the DAR annexes related to the robust study summaries and the assessment summaries which constitute the basis for the hazard identification and risk assessment, both intentions should be kept in mind and addressed, allowing the use of the text related to the hazard identification as the starting point for the CLH report and DAR hazard identification chapter.

It was also mentioned that currently some DARs do not contain a proper presentation of the evidence related to the hazard identification and its comparison with the CLP classification criteria. It was highlighted that this is an essential part of the CLH report and should be specifically considered. The current RAC experience might offer further suggestions for reporting the weight of evidence and the comparison of data with the criteria, and some examples were presented during the workshop.

4.2. Practicalities for submission of pesticide dossiers in IUCLID format

The OECD Expert Group on the Electronic Exchange of Pesticide Data makes an effort to support the harmonization of the international submission formats used for pesticide registration (Caddy, eIndex, ePRISM). This harmonized format is called GHSTS (Global Harmonized Submission Transport Schema) and will be finalized in 2012. At present it is not possible to submit a full document-based pesticide dossier from a company to the authority using IUCLID 5, which is endpoint record-based. The answer should be found by ECHA by evaluating the proposals collected in a public consultation.

- The objective of this public consultation, organized in collaboration between OECD and the ECHA, is to receive input and exchange ideas on the next generation of the IUCLID software from stakeholders not represented at the OECD IUCLID User Group Expert Panel.
- After a few years of experience in using IUCLID 5 as a tool for collecting, storing and exchanging information on chemicals in the OECD, and for national and regional chemical review programmes, it is time to plan for the next generation of the IUCLID software and to adapt it to fit the evolving needs of a growing user community. Example developments could be the extension of IUCLID to specific information relevant for pesticides or information on exposure and risks related to uses of substances, or the development of several user interfaces adapted for a specific purpose connected to the same core database.

This next generation of the IUCLID software might also be useful for the submission of a future PPP dossier and/or a DAR, as well as the CLH report. The Harmonized Templates were implemented to store structured data from studies on an endpoint record level. This technique is used in IUCLID.

- The content of the XML files according to the Harmonized Templates shall replace the Tier II summary level (Word, PDF) to prevent a duplicate lifecycle management by the companies of a text and of the corresponding structured data set.
- Today the authorities have to produce a duplicate lifecycle management of a CLH text and a technical CLH dataset in parallel over a long period. Why is it necessary to produce two versions of a CLH dossier, a text processor CLH dossier and the technical IUCLID data file?

A mutual understanding of the needs and workload implications was the starting point for this discussion. There is a clear benefit in having an IUCLID 5 dossier for all substances, including PPP active substances, but on the other hand there is an additional workload for the CAs when preparing an IUCLID 5 dossier from a dossier presented in a different format. Over the long-term the OECD approach may provide a fully compatible solution and this was recognized as the best solution.

The workshop participants recognized that the role of the PPP CAs should be equivalent to the role of the REACH/CLP and biocide CAs: to revise and update the IUCLID 5 dossier presented by the relevant companies. Therefore, before a fully compatible submission

system is developed, the alternative should be to request the companies to include in their submission an IUCLID 5 dossier for the studies relevant for classification and labelling.

4.3. Improve harmonized interpretation and reporting

The ECHA and EFSA processes represent the scientific assessments of the available information in order to establish solid scientifically based conclusions for supporting the decision-making process by the European Commission. ECHA and EFSA have specific mandates, defined in their respective regulations. The workshop discussions and the conclusions presented below should be understood and implemented taking into account the different and independent roles and mandates of ECHA and EFSA, and the European Commission.

The conclusion that the CMR-related **cut-off criteria** for active substances to be included in PPP are met is based on a conclusive scientific assessment on the substance with regard to the fulfilment of the approval criteria proposed by EFSA[2] and on the opinion of ECHA. In order to support such a conclusion early in the evaluation process under the PPP Regulation, common interpretation of the classification criteria for CMR properties in both contexts (EFSA and ECHA) would be an important prerequisite. Both agencies should cooperate to achieve a common interpretation of the underlying studies, particularly in terms of reliability and relevance, and to explain any divergence and deviation if needed.

Classification as CMR category 1A or 1B will exclude an active substance from approval and subsequent use in PPPs (unless exposure is negligible in case of CR), whereas classification as CMR category 2 allows approval. The credibility of the scientific assessments of CMR properties could suffer if conclusions under the PPP Regulation and under the CLP Regulation were inconsistent, e.g.:

- if a CLP decision adopted by the Commission on the basis of a RAC opinion (CMR category 1A or 1B) made it necessary to revoke an active substance approval, which was adopted at an earlier time point or
- if active substance approvals were declined earlier in the process on the grounds of an RMS or EFSA proposal for CMR category 1A or 1B classification, but later a CLP decision adopted by the Commission on the basis of the RAC opinion resulted in CMR category 2 classification which would have allowed the approval of the active substance.

Similarly, divergences in the answer to the question of whether a substance should be classified as CMR category 2 or should not be classified would also have consequences at PPP authorization level and even at active substance approval level (relevance of groundwater metabolites). Harmonized application of the CLP criteria for CMR classification within the EU Member States and by different Expert Meetings is therefore essential.

[2] Article 12(2) of Regulation 1107/2009 lays down that "…the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4… "

Although detailed criteria for hazard classification and labelling of substances have been laid down under the CLP Regulation, particularly the specific criteria for CMR classification requires expert judgement and consideration of many different factors (e.g., weight and strength of evidence, mechanism or mode of action and its relevance to humans) included in the available relevant experimental data and the additional reliable information.

Based on the experience from various national and international Expert Meetings, it seems obvious that the interpretation of CMR data from experimental tests and epidemiological studies by different Expert Meetings in ECHA and EFSA, i.e., the RAC and the Pesticide Risk Assessment Peer Review (PRAPeR) meeting, does not necessarily lead to the same opinion and proposal on classification, even though the same data have been evaluated. The current RAC experience already indicates a significant number of borderline cases as being particularly problematic. The workshop participants considered that the optimal solution would be an involvement of the experts at an early stage. This requires coordination within the rapporteur MS under the PPP process, as well as between EFSA and ECHA. Ideally, the RAC opinion on harmonized classification and labelling should be the basis for the EFSA conclusion on the cut-off criteria related to CMR properties; if this is not feasible in all cases, the RAC opinion on the CMR classification should be at least available for the Commission for their decision-making process on the approval. There is a special need for a common interpretation of the criteria for the classification of substances for reproductive toxicity (paternal and maternal toxicity, consideration of potency and setting of specific concentration limits, developmental versus lactation effects, etc.).

When expert judgement and consideration of many different factors (e.g., weight and strength of evidence, mechanism or mode of action and its relevance to humans) is needed, common scientific understanding is essential under both regulations.

The workshop participants considered that the cooperation of the experts involved in both processes is essential and encouraged ECHA and EFSA to consider this need when establishing their processes. The ideal solution, particularly for borderline cases, would be to organize a single detailed expert discussion that could feed into both processes. The working procedures from RAC and EFSA already allow the participation of invited experts and a set of consultations with the committees. ECHA and EFSA were requested to coordinate the involvement of the relevant experts, ensuring that all relevant information is available to the experts, and to establish mechanisms for facilitating the exchange of views among the experts early in the process for identifying divergent interpretations, and organize ad hoc expert discussion platforms in order to try to get consensus on the scientific interpretation of the data.

The rapporteur MS under the PPP Regulation, acting as dossier submitter for the CLH dossier, plays a key role in both processes. It is essential that when reporting the studies' results, weight of evidence and its comparison with the CLP criteria, the MS experts consider specifically the RAC needs and previous opinions on similar cases. Following the RAC decision, the RAC Manual of Conclusions and Recommendations will be available to the CAs in order to facilitate this process.

5. Main conclusions and recommendations

This chapter includes a summary of the main conclusions agreed upon by the different breakout groups and a table presenting the main recommendations for actions to follow up.

It has to be underlined that the information below refers to those conclusions and recommendations made most frequently by the experts in the breakout groups' sessions and in plenary.

The main conclusions of the workshop can be summarized as follows:

- need to inform ECHA as early as possible on a potential candidate for CLH classification;
- call for prioritization of proposals for harmonized classification and labelling suggesting classification as CMR;
- the importance of increased cooperation and awareness among the different competent authorities;
- ensure consistency with respect to information evaluated under both processes and harmonization of the currently different formats for hazard assessment;
- progress toward a harmonized electronic system for submission of data;
- the relevance of the proper presentation of evidence related to hazard identification and comparison with CLP criteria for harmonized interpretation on CMR studies;
- harmonized reporting on CMR studies and integration into the current reporting formats under the two processes.

The workshop concluded that in the long-term "one substance, one dossier, one procedure and one discussion" would be the ideal situation.

Disclaimer

This document is based on the workshop report as published in the SANCO webpage which was elaborated upon by members of the Organizing Committee of the Workshop including members of the European Commission DG Health and Consumers, of the European Chemicals Agency (ECHA), of the European Food Safety Authority (EFSA) and Member States' representatives. It does not necessarily reflect the views of the Commission Services, ECHA services or Member State agencies, but it reports the discussed topics and outcomes of the workshop. The authors and the representatives mentioned in the Acknowledgement Section were all members of the Organizing Committee.

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Cooperation at European level in the assessment of human health hazards of active substances in Plant Protection Products under Regulation (EC) No 1107/2009 and the harmonized classification and labelling of active substances under Regulation (EC) No 1272/2008.[3]

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