**CoCh REPORT**

**According to *Article 43*  of REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC:**

**Renewal of authorization**

**Plant Protection Product:**

**Trade names in cMS:**

**Formulation/Development code**

**Registration Holder:**

**Content of Active substance/es:**

**Type of formulation:**

**ZRMS:**

**cMS:**

**Date of submission:**

| Information | Y/N | Information, summary or justification provided |
| --- | --- | --- |
| a copy of the authorisation of the plant protection product; |  |  |
| any new information required as a result of amendments in data requirements or criteria; |  |  |
| evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval; |  |  |
| any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein; |  |  |
| a report on the monitoring information, where the authorisation was subject to monitoring.(monitoring information regarding the a.s. approval and national monitoring programs for information) |  |  |

**Additionally, the following information must be submitted to facilitate the evaluation process:**

| Information | Y/N | Information, summary or justification provided |
| --- | --- | --- |
| A GAP list in English with the already authorized uses in the zoneFor each GAP, concerned MS must be reported |  |  |
| A notifier declaration that there is no modification of the GAP requested or justification of the modification (new endpoints, outcome of risk assessment, risk envelop approach) |  |  |
| Declaration signed by the manufacturer that there has not been any modification with regard to the composition of the authorized product under uniform principles, or justification of the need to make a minor change due to the renewal of the approval of the active |  |  |
| Updated DRR (Part A; B and C) indicating where there is new information not previously reviewed in the zone |  |  |
| Justification for each data point for which not all information can be submitted |  |  |
| List of cat 4 studies and submission date and justification for each of them with a proof that the studies have been initiated or commissioned. |  |  |
| A signed statement confirming that the authorized plant protection products and uses are in compliance with the conditions and restrictions of the renewal of the approval. |  |  |
| A statement confirming accessing to Annex II data |  |  |

**Conclusion of the ZRMS:** *[CLICK IN THE GREY BOXES AS APPROPRIATE AND SELECT THE APPROPRIATE TEXT]*

**[ ]  Complete**

**[ ]  Not Complete**

The zRMS \_\_\_\_\_\_\_\_\_\_\_\_\_, appointed to coordinate the renewal of authorization of the plant protection product \_\_\_\_\_\_\_\_\_\_, whose authorization holder is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on behalf of the NORTHERN/CENTRAL/SOUTHERN ZONE confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The zRMS \_\_\_\_\_\_\_\_\_\_\_\_\_, informs that the applicant **has NOT submitted** a justification for which not all information has been submitted at the three months deadline

**[ ]  Postponed**

The zRMS \_\_\_\_\_\_\_\_\_\_\_\_\_, appointed to coordinate the renewal of authorization of the plant protection product \_\_\_\_\_\_\_\_\_\_, whose authorization holder is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on behalf of the NORTHERN/CENTRAL/SOUTHERN ZONE confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The zRMS \_\_\_\_\_\_\_\_\_\_\_\_\_, informs that the applicant has submitted a justification for which not all information has been submitted at the three months deadline

[*SELECT AS APPROPRIATE*]

*due to new endpoints decided at the time of the renewal of approval of the active substance* ***(cat 4 studies)***

*due to new guidance document published before the time of the renewal of approval of the active substance* ***(cat 4 studies)***

*due to the presence of a second active substance, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, for which is expected to expire within twelve months of the renewal of approval of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

The zRMS \_\_\_\_\_\_\_\_\_\_\_\_\_, has checked the appropriateness of this justification and has considered **ACCEPTABLE** the postponement of the submission of the following studies in the indicated date:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Annex Point** | **Study title (if available ) or study type** | **Study duration** | **Completion date/report number (if available)** | **Justification accepted by the ZRMS (including if study is a cat4 study)** |
|  |  |  |  |  |
|   |   |   |   |   |

In accordance with the assessment of the provisions in the planning of the applicant, the submission of the documentation is expected by *MONTH YEAR in ZRMS*. Therefore, the zRMS \_\_\_\_\_\_\_\_\_ postpones that start of the assessment to *DAY MONTH YEAR.*

This is reported to concerned Member states, to make a decision on the extension of expiry dates of the authorizations of plant protection products which can be affected by this evaluation.

*Date and signature*