[redacted])

From: [redacted]@bvl.bund.de>
Sent: vendredi 20 novembre 2020 08:13
To: [redacted]@ages.at'; [redacted]@ages.at'; [redacted]@ages.at'; [redacted]@ages.at'; [redacted]@health.fgov.be'; [redacted]@sante.belgique.be'; [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](AGRI); [redacted]@ukzuz.cz' [redacted]; [redacted]@MST.dk' [redacted](EFSA); [redacted]@minagric.gr'; [redacted]@mapa.es'; [redacted]@inia.es'; [redacted]@tukes.fi'; [redacted]@tukes.fi'; [redacted]@anses.fr'; [redacted]@anses.fr'; [redacted]@anses.fr'; [redacted]@anses.fr'; [redacted]@minagric.gr'; [redacted]@bpi.gr'; [redacted]@minagric.gr'; [redacted]@nebih.gov.hu'; [redacted]@agriculture.gov.ie'; [redacted]@sanita.it'; [redacted]@vatzum.lt'; [redacted]@asta.etat.lu'; [redacted]@vaad.gov.lv'; [redacted]@mccaa.org.mt'; [redacted]@mccaa.org.mt'; [redacted]@ctgb.nl'; [redacted]@mattilsynet.no'; [redacted]@minrol.gov.pl'; [redacted]@minrol.gov.pl'; [redacted]@dgav.pt'; [redacted]@dgav.pt'; [redacted]@kemi.se'; [redacted]@gov.si'; [redacted]@gov.si'; [redacted]@uksup.sk'
Cc: [redacted](SANTE); [redacted](HERA); [redacted](SANTE); [redacted](SANTE); [redacted]
Subject: AW: PAI and IZSC - 24-25 November 2020: Final PAI agenda (rev.3) and additional documents for PAI item 07 (GD on data matching) - NL
Attachments: PAI 2020-11 Item 07a - Draft_GD_data_matching_-_Revision_1.1__19-11-2020 _clean.docx; PAI 2020-11 Item 07b - Draft_GD_data_matching_-_Revision_1.1__ 19-11-2020_TRACK CHANGES.docx; PAI 2020-11 Item 07c - COMMENTING_TABLE_DATA_MATCHING_Collated_comments-UK_and_NL_response_ 19112020_.docx; PAI 2020-11 Item 07d - Draft_data_matching_guidance_document_-_points_for_discussion_with_PAI_November_ 2020.docx; PAI Agenda 2020-11 draft_rev.3.docx

Dear colleagues,

To prepare for the PAI meeting on 24. November you can find attached four new documents to PAI agenda item 07 (GD on data matching - NL) and the updated final agenda (rev.3).
The new documents are the revised GD on data matching (two versions; track changes + remarks and a clean version), the open points document and the commenting table (with UK and NL response).

The documents have already been uploaded to CIRCABC under
Link to PAI documents (including the agenda and additional documents for item 07):
https://circabc.europa.eu/w/browse/61dacc88-ba02-4e8d-b9d4-60eb47c673ee

Link to IZSC documents (including the agenda):
https://circabc.europa.eu/w/browse/d5aab73b-8656-4bb4-86a3-35d6af78c851

Best regards,

[redacted]

on behalf of the PAI/IZSC secretariat
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Referat 202 - Verfahrenssteuerung Mittel
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

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-----Ursprüngliche Nachricht-----
Von:
Gesendet: Donnerstag, 19. November 2020 12:23
An: @ages.at' @ages.at>; @ages.at' @ages.at>; @ages.at' @ages.at>; @ages.at' @ages.at>; @ages.at' @ages.at>; @health.fgov.be' @health.fgov.be>; @sante.belgique.be' @sante.belgique.be>; @ec.europa.eu' @ec.europa.eu>; @ec.europa.eu' @ec.europa.eu>; @ec.europa.eu' @ec.europa.eu>; @ec.europa.eu' @ec.europa.eu>; @ec.europa.eu' @ec.europa.eu>; @ext.ec.europa.eu' @ext.ec.europa.eu>; @ukzuz.cz' @ukzuz.cz>; @bvl.bund.de>; @MST.dk' @MST.dk>; @efsa.europa.eu @efsa.europa.eu>; @minagric.gr' @minagric.gr>; @mapa.es' < @mapa.es>; @inia.es' < @inia.es>; @tukes.fi' < . @tukes.fi>; @tukes.fi' < . @tukes.fi>; @anses.fr' < @anses.fr>; . @anses.fr' < @anses.fr>; @anses.fr' < @anses.fr>; @anses.fr' < . @anses.fr>; @minagric.gr' < @minagric.gr>; @bpi.gr' < @bpi.gr>; @minagric.gr' < @minagric.gr>; @nebih.gov.hu' < @nebih.gov.hu>; . @agriculture.gov.ie' < @agriculture.gov.ie>; @sanita.it' < @sanita.it>; @vatzum.lt' < . @vatzum.lt>; . @vatzum.lt' < @vatzum.lt>; @asta.etat.lu' < @asta.etat.lu>; @vaad.gov.lv' < @vaad.gov.lv>; . mccaa.org.mt' < @mccaa.org.mt>; @mccaa.org.mt' < @mccaa.org.mt>; @ctgb.nl' < . @ctgb.nl>; . @mattilsynet.no' < @mattilsynet.no>; @minrol.gov.pl' < @minrol.gov.pl>; @minrol.gov.pl' < @minrol.gov.pl>; @dgav.pt' < @dgav.pt>; @dgav.pt' < @dgav.pt>; @kemi.se' < . @kemi.se>; @gov.si' < @gov.si>; @gov.si' < . @gov.si>; @uksup.sk' < @uksup.sk>
Cc: @ec.europa.eu' < @ec.europa.eu>; @ec.europa.eu' < . @ec.europa.eu>; . @ec.europa.eu' < @ec.europa.eu>;

[redacted]@ec.europa.eu' <[redacted]@ec.europa.eu>; [redacted] ([redacted]
<[redacted]@ctgb.nl>
Betreff: AW: PAI and IZSC - 24-25 November 2020: Final agenda and documents for the meetings

Dear colleagues,

Attached you can find the updated final agenda (rev.2) for the November 2020 WEBEX meetings of the PAI and the IZSC with all meeting docs!

The documents have already been uploaded to CIRCABC under Link to IZSC documents (including the agenda): https://circabc.europa.eu/w/browse/d5aab73b-8656-4bb4-86a3-35d6af78c851
Link to PAI documents (including the agenda): https://circabc.europa.eu/w/browse/61dacc88-ba02-4e8d-b9d4-60eb47c673ee

Additional topics are:
IZSC: AOB 01 - Questionnaire Monitoring of pesticides in air and deposition - DE
PAI: AOB 01 - Pinoxaden - new classification vs confirmatory data - SE

Kindly reminder:
Please send an update of the confirmatory data table until, if you have not already done (see my e-mail sent on 9 November 2020).
Thank you very much in advance.

Best regards,

[redacted]
on behalf of the PAI/IZSC secretariat

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[redacted]
Referat 202 - Verfahrenssteuerung Mittel Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

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-----Ursprüngliche Nachricht-----
Von: [redacted]
Gesendet: Dienstag, 17. November 2020 15:56
An: [redacted]@ages.at' [redacted]@ages.at>; [redacted]@ages.at' <[redacted]@ages.at>; [redacted]@ages.at' <[redacted]@ages.at>; [redacted]@ages.at' <[redacted]@ages.at>; [redacted]@health.fgov.be' <[redacted]@health.fgov.be>; [redacted]@sante.belgique.be'

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Cc: @ec.europa.eu; @ec.europa.eu; @ec.europa.eu;
@ec.europa.eu; @ctgb.nl>
Betreff: PAI and IZSC - 24-25 November 2020: Final agenda and documents for the meetings

Dear colleagues,

Attached you can find the final agenda for the November 2020 WEBEX meetings of the PAI and the IZSC with all meeting docs!
Further items will be discussed under AOB.

The documents have already been uploaded to CIRCABC under Link to IZSC documents:
https://circabc.europa.eu/w/browse/d5aab73b-8656-4bb4-86a3-35d6af78c851
Link to PAI documents: https://circabc.europa.eu/w/browse/61dacc88-ba02-4e8d-b9d4-60eb47c673ee

Greetings from Braunschweig!

Best regards,

on behalf of the PAI/IZSC secretariat

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Referat 202 - Verfahrenssteuerung Mittel Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

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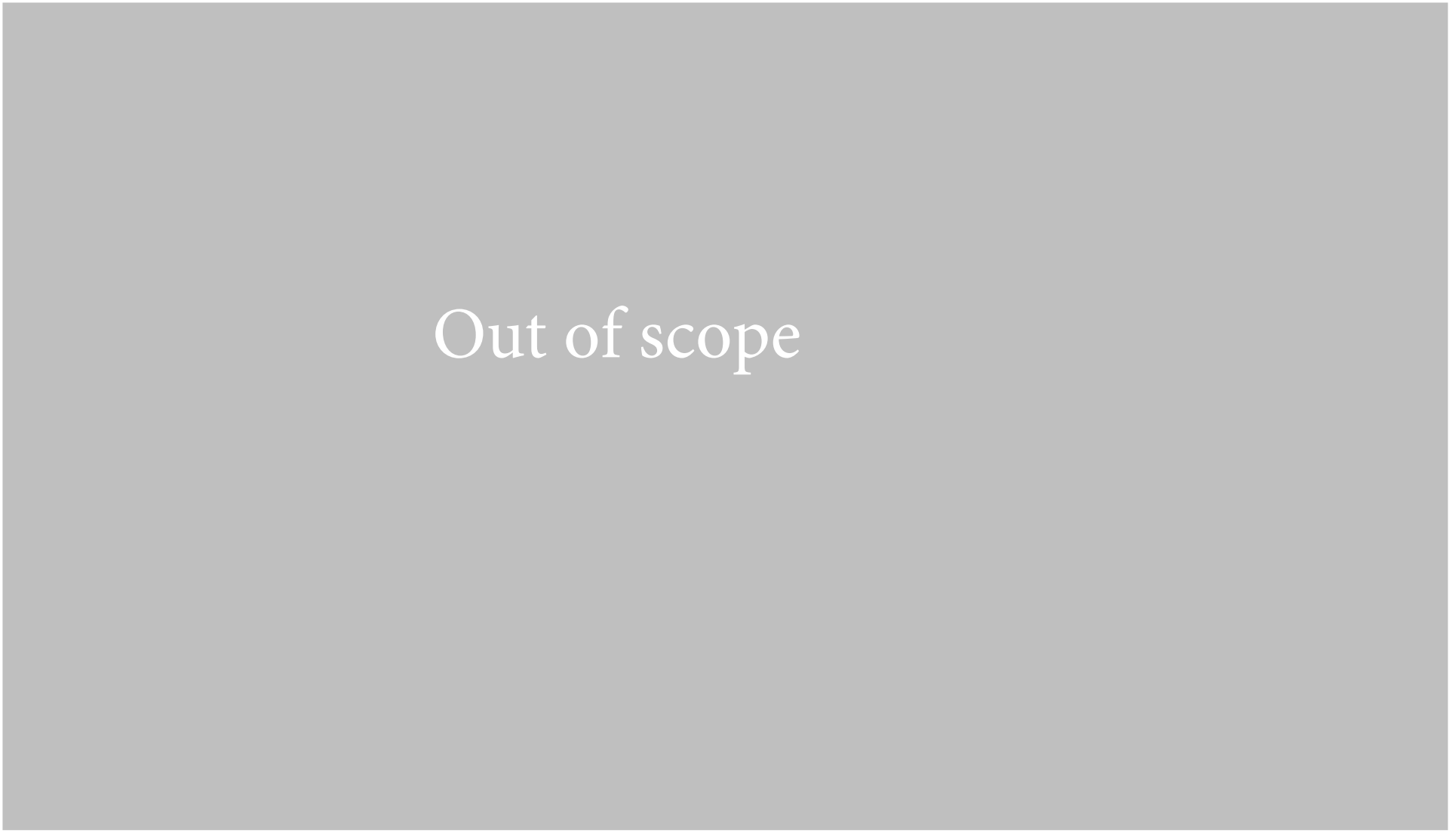
Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope


Out of scope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Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
Out of scope				
ECPA	General	Considering a case where the submission of the Data Matching (DM) to the RMS is done out of the AIR process (for example 2 years after the renewal of the AI), which timeline is granted to the RMS to conclude on DM and to put the conclusions on CIRCA BC.? In that situation, a zRMS (different than the RMS) may have to wait for the DM of the RMS to move forward on its zonal application if the RMS takes too long.	UK: Section 3.7.2 of the Article 43 renewal guidance document SANCO/2010/13170 rev. 14, 7 October 2016 states that '*The data matching check should be **performed by the active substance RMS** as soon as possible after the 3 month deadline for application (ideally **within a month**)*'. Assuming this situation is Article 33 it is probable that a timeline is not specified. Member States and COM to consider whether the information provided needs to be updated.	NL: agree with UK comment. We added explanation on differences in data matching for article 43 and article 33 applications (although most of the process is the same for both types of applications).

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	General	Considering a case where the submission of the Data Matching (DM) to the RMS is done out of the AIR process (for example 2 years after the renewal of the AI), is it acceptable that the applicant submit to a different MS than RMS? In some instances, RMS is not able to conduct the DMC.	UK: For reasons of efficiency the RMS has been encouraged to do the work because of their experience with an active substance. However, the option to go to another member state could be considered.	NL: see point above. We consider the data matching check for both art. 43 and art.33 purposes should be done by the RMS, for consistency reasons. This is included in revised version.
ECPA	General	Guidance on what exactly needs to be submitted with art 43 for PPPs to zRMS and cMS would be welcomed. **Proposed wording:** Given that the DMC table is made available to all MS by RMS on CIRCABC, only reference to the table is necessary upon application for Art 43 of PPP containing that active substance.	UK: We would favour provision of the data matching table itself.	NL: we agree to the position of ECPA with regard to making reference to the table on CIRCABC. However, this is part of the art 43 process (not data matching). We will leave the decision to the individual MS.

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	General	Article 60 lists must be corrected where appropriate for the visibility of all parties, and not individually in relation to data matching arguments made by individual applicants. The Article 60 list is fundamental to the process and must be carefully prepared and reviewed. This is necessary to protect all parties and ensure a level playing field. (see comment on appendix 2).	UK: Agree. Where Article 60 lists are wrong they should be amended. When amending the Article 60 list of necessary studies we would suggest that the RMS strikethrough studies that no longer need to be matched (rather than deletion) and provide a comment as to why the study is no longer considered necessary. This would aid transparency/record of decisions taken. The need for correction should be covered in a guidance document.	NL: This is out of the scope of the guidance document on data matching. It may depend on the specific product of a non-notifier whether a study is necessary or not.

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
Out of scope				

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope

Out of scope

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope

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Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Out of scope

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Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1

Commenting table on **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL SANCO/10328/2004**

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
Out of scope				

Out of scope

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	Applicants must match all required data included in the **Article 60 list**, and this should be expressed clearly. The Article 60 list is the only visible reference point for different applicants and so the only basis for matching. Rather than stating "the relevant" data (which is potentially unclear) explicit reference should be made to the Article 60 list. **Current wording:** Applicants must demonstrate access to, or match, the relevant protected active substance data relied on during approval or renewal of approval of the active substance. **Proposed wording:** Applicants must demonstrate access to, or match, the ~~relevant~~ protected active substance data relied on during approval or renewal of approval of the active substance set out in the Article 60 list.	UK. Agree – this provides greater clarity. The draft guidance document should be amended.	NL: Reference to the necessary studies in the article 60 list has been taken up in the revised version.

ECPA	2	Data matching checks should be made immediately (as noted in other Guidance within **one month**) to avoid prejudice to data owners. For example, from the moment an Article 43 extension is granted, the product is reliant on the active substance data package as provided by the notifier(s) until any alternate arguments are accepted (as there is no other basis for the data requirements for that product to have been met). Therefore this could mean allowing reliance on protected data for months (or even years) without payment of compensation. This is particularly damaging if the arguments are ultimately not accepted or an extended product is not pursued in a given MS or zone. A "sense check" should be made by the RMS and flagged to the later zRMS/cMS. **Current wording**: Assessment of "Evidence that the protected studies are not relevant to the product/use e.g. by providing a case" should be carried out by the zonal RMS/MSs during the process of national product authorisation. **Proposed wording:** Assessment of "Evidence that the protected studies are not relevant to the	UK: We do not agree with the proposed amendment. Timelines do not allow for detailed consideration during the data matching check. Where the argument has been made that for example crops are not present in the GAP of the formulation the UK has concluded that this argument for non-provision is acceptable. However, we highlight in our response in the data matching table that '*cMS may wish to check that this is the case for uses they are considering*'. We also update our internal compliance file-notes to record that data for 'x' use(s) is not matched as a future cross reference.	NL: Agree with UK. However, the RMS will need to check the reasoning of the applicant to some extent to be able to draw a conclusion. Text amended in rev. 1.1.

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
		product/use e.g. by providing a case" should be carried out by the RMS and later confirmed by the zonal RMS/MSs during the process of national product authorisation.		
ECPA	2	Given that there are different possibilities to "match" a point, the wording should be "to address" **Current wording:** Applicants must demonstrate access to, or match, the relevant protected active substance data relied on during approval or renewal of approval of the active substance. Applicants may demonstrate access by providing: **Proposed wording:** Applicants must ~~demonstrate access to, or match~~ address~~,~~ the relevant protected active substance data relied on during approval or renewal of approval of the active substance. Applicants may ~~demonstrate access~~ address the protected data by providing:	UK: We disagree with the first amendment. Applicants are required to demonstrate access or match studies. This can be done in a number of ways. We accept the second amendment ie.: 'Applicants may ~~demonstrate access~~ do this by providing:'. The draft guidance document should be amended to reflect this second amendment.	NL: agree with UK. Point is amended in rev. 1.1.

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	**Existing wording :** - Letter(s) of access from the data owner….; - Matching studies (except vertebrate studies*); - Evidence that the protected studies are not relevant to the product/use …. **Proposed wording :** - Letter(s) of access from the data owner….; - Matching studies (except vertebrate studies*); - Evidence that the protected studies are not relevant to the product/use …. ; - Evidence that the data protection claims are not valid.	UK: Agree the proposed addition: - 'Evidence that the data protection claims are not valid'. We would also suggest adding a further point (as a new bullet 3) covering arguments in relation to whether a reference study or an equivalent study is unprotected as follows: - 'Evidence whether a reference study or an equivalent study is unprotected.' The draft guidance document should be amended.	NL: agree this could be added (although it seems obvious that these possibilities exist).

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	Applicants must demonstrate access to, or match, … The wording is not entirely realistic. At time of submission of the data matching table (which happens as soon as possible after the vote), data access to vertebrates cannot start before agreement with the RMS on the relevant studies to match (as sometimes some studies are not relevant to the product/use. If negotiations are started before data matching conclusion (or at least RMS preliminary review), and if some studies need to be added/excluded from the negotiations, this can be pointed to delaying tactics, etc … I suggest the following amendment to the first bullet point: -Letter(s) of access from the data owner (or for vertebrate studies, evidence that negotiations are ongoing/all possible steps have been taken to gain access);	UK: Agree that part of demonstrating access in relation to vertebrate studies could be evidence that negotiations are underway as already stated in the text.	NL: agree.

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	Flexibility is necessary considering that data protection enforcement is a prerogative of individual MS. However, this should be made clear and where differences occur, they should be flagged. **Current Wording:** Conclusions of the Data Matching assessment represent the opinion of the RMS that in principle should be followed by MS, however each MS considering their national legislation could adopt a different position. **Proposed Wording:** Conclusions of the Data Matching assessment represent the opinion of the RMS that in principle should be followed by MS in relation to the scientific assessment of matching studies. However each MS must check the protected status of relevant data in their territory	UK: Disagree with the proposed amendments. This addition was requested by MS ES to take account of situations involving data protection issues, Cat 4 studies and arbitration procedures. It would be useful if ES could provide some further clarification on this point and also a view on whether the proposed ECPA amendment is acceptable. We consider that the second sentence on checking the protected status of relevant data is already covered by point 6 in the draft data matching guidance document.	NL: agree with UK on first sentence.. For clarity we would support the second sentence proposed by ECPA. Text added in revision 1.1.to 'Procedural aspects of data matching' (point 2 in revised version): *Conclusions of the Data Matching assessment represent the opinion of the RMS that in principle should be followed by MS. However each MS must check the protected status of relevant data in their territory and, in case of limited data access, check whether restrictions should apply to the authorized uses.*

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	**Current wording:** Applicants must demonstrate access to, or match, the relevant protected active substance data relied on during approval or renewal of approval of the active substance. Applicants may demonstrate access by providing: (…) **Comment:** See also point 3.7.2 of the Art. 43 Guidance Document. The timeline should be inserted in the Data matching GD as well, in order to show all provisions on data matching together in one place. **Proposed additional wording in red:** For Art 43 applications applicants must demonstrate, within 3 months of the date of application of the renewal of approval of the active substance, access to, or match, the relevant protected active substance data relied on during approval or renewal of approval of the active substance. Applicants may demonstrate access by providing: (…)	UK: Disagree with the proposed amendment as we consider that it is not necessary. The draft data matching guidance document relates to the process of data matching whereas the Article 43 renewal guidance document SANCO/2010/13170 rev. 14, 7 October 2016 covers the overall procedures for product renewal including deadlines.	NL: We feel the need to take up a section on process and timelines in this working document (to make it a 'standalone document'). Of course such a section should be in line with the art. 43 guidance document. This was also discussed and agreed with AT (bilateral discussion on 14-7-2020).

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	2	**Current wording:** Letter(s) of access from the data owner (or for vertebrate studies, evidence that negotiations are ongoing/all possible steps have been taken to gain access); **Comment:** It would be good to provide some examples what kind of evidence is accepted.	UK: Disagree. We do not see a need for examples. In the absence of letters of access we would consider copies of correspondence between the relevant parties detailing requests for data access/status of negotiations to be evidence. The acceptability of this evidence will be considered by the RMS. Do Member States have any further views?	NL: the text of UK could be used as example: 'e.g. in the absence of letters of access copies of correspondence between the relevant parties detailing requests for data access/status of negotiations to be evidence. The acceptability of this evidence will be considered by the RMS.' This is amended in the revised version.
ECPA	2	**Additional wording in red** As the RMS for the original approval or renewal of the active substance is carrying out data matching on behalf of Member States, all study protocols/plans, letters of access and associated documents supporting product renewal must be submitted. The data matching check should be performed by the active substance RMS as soon as possible ideally within 1 month.	UK: We do not consider that this amendment is needed as it is covered by Art 43 Section 3.7.2: 'The data matching check should be performed by the active substance RMS to the timeline set out in Section 3.7.2 of the Article 43 renewal guidance document SANCO/2010/13170 rev. 14, 7 October 2016'.	NL: We feel the need to take up a section on process and timelines in this working document (to make it a 'standalone document'). Of course such a section should be in line with the art. 43 guidance document. This was also discussed and agreed with AT (bilateral discussion on 14-7-2020).

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ECPA	3	There is a need for guidance on what constitutes « acceptable/unacceptable justifications ». Could a table be provided ? What is a « generic/general argument » ?	UK: In part this is the purpose of Appendix 2 to the draft data matching guidance document which provides examples of recurring issues and RMS opinions. This Appendix could be re-visited and further updated with more examples if that would be considered helpful.	NL: agree with ECPA and UK comment. This will be addressed in the update which is under revision now

ECPA	3	The Article 43 Renewal Guidance set threshold requirements that matching studies must be at least: GLP, use the same methodology , and the endpoint must be within the same order of magnitude. This Guidance should set out that while the threshold requirements always apply, in general when considering matching a reviewer must be able to conclude that the claimed matching study would have been accepted in place of the relevant Article 60 list study during the earlier regulatory process, including when considering weight of evidence approaches. **Current wording:** General/generic arguments should not be used and will not be accepted. All cases submitted need to be considered legitimate before data matching can be claimed. **Proposed wording:** General/generic arguments should not be used and will not be accepted. All cases submitted need to be considered legitimate before data matching can be claimed. Where an applicant addresses a data point with a study that is claimed to match, it must be possible to conclude	UK: Agree that as RMS we would need to be satisfied that the cited information/studies alone would be acceptable in addressing the data point. However, we consider the amendment to the text unnecessary. See also page 34.	NL: agree with UK. However, the text will in some way be clarified in the new version.

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		that the earlier regulatory process would have been equally successful had the matching study been used instead.		

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	4	**Current wording:** 4. Applicants are required to match each data point not each study. This is particularly true where multiple notifiers are involved during active substance renewal. **Proposed wording:** 4. Applicants are required to ~~match~~ address each data point not each study. This is particularly true where multiple notifiers are involved during active substance renewal.	UK: We could accept the proposed amendment but suggest that this point could be amended further as follows: '4. Applicants are required to ~~match~~ address each data point but not necessarily match each study. This is particularly true where multiple notifiers are involved during active substance renewal.' See also response on page 26.	NL: agree with UK. Have taken up proposal by UK in draft updated version.

ECPA	4	Care must be taken to ensure that the Article 60 list of studies is properly understood and compared. For example, studies that contribute to a weight of evidence approach in the initial regulatory process (extent, quality and consistency of data available) must also be matched. If a study appears on the Article 60 list this is clear evidence that it was necessary during the regulatory process. Where there are multiple notifiers different solutions may be presented for the same technical challenge. Applicants may choose to follow one of the approaches, but only by matching all of the necessary studies for that approach and ensuring that the dataset is considered sufficient to ensure the same outcome. **Current wording:** Applicants are required to match each data point not each study. This is particularly true where multiple notifiers are involved during active substance renewal. **Proposed wording:** Applicants are required to match each data point, but not necessarily each study. This is for example the case ~~particularly true~~ where multiple notifiers are involved	UK: We generally agree with the proposed amendment but for clarity propose slightly amended wording as follows: 'Applicants are required to ~~match~~ address each data point, but not necessarily match each study. This is for example the case ~~particularly true~~ where multiple notifiers are involved during active substance renewal, where different solutions may be presented for the same technical challenge. Whatever the approach followed by the applicants it should be ensured that the dataset is sufficient to ensure the ~~same outcome~~ data point is addressed.'	NL: agree to amendment as proposed by UK. This has been amended in the revision of the guidance document.

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		during active substance renewal, where different solutions may be presented for the same technical challenge. Whatever the approach followed by the applicants it should be ensured that the dataset is sufficient to ensure the same outcome.		

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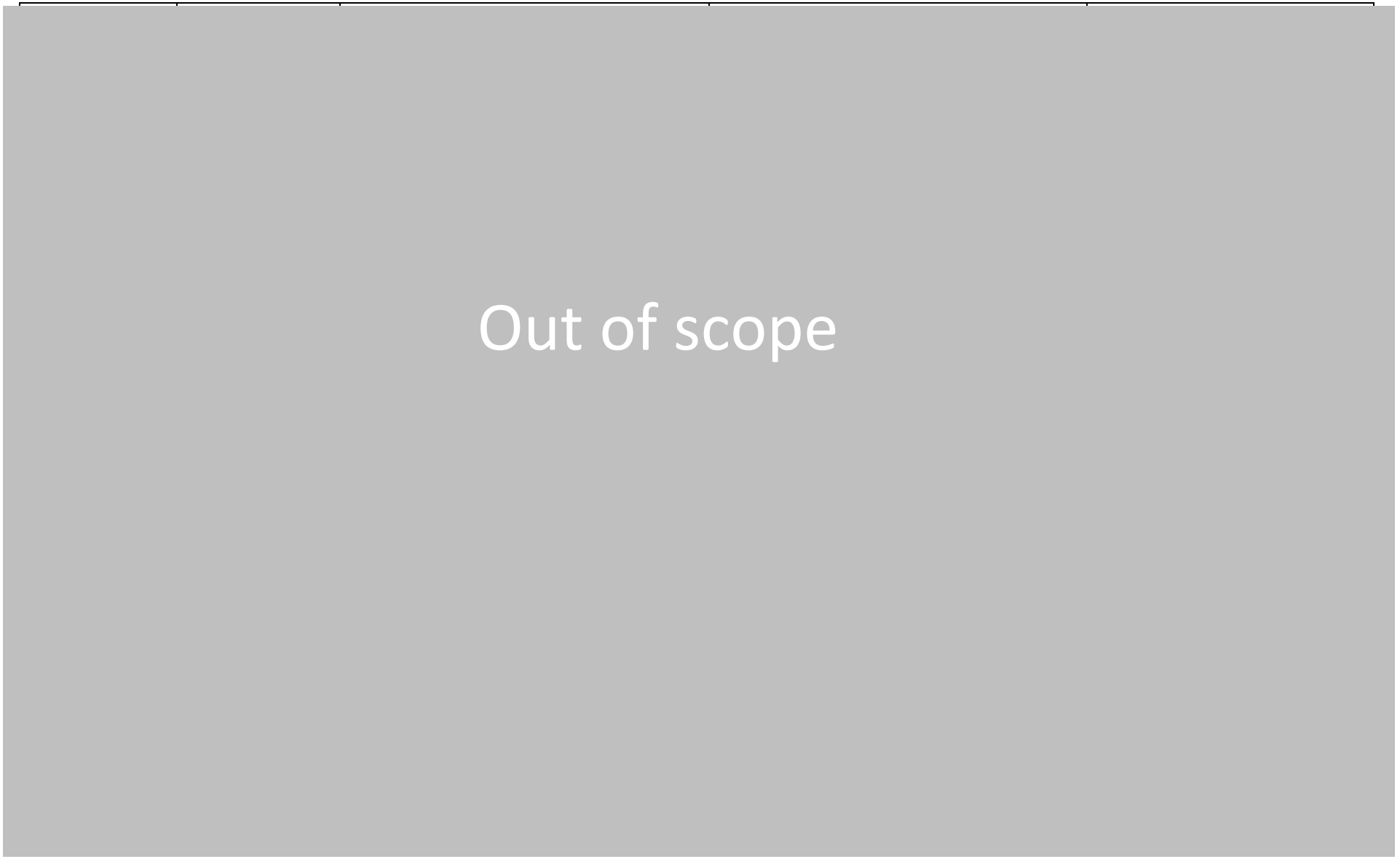
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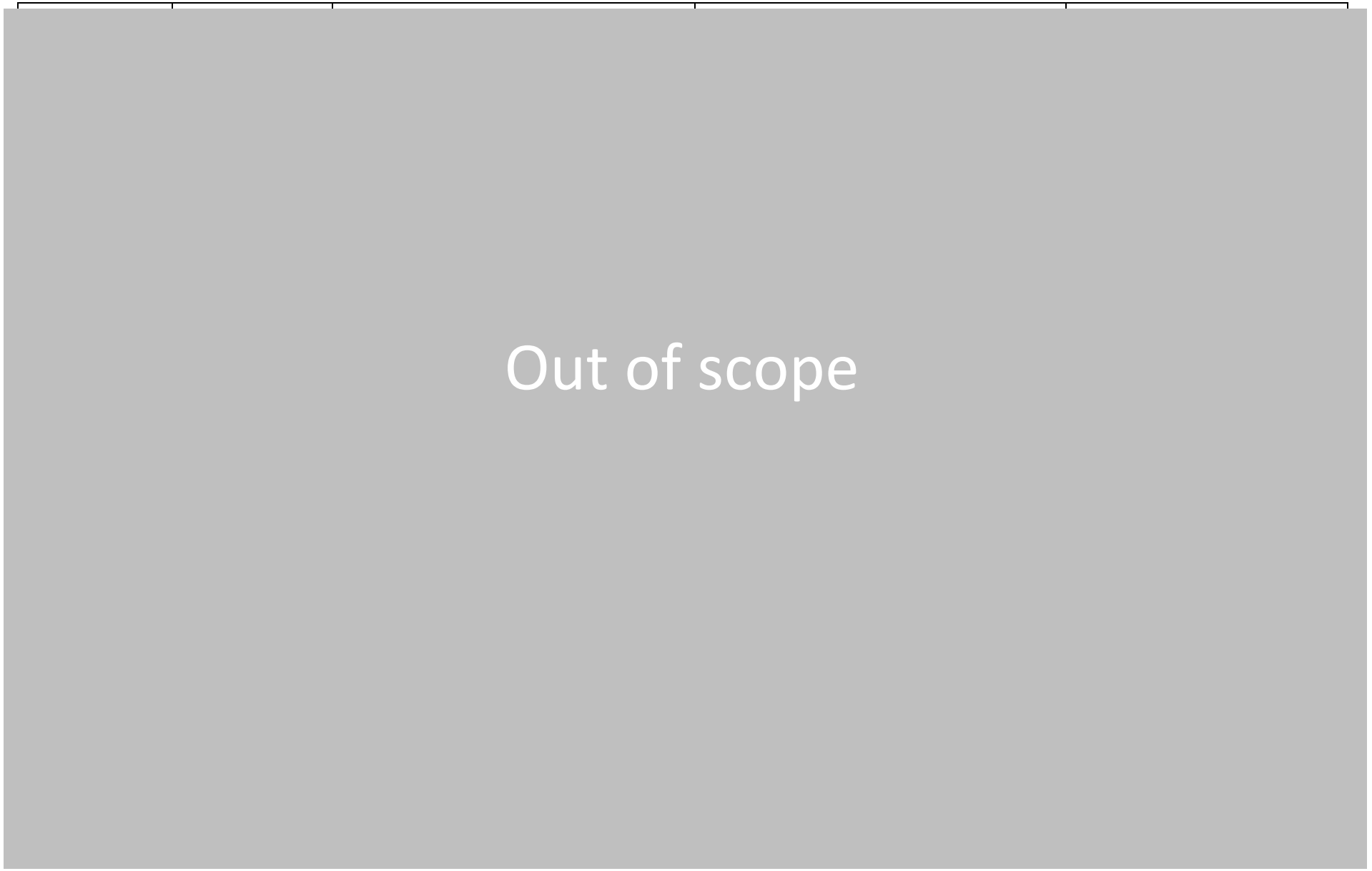
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ECPA	5	The Article 43 Renewal Guidance set threshold requirements that matching studies must be at least: GLP, use the same methodology , and the endpoint must be within the same order of magnitude. This Guidance should set out that while the threshold requirements always apply, in general when considering matching a reviewer must be able to conclude that the claimed matching study would have been accepted in place of the relevant Article 60 list study during the earlier regulatory process. **Current wording :** Therefore, it is important that applicants make clear if the endpoint/outcome from their matching study is within an order of magnitude of the EU agreed endpoint or shows the same outcome (e.g. genotoxicity for metabolites). Otherwise an explanation is required regarding the consequences for the product assessment. If the matching endpoint is significantly more critical than the EU agreed endpoint this may constitute adverse data. (Adverse data is dealt with under a separate process in accordance with Article 56). **Proposed wording**	UK: Agree that as RMS we would need to be satisfied that the cited information/studies alone would be acceptable in addressing the data point. However, an amendment to the text is considered unnecessary. See our previous response on page 24.	NL: agree with UK

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		Therefore, it is important that applicants make clear if the endpoint/outcome from their matching study is within an order of magnitude of the EU agreed endpoint or shows the same outcome (e.g. genotoxicity for metabolites). Otherwise an explanation is required regarding the consequences for the product assessment. If the matching endpoint is significantly more critical than the EU agreed endpoint this may constitute adverse data. (Adverse data is dealt with under a separate process in accordance with Article 56). Where an applicant addresses a data point with a study that is claimed to match, it must be possible to conclude that the earlier regulatory process would have been equally successful had the matching study been used instead.		

ECPA	6	Only an individual MS can confirm the protected status of studies. The RMS should immediately flag any claims or disputes regarding the status of protected studies at the data matching check. For example, if an applicant claims that a study is not protected while a notifier claims that it is protected, that should be investigated and clarified immediately by the MS involved as a fundamental component of the data matching check. This assessment needs to happen at the data matching check conducted by the RMS, and not only later during product authorisation, as reliance on protected data begins immediately (in the case of Article 43 renewals). **Current wording:** Given that data protection is a Member State issue the RMS can check the data protection status of studies in their country but other Member States will need to check data protection to establish if the study can be accessed to support product authorisation in that Member State. **Proposed wording:** Given that data protection is a Member State issue the RMS shall check the data	UK: We do not agree the second amendment ('*Where there is any dispute….without delay*'). Although this would seem a reasonable suggestion the timelines do not allow for this dialogue with other Member States.	NL: agree with UK. We stress that responsibility for data protection check lies with the individual MS, and cannot be checked in full detail by the RMS.

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		protection status of studies in their country but other Member States will need to check data protection to establish if the study can be accessed to support product authorisation in that Member State. Where there is any dispute regarding the protected status of a study during the data matching check, the RMS should seek clarification from the relevant MS and concerned parties without delay.		

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ECPA	7	**Current wording:** *Agreement to a category 4 delay will not normally be confirmed until after the renewal application has been received* This is not practically possible. The Cat4 delay must be concluded before the renewal application has been submitted by the applicant. Otherwise, the applicant cannot be certain before the submission on where the product Art 43 stands. Practically speaking the applicant can start preparing for the Cat4 request soon after the EFSA opinion publication and submit the Cat4 request to the RMS as soon as the vote took place. Discussions can be initiated with the RMS between EFSA conclusion and the vote I suggest the following amendment: **Proposed wording:** Agreement to a category 4 delay should be confirmed before the product renewal application has been received	UK: Disagree. Notification is required 2 months after the EFSA conclusion giving an indication then that a Cat.4 extension may be required. The extension cannot be confirmed, however, until the full data matching check has been completed.	NL: this sentence seems to give difficulties for interpretation. Our interpretation was: 'Agreement to a category 4 delay will normally be confirmed together with the data matching conclusion by the RMS.' This is amended in the revised version

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	7	Article 43 Guidance sets out clear limits for Cat 4 data and should be cross referenced with SANCO/2010/13170. Cat 4 criteria also do not include claims that there was insufficient time to negotiate access to a study with a data owner. **Current wording:** Why there was insufficient time from publication of the EFSA conclusion to submission of the product renewal dossier to generate an equivalent study or negotiate access to the original study. **Proposed wording:** Why there was insufficient time from publication of the EFSA conclusion to submission of the product renewal dossier to generate an equivalent study. ~~or negotiate access to the original study~~.	UK: Cross referencing between GDs to be considered by COM/MS. Can agree to the deletion of the text – probably not a Cat.4 reason, and insufficient time to agree access would not be an issue provided evidence is provided that negotiations have started.	NL: art 43 guidance makes clear that cat. 4 data is intended exclusively for data requests that could not be anticipated before the EFSA conclusions for the active substance were available. How an applicant could fulfil the cat. 4 data is not prescribed. Proposal (to be discussed with MS): *Why there was insufficient time from publication of the EFSA conclusion to submission of the product renewal dossier to generate an equivalent study or, alternatively, negotiate access to the original study (evidence that negotiations have been started must be provided).*
ECPA	7	**Comment on last sentence of Section 7:** What exactly means satisfactory justification? Clearer wording should be presented.	UK: Disagree. This cannot be clearly specified, needs to be considered on a case by case basis.	NL: agree with UK.

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ECPA	8	The Article 43 Guidance threshold requirements (GLP, methodology, order of magnitude) must always be made out and this should be made clear. In addition, the RMS should not accept multiple sequential arguments, as data matching must occur quickly. If any difficulties are identified in the data matching table the RMS should contact the applicant with a single time-limited opportunity to respond. Data matching should not be an iterative and drawn out process, as during that time applicants are reliant on protected data without the payment of compensation. Further, matching must occur quickly to avoid eroding the period of data protection itself. **Current wording:** …the RMS should check whether the studies submitted were conducted according to Good Laboratory Practices (GLP), used the same protocol/methodology as the data to be matched and that the endpoint is within the same order of magnitude as the reference study. However, the situation can be more complex than that, and experience to date has seen a wide variety of data matching arguments being made	UK: Agree to the proposed additional text at the end of the section. Consideration needs to be given to how long the single time-limited opportunity to respond should be.	NL: agree with UK

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
		by applicants that have required more detailed consideration. **Proposed wording:** …the RMS should check whether the studies submitted were conducted according to Good Laboratory Practices (GLP), used the same protocol/methodology as the data to be matched and that the endpoint is within the same order of magnitude as the reference study (as threshold requirements for matching). However, the situation can be more complex than that, and experience to date has seen a wide variety of data matching arguments being made by applicants that have required more detailed consideration. In all cases the RMS should not accept multiple sequential arguments. If any difficulties are identified in the data matching table, the RMS should contact the applicant with a time-limited opportunity to respond. In case an adequate response is not received by the deadline, the dossier should be considered as incomplete and the related authorisations should be withdrawn.		

Organisation	Section	Comments	Reply and Outcome UK	Considerations NL-rev 1.1
ECPA	8	**Comment :** Essential to have the complete wording from Reg 1107/2009, Article 59 (1)(b). SANTE/2016/11449 requires that in the basic table in the Appendix as well. **Proposed additional wording** in red : According to the Guidance Document on the Renewal of Authorisations (SANCO/2010/ 13170 rev. 14 October 2016) the RMS should check whether the studies submitted were conducted according to Good Laboratory Practices (GLP) or Good Experimental Practice (GEP), used the same protocol/methodology as the data to be matched and that the endpoint is within the same order of magnitude as the reference study.	UK: Agree.	NL: Agree. Text amended in the document.

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ECPA	9	**Additional proposed wording:** On completion of the DMC, the outcome should be made available to the applicant and reference to the table provided for subsequent reference in Art.43 submissions (see appendix 1).	UK: Agree, text needs to be added to reflect that the outcome should be made available to the respective applicants (although disagree with the rest of the sentence "..and reference to the table ..").	NL: Agree with UK. Text amended in the document.

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ECPA	Annex	Several of the examples cited in the Annex are problematic. In particular, the examples in rows 1,11,14,17,21,26,28,29,31 and 33 all suggest that an individual applicant may gain an exemption from matching a study included in the Article 60 list by arguing that the study was somehow not originally required for the approval/authorisation. However, that is precisely the decision that is made in including the study in the Article 60 list. This approach would mean treating different applicants differently regarding regulatory requirements. If an error is detected in the Article 60 list, it must be publicly corrected for the benefit of all applicants. We propose noting for the examples in these rows that any such arguments can only be successful if the RMS accepts that the Article 60 list itself will be amended on the same basis.	UK: Relates again to the 'relied on vs necessary' issue. It can be the case that some studies considered as necessary for the renewal of the active may not be necessary for authorisation of the product. Agree that if an error is detected in the list it should be publicly corrected (although incorrectly listed studies should be struck through, not deleted, for transparency).	NL: agree with UK

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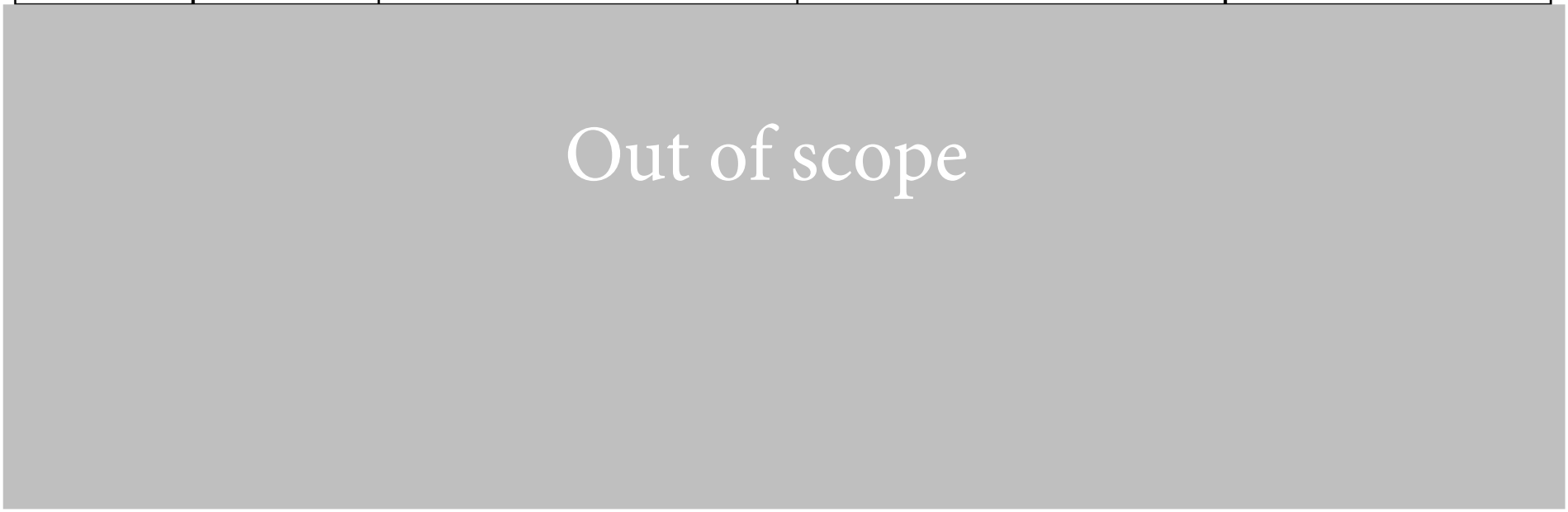
ECPA	Appendix 2	The appendix 2 provides examples of cases including the response of the RMS to the justification of the applicant. Is there any possibility for a procedure allowing the applicant to answer to the "RMS Opinion/Response" in case of any rejection from the RMS?	UK: Yes, a single time-limited opportunity to answer the RMS response should be provided where the data matching case is not accepted by the RMS/zRMS.	NL: agree with UK.



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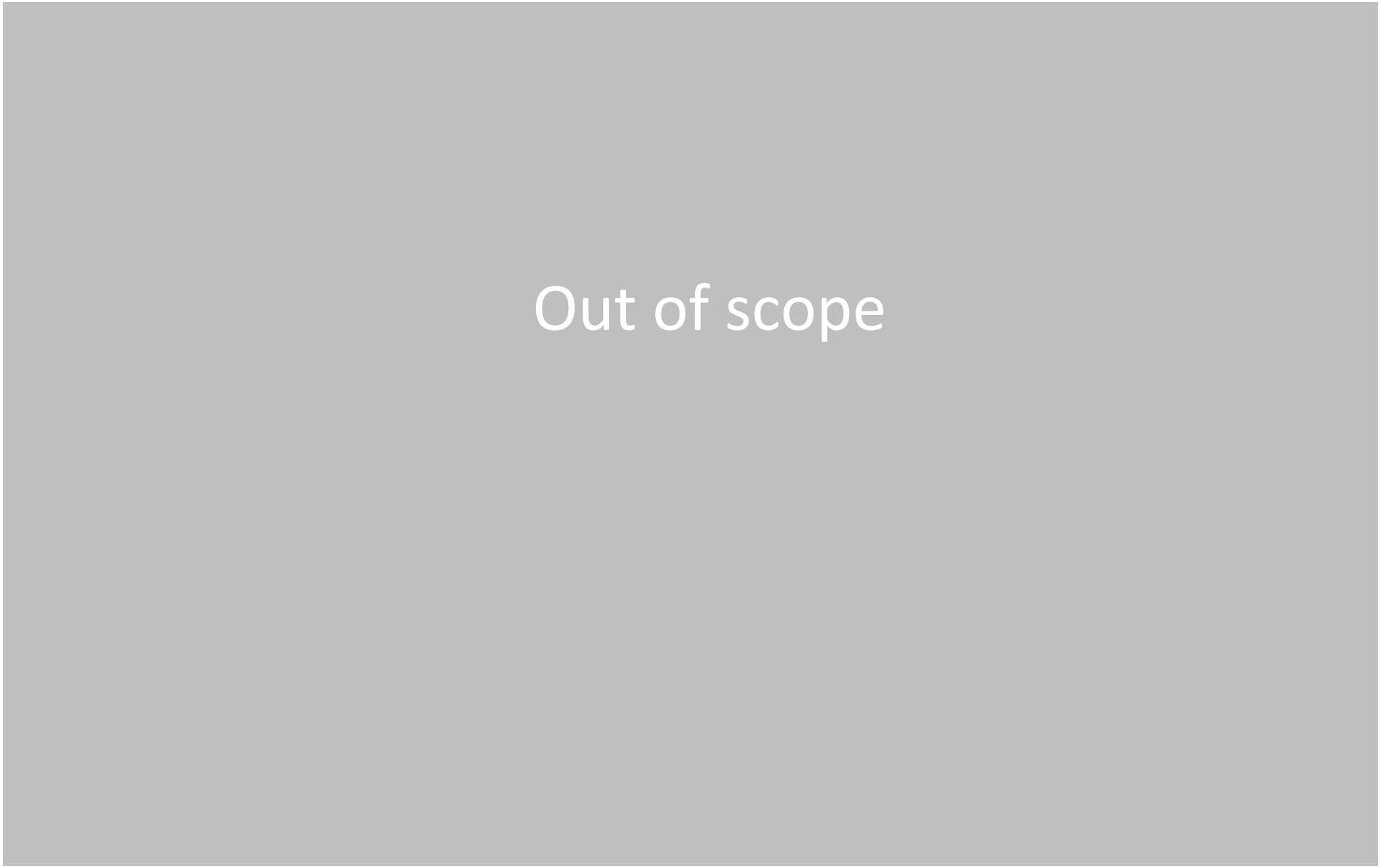
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