LET/20/LO/32450
27 March 2020

Klaus Berend
DG Sante -Unit E.4 - Pesticides and Biocides
1049 Brussels
Belgium
European Commission
klaus.berend@ec.europa.eu

ECPA letter to DG SANTE on regulatory impact of the covid-19 situation

Dear Dr Berend

In view of the current situation due to the covid-19 pandemic, we would like to inform you about the foreseen impact on regulatory deadlines linked to plant protection products processes.

ECPA members have started compiling examples of deadlines being already, or about to be, impacted by the current lockdown across Europe. This stems from:

- Company organizations operating on essential functions only mode, with reduced capacity to generate data, complete ongoing studies, initiate new studies and prepare regulatory dossiers
- Reduced national authorities' ability to process applications.
- Contract research organisations and third party laboratories temporarily suspending operations, with severely reduced capacity to generate information for companies.
- The lack of testing materials and inability to conduct labs/field trials due to missing equipment (e.g. delivery on site), plus the inability to transport materials, which are blocked by customs in several countries worldwide.
- Long-term studies (e.g. field/seasonal studies) due to start in 2020, which have been cancelled for the above reasons. Hoping studies can start in 2021, but this will impact submission timelines for submissions in 2020 and subsequent years.

ECPA member companies will continue to keep competent authorities informed on those developments in a timely and documented manner. The processes and associated deadlines to be affected in 2020 but also in subsequent years may concern any of the following:

- Submission of active substance and plant protection products dossiers, whether supporting new applications or renewals
- Provision of confirmatory data
- Submission of MRL dossiers
- Provision of information to EFSA
- No possibility to conduct meetings including pre-submission discussions even by phone with the rapporteur member state (or zonal RMS).

Please find in annex to this letter an overview table of concrete examples collected to date, identifying the process and the applicable area. The list will evolve as the situation unfolds and new information is available to applicants. ECPA will continue to inform your services accordingly.

Similarly to what ECHA has now announced[1], we invite the Commission, EFSA and Member States to consider which flexibility measures could be adopted to keep the regulatory system functional while avoiding the negative consequences of missed submission deadlines beyond

[1] https://echa.europa.eu/covid-19

applicants' control. Such flexibility will be essential for companies submitting incomplete substance renewal dossiers, in the hope the missing elements could potentially be submitted later in the Stop-the-Clock period.

Should you have any questions please do not hesitate to contact me.

Yours sincerely

Laurent Oger
Director of Regulatory Affairs

Cc: Karin Nienstedt (DG SANTE)
Manuela Tiramani (EFSA)

Annex – Examples of impacts on regulatory deadlines collected from ECPA member companies – situation on the 27 March 2020

Affected process	Deadline	Area	Reason
All dossiers	2020	Information Technology	Electronic file transfer. OK for big dossier because 50GB but need a zip file that could not work or take too much time
All dossiers in France	2020	Shipment	Submission of DVD is requested (not only electronically). Lack of flexibility from the authority
All dossier		All	All samples stored in a lab facility, which informed the company that the shipments would not be possible or very delayed. This is making it complicated to plan studies in the coming months.
AS Renewal Dossier	2021	Residue	Issue if not able to treat residue study by end of May 2020. The consequence is no data will be available at AIR submission; this particular study is critical for risk assessments.
AS Renewal Dossier	Next 6 months	E-fate	CRO access to the lab to collect samples; only one at a time to reduce exposure
AS Renewal Dossier	2021	Toxicology	Studies likely delayed by the CRO due to reduction in resources
AS Renewal Dossier	2021	E-fate	No possibility to set up mandatory field study - season lost - delay by 1 year
AS Renewal dossier	2021	Pre-submission meeting	No possibility to have a face-to-face pre-submission meeting within the next months, and given the complexity of some of the issues, a teleconference meeting is not a good substitute
AS Renewal Dossier	2021	Data requirements & Dossier submission	Company facilities are closed, cannot receive/ship material, contractors are closed, which will impact the ability to submit a full dossier (covering all necessary data requirements) at the mandated timeline. For instance: - For new studies: impossible to predict when data could be generated. - For 2020 seasonal outdoor studies, like residue, bee, and other ecotox studies: unknown if they will be actually run.
AS Renewal dossier	2021	E-Fate	2020 outdoor study to be performed in Italy. Impossible to know if any work can be safely performed this season.
AS Renewal dossier	2021	Pollinator	2020 outdoor studies to be performed in Spain and Germany. Impossible to know if any work can be safely performed this season.
AS Renewal dossier	Next 6 months	Finalization of studies and study reports under GLP / Compiling dossier	Not all employees from CROs can completely work from home

AS Renewal dossier	Next 6 months	Finalization of studies and study reports under GLP / Compiling dossier	Not all employees from CROs can completely work from home
AS Renewal dossier	2021	Pre-submission meeting	Pre-submission meeting was cancelled by RMS (Austria)
AS Renewal dossier	2021	Closing test facilities & closing of a residue laboratory (internal & external & worldwide)	Interrupting ongoing studies (e.g. residue) & start of studies cancelled
AS Renewal dossier	2022	Closing test facilities & closing of a residue laboratory (internal & external & worldwide)	Interrupting ongoing studies (e.g. residue) & start of studies cancelled
AS Renewal dossier	later than 2022	Closing test facilities (internal & external & worldwide)	Interrupting ongoing studies (e.g. residue) & start of studies cancelled. Synthesis of metabolites cancelled -> metabolism studies will not start in time. Preparation of renewal dossiers at least 5 years in advance to submission !!!
AS Renewal Dossier	2023	Soil / E-fate	Soil dissipation studies. Delay in sample shipment may jeopardise the field phase for 1 year as application has to be done according to representative GAP.
AS Renewal Dossier	Next 6 months		(1) Delayed response from laboratories due to reduced staff allowed to work on the same time in the same location. (2) Response of consultants involved and decision making slowed down due to impossibility of physical meetings.
AS Renewal Dossier	2021	Initially synthesis of parent radiolabelled test article for use in e-fate, ecotox and tox studies	Radiolabelled parent test article required. Complex process involving non-chemical and chemical synthesis. Limited number of facilities able to produce 14-C radiolabelled material. Facility placed on lockdown with limited activities on-going mainly related to essential/safety. Covid-19 impact on staff will further limit operations at the facility. Currently, production likely to be delayed with timelines now being undetermined. Subsequent regulatory studies requiring this material will be further delayed.
AS Renewal Dossier	2021	Earthworm Field Study	Study due to start Spring 2020. CRO have just indicated they are no longer able to conduct the study in Spring 2020 due to the restrictions being place on companies in Germany and the UK regarding people movement for "non-essential" work.
AS Renewal Dossier	2020	Operator Exposure	Planned Field study: start delayed because of Corona (key study for renewal, was agreed to be delivered to the RMS during evaluation process before end of Q4)

AS Renewal Dossier	2020	Soil Dissipation studies	Planned Field study: start delayed because of Corona (key study for renewal, was agreed to be delivered to the RMS during evaluation process before end of Q4)
AS submission	2021	Pre-submission meeting	No possibility to have the pre-submission meeting
AS submission	2020	ED	CRO has stopped all laboratory work = > this leads to an increased bottle neck in ED trials
AS submission	2020	Phys-Chem	Supply of active and metabolites for studies, labs closing down in US for 3 weeks minimum
Confirmatory Data	2020	ED studies	Start of studies cancelled
Confirmatory Data	2020	Pollinator	Field study cancelled and season missed because of CRO closed
Confirmatory data	Next 6 months	Groundwater	Several reports related to an ongoing groundwater monitoring study will be delayed 2-3 months due to shortage of CRO capacity
Mandated ED testing	Next 6 months	Ecotoxicology	CRO stopped activity on March 18th 2020, with no reopening date (Confinement linked)
Mandated ED testing	2022	Ecotoxicology	Lab in France closed, timelines on study will be delayed, study starting later than planned. Unknow impact on timelines however could see need to extend 30 month window
Mandated ED testing	2020	Sample supply	Shipment of sample to USA facilities delayed due to customs reasons (COVID)
Matching data	Next 6 months	Annex II studies	Synthesis of a metabolite delayed making impossible to cope with deadline April 2020
MRL confirmatory data	2020	Residues	Delay in sample dispatch for analysis: The risk is too high to dispatch frozen samples to the analytical laboratory.
MRL submission	Now	Residues	Consulting resources not available
MRL submission	2021	Storage stability	Storage stability residue: no delivery of chemicals to the CRO
MRL submission	2021	Toxicology	Toxicology vertebrates: experimental delays (which will cause delay in bioanalytics)
MRL submission	2021	Residues	Residue: residue analysis stopped due to the lab closing (full lockdown in Spain)
New active dossier submission	Now	ECHA meeting for classification	ECHA meeting was cancelled. Further impact on approval process unknown
New product	2020	Efficacy trials	Field trials cancelled/postponed loss of 1 year for new registration/innovation (to early to know how many products)
New product	2020	Phys-Chem	Lab closed in India and delay in getting raw material for synthesis of metabolite
New product	2020	Phys-Chem	Synthesis delayed: studies substance is needed will be delayed
New product	2021	Phys-chem	No start of new studies in the lab. Availability of phys-chem properties and storage stability data will be delayed for dossier submission

New product	2021	Phys-chem	No start of new studies in the lab. Availability of phys-chem properties and storage stability data will be delayed for dossier submission
New product	2020	Toxicology	Toxicological studies (several genotox studies (Ames test + micronucleus test)
Product renewal	2020	Groundwater	No possibility to have a leeching study finalised due to sampling cancelled (from last Autumn application)
Product renewal	Next 6 months	Closing test facilities (internal & external & worldwide)	Interrupting ongoing residues analysis or method validation
Product renewal	Next 6 months	Toxicology	Toxicological studies (several genotox studies (Ames test + micronucleous test) and +
Product renewal	2020	E-fate	Ecotox (earthworm)
Product renewal	2020	Groundwater	No possibility to have a leeching study finalised due to sampling cancelled (from last Autumn application)
Product renewal	Next 6 months	Toxicology Methods of analysis	Toxicology: Study reporting and QA Methods of analysis: Study reporting and QA
Renewal dossier evaluation (s-t-c)	Now	Meeting with RMS	No appointment can be scheduled: It was cancelled due to COVID.