REGISTRATION REPORT

Part A

Risk Management

Product code: A17072C

Product name: CALLISTO PLUS

Chemical active substances:

Dicamba, 120 g/L
Mesotrione, 50 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: SYNGENTA France S.A.S.

Date: November 2021

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PART A
RISK MANAGEMENT

1 Details of the application

The company SYNGENTA France S.A.S. has requested an extension for marketing authorisation in France for the product CALLISTO PLUS (product code: A17072C, marketing authorisation No 2160248), containing 120 g/L dicamba[1] and 50 g/L mesotrione[2] as an herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of SYNGENTA France S.A.S.'s application to market CALLISTO PLUS (A17072C) in France as an herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the label extension of this product in France and in other MSs of the Southern zone.

The present application (2018-3859) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) No 1107/2009[3], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[4]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of CALLISTO PLUS (A17072C) has been made using endpoints agreed in the EU peer reviews of dicamba and mesotrione. It also includes assessment of data and information related to CALLISTO PLUS (A17072C) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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1 Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin.

2 Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

3 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

4 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

5 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

This document also describes the specific conditions of use and labelling required for France for the registration of CALLISTO PLUS (A17072C).

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substances.

1.3 Justification for submission of tests and studies

According to the applicant:

"Art. 33 (3) c Justification of steps taken to avoid animal testing and duplication of such testing:

There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Art. 33 (3) d Reasons for submission of tests and study reports:

Since this product was previously registered there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain re-approval new tests and study reports are provided."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CALLISTO PLUS (A17072C), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	A17072C.
Product name in MS	CALLISTO PLUS.
Authorisation number	2160248.
Use	Professional use.
Low risk (article 47)	No.
Function	Herbicide.
Applicant	SYNGENTA France S.A.S.
Active substances (incl. content)	Dicamba, 120 g/L. Mesotrione, 50 g/L.

Formulation type	Suspension concentrate [SC].
Packaging	Packaging not changed.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for CALLISTO PLUS (A17072C) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

Classification not changed.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

Refer to marketing authorisation: no label extension of marketing authorisation granted.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017 [6] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

[6] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021[7] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[8] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:
Refer to marketing authorisation: no label extension of marketing authorisation granted.

The other conditions of use specified in the previous evaluations are not changed.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

[7] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456
[8] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: Nov.2021

PPP (product name/code):	CALLISTO PLUS/A17072C	Formulation type:	SC [a, b]
Active substance 1:	Dicamba	Conc. of as 1:	120* g/L [c]
Active substance 2:	Mesotrione	Conc. of as 2:	50** g/L [c]
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	Syngenta	Professional use:	☒
Zone(s):	Southern [d]	Non professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Sugarcane	F	Broad Leaved Weeds (annual/perennial)	Spraying	BBCH 12-19	a) 1 b) 1	-	a) 2.0 b) 2.0	a) 240** + 100* b) 240** + 100*	80-400	**F**	**Not acceptable** (ground water, aquatic organisms, bees, selectivity)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Not relevant.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of A17072C / CALLISTO PLUS (A17072C) applied post-emergence is considered as acceptable on broadleaved weeds for the requested use.
- Considering the absence of data on selectivity on sugarcane, the risk of phytotoxicity can't be excluded. The evaluation of the selectivity of the product CALLISTO PLUS (A17072C) can't be finalised for the requested use.
- In the absence of data regarding the impact of CALLISTO PLUS (A17072C) on yield and quality, the risk of negative effect can't be excluded. The evaluation of the impact of the product CALLISTO PLUS (A17072C) on yield and quality can't be finalised.
- The risk of negative impact on propagation is considered as negligible.
- The risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.
- The risk of resistance development or appearance to mesotrione and dicamba does not require a monitoring for the requested use.

3.3 Methods of analysis (Part B, Section 5)

Not relevant.

3.4 Mammalian toxicology (Part B, Section 6)

<table>
<tr><td colspan="5">Active substance: dicamba</td></tr>
<tr><td>ADI
mg kg bw/d</td><td colspan="3">0.3</td><td rowspan="4">EU (2009)</td></tr>
<tr><td>ARfD
mg/kg bw</td><td colspan="3">0.3</td></tr>
<tr><td>AOEL
mg/kg bw/d</td><td colspan="3">0.3</td></tr>
<tr><td>AAOEL</td><td colspan="3">-</td></tr>
<tr><td rowspan="2">Dermal absorption</td><td colspan="4">Based on an in vitro human study performed on formulation, according to guidance on dermal absorption (Efsa 2017):</td></tr>
<tr><td>Concentrate (tested)
120 g/L</td><td>Diluted formulation (tested)
3 g/L</td><td>Diluted formulation (tested)
0.6 g/L</td></tr>
</table>

	In vitro (human) %	24	27	11
		Concentrate (used in formulation) 120 g/L	Spray dilution (used in formulation) 3 g/L	
	Dermal absorption endpoints %	**25**	**28**	
Oral absorption	**>80%**			

Active substance: **mesotrione**				
ADI mg/kg bw/d	0.01		EU (2017)	
ARfD mg/kg bw	0.02			
AOEL mg/kg bw/d	0.005			
AAOEL	-			
Dermal absorption	Based on an in vitro human study performed on formulation according to guidance on dermal absorption (Efsa 2017):			
		Concentrate (tested) 50 g/L	Diluted formulation (tested) 1.25 g/L	Diluted formulation (tested) 0.25 g/L
	In vitro (human) %	0.2	1.9	3.9
		Concentrate (used in formulation) 50 g/L	Spray dilution (used in formulation) 0.25 g/L	
	Dermal absorption endpoints %	**0.2**	**3**	
Oral absorption	**50%**			

3.4.1 Acute toxicity

CALLISTO PLUS (A17072C) containing 120 g/L dicamba and 50 g/L mesotrione has no acute oral, inhalational and dermal toxicity. CALLISTO PLUS (A17072C) is not irritating to the rabbit skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Model data		dicamba	mesotrione
	Level of PPE	**% AOEL**	**% AOEL**
Application : Tractor / *down* **Outdoor** **Sugar cane**			
Application rate: 2 L/ CALLISTO PLUS /ha		0.24 kg dicamba / ha	0.1 kg mesotrione / ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall	49.80	19.33

Model data		dicamba	mesotrione
	Level of PPE	**% AOEL**	**% AOEL**
Application : Manual-knapsack / *down* **Outdoor** **Sugar cane**			
Application rate: 2 L/ CALLISTO PLUS /ha		0.24 kg dicamba / ha	0.1 kg mesotrione / ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall	29.78	93.08

According to the model calculations, when application is performed with tractor-mounted or manual knapsack, it can be concluded that the risk for the operator using CALLISTO PLUS (A17072C) is acceptable with a working coverall.

3.4.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop inspection/irrigation or searching, reaching, picking activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is summarised in table below:

		dicamba	mesotrione
	Level of PPE	**%AOEL**	**%AOEL**
Activity: inspection/irrigation Outdoor Work rate: 2 hours/day Interval between applications: 365 days			
DT50: 30 days			
DFR: 3 µg/cm²/kg a.s./ha			
Nb applications x Application rate (kg as/ha)		1 x 0.24 kg dicamba/ha	1 x 0.1 kg mesotrione/ha
Body weight: 60 kg	Work wear (arms, body and legs covered)	3.14	5.6

It is concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander and resident exposure

Bystander : EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[10].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

Resident: Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child):

Model (AOEM) - All pathways (mean)	**% AOEL dicamba**	**% AOEL mesotrione**
Resident (children)	7.81	35.61
Resident (adults)	2.72	9.35

3.4.5 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

[10] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

A cumulative assessment for operators, bystanders/residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.
Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operators *Tractor mounted*	Working coverall during mixing/loading and application	**Dicamba**	0.50
		Mesotrione	0.22
	Cumulative risk operators (HI)		**0.72**
Operators *Manual knapsack*	Working coverall and gloves during mixing/loading and application	**Dicamba**	0.14
		Mesotrione	0.77
	Cumulative risk operators (HI)		**0.91**
Bystanders /Residents	Children - All pathways (mean)	**Dicamba**	0.08
		Mesotrione	0.36
	Cumulative risk bystanders/residents (child) (HI)		**0.44**
	Adults - All pathways (mean)	**Dicamba**	0.028
		Mesotrione	0.09
	Cumulative risk bystanders/residents (adult) (HI)		**0.118**
Worker	Working coverall and gloves	**Dicamba**	0.03
		Mesotrione	0.06
	Cumulative risk workers (HI)		**0.09**

The Hazard Index is < 1. Thus combined exposure to all active substances in CALLISTO PLUS (A17072C) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for dicamba and mesotrione as laid down in Reg. (EU) No 396/2005 is not expected.

The chronic and the short-term intakes of dicamba and mesotrione residues are unlikely to present a

public health concern.
As far as consumer health protection is concerned, FR, zRMS agrees with the authorisation of the intended uses.

According to available data, no specific mitigation measures should apply.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of mesotrione, dicamba and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC_{soil} and FOCUS step 1 & 2 PEC_{sw} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment. The FOCUS Step 3 PEC_{sw} calculations provided by the applicant do not covered the entire application windows proposed in the GAPs table. Therefore, the risk assessment for mesotrione cannot be finalised for the requested use on sugarcane.

PEC_{gw} for dicamba, mesotrione and metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000[11]. However, calculations provided by the applicant do not covered the entire period of application as proposed in the GAPS table for sugarcane use. Therefore, the risk assessment of groundwater contamination for dicamba, mesotrione and their metabolites cannot be finalised for the requested use on sugarcane.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the requested use.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk (including drinking water), indicating that the risk to birds is acceptable following use of A17072C according to the proposed use pattern.

Mammals

[11] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk, indicating that the acute risk to mammals is acceptable following use of A17072C according to the proposed use pattern. Also, the risk assessment for drinking water exposure from puddles showed acceptable risk.

The long-term TER values for dicamba, calculated for recommended scenarios, exceed the trigger value of 5, indicating acceptable risk. However, the long-term TER values for mesotrione and consequently those for the additive risk assessment fall below the trigger of 5. Acceptable long-term risk to small omnivorous and herbivorous mammals from mesotrione and potential additive toxicity could be demonstrated in a refined risk assessment

3.7.2 Effects on aquatic species

For the intended use sugarcane, the risk assessment for aquatic organisms cannot be finalised since valid PEC_{sw} Step 3 and Step 4 values are not available for this use.

3.7.3 Effects on bees

The acute risk of A17072C to honeybees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with A17072C, dicamba and mesotrione, and exposure rates following application at the maximum single rate of 2.24 kg A17072C/ha, equivalent to 240 dicamba/ha and 100 g mesotrione/ha.

All the hazard quotients for A17072C are less than 50, indicating that the acute oral and contact risk to bees is acceptable following use of A17072C according to the proposed use pattern.

The new data requirement of Regulation (EC) No 284/2013 have to be applied to the current evaluation considering the submission date of the dossier. According to new requirements of Regulation (EC) No 284/2013:

- Toxicity data for active substance are not sufficient to determine the risk assessment of a mixture when more than one active substance is used in the formulation, synergic effects between the different active substances cannot be excluded.
- Data on chronic effects on adult bees and on development of bees should have been submitted by applicant as exposure of bees to the formulation cannot be excluded. For the data on development of bees, zRMS highlights that potential effects on emergence have to be observed in the study to be considered sufficient to fully address this data requirement.

Therefore, the risk to bees cannot be completely fulfilled. Thus, Member States may consider the risk for bees as not finalised or required mitigation measures to avoid exposure of bees, and/or request chronic adults and larvae toxicity studies at post-registration. At national level, zRMS will conclude that the risk for bees is not finalised.

3.7.4 Effects on other arthropod species other than bees

At Tier I, the in-field and off-field HQ values were below the trigger value for the worst-case use scenario (1 x 2.0 L A17072C/ha in maize) indicating that the risk to non-target arthropods is acceptable following the use of A17072C according to the proposed use pattern

3.7.5 Effects on soil organisms

Soil meso- and macrofauna
The acute and long-term risk of A17072C, dicamba and mesotrione, and relevant metabolites was evaluated where relevant for earthworms, Collembola and Hypoaspis. The risk assessment demon-strated that the risk to non-target soil meso- and macrofauna is acceptable following use of A17072C according to the proposed use pattern.

Soil micro-organisms
All no-effect levels of A17072C, dicamba, mesotrione and relevant metabolites exceeded the relevant PECsoil values, indicating that the risk to soil micro-organisms is acceptable following use of A17072C according to the proposed use pattern.

3.7.6 Effects on non-target terrestrial plants

The risk of A17072C to non-target terrestrial plants was assessed from TER values using the A17072C toxicity data from Tier II studies, and the maximum off-field predicted environmental residues (PERs). TER values, calculated from worst-case endpoints from seedling emergence and vegetative vigour studies with 10 species and a $PER_{off\text{-}field}$ value at 1 m from the treated crop, indicated a potential risk to off-field non-target plants. The risk was refined using a probabilistic risk assessment and considering mitigation with buffers and spray drift reduction technology.

The risk to non-target terrestrial plants in off-crop areas is acceptable following use of A17072C (1 x 2.0 L/ha) according to the proposed use pattern, provided the following mitigation is implemented:

- 1 m buffer and 90% drift reduction mitigation or
- 5 m buffer and 50% drift reduction mitigation or
- 10 m buffer

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

For dicamba, all metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater as-sessment is required.

For mesotrione,

- Metabolite AMBA has not the potential to reach the groundwater in concentrations above 0.1 µg/L.
- Metabolite MNBA concentration is above the trigger value in groundwater (0.121 µg/L). Results of the accepted toxicological studies is given in the following table. MNBA is not considered relevant from a toxicological point of view.

- **Summary of the results of toxicity studies for MNBA**

Type of test, species (Guideline)	Result	Acceptability	Reference
Acute oral toxicity	LD_{50} >5000mg/kg	Yes	Robinson (1996)*
28 day oral toxicity study in the rat	NOAEL >1000mg/kg	Yes	Milburn (1998)*

Type of test, species (Guideline)	Result	Acceptability	Reference
(gavage)			
90 day dietary toxicity study in the rat	NOAEL 650ppm (50.6 mg/kg) males 3000ppm (263.7 mg/kg) females	Yes	Rattray (2000)*
Bacterial Reverse Mutation	Not genotoxic	Yes	Callander (1996)*
In vitro Cytogenetics	Not genotoxic	Yes	Fox (200)*
Unscheduled DNA Synthesis (UDS) *in vivo*	Not genotoxic	Yes	Clay (2000)*
Rat Bone Marrow Micronucleus test *in vivo*	Not genotoxic	Yes	Fox (2000)*
Developmental toxicity study in the rat	NOAEL >1000mg/kg	Yes	Pottle (2016)
Two generation reproduction study in the rat	NOAEL >1000mg/kg	Yes	Gilmore (2016)
Effects of MNBA on HPPD	MNBA does not inhibit HPPD	Yes	Elcombe and Meadowcroft (1998)*
MNBA: Biotransformation in the rat	MNBA is quantitatively metabolised to AMBA	Yes	Gledhill (2000)*

* Indicates that a study was reviewed at EU level.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substances dicamba and mésotrione are not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et à la demande associée

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active mésotrione, et d'extension d'usage majeur du produit phytopharmaceutique ***CALLISTO PLUS***

de la société	*SYNGENTA FRANCE SAS*
enregistrées sous les	*n°2017-2370 et 2018-3859*

Vu les conclusions de l'évaluation de l'Anses du 9 mars 2021 et du 5 novembre 2021,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits règlementés de l'Anses le 5 novembre 2021,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Noms du produit	CALLISTO PLUS CALLIDO PLUS MERISTO PLUS LUMESTRA PLUS LUMICA PLUS LUMEO PLUS CALUMA PLUS
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 1228 Chemin de l'Hobit 31790 SAINT SAUVEUR France
Formulation	Suspension concentrée (SC)
Contenant	120 g/L - dicamba 50 g/L - mésotrione
Numéro d'intrant	957-2012.01
Numéro d'AMM	2160248
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2023.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 22/11/2021

DocuSigned by:
Charlotte Grastilleur
AE281A855A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Modalités d'autorisation du produit

Vente et distribution

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

Emballage	Contenance
Bouteilles en polyéthylène haute densité / polyamide	1 L
Bouteilles en polyéthylène téréphtalate	1 L
Bidons en polyéthylène haute densité	10 L
Bidons en polyéthylène haute densité fluoré	5 L ; 20 L

Classification du produit

La classification retenue est la suivante :

Catégorie de danger	Mention de danger
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme

EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique

Pour les phrases P se référer à la règlementation en vigueur.

Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15555901 Maïs*Désherbage	**2 L/ha**	**1/an**	entre les stades BBCH 12 et BBCH 19	F (BBCH 19)	5	-	20	-
	Uniquement sur maïs. La possibilité de fractionnement de la dose est retirée, car les données disponibles ne permettent pas de s'assurer que ce mode d'application ne présente pas de risque d'effet nocif ou inacceptable.							

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
13205901 Canne à sucre*Désherbage	2 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les organismes aquatiques, ni de démontrer la sélectivité du produit.		

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 48 heures.

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Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente.

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures pendant une période de 6 mois.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Il appartient à l'agriculteur multiplicateur, avant toute utilisation du produit, de consulter le semencier concerné ou de respecter les préconisations du prestataire de production concerné.

- Préciser les conditions optimales d'installation des cultures suivantes et de remplacement.

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

Dans le livret, le tableau des usages :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLE	DOSE AUTORISEE	PERIODE D'APPLICATION	DELAI AVANT RECOLTE	NOMBRE D'APPLICATION	ZONE NON TRAITEE
Maïs (grain et fourrage)*	désherbage	2 l/ha	BBCH 12 à BBCH 19	BBCH 19 max	1 application (fractionnement possible à condition de ne pas dépasser la dose de 2 l/ha au total/ha/an).	5 mètres (dont 5 mètres de DVP**) par rapport à un point d'eau et 20 mètres par rapport à la zone non cultivée adjacente

* Le maïs doux est exclu de cet usage. En production de semences, il est recommandé de s'assurer de l'absence de phytotoxicité et de contacter l'obtenteur des variétés concernées.
** DVP : Dispositif Végétalisé Permanent non traité.

est remplacé par le suivant :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLE	DOSE AUTORISEE	PERIODE D'APPLICATION	DELAI AVANT RECOLTE	NOMBRE D'APPLICATION	ZONE NON TRAITEE
Maïs (grain et fourrage)*	Désherbage	2 L/ha	BBCH 12 à 19	BBCH 19 max	1 application (fractionnement possible à condition dene pas dépasser la dose de 2 l/ha au total/ha/an)	5 mètres (dont 5 mètres de DVP**) par rapport à un point d'eau et 20 mètres par rapport à la zone cultivée adjacente
Canne à sucre	Désherbage	2 L/ha	traiter jusqu'à une hauteur de canne de 120cm	soit un DAR de 6 à 7 mois		

* Le maïs doux est exclu de cet usage. En production de semences il est recommandé de s'assurer de l'absence de phytotoxicité et de contacter l'obtenteur des variétés concernées.
** DVP : Dispositif Végétalisé Permanent non traité

Dans ce même livret, à la suite du paragraphe sur le maïs, un paragraphe canne à sucre est ajouté :

UTILISATION DE CALLISTO PLUS SUR CANNE A SUCRE :
CALLISTO PLUS s'utilise en post-levée des adventices.
Afin d'assurer une bonne pénétration et une bonne diffusion des substances actives par systémie, le traitement doit être réalisé sur :
- dicotylédones annuelles à des stades jeunes (2 à 6 feuilles maximum),
- dicotylédones vivaces et lianes à des stades développés mais toujours avant formation des organes floraux.
L'application doit être soignée en évitant qu'une végétation trop développée ne fasse obstacle à la pulvérisation ("effet parapluie").
La dose de CALLISTO PLUS et l'emploi éventuel d'un herbicide partenaire associé seront raisonnés, en fonction de la nature de la flore.

De nombreuses dicotylédones sont sensibles à CALLISTO PLUS, dont :
Portulaca oleracea, Cardiospermum halicacabum, Mucuna pruriens, Merremia aegyptia, Sigesbeckia orientalis, Amaranthus dubius, Ipomeae sp.

Sensibilité des cultures :
Cultures voisines sensibles : éviter toutes projections de CALLISTO PLUS ou dérives d'embruns lors de la pulvérisation vers les cultures voisines sensibles connues : cultures légumières, bananier, pomme de terre, cultures florales et ornementales, agrumes et autres arbres fruitiers.
À proximité de ces cultures, préférer l'utilisation de buses à injection d'air.
Cultures suivantes dans le cadre de la rotation : nous consulter.

Stades et doses d'application recommandés
Pour lutter contre une flore de dicotylédones annuelles et vivaces, CALLISTO PLUS s'utilise en une application unique à la dose de 2 l/ha. En cas de levées échelonnées dans le temps ou en cas de forte infestation pouvant former une masse végétale compacte, il est possible de fractionner l'application de CALLISTO PLUS.
L'intervention plus spécifique sur les lianes doit être effectuée sur des adventices développées pour avoir une surface foliaire suffisante, mais avant la formation des organes floraux.
Dans tous les cas, la dose totale ne doit pas dépasser 2 l/ha.

Sur l'étiquette DOS, nous proposons de remplacer le tableau des usages :

CULTURES AUTORISÉES, UNIQUEMENT :	CIBLE	DOSE AUTORISEE	DÉLAI AVANT RÉCOLTE ou STADE D'APPLICATION
Maïs*	Désherbage	2 L/ha**	Traiter entre BBCH 12 et 19

* Le maïs doux est exclu de cet usage. En production de semences il est recommandé de s'assurer de l'absence de phytotoxicité et de contacter l'obtenteur des variétés concernées.
** Fractionnement autorisé à condition de ne pas dépasser la dose de 2 L au total/ha/an.

par le suivant :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLE	DOSE AUTORISEE	DELAI AVANT RECOLTE ou STADE DE LA CULTURE
Maïs*	Désherbage	2 L/ha**	traiter entre BBCH 12 et 19
canne à sucre	Désherbage	2 L/ha**	traiter jusqu'à une hauteur de canne de 120cm

* Le maïs doux est exclu de cet usage. En production de semences il est recommandé de s'assurer de l'absence de phytotoxicité et de contacter l'obtenteur des variétés concernées.
** Fractionnement autorisé à condition de ne pas dépasser la dose de 2 L au total/ha/an .

Appendix 3 Letter of Access

Not applicable.