REGISTRATION REPORT
Part A

Risk Management

Product name: **Arigo (DPX-Q9H36 51WG)**

Active Substances: **Mesotrione 360 g/kg,**
Nicosulfuron 120 g/kg and
Rimsulfuron 30 g/kg

Central Zone

Zonal Rapporteur Member State: Czech Republic

NATIONAL ADDENDUM - Germany

Applicant: **DuPont de Nemours**

Date: **12/02/2013**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of ARIGO containing mesotrione, nicosulfuron and rimsulfuron in Germany. This evaluation is required subsequent to the inclusion of mesotrione, nicosulfuron and rimsulfuron on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in DPX-Q9H36 51WG Registration Report, Part B Sections 1-7 and Part C from the Czech Republic and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to ARIGO where that data has not been considered in the EU review. Otherwise assessments for the safe use of ARIGO have been made using endpoints agreed in the EU review of mesotrione, nicosulfuron and rimsulfuron.

This document describes the specific conditions of use and labelling required for Germany for the registration of ARIGO.

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

Appendix 2 of this document is a copy of the approved product label for Germany.
The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.
Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by DuPont de Nemours on 25 August 2011.

The application was for approval of ARIGO, a water dispersible granules formulation (blend) containing 360 g/kg mesotrione, 120 g/kg nicosulfuron and 30 g/kg rimsulfuron for use as a herbicide for use in maize to control a range of grass and broad-leaved weeds.

1.2 Annex I inclusion

Mesotrione, as set out in the Annex of Part A of Commission implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, this active substance shall be deemed to have been approved under Regulation (EC) No 1107/2009 (repealing Directive 91/414/EEC).

These concerns for mesotrione have been addressed within the current submission. The notifier and data owner is Syngenta Crop Protection AG.

The SANCO report for mesotrione (SANCO/1416/2001 –Final, 14 April 2003) is considered to provide the relevant review information or a reference to where such information can be found.

The Annex of Regulation (EU) No 540/2011:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 April 2003 shall be taken into account. The Annex of Regulation (EU) No 540/2011 states that no particular issues have been identified as requiring short term attention from the Member States.

Nicosulfuron, as set out in the Annex of Part A of Commission implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, this active substance shall be deemed to have been approved under Regulation (EC) No 1107/2009 (repealing Directive 91/414/EEC).

DuPont was not the notifier for the Annex I inclusion of nicosulfuron. DuPont manufactures technical nicosulfuron which is used in DuPont products. Technical nicosulfuron from DuPont was evaluated by Belgium and deemed to be equivalent to the technical material evaluated for the Annex I inclusion. DuPont has a complete Annex II data set for nicosulfuron, the RMS opinion on the completeness of the DuPont dossier was published on CIRCA on 1 February 2010.

The Annex of Regulation (EU) No 540/2011 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

The Annex of Regulation (EU) No 540/2011:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account In this overall assessment, Member States must pay particular attention to:

The potential exposure of the aquatic environment to metabolite DUDN (DuPont code IN-77799) when nicosulfuron is applied in regions with vulnerable soil conditions,

The protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,

The protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone,

The protection of groundwater and surface water under vulnerable soil and climatic conditions.

These concerns have been addressed within the current submission.

Rimsulfuron, as set out in the Annex of Part A of Commission implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, this active substance shall be deemed to have been approved under Regulation (EC) No 1107/2009 (repealing Directive 91/414/EEC).

The Annex of Regulation (EU) No 540/2011 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

The Annex of Regulation (EU) No 540/2011:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rimsulfuron, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. In this overall assessment, Member States must pay particular attention to:

The protection of non-target plants and groundwater in vulnerable situations, risk mitigation measures should be included where appropriate.

These concerns have been addressed within the current submission.

1.3 Regulatory approach

To obtain approval the product ARIGO must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first approval of this product/use in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ARIGO, it is indicated in the reference lists in Appendix 1 of the Registration report, Part B, sections 1 – 7 and Part C.

1.5 Letters of Access

Data access has been proven. A letter of access for the use of Mesotrione studies owned by Syngenta has been provided.

2 Details of the authorisation

2.1 Product identity

Product Name	DPX-Q9H36 51WG - Arigo
Authorization Number (for re-registration)	007526-00
Function	herbicide
Applicant	DuPont de Nemours
Composition	30 g/kg rimsulfuron 120 g/kg nicosulfuron 360 g/kg mesotrione
Formulation type	Water dispersible granules [Code: WG]
Packaging	330 to 1650 g bottles, HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following is proposed in accordance with Directive 99/45/EC in combination with the latest classification and labelling guidance under Directive 67/548/EEC (i.e. in the 18th ATP published as Directive 93/21/EEC):

Symbol(s)/Indication(s) of danger:	
N	Dangerous for the environment
Xn	Harmful
Risk phrases:	
R22	Harmful if swallowed
R41	Risk of serious damage to eyes
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
RA134	Contains 2-aminosulfonyl-N,N-dimethylnicotinamid. May produce allergic reaction
RA155	Contains urea, polymer with formaldehyde. May produce allergic reactions
Safety phrases:	
S2	Keep out of the reach of children
S13	Keep away from food, drink and animal feeding stuffs
S24	Avoid contact with skin
S26	In case of contact with the eyes, rinse thoroughly and seek medical advice
S35	This material and its container must be disposed of in a safe way
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S46	If swallowed, seek medical advice immediately and show this container or label
S57	Use appropriate container to avoid environmental contamination.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	

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

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
Hazard pictograms:	

GHS 09	
Signal words:	
Danger	
Hazard statements:	
H302	Harmful if swallowed
H318	Causes serious eye damage
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Special rule for labelling of PPP:	
EUH208-0113	Contains 2-aminosulfonyl-N,N-dimethylnicotinamid. May produce allergic reaction
EUH208-0137	Contains urea, polymer with formaldehyde. May produce allergic reactions
EUH401	To avoid risks to man and the environment, comply with the instructions for use
Supplemental labelling information	

2.2.3 R and S phrases under Directive 2003/82/EC (Annex IV and V)

Risk Phrases: None.
Safety Phrases: None.

2.2.4 Other phrases

Labelling phrases for human health protection

SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

Phrases for IPM/sustainable use

WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
WP734	Damage is possible to the crop.
WH960	The risk of replanting has to be indicated on the package and in the instructions of use. Particularly the endangered succeeding crops have to be declared and measures for a

	risk management have to be described.
WH951	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
WMB	Mode of Action (HRAC-Group): B
WMF2	Mode of action (HRAC-Group): F2
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

Phrases for protection of the environment

NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW265	The product is toxic for higher aquatic plants.
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NG200	The plant protection product may only be used for the crop growth stages stipulated by authorisation.
NG326-1	The maximum application rate of 45 g nicosulfuron per hectare for the same area – even in combination with other plant protection products containing this active substance – may not be exceeded.
NG327	Products containing the active substance nicosulfuron must not be used in the following calendar year on the same area.

NW 605-1	When applying the product on areas adjacent to surface waters – except only occasionally but including periodically water bearing surface waters – the product must be applied with equipment which is registered in the index of ‘Loss Reducing Equipment’ of 14 October 1993 (‘Bundesanzeiger’ [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with “*”. 50 % and 75 % drift reduction: 5 m buffer; 90 % drift reduction: no buffer required but no use directly adjacent to waterbodies
NW 606	When applying the product on areas adjacent to surface waters – except only occasionally but including periodically water-bearing surface waters – the product

	must be applied observing the minimum buffer zone stated below. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. Minimum buffer zone: 10 m
NW 706	Between treated areas which have an incline of more than 2 % and surface waters – including periodically but excluding occasionally water-bearing surface waters – there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 20 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.
NT108	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

2.3 Product uses

GAP rev. (1), date: 2013-01-23

PPP (product name/code)	Arigo (007526-00/00)	Formulation type:	WG
active substance 1	Rimsulfuron	Conc. Of as 1:	30 g/kg
active substance 2	Nicosulfuron	Conc. Of as 2:	120 g/kg
active substance 3	Mesotrione	Conc. Of as 3:	360 g/kg

Applicant :	DuPont de Nemour	professional use	X
Zone(s) :	central zone	non professional use	☐
Verified by MS:	yes		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season]	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Maize ZEAMX	F	annual monocotyledonous weeds TTTMS annual	spraying	BBCH 12 – 18; post-emergence	a) 1 b) 1	a) 0.33 b) 0.33	Rimsulfuron a) 0.01 b) 0.01 Nicosulfuron a) 0.04	200 – 400	F	WH9161 WP734 NW 605-1 (50 an 75 % drift reduction: 5 m

				dicotyledonous weeds TTTDS					b) 0.04 Mesotrione a) 0.119 b) 0.119			buffer; 90 % drift reduction: no buffer required) NW 606 (without drift reduction: 10 m buffer) NW706 NT108 mandatory tank mix with DU PONT TREND (004873-00/00) a) 0.3 L/ha b) 0.3 L/ha

<u>General remarks/explanations:</u>

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:

<u>Type:</u> *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes – GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

<u>Conc. Of as:</u> g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

<u>Explanations to the particular columns:</u>

No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.
Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group – at least in a footnote).
If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).
Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).
Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling 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. If necessary – in case of pest groups – exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.
Application details:
Method / Kind:
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.
Timing of Application / Growth stage of crop & season:
Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.
Number of applications and interval between applications
a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.
It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.
Application rate:
Application rate of the product per ha:
a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.
Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.
For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.
See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).
Application rate of the active substance per ha:
a)-(Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.
The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.
Water L/ha:
It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
PHI (days) – minimum pre harvest interval: PHI – minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).
Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
The test item Arigo was a blend of 72 % of Mesotrione 50WG (DPX-YP307-013), 16 % of Nicosulfuron 75WG (DPX-V9360-166) and 12 % of Rimsulfuron 25SG (DPX-E9636-157). For the evaluation of physical and chemical properties, the required quantities of the test item were blended by weighing individual granule formulation Mesotrione 50WG, Nicosulfuron 75WG and Rimsulfuron 25SG in the ratio 72 : 16 : 12.
The appearance of the product is that of a mixture of white and off-white granules, with no odour. It is not explosive and has no oxidising properties. The self-ignition temperature of DPX-Q9H36 51WG is 353.2°C. In aqueous solution, it has a pH value between 4.3 to 4.4 pH units. The preparation was tested for dustiness in accordance with CIPAC Method MT 171 and found to be “essentially non-dusty.” The stability data indicate a shelf life of at least two years at ambient temperature. Regarding the persistent foaming a value of 81 mL after 1 minute was measured. This value is too high, but after 3 min the value is acceptable and there seems to be no problems during application.
Except for persistent foaming its technical characteristics are acceptable for a water-dispersible granule formulation.
The zRMS did an analysis of the content of the active substances. It was found, that the content of rimsulfuron was not in compliance with the FAO specification. Due to degradation the value was too low. Therefore the zRMS recommended an overdosage of the rimsulfuron. An overdosage of rimsulfuron is not allowed for the authorisation of Arigo in Germany. The shelf life study at room temperature does not show any degradation of rimsulfuron after two years. If after that time the content of the active substance may be to low the applicant has to ensure that the traders know about this problem.

Implications for labelling: *None*

Compliance with FAO specifications:
The product Arigo complies with FAO specifications except the persistent foaming.

Compliance with FAO guidelines:
The product Arigo complies with FAO specifications, as far as could be assessed.

Compatibility of mixtures:
No tank mixtures with other plant protection products are foreseen. But according to the instructions for use the additive DuPont Trend should be used.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling Arigo has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The provided method for the analysis of the active substances in the formulation uses an HPLC/UV system with a Zorbax Eclipse XDB-C8 column. It was successfully evaluated and meets the EU criteria with respect to linearity, precision, (repeatability), accuracy (recovery), and specificity.
There is currently no CIPAC method available for the determination of mesotrione. For nicosulfuron the method CIPAC/4443 and for rimsulfuron the method CIPAC/4445 is available. Both methods are usable for WG-formulations.
Also for the determination of the relevant impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one in mesotrione formulated materials a method is available: LC/MS using a Waters BEH C18 column with MS-detection. The method was validated for other formulations than Arigo. Therefore appropriate information about the selectivity of the method for Arigo is missing. The LOQ of the method was determined taking the lowest calibration level into account. The LOQ of 1 µg/g according to the product is higher than the maximum acceptable level of 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one in Arigo of 0.72 µg/g. The presented data show, that the method should also be suitable for the lower level but nevertheless further data should be submitted.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Sufficiently analytical methods are available to ensure the enforcement of the respective limits.
However, the following deficiencies have been identified:

- An analytical method, the respective ILV and the respective confirmatory method for the determination of residues in commodities with high oil content and in commodities with high acid content
- An ILV and the validiation of a second MRM with respect to the analytical method for the determination of residues in dry commodities and in commodities with high water content and in commodities with high acid content
- The validiation of a second MRM with respect to the analytical methods for the determination of residues in food of animal origin (fat) and soil.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

ARIGO was not the representative formulation evaluated for the Annex I inclusion of mesotrione, nicosulfuron or rimsulfuron. Acute toxicity tests were not carried out using ARIGO. ARIGO is a blend of three formulations that contains mesotrione, nicosulfuron and rimsulfuron in a 12:4:1 ratio. The representative formulations Mesotrione 50WG, Nicosulfuron 75WG and Rimsulfuron 25SG have each been fully tested for acute toxicity and the results are bridged to determine the toxicity of the blend ARIGO. The acute toxicity of ARIGO is expected to be similar to that of its components. According to the Directive 2001/59/EC, and taking into account all submitted data classification for acute toxicity is not required for ARIGO.
Therefore, all relevant data were provided and are considered adequate.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to ARIGO was not evaluated as part of the EU review of mesotrione, nicosulfuron or rimsulfuron, although operator exposure for different formulations applied to the same crop at a higher application rate were submitted and evaluated in the EU review. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure to mesotrione was assessed against the AOEL agreed in the EU review (0.015 mg/kg bw/day). Data on dermal absorption of mesotrione applied as ARIGO provided by DuPont was re-calculated. Operator exposure was modelled using UK OPEX and German models.

Operator exposure to nicosulfuron was not assessed against the AOEL (0.15 mg/kg bw/day) proposed by DuPont, but against the AOEL agreed in the EU review (0.8 mg/kg bw/day). Data on dermal absorption of nicosulfuron applied as ARIGO provided by DuPont was re-calculated Operator exposure was modelled using UK OPEX and German models.

Operator exposure to rimsulfuron was assessed against the AOEL (0.07 mg/kg bw/day) agreed in the EU review. Data on dermal absorption of rimsulfuron applied as ARIGO provided by DuPont was re-calculated Operator exposure was modelled using UK OPEX and German models.
According to the model calculations, it can be concluded that the risk for the operator using ARIGO on maize is acceptable with the use of personal protective equipment, gloves for mixing and loading.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Bystander exposure to ARIGO was not evaluated as part of the EU review of mesotrione, nicosulfuron or rimsulfuron, although bystander exposure for different formulations applied to the same crop at a higher application rate were submitted and evaluated in the EU review. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Worker exposure to ARIGO was not evaluated as part of the EU review of mesotrione, nicosulfuron or rimsulfuron, although worker exposure for different formulations applied to the same crop at a higher application rate were submitted and evaluated in the EU review. Therefore all relevant data and risk assessments have been provided and are considered to be adequate. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with ARIGO. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Implications for labelling resulting from operator, worker, bystander assessments:

Hazard Symbol: -
Indication of danger: -
Risk Phrases: -
Safety Phrases: S2, 13, 24, 26, 36/37/39, 46
R and S phrases under Directive 2003/82/EC (Annex IV and V): -
SF245-01: Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Other phrases: -

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

ARIGO 51WG was not the representative formulation evaluated for Annex I inclusion or for the establishment of EU MRLs for mesotrione, nicosulfuron or rimsulfuron.

The EU MRL evaluation of mesotrione reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA model. The MRLs for mesotrione are published in Annexes of Regulation (EC) No 396/2005. The MRL is set at the LOQ of 0.05 mg/kg of the methods.

The EU temporary MRL for nicosulfuron in maize has been established at 0.1 mg/kg (Regulation EC 149/2008 amending Regulation 396/2005) on the basis of existing member state MRLs. The EFSA conclusion on nicosulfuron proposes an MRL for maize grain of 0.01 mg/kg, the LOQ of the analytical method. This MRL is proposed on the basis of the evaluation of data generated using a liquid formulation of nicosulfuron at a higher application rate than that proposed for nicosulfuron when applied as ARIGO. Thus the proposed use of ARIGO is covered by the temporary and proposed EU MRLs. Residue trials have been conducted using the Nicosulfuron 75WG formulation, a component of the ARIGO blend, at the critical EU GAP rate of 60 g a.s./ha applied in maize at BBCH growth stage 18. The results show that MRLs resulting from the use of nicosulfuron applied as Nicosulfuron 75WG are within the temporary and proposed EU MRLs.

EU MRLs for rimsulfuron in maize, potato, and tomato were established in Commission Directive 2007/62/EC and are included in Annex II to Regulation (EC) No. 396/2005. The MRL is set at 0.05 mg/kg, the LOQ of the methods. This MRL is proposed on the basis of the evaluation of data generated using a WG formulation of rimsulfuron at a higher application rate than that proposed for rimsulfuron when applied as ARIGO.

The proposed uses of ARIGO are within those supported for the EU MRL assessment for mesotrione, nicosulfuron and rimsulfuron, therefore no further evaluation is required for national registration of ARIGO.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.01 mg/kg bw/day for mesotrione, the ADI of 2 mg/kg bw/day for nicosulfuron and the ADI of 0.1 mg/kg bw/day for rimsulfuron. It can therefore be concluded that acceptable margins of safety exist for consumers. TMDI calculations using the EFSA model, were performed to take account of all crops to which mesotrione, nicosulfuron and rimsulfuron may be applied.

According to the current EFSA model, the chronic exposures (WHO Cluster Diet E) are:

Mesotrione 12 % of ADI,
nicosulfuron 0,08 % of ADI and
rimsulfuron 1,2 % of the ADI.

Based on the different calculations made to estimate the risk for consumer though diet and other means it can be concluded that the use of product ARIGO does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product DPX-Q9H36 51WG (=ARIGO) in its intended uses in maize is documented in detail in the core assessment of the plant protection product DPX-Q9H36 51WG dated from July 2012 performed by Czech Republic.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of ARIGO in Germany according to its intended use in maize (use No. 00-001).

Metabolites of Mesotrione

No new study on the fate and behaviour of Mesotrione or ARIGO has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of mesotrione has already been performed for EU approval (see SANCO/1416/2001 – 14/04/2003). The metabolites are considered toxicologically and ecotoxicologically not relevant and did not penetrate into groundwater. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

For details see Part B, National Addendum, section 5, chapter 5.3.1.

However, the leaching potential into groundwater of the soil metabolites MNBA and AMBA will be assessed for the application of the plant protection product and its intended uses. Additionally, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of MNBA and AMBA are included.

Metabolites of Nicosulfuron

No new study on the fate and behaviour of nicosulfuron or the plant protection product DPX-Q9H36 51WG (=ARIGOA) has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of nicosulfuron has already been performed for EU approval (see SANCO/3780/07 – rev. 1 from 22 January 2008). The metabolites are considered toxicologically and ecotoxicologically not relevant. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

For details see Part B, National Addendum, section 5, chapter 5.3.2.

However, the leaching potential into groundwater of the soil metabolites of nicosulfuron will be assessed for the application of the plant protection product and its intended uses. Additionally, the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration will be performed for the soil metabolites of nicosulfuron.

Metabolites of Rimsulfuron

No new study on the fate and behaviour of rimsulfuron or ARIGO has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of rimsulfuron has already been performed for EU approval (see SANCO/10528/2005 – 27/01/2006). The metabolites are considered toxicologically and ecotoxicologically not relevant. Therefore no new risk assessment of these metabolites for aquatic organisms hence no exposure assessment is necessary. However regarding terrestrial organisms, the risk assessment of these metabolites for EU approval of rimsulfuron is not considered sufficient enough for approval of plant protection products in Germany. Thus, PECsoil values of the metabolites IN-7094 and IN-E9260 were calculated for the intended uses of ARIGO in maize.

For details see National Addendum, section 5, chapter 5.3.3.

Additionally, the leaching potential into groundwater of the soil metabolites IN-70941, IN-70942, and IN-E9260 will be assessed for the application of the plant protection product and its intended uses. Additionally, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of IN-70941, IN-70942, and IN-E9260 are included.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product ARIGO in maize according to use no. 00-001, PECsoil was calculated for the active substance mesotrione considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance mesotrione in soil the accumulation potential of mesotrione was not considered.

For the intended use of the plant protection product ARIGO in maize according to use no. 00-001, PECsoil was calculated for the active substance nicosulfuron considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance nicosulfuron in soil the accumulation potential of nicosulfuron was not considered. Therefore PECsoil used for risk assessment comprises background concentration in soil (PECaccu) considering a tillage depth of 20 cm (arable crop) and the maximum annual soil concentration PECact considering the relevant soil depth of 2.5 cm.

For the intended use of the plant protection product ARIGO in maize according to use no. 00-001, PECsoil was calculated for the active substance rimsulfuron considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance rimsulfuron in soil the accumulation potential of rimsulfuron was not considered. Additional PECsoil values were calculated for the soil metabolites IN-70941 and IN-E9260 of rimsulfuron. Due to the slow degradation of IN-70941 and IN-E9260, the accumulation potential of these metabolites was considered.

Additional $PEC_{soil,act}$ was calculated for the formulation ARIGO for a soil depth of 2.5 cm.

Details are given in Part B National Addendum-Germany, Section5, chapter 5.5.

The results for PEC soil for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

Results of modelling with FOCUS-PELMO 5.5.3 show that concentrations of ≥ 0.1µg/L of the active substance mesotrione in groundwater cannot be excluded for a yearly application of ARIGO in the intended use in maize. However, a groundwater contamination of the active substance mesotrione in concentrations of ≥ 0.1 µg/L can be excluded for only one application of ARIGO every other year the intended use in maize.

For the metabolite MNBA of mesotrione, concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. However, the metabolite MNBA is classified as not relevant for groundwater (see National Addendum, part B, section 8).

For the metabolite AMBA of mesotrione, concentrations of ≥ 0.1µg/L in groundwater cannot be excluded for a yearly application of ARIGO in the intended use in maize. However, for only one application every other year concentrations of ≥ 0.1µg/L in groundwater can be excluded for the metabolite AMBA.

Results of modelling with FOCUSPELMO 5.5.3 show that the active substance nicosulfuron is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses when applied only every other year.

For the metabolites HMUD, UCSN, ASDM and AUSN concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. The metabolites are considered to be ecotoxicologically not relevant.

Results of modelling with FOCUS-PELMO 5.5.3 show that the active substance rimsulfuron is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of ARIGO in maize.

For the metabolite IN-70942 of rimsulfuron concentrations of ≥ 0.1µg/L in groundwater can be excluded. For the metabolites IN-70941 and IN-E9260 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. However, the metabolites IN-70941 and IN-E9260 are classified as not relevant for groundwater (see National Addendum, part B, section 5, table 5.3-7).

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1

Consequences for authorization:

All uses NG 200, NG 326 and NG 327

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance mesotrione due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded. According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites MNBA and AMBA of mesotrione due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can also be excluded.

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance nicosulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance rimsulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded. According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites IN-70941, IN-70942 and IN-E9260 of rimsulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.2.

Consequences for authorization:

None

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product ARIGO in maize according to use no. 00-001, PECsw was calculated for the active substances mesotrione, nicosulfuron and rimsulfuron considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance mesotrione is < 10^{-5} Pa. Hence the mesotrione is regarded as non-volatile. Therefore exposure of surface water by mesotrione due to deposition following volatilization was not to be considered.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance nicosulfuron is < 10^{-5} Pa. Hence the active substance nicosulfuron is regarded as non-volatile. Therefore, exposure of surface water by the active substance nicosulfuron due to deposition following volatilization was not considered.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance rimsulfuron is < 10^{-5} Pa. Hence the rimsulfuron is regarded as non-volatile. Therefore, exposure of surface water by the rimsulfuron due to deposition following volatilization was not considered.

The concentration of the active substances mesotrione, nicosulfuron and rimsulfuron via spray drift and volatilization with subsequent deposition in an adjacent ditch was calculated with EVA 2.1.

The concentration of the active substances mesotrione, nicosulfuron and rimsulfuron in an adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

Not relevant due to low volatility.

Implications for labelling resulting from environmental fate assessment

NG 200	The plant protection product may only be used for the crop growth stages stipulated by authorisation.
NG 326-1	The maximum application rate of 45 g nicosulfuron per hectare for the same area – even in combination with other plant protection products containing this active substance – may not be exceeded.
NG 327	Products containing the active substance nicosulfuron must not be used in the following calendar year on the same area.

Further data requirements:

Submission of the results of a groundwater monitoring for the nicosulfuron and metabolites according to § 36 paragraph 5 PflSchG during the first 3 years after authorization. The concept has to be developed together with the authorization agencies. The monitoring results have to be submitted annually.

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product DPX-Q9H36 51WG (=ARIGO) in its intended uses in maize is documented in detail in the core assessment of the plant protection product DPX-Q9H36 51WG dated from July 2012 performed by Czech Republic. The intended use (use No. 00-001) in Germany is generally covered by the uses evaluated in the course of the core assessment by the Czech Republic.

The following chapters summarize specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of DPX-Q9H36 51WG in Germany according to its intended use in maize (use No. 00-001).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances mesotrione, nicosulfuron, and rimsulfuron according to the intended use of the formulation DPX-Q9H36 51WG in maize achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

Based on the presumptions of the screening step and the refinements of the chronic toxic endpoint of mesotrione and refinement for mesotrione residues in immature maize (DT_{50} = 0.5 d), the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substances mesotrione, nicosulfuron, and rimsulfuron according to the intended use of the formulation DPX-Q9H36 51WG in maize achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals.

For details of the risk assessment see Core Assessment, Part B, Section 6, Point IIIA 10.1 (birds) and IIIA 10.3 (terrestrial vertebrates other than birds) and National Addendum Germany, Section 6, Point 6.2 (birds) and Point 6.3 (other terrestrial vertebrates), respectively.

Consequences for authorization:

None

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended uses of DPX-Q9H36 51WG in maize based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter IIIA 10.2.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances mesotrione, nicosulfuron, and rimsulfuron are < 10^{-5} Pa. Therefore, exposure of surface water by the active substances mesotrione, nicosulfuron, and rimsulfuron due to deposition following volatilization was not considered. The concentration of the formulation DPX-Q9H36 51WG in surface water was calculated using the model DRIFTOX 4.0.

The aquatic risk assessment of spray drift entries in surface water by the use of DPX-Q9H36 51WG in maize according to use No. 00-001 is based on the effects of DPX-Q9H36 51WG to the aquatic plant *Lemna*.

Based on the relevant toxicity of the formulation DPX-Q9H36 51WG, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to DPX-Q9H36 51WG according to the use No 00-001 only achieve the acceptability criteria of TER $\geq$ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 when appropriate risk mitigation measures (10 m buffer stripe or drift reducing technique) are applied.

For details see Part B, National Addendum-Germany, Section 6, chapter 6.4.3.

2. Exposure by surface run-off and drainage

The concentration of the active substances mesotrione, nicosulfuron, and rimsulfuron in an adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substances mesotrione, nicosulfuron, and rimsulfuron due to run-off and drainage according to the use No 00-001 achieve the acceptability criterium of TER $\geq$ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2, when appropriate risk mitigation measures are applied. The TER(mix) assuming a dose and effect additivity of the three active ingredients does not achieve the acceptability criterium of TER $\geq$ 10. However, due to the steep concentration-effect-relationship observed in the *Lemna* study with the formulation DPX-Q9H36 51WG with the NOEC only 3.2 times lower than the EC_{50} of DPX-Q9H36 51WG, the slight deviations of the TER(mix) = 8.3 and TER(mix) = 8.6 from the proposed acceptability criterium of 10 indicate an acceptable risk for aquatic organisms. Risk mitigation measures need to be applied.

For details see Part B, National Addendum-Germany, Section 6, chapter 6.4.3.

Consequences for authorization:

For the authorization of the plant protection product DPX-Q9H36 51WG the following labelling and conditions of use are mandatory:

<u>Required Labelling</u>

NW 262	rimsulfuron: *Selenastrum capricornutum,* NOEC: 0.625 mg/L
NW 263	rimsulfuron: *Daphnia magna,* NOEC: 0.82 mg/L
NW 265	nicosulfuron: *Lemna gibba,* NOEC: 0.0020 mg/L

<u>Conditions for use</u>

All uses	NW 605-1 (50 an 75 % drift reduction: 5 m buffer; 90 % drift reduction: no buffer required) NW 606 (without drift reduction: 10 m buffer) NW 706 (conventional: 20 m)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

The acute risk to honey bees from use of DPX-Q9H36 51WG was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (EPPO 2003) as follows:

$$\textit{Hazard Quotient} = \frac{\textit{Maximum application rate (g formulation/ha)}}{\textit{Acute } LD_{50} \textit{ (}\mu g \textit{ formulation/bee)}}$$

Hazard quotients were calculated for oral exposure (Q_{ho}) and contact exposure (Q_{hc}) to DPX-Q9H36 51WG (see table below). A hazard quotient of less than 50 indicates a low risk to bees in the field.

Test substance	Exposure route	LD_{50} (µg /bee)	Maximum single application rate (g/ha)	Hazard quotient (HQ)	HQ assessment trigger
Mesotrione	Oral	= >11	120	10.9	< 50
	Contact	= >100	120	1.2	
Nicosulfuron	Oral	>1000 mg a.s./L in diet*	40	-	
	Contact	76	40	0.52	
Rimsulfuron	Contact	100	10	0.1	
Rimsulfuron 25 WG + IN-KG691 surfactant	Oral	41.1	10	0.24	
	Contact	27.9	10	0.36	
DPX-Q9H36 51WG + IN-KG691 surfactant	Oral	>209.6	330	1.6	
	Contact	190.9	330	1.7	

All hazard quotients (HQ) are considerably less than 50, indicating that DPX-Q9H36 51WG applied at the maximum use rate in maize poses low risk to bees.

Consequences for authorization:

NB6641

Other non-target arthropods

According to the herbicidal effects of the formulation DPX-Q9H36 51WG the effect values for non-target terrestrial arthropods demonstrate a substantially lower toxicity than the effects values determined for non-target plants. The latter are, therefore, relevant for the risk assessment for terrestrial biocoenosis. A quantitative risk assessment for non-target terrestrial arthropods was for that reason not conducted in the national addendum. For details please refer to the core assessment Part B, section 6, chapter IIIA 10.5.

Consequences for authorization:

None

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

Based on the predicted concentrations of mesotrione, nicosulfuron, rimsulfuron, and DPX-Q9H36 51WG in soil, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to DPX-Q9H36 51WG according to the GAP achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of DPX-Q9H36 51WG in maize according to the label.

For details please refer to the core assessment Part B, section 6, chapter IIIA 10.6 and to Part B, National Addendum-Germany, Section 6, chapter 6.7.

Consequences for authorization:

None

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of DPX-Q9H36 51WG in maize, data on the effects on organic matter breakdown (litterbag) is not required although metabolites of the active substances nicosulfuron and rimsulfuron meet the trigger on degradation in soil (DT_{90} > 365 d, 90^{th} percentile lab data or max. field data).

For details please refer to the core assessment Part B, section 6, chapter AIII 10.6.7 and to Part B, National Addendum-Germany, Section 5, chapter 5.4.1.

Consequences for authorization:

None

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

The Predicted Environmental Concentrations of the formulation DPX-Q9H36 51WG and its active substances mesotrione, nicosulfuron, and rimsulfuron in soil were below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure, indicating that the proposed use of DPX-Q9H36 51WG poses an acceptable risk to soil microorganisms.

For details please refer to the core assessment Part B, section 6, chapter AIII 10.7.

Consequences for authorization:

None

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

Based on the predicted rates of mesotrione, nicosulfuron, and rimsulfuron /DPX-Q9H36 51WG in off-field areas, the TER values describing the risk for non-target plants following exposure to mesotrione, nicosulfuron, and rimsulfuron /DPX-Q9H36 51WG according to the GAP of the formulation DPX-Q9H36 51WG achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of DPX-Q9H36 51WG in maize according to the label in conjunction with the proposed risk mitigation measures.

For details please refer to the national addendum Part B, section 6, chapter 6.9.

Consequences for authorization:

For the authorization of the plant protection product DPX-Q9H36 51WG, following labelling and conditions of use are mandatory:

<u>Conditions for use</u>

All uses	NT 108

Implications for labelling resulting from ecotoxicological assessment:

Hazard Symbol: N
Indication of danger: dangerous for the environment
Risk Phrases: R50/53
Other phrases: NW262, NW264, NW265, NG200, NG 326-1, NG327, NW468, NW605-1, NW 606, NW706, NT108

Classification & Labelling according to directive 1272/2008

Danger Symbol:	GHS09
Hazard Statements:	H400, H410

3.1.7 Efficacy (Part B, Section 7, Point 8)

Summary and assessment of data according to Points IIIA 6.1 to 6.5

It is apparent from the results there are no differences between data from different EPPO zones.

The influence of the geographic location of trials on the performance of the tested product was not significant. Therefore, summary results from EPPO zones can also be considered relevant to support authorisation in cMS.

Crop and/ or situation		Corn (Field and Silage)
Member state or country		Austria, Czech Republic, Germany, Hungary, Poland, Slovakia
F G or I		F
Pests or group of pests controlled		Grass & Broad-leaf weeds
Application	method kind	broadcast, ground directed spraying
	Growth stage	between BBCH 12 and BBCH 18 (from 2 leaves to 8 leaves of the crop)
	number max	1
Application rate per treatment	kg a.s./hL min max	N/A
	water L/ha min max	200-400
	g a.s./ha/season max	39.6 g nicosulfuron + 9.9 g rimsulfuron + 118.8 g mesotrione
PHI (days)		none
Remarks:		TREND 90 should be added at 0.1%

DPX-Q9H36 51WG is a water-dispersible herbicide that contains 360 g/kg mesotrione, 120 g/kg nicosulfuron and 30 g/kg rimsulfuron. It will be applied once per crop and season. The maximum application dose is 168.3 g a.s./ha = single application DPX-Q9H36 51WG 330 g/ha + surfactant Trend 90 0,1% ™.

DPX-Q9H36 51WG is to be used in agricultural situations and under field conditions only. DPX-Q9H36 51WG is a selective herbicide which controls grass (annual and perennial) and broad leaf weeds in maize. The sensitivity of the weeds should be classified at the national level (cMS).

Consequences for authorization:
WH9161

DPX-Q9H36 51WG will be recommended for use on silage and grain maize varieties in the following countries of the EU central zone: Austria, Belgium, Czech Republic, Germany, Hungary, Poland, Romania, and Slovakia.

The results of the product testing demonstrated the benefit of combined products containing active substances with complementary effects, compared to products with one single active substance.

Thirty-three dose response field trials were carried out between 2009 and 2010 in Belgium, the Czech Republic, Great Britain, Germany, Hungary and Poland. The results demonstrated that 168.3 g a.s./ha (330 g product/ha) was the minimum effective dose of DPX-Q9H36 51WG required to provide effective and consistent control on the tested weeds.

Thirty-four efficacy trials were carried out between 2009 and 2010 in the central zone. Results from six different European countries demonstrated that DPX-Q9H36 51WG controls grass and broad leaf weed species in maize. The efficacy of DPX-Q9H36 51WG was comparable to or better than the performance of the reference standards. A positive effect of the addition of a surfactant, as recommended in the GAP, was observed.

Quality and quantity of yield were assessed in various trials either set up as specific phytotoxicity trials or as efficacy trials. An application of DPX-Q9H36 51WG at the recommended and at the double application rate increased the thousand grain weight, and resulted in higher starch content than the plants grown in the untreated plots. Starch content of the reference products was comparable. Yield quantity in terms of silage was increased compared to the reference product, while the yield of whole plants was increased compared to the untreated control and at least as high as for the reference products. Grain yield in terms of fresh and dry biomass were in general as high as the reference standards and higher than the untreated check in the majority of trials. Plant quality and yield quantity were not negatively influenced by the application of the test product. Thus, DPX-Q9H36 51WG can be safely applied to maize plants at the recommended dose of 168.3 g a.s./ha (330 g product/ha).

Crop tolerance was evaluated in 60 selectivity and efficacy trials which were carried out in Belgium, Czech Republic, Germany, Great Britain, Poland and Hungary on silage and field maize. Application of DPX-Q9H36 51WG to maize at rates of up to 336.6 g a.s./ha (2× the highest GAP rate) did not cause any phytotoxicity symptoms (noted as percentage of stunting, chlorosis or general phytotoxicity) in the majority of trials during the test period of 2009 and 2010. In 19 trials, symptoms were recorded; however, in the majority of trials these symptoms were no longer detectable after 51 days and had no impact on maize yield. The transient symptoms of phytotoxicity were observed. These effects are considered acceptable. Nevertheless, the restriction should be put on the label.

Consequences for authorization:
WP734

Adverse effects on plant parts (seed) used for propagation purposes did not occur. The latest time of application for DPX-Q9H36 51WG is crop growth stage BBCH 18. Since applications of DPX-Q9H36 51WG are made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. The germination of maize seeds was not negatively affected by the application of DPX-Q9H36 51WG.

DPX-Q9H36 51WG has been developed for use in maize as this crop is tolerant to mesotrione, nicosulfuron, and rimsulfuron and can be safely treated without any adverse impact on the final crop product, when used according to local recommendation. It is recommended that after the application of DPX-Q9H36 51WG in maize crop all winter cereals, including durum wheat, and spring cereal crops may be planted. In the case of drilling winter oil seed rape soil ploughing (15 cm) followed by cultivation is recommended. In the following spring any spring cereal crop may be drilled, for sunflower soil ploughing (15 cm) followed by cultivation is recommended. Do not sow any other crop at that time.

In case of crop failure for any reason, only maize may be sown after application of DPX-Q9H36 51WG, before sowing, it is recommended that the soil is ploughed.

Consequences for authorization:
WH960

No specific adjacent crop studies were conducted with DPX-Q9H36 51WG, however studies conducted on non-target plants were done and the results are presented. Non-target terrestrial plant response to DPX-Q9H36 51WG applied with IN-KG691 surfactant was evaluated on ten plant species (oat, sorghum, and corn as monocotyledonous species and oilseed rape, onion, cucumber, pea, soybean, sugar beet, and tomato as dicotyledoneous species). Effects on seedling emergence and early growth following soil surface application prior to emergence and the effects on vegetative vigour of young seedling plants following foliar exposure were assessed. Based on the probabilistic assessment using the SSD approach, DPX-Q9H36 51WG applied with IN-KG691 surfactant can be considered to be safe to non-target terrestrial plants for pre-emergent exposure with a 1-meter buffer and for post-emergent exposure with a 5 meter buffer. No further mitigation is necessary. Nevertheless, due to the nature of the product the restriction should be put on the label.

Consequences for authorization:
Please refer to the ecotox section.

DPX-Q9H36 51WG contains mesotrione, a potent bleaching herbicide that belongs to the triketone herbicide family (HRAC Group F2), and rimsulfuron and nicosulfuron, both sulfonylurea herbicides whose activity is based on the inhibition of the acetolactate synthase enzyme (ALS) (HRAC Group B). DPX-Q9H36 51WG is a post-emergence herbicide for the control of grass (annual and perennial) and broad-leaved weeds in corn with three herbicides and two different and independent mode of action.

Consequences for authorization:
WMF2, WMB

Resistance to sulfonylureas is well documented, with the first case recorded in United States in 1987. Since then further cases have been reported including grass and broad-leaved weed resistance in Europe. Monitoring programs conducted by DuPont in corn fields on TITUS® 25WG (rimsulfuron) has identified the appearance of resistant biotypes of *Echinochloa cruss-galli* to rimsulfuron, and cross resistance to nicosulfuron in Italy and Austria. Resistance to triketon herbicide family has been recently known. The probability that weeds develop resistant to rtiketones is very low, mainly because: a) this mode of action is relatively recent in the market, b) triketone herbicide competes with and is structurally similar to the subtracte of the HPPD enzyme, which means that a naturally occurring mutations that diminish the binding of the herbicide to the enzyme are also likely to reduce the binding of the subtract penalizing the function of the enzyme (fitness cost), c) mutants showing resistance to HPPD inhibitors are relatively infrequent. Only one case of resistance to triketon herbicides has been published, triketone resistant *Amaranthus tuberculatus* (common waterhemp) was reported in the Unites States in 2009. No resistant cases have been recorded in Europe. Although the HPPD inhibitors are considered as “low risk” compounds, the presence of sulfonylurea herbicides in DPX-Q9H36 51WG and its high risk resistant profile, indicate that the unmodified use of DPX-Q9H36 51WG could lead to the development of resistant weeds, therefore a management plan should be promoted for the commercial use of DPX-Q9H36 51WG. The product DPX-Q9H36 51WG, containing mesotrione (Mesotrione 50WG), nicosulfuron (Nicosulfuron 75WG) and rimsulfuron (Rimsulfuron 25SG), is a good strategy to prevent the development and spread of resistant biotypes of *Echinochloa cruss-galli*, base on the use of 2 different mode of action, ALS and HPPD, able to control the target resistant weed has already been proven under greenhouse conditions (see EU Biological Dossier, DuPont-31939). In order to responsibly manage and maintain the activity of the active substances in DPX-Q9H36 51WG, it is recommended that resistance management strategies are applied. The commercial product, should be used in rotation with herbicides with a different mode of action that are also active against the target weeds, cultural and mechanical practices should be implemented when possible and appropriate, monoculture situations should be avoided, destruction of all seeds produced by the weeds not controlled by the herbicide application is recommended. In addition, a monitoring program to determine any shifts in sensitivity toward the product will be also implemented.

Consequences for authorization:
WH951

The risk to non-target arthropods is assessed using the approach recommended in the published ESCORT 2 document (Candolfi *et al*. 2001). The potential risk of DPX-Q9H36 51WG to in-field non-target arthropods was assessed by calculation of the hazard quotients (HQ = exposure/toxicity) with the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) values according to the following formula:

$$\text{In field HQ} = \frac{\text{application rate (g product/ha)} \times \text{MAF}}{LR_{50}}$$

In-field HQ values for *Typhlodromus pyri* (LR_{50} > 333 g product/ha) and *Aphidius rhopalosiphi* (LR_{50} > 333 g product/ha) were < 2, indicating safety of DPX-Q9H36 51WG plus IN-KG691 surfactant. These assessments demonstrate that DPX-Q9H36 51WG is safe to non-target arthropods when used according to the proposed GAP.

Consequences for authorization:
NN1001, NN1002

In conclusion, DPX-Q9H36 51WG should be registered to control broadleaf and grass weeds in maize at an application rate of 330 g product/ha (168.3 g a.s./ha) + surfactant Trend 90 0,1% ™.

3.2 Conclusions

The product Arigo is a blend of three different WG formulation and is used as herbicide. For the evaluation of physical and chemical properties, the required quantities of the test item were blended by weighing individual granule formulation Mesotrione 50WG, Nicosulfuron 75WG and Rimsulfuron 25SG in the ratio 72 : 16 : 12. Except for persistent foaming its technical characteristics are acceptable for a water-dispersible granule formulation. The product Arigo complies with FAO specifications except the persistent foaming.
The provided method for the analysis of the active substances in the formulation uses an HPLC/UV system with a Zorbax Eclipse XDB-C8 column. It was successfully evaluated and meets the EU criteria with respect to linearity, precision, (repeatability), accuracy (recovery), and specificity.
Also for the determination of the relevant impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one in mesotrione formulated materials a method is available. Some information regarding the validation is missing (see 3.3).
With respect to efficacy/IPM and sustainable use criteria, DPX-Q9H36 51WG should be authorized to control broadleaf and grass weeds in maize at an application rate of 330 g product/ha (168.3 g a.s./ha) + surfactant Trend 90 0,1% ™. Based on the data on residues and toxicology, an authorisation can be granted. Based on the data on fate and ecotoxicology, an authorisation can be granted. The specific risk management measures outlined should be applied.

An authorisation can be granted.

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

Regarding the analysis of the relevant impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one appropriate information about the selectivity of the method for Arigo is missing. The LOQ of the method of 1 µg/g according to the product is higher than the maximum acceptable level of 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one in Arigo of 0.72 µg/g. The presented data show, that the method should also be suitable for the lower level but nevertheless further data should be submitted.

AnnexIII point	Data
KIIIA 5.2.4	Further information regarding the selectivity of the method for Arigo and regarding the validation data for the maximum acceptable level of 0.72 µg/g for the relevant impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one in the product.
KIIA 7.12	3-year groundwater monitoring study for nicosulfuron and metabolites

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Mit Zustellungsurkunde

DuPont de Nemours
(Deutschland) GmbH
- Abt. Pflanzenschutz -
Hugenottenallee 173 -175
63263 Neu-Isenburg

Dr. Dietmar Gottschild
Referent

TELEFON +49 (0)531 299-3512
TELEFAX +49 (0)531 299-3002
E-MAIL dietmar.gottschild@bvl.bund.de
INTERNET www.bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.007526-00/00.61577

DATUM 30. Januar 2013

ZV3 007526-00/00

ARIGO

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	360 g/kg	Mesotrione
	120 g/kg	Nicosulfuron
	30 g/kg	Rimsulfuron

Zulassungsnummer: 007526-00

Versuchsbezeichnung: DPB-79436-H-0-WG

Antrag vom: 25. August 2011

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. Juli 2017.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007526-00/00-001	Einjährige einkeim-blättrige Unkräuter, Einjährige zweikeim-blättrige Unkräuter	Mais	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281) festgesetzt:

(NG200)

Das Pflanzenschutzmittel darf nur in den bei der Zulassung festgesetzten Entwicklungsstadien der Kultur eingesetzt werden.

Begründung:

Die Begrenzung der Aufwandmenge und des Anwendungsintervalls für den Wirkstoff Nicosulfuron zielt darauf ab, den maximal resultierenden Wirkstoffeintrag in den Boden auf 33,75 g a.i./ha alle zwei Jahre zu beschränken. Dies ist nur gewährleistet, wenn die Anwendung der zugelassenen Mittel nicht vor dem in der Indikationen vorgesehenen Mais-Entwicklungsstadium BBCH 12-18, also bei einer Interzeption von mindestens 25% erfolgt.

(NG326-1)

Die maximale Aufwandmenge von 45 g Nicosulfuron pro Hektar auf derselben Fläche darf - auch in Kombination mit anderen diesen Wirkstoff enthaltenden Pflanzenschutzmitteln - nicht überschritten werden.

Begründung:

Für den Wirkstoff Nicosulfuron wurden alle vorhandenen Daten für Simulationsrechnungen mit dem Simulationsprogramm FOCUSPELMO5.5.3 verwendet. Als besonders sensibler Inputparameter erweist sich nach wie vor der Koc. Des Weiteren wurden der Plant uptake Faktor variiert (0 bzw. 0,5) und die Applikation (Anwendung jedes Jahr und alle 2 Jahre). Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 5, Kapitel 5,7).

Auf der Grundlage vorliegenden Lysimeterversuche sind bei einer einmaligen Anwendung von 40 g/ha Nicosulfuron, Einträge des Wirkstoffs > = 0,1 µg/l in das Grundwasser nicht zu erwarten. Bei einer maximalen Anwendung von 60 g/ha dagegen können Einträge des Wirkstoffes in Konzentrationen > = 0,1 µg/L in das Grundwasser nicht ausgeschlossen werden. Der Wirkstoff wurde in den entsprechenden Lysimeterstudien jedoch nur im ersten Jahr appliziert. Einträge des Wirkstoffs Nicosulfuron von > = 0,1 µg/L bei jährlicher Anwendung von 40 g/ha können daher ebenfalls nicht ausgeschlossen werden. Mit Hilfe von Simulationsrechnungen wurde daher für die Anwendung von Mitteln, die den Wirkstoff Nicosulfuron enthalten, eine maximale Aufwandmenge von 45 g/ha in jedem zweiten Kalenderjahr pro Fläche festgelegt, um Einträge von Nicosulfuron in Konzentrationen > = 0,1 µg/L in das Grundwasser auszuschließen.

(NG327)
Auf derselben Fläche im folgenden Kalenderjahr keine Anwendung von Mitteln mit dem Wirkstoff Nicosulfuron.
Begründung:
siehe Begründung für NG 326-1

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Aufgrund der Auswirkungen der Wirkstoffe Mesotrione, Nicosulfuron und Rimsulfuron gegenüber aquatischen Organismen (z.B. Nicosulfuron: [EC50] = 0,0011 mg/L (Lemna gibba)) besitzt das o.g. Pflanzenschutzmittel einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d.h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes (§ 1 Nr. 3 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG)) unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung
durchsetzbar zu begegnen.

Für die Anwendungen 007526-00/00-001:

(NT108)

Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist.

Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.

Begründung:

Das Pflanzenschutzmittel DPX-Q9H36 51WG bzw. die darin enthaltenen Wirkstoffe Mesotrione, Nicosulfuron und Rimsulfuron weisen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 2,88 g DPX-Q9H36 51WG/ha für den Pflanzenwachstumstest (vegetative vigour). Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT 108 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels DPX-Q9H36 51WG zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.9).

Für die Anwendungen 007526-00/00-001:

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel DPX-Q9H36 51WG bzw. die darin enthaltenen Wirkstoffe Mesotrione, Nicosulfuron und Rimsulfuron weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Pflanzen auf. Bewertungsbestimmend ist hier die EC50 für Lemna gibba von 0,0062 µg DPX-Q9H36 51WG/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels DPX-Q9H36 51WG und seiner Wirkstoffe in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.4).

Für die Anwendungen 007526-00/00-001:
(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m
Begründung:
siehe Begründung für die NW605-1.

Für die Anwendungen 007526-00/00-001:
(NW706)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss
eine Mindestbreite von 20 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

Begründung:
Die im Pflanzenschutzmittel DPX-Q9H36 51WG enthaltenen Wirkstoffe Mesotrione, Nicosulfuron und Rimsulfuron weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Pflanzen auf. Bewertungsbestimmend ist hier die EC50 für Lemna von 0,0011 mg Nicosulfuron/L. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 7500 mg/L; DT50 Boden = 36,6 d; KOC = 29), einer Berechnung der über den Pfad Oberflächenabfluss zu erwartenden Einträge mit dem Modell Exposit 3.01 und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 706 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Nicosulfuron in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.4).

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	**Verpackungs-material**	**Anzahl**		**Inhalt**		
		von	**bis**	**von**	**bis**	**Einheit**
Flasche	HDPE	1		330,00	1650,00	g

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(NW262)
Das Mittel ist giftig für Algen.

(NW263)
Das Mittel ist giftig für Fischnährtiere.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(WMB)
Wirkungsmechanismus (HRAC-Gruppe): B

(WMF2)
Wirkungsmechanismus (HRAC-Gruppe): F2

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:

(WH951)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das Resistenzrisiko hinzuweisen. Insbesondere sind Maßnahmen für ein geeignetes Resistenzmanagement anzugeben.

(WH960)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das hohe Nachbaurisiko hinzuweisen. Insbesondere sind gefährdete Folgekulturen zu benennen und Möglichkeiten für das Risikomanagement zu beschreiben.

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 5 PflSchG verbunden:

Dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit sind Unterlagen zu den nachfolgend aufgeführten Punkten und den dabei jeweils genannten Terminen vorzulegen:

Antragspunkt:

KIIA 7.12

Termin:

30.06.13

Begründung:

Vorlage der Ergebnisse eines mehrjährigen Grundwassermonitorings für den Wirkstoff Nicosulfuron . Das Konzept ist mit den am Zulassungsverfahren beteiligten Behörden abzustimmen. Die Ergebnisse sind jährlich zu berichten.

Für den Wirkstoff Nicosulfuron wurden alle vorhandenen Daten für Simulationsrechnungen mit dem Simulationsprogramm FOCUSPELMO5.5.3 verwendet. Als besonders sensibler Inputparameter erweist sich nach wie vor der Koc. Des Weiteren wurden der Plant uptake Faktor variiert (0 bzw. 0,5) und die Applikation (Anwendung jedes Jahr und alle 2 Jahre). Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 5, Kapitel 5,7).

Auf der Grundlage der vorliegenden Lysimeterversuche sind bei einer einmaligen Anwendung von 40 g/ha Nicosulfuron, Einträge des Wirkstoffs > 0,1 µg/l in das Grundwasser nicht zu erwarten. Bei einer maximalen Anwendung von 60 g/ha dagegen können Einträge des Wirkstoffes in Konzentrationen > 0,1 µg/L in das Grundwasser nicht ausgeschlossen werden. Der Wirkstoff wurde in den entsprechenden Lysimeterstudien jedoch nur im ersten Jahr appliziert. Einträge des Wirkstoffs Nicosulfuron von > 0,1 µg/L bei jährlicher Anwendung von 40 g/ha können daher ebenfalls nicht ausgeschlossen werden. Mit Hilfe von Simulationsrechnungen wurde daher für die Anwendung von Mitteln, die den Wirkstoff Nicosulfuron enthalten, eine maximale Aufwandmenge von 45 g/ha in jedem zweiten Kalenderjahr pro Fläche festgelegt, um Einträge von Nicosulfuron in Konzentrationen > 0,1 µg/L in das Grundwasser auszuschließen.

Zum Schutz der Ressource Grundwasser ist die Hinlänglichkeit der für den Wirkstoff Nicosulfuron festgesetzten Beschränkung der Anwendung auf alle 2 Jahre auf der gleichen Fläche auf der Grundlage eines zulassungsbegleitenden Grundwassermonitorings gem. § 36 Abs. 5 PflSchG zu belegen.

Ich weise darauf hin, dass diese Forderung erstmals zum Mittel 006258-00/00 ACCENT mit Frist bis zum 30.6.2012 erhoben wurde und bitte um umgehende Vorlage des 2. Interimberichts.

Unter Berücksichtigung der für die Erarbeitung dieser Unterlagen sowie ihrer Prüfung erforderlichen Zeitdauer sind die Studien zu den oben genannten Terminen vorzulegen. Ich weise darauf hin, dass mir § 36 Abs. 5 S. 3 PflSchG für den Fall der nicht fristgerechten Erfüllung dieser Auflage die Möglichkeit eröffnet, das Ruhen der Zulassung anzuordnen. Ferner eröffnet mir in diesem Fall § 49 Abs. 2 Nr. 2 VwVfG auch die Möglichkeit des Widerrufs der Zulassung.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß § 4 Gefahrstoffverordnung

Gefahrensymbole: N, Xn
Gefahrenbezeichnungen: Umweltgefährlich, Gesundheitsschädlich

Gefahrenhinweise (R-Sätze):

R 50/53: Sehr giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

R 22 : Gesundheitsschädlich beim Verschlucken

R 41 : Gefahr ernster Augenschäden

Sicherheitshinweise (S-Sätze):

S 36/37/39 : Bei der Arbeit geeignete Schutzkleidung, Schutzhandschuhe und Schutzbrille/Gesichtsschutz tragen

S 2 : Darf nicht in die Hände von Kindern gelangen

S 13 : Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten

S 24 : Berührung mit der Haut vermeiden

S 26 : Bei Berührung mit den Augen gründlich mit Wasser abspülen und Arzt konsultieren

S 35: Abfälle und Behälter müssen in gesicherter Weise beseitigt werden

S 46 : Bei Verschlucken sofort ärztlichen Rat einholen und Verpackung oder Etikett vorzeigen

S 57 : Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden

Enthält 2-Aminosulfonyl-N,N-dimethylnicotinamid. Kann allergische Reaktionen hervorrufen.

Enthält Harnstoff-Formaldehyd-Kondensat. Kann allergische Reaktionen hervorrufen.

Zur Vermeidung von Risiken für Mensch und Umwelt ist die Gebrauchsanleitung einzuhalten.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

(S2) Gefahr

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0113)

Enthält 2-Aminosulfonyl-N,N-dimethylnicotinamid. Kann allergische Reaktionen hervorrufen.

(EUH 208-0137)

Enthält Harnstoff-Formaldehyd-Kondensat. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H302)

Gesundheitsschädlich bei Verschlucken.

(H318)

Verursacht schwere Augenschäden

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):

- keine -

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):
- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB6641)
Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)
Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN1002)
Das Mittel wird als nicht schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

Weitere Hinweise und Bemerkungen
Ich möchte Sie darauf hinweisen, dass folgende Mängel bei der Bewertung des Antrages festgestellt wurden:

a) Zu KIIA 4.3 (Lebensmittel pflanzlichen Ursprungs):
Ein validiertes Analyseverfahren (Primärmethode) zur Bestimmung von Rückständen von Mesotrione (Summe aus Mesotrione und MNBA (4-Methylsulfonyl-2-nitrobenzoesäure), ausgedrückt als Mesotrione) in sauren und fettreichen pflanzlichen Lebensmitteln ist vorzulegen.
Begründung:
Zur Überwachung von Höchstgehalten werden Analyseverfahren für die o. g. Matrixtypen benötigt (siehe hierzu auch Nachrichtenbl. Deut. Pflanzenschutzd. 55 (2003) 275).

b) Zu KIIA 4.3 (Lebensmittel pflanzlichen Ursprungs):
Eine geeignete Analysemethode zur Bestimmung von Mesotrione (Summe aus Mesotrione und MNBA (4-Methylsulfonyl-2-nitrobenzoesäure), ausgedrückt als Mesotrione) in sauren und fettreichen Probenmaterialien ist durch ein unabhängiges Labor zu validieren (ILV). Alternativ können auch Studien zu einer oder mehreren neuen Analysemethoden vorgelegt werden, wenn diese in zwei voneinander unabhängigen Laboren validiert worden sind.
Begründung:

Um sicher zu stellen, dass sich vorgeschlagene Analyseverfahren allgemein eignen, ist gemäß Leitlinie SANCO/825/00 eine unabhängige Validierung erforderlich.

c) Zu KIIA 4.3 (Lebensmittel pflanzlichen Ursprungs):
Ein validiertes Absicherungsverfahren zur Bestimmung von Rückständen von Mesotrione (Summe aus Mesotrione und MNBA (4-Methylsulfonyl-2-nitrobenzoesäure), ausgedrückt als Mesotrione) in sauren und fettreichen pflanzlichen Lebensmitteln ist vorzulegen.
Begründung:
Um falsch positive Ergebnisse in der Überwachung zu vermeiden, ist gemäß Leitlinie SANCO/825/00 für die o. g. Matrixtypen ein validiertes Absicherungsverfahren erforderlich (siehe hierzu auch Nachrichtenbl. Deut. Pflanzenschutzd. 55 (2003) 275). Die Anforderungen hinsichtlich des Umfangs der Validierung von Absicherungsverfahren sind weiter präzisiert worden (siehe hierzu auch Nachrichtenbl. Deut. Pflanzenschutzd. 52 (2000) 292 bzw. Bundesanzeiger Nr. 232, Seite 23089 vom 09.12.2000).

d) Zu KIIA 4.3 (Lebensmittel pflanzlichen Ursprungs):
Die Analysemethode von Crook (2001) zur Bestimmung von Mesotrione (Summe aus Mesotrione und MNBA (4-Methylsulfonyl-2-nitrobenzoesäure), ausgedrückt als Mesotrione) in trockenen und wasserhaltigen Probenmaterialien ist durch ein unabhängiges Labor zu validieren (ILV). Alternativ können auch Studien zu einer oder mehreren neuen Analysemethoden vorgelegt werden, wenn diese in zwei voneinander unabhängigen Laboren validiert worden sind.
Begründung:
Um sicher zu stellen, dass sich vorgeschlagene Analyseverfahren allgemein eignen, ist gemäß Leitlinie SANCO/825/00 eine unabhängige Validierung erforderlich.

e) Zu KIIA 4.3 (Lebensmittel pflanzlichen Ursprungs):
Damit Ergebnisse der Bestimmung von Mesotrione (Summe aus Mesotrione und MNBA (4-Methylsulfonyl-2-nitrobenzoesäure), ausgedrückt als Mesotrione) in trockenen und wasserhaltigen Matrices mittels Flüssigchromatographie/Tandem-Massenspektrometrie (LCMS/MS) einfach abgesichert werden können, ist ein 2. Übergang zu validieren.
Begründung:
Als Beleg der Spezifität der LC-MS/MS-Methode ist die Validierung nur eines Übergangs nicht ausreichend (nähere Erläuterungen hierzu siehe Nachrichtenbl. Deut. Pflanzenschutzd. 57 (2005) 157).

f) Zu KIIA 4.3 (Lebensmittel tierischen Ursprungs):
Damit Ergebnisse der Bestimmung von Nicosulfuron in Fett mittels

Flüssigchromatographie/Tandem-Massenspektrometrie (LC-MS/MS) einfach abgesichert werden können, ist ein 2. Übergang zu validieren.

Begründung:

Als Beleg der Spezifität der LC-MS/MS-Methode ist die Validierung nur eines Übergangs nicht ausreichend (nähere Erläuterungen hierzu siehe Nachrichtenbl. Deut. Pflanzenschutzd. 57 (2005) 157).

g) Zu KIIA 4.4 (Boden / 2. MRM):

Damit Ergebnisse der Bestimmung von Mesotrione (Mesotrione + MNBA + AMBA) in Boden mittels Flüssigchromatographie/ Tandem-Massenspektrometrie (LC-MS/MS) einfach abgesichert werden können, ist ein 2. Übergang zu validieren.

Begründung:

Als Beleg der Spezifität der LC-MS/MS-Methode ist die Validierung nur eines Übergangs nicht ausreichend (nähere Erläuterungen hierzu siehe Nachrichtenbl. Deut. Pflanzenschutzd. 57 (2005) 157).

Zu KIIIA1 6.2.8:

Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WMB: Rimsulfuron und Nicosulfuron; WMF2: Mesotrione):

Die HRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Rimsulfuron und Nicosulfuron sowie Mesotrione) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

Zu: KIIIA1 5.2.4:

Weitere Informationen zur vorgelegten Analysemethode zur Bestimmung der im Wirkstoff Mesotrione enthaltenen relevanten Verunreinigung 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one im Pflanzenschutzmittel sind vorzulegen.

Begründung:

Nach Artikel 29 Absatz 1 Buchstabe f der Verordnung (EG) Nr. 1107/2009 darf ein Pflanzenschutzmittel nur zugelassen werden, wenn die relevanten Verunreinigungen bestimmt werden können. Die vorgelegte Analysenmethode wurde mit anderen Formulierungen validiert. Daher sind weitere Informationen zur Selektivität der vorgelegten Methode in der Formulierung Arigo vorzulegen wie z.B. Beispielchromatogramme. Weiterhin ist das Niveau, an dem die Validierung der Methode vorgenommen wurde, höher als der für die vorliegende Formulierung zulässige Höchstgrenze von 0,72 µg/g bezogen auf das Produkt. Der LOQ, welche anhand des niedrigsten Kalibrierstandards festgelegt wurde, beträgt z.B. 1 µg/g bezogen auf das Produkt. Daher sind weitere Daten bezüglich der Niveaus von 0,72 µg/g vorzulegen.

Zu der Fassung der Anwendung
Entsprechend der Gebrauchsanleitung wurde das Schadorganismenspektrum auf einjährige ein- und zweikeimblättrige Unkräuter begrenzt.
Die Angabe zur Aufwandmenge des Mischungspartners DU PONT TREND wurde als metrische Einheit mit 0,3 l/ha umgesetzt.

Zum Etikett
Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:
"Enthält ca. 75 g /kg Kaolin (Al.-silikat) als Füllstoff
Begründung:
Kaolin (Al.-silikat) (CAS 1332-58-7) wurde in der EU als Wirkstoff betrachtet. Eine Verwendung von Kaolin (Al.-silikat) als Beistoff in Pflanzenschutzmitteln ist daher nach Auffassung des BVL deklarationspflichtig.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Hans-Gerd Nolting
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007526-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Mais
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	12 bis 18
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	in Mischung mit: 004873-00 DU PONT TREND (0,3 l/ha)
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	330 g/ha in 200 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WP734)
Schäden an der Kulturpflanze möglich.

2.3 Wartezeiten

(F)	Freiland: Mais Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT108)
Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist.
Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
10 m

(NW706)
Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss
eine Mindestbreite von 20 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: DPX-Q9H36 51WG

Active Substances:

Mesotrione	**360 g/kg**
Nicosulfuron	**120 g/kg**
Rimsulfuron	**30 g/kg**

Central Zone
Zonal Rapporteur Member State: Czech Republic

NATIONAL ADDENDUM – Germany

Applicant : E. I. du Pont de Nemours and Company
Date: January 2013

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product ARIGO (Code: DPX-QH936 51WG) in its intended uses in Maize is documented in detail in the core assessment of the plant protection product DPX-QH936 51WG dated from July 2013 performed by Czech Republic.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product ARIGO in Germany according to uses listed in Appendix 3.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation ARIGO

Code	DPX-Q9H36 51WG		
plant protection product	ARIGO		
applicant	E. I. du Pont de Nemours and Company		
Formulation type	Water dispersible granule		
active substances (as)	Mesotrione	Nicosulfuron	Rimsulfuron
Concentration of as	360	120	30

Data pool/task force	None
letter of access/cross reference	Letter of Access for Mesotrione from Syngenta (date: 15/02/2011)
existing authorisations in DE	None

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

Table 5.2-1: Classification of intended uses in Germany for ARIGO

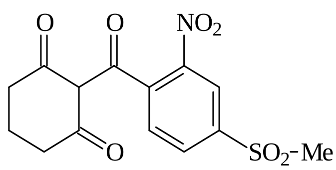
use No	Crop/growth stage	Application method Drift scenario	Number of applications, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Maize BBCH 12	Spray/ Agriculture	1 application Time: 7th of May 25% interception	118.8 g/ha Mesotrione 39.6 g/ha Nicosulfuron 9.9 g/ha Rimsulfuron	89.1 g/ha Mesotrione 29.7 g/ha Nicosulfuron 7.425 g/ha Rimsulfuron

5.3 Information on the active substances

5.3.1 Mesotrione

5.3.1.1 Identity, further information of Mesotrione

Table 5.3-1 Identity, further information of Mesotrione

Active substance (ISO common name)	Mesotrione
IUPAC	2-(4-Mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
Function	Herbicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/10/2003
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.
Confirmatory data	None
RMS	UK
Molecular formula	$C_{14}H_{13}NO_7S$
Molecular mass	339.3
Structural formula	

5.3.1.2 Physical and chemical properties of Mesotrione

Please refer to Table 2 of the Core Assessment, Part B, Section 5.

5.3.1.3 Metabolites of Mesotrione

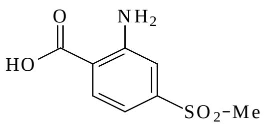
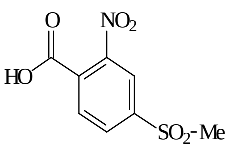
Environmental occurring metabolites of Mesotrione requiring further assessment according to the results of the assessment of Mesotrione for EU approval are summarized in Table 5.3-2.

No new study on the fate and behaviour of Mesotrione or ARIGO has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/1416/2001 – 14/04/2003. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary for approval of ARIGO in Germany.

However, the leaching potential into groundwater of the soil metabolites MNBA and AMBA will be assessed for the application of the plant protection product and its intended uses. Additionally, the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration will be performed for the soil metabolites of MNBA and AMBA.

Table 5.3-2: Metabolites of Mesotrione potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

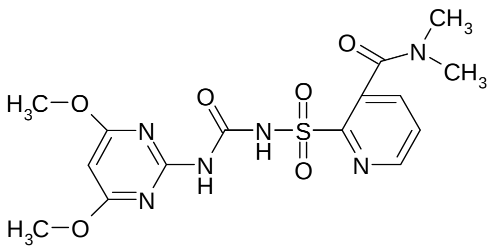
Metabolite	**Structural formula/ Molecular weight**	**occurrence in compartments (Max. at day/**	**Status of Relevance (SANCO/1416/2001 – 14/04/2003)**
AMBA (2-Amino-4-methylsulfonyl-benzoesäure)	 M = 215 g/mol	Soil, aerob: 9.4 & 9.7% max. at day 18 & 23 (subsequent samples) Water of water/sediment studies: 11.5% at day 14 Sediment of water/sediment studies: 7.9 & 7.0% at day 56 & 69 (subsequent samples)	Aquatic organisms: Water: not assessed Sediment: not assessed Terrestrial organisms: not assessed Groundwater: not relevant (Step 2)[1)]
MNBA (4-Methylsulfonyl-2-nitro-benzoesäure)	 M = 245 g/mol	Soil, aerob: 57.2% at day 28 Water of water/sediment studies: 7.4% at day 3 (1 x >5%) Sediment of water/sediment studies: 0.6% max at day 3	Aquatic organisms: Water: not assessed Sediment: not applicable Terrestrial organisms: not assessed Groundwater: not relevant (Step 2)[1)]

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Nicosulfuron

5.3.2.1 Identity, further information of Nicosulfuron

Table 5.3-3 Identity, further information of Nicosulfuron

Active substance (ISO common name)	Nicosulfuron
IUPAC	2-(4,6-Dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)- *N*,*N*-dimethylnicotinamid
Function	herbicide
Status	approved; Annex I (91/414/EWG) yes
Date of approval	29.03.2008 / SANCO/3780/07 – rev. 1 (22 January 2008)
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: - the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, - the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, - the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, - the protection of groundwater and surface water under vulnerable soil and climatic conditions.
Confirmatory data	none
RMS	UK
Molecular formula	$C_{15}H_{18}N_6O_6S$
Molecular mass	410.14
Structural formula	
Smiles code	c1(nc(nc(c1)OC)NC(=O)NS(=O)(=O)c1ncccc1C(=O)N(C)C)OC

5.3.2.2 *Physical and chemical properties of Nicosulfuron*

Table 5.3-4 Physical and chemical properties of Nicosulfuron

Melting point (state purity)	140-161°C (purity 99-99.8%)
Boiling point (state purity)	Not determined – substance decomposes before boiling point is reached.
density (state purity)	1.450 g/cm^3 at 20.0 ± 0.5°C (purity = 99.8%)
Vapour pressure (in Pa, state temperature)	< 8 x 10^{-10} Pa @ 25°C
Henry's law constant (Pa m^3 mol $^{-1}$)	1.48 x 10^{-11} Pa m^3 mol^{-1} at 20°C.
Solubility in water (g/l or mg/l, state temperature)	pH 5.0: 0.25g/l at 19.7°C pH 6.5: 7.5g/l at 19.7°C pH 9.0: 76.4g/l at 20°C ± 1.0°C
Partition co-efficient (log P_{OW}) (state pH and temperature)	pH 2.3-2.4: log P_{OW} = 0.61 at 20-21°C
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5: DT_{50} = 14.6 days at 25°C pH 7.32: DT_{50} was not reached after 32 days at 25°C pH 9.50: DT_{50} was not reached after 32 days @ 25°C
Dissociation constant	pKa_1 = 4.78 ± 0.05 at 20°C pKa_2 = 7.58 ± 0.05 at 20°C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Absorbance maximum = 239nm No absorbance >290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	pH 5: DT_{50} = 9-12 days pH 7: DT_{50} = 46-85 days pH 9: DT_{50} = 46-69 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	DT_{50} = 18.7 hours

5.3.2.3 *Metabolites of Nicosulfuron*

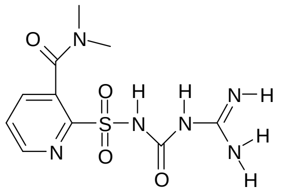
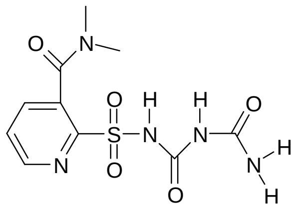
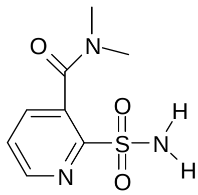
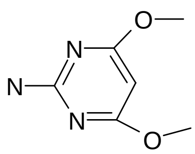
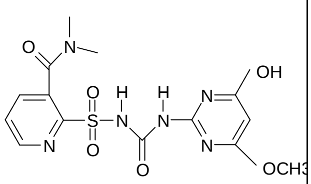
Environmental occurring metabolites of Nicosulfuron requiring further assessment according to the results of the assessment of Nicosulfuron for EU approval are summarized in Table 5.3-25.

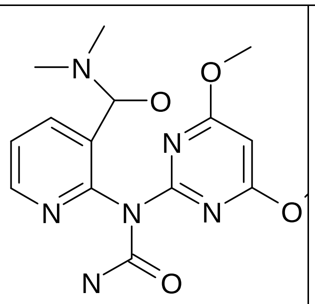
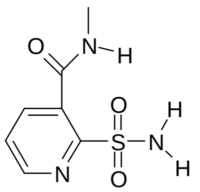
No new study on the fate and behaviour of Nicosulfuron has been performed. Hence no potentially new metabolites need to be considered. All potencially relevant metabolites are summarised in table 5.3-5.

However, the leaching potential into groundwater of the soil metabolites of Nicosulfuron will be assessed for the application of the plant protection product and its intended uses. Additionally, the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration will be performed for the soil metabolites of Nicosulfuron.

Table 5.3-5: Metabolites of Nicosulfuron potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Molecular weight (g/mol)/ Structural formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance**
AUSN (IN-HYY21) (2-(3- amidinoureidos	314,36	soil; aerob; max 34.9% on day 120. Water; max. 5.9% on day 102, increasing Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms:

ulfonyl)-N,N-imethylnicotinamide)			Soil: not relevant Groundwater: relevant
UCSN (IN-GDC42) (N,N-dimethyl-2-ureidocarbonyl-sulfamoylnicotinamide)	315,3 	soil; aerob; max. 11% on day238 Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: Soil: not relevant Groundwater: relevant
ASDM (IN;-V9367) N,N-dimethyl-2-sulfamoyl-nicotinamide	229,2 	soil; aerob; max. 21.5% on day 85 water; 6.9% on day 177; increasing	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: Soil: not relevant Groundwater: relevant
ADMP IN-J0290 2-amino-4,6-dimethoxypyrimidine	155,16 	soil; aerob; max. 7.2% on day 31	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant
HMUD (IN-37740) 2-(4-hydroxy-6-methoxypyrimidin-2-ylcarbamoylsulfamoyal)-N,N-dimethylnicotinamide	336,4 	soil; aerob; max. 18.5% on day 56 water; max. 22.3% on day 102; increasing sediment; max. 6.8% on day 102 indreasing to the end of study	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant
IN-77799 (Nicosulfuron Ipso Precursor) entspricht offensichtlich DUDN (Peer review)	348,36	hydrolysis >10% but only under acidic conditions (pH=5)	Aquatic organism: Water: not relevant Groundwater: not relevant

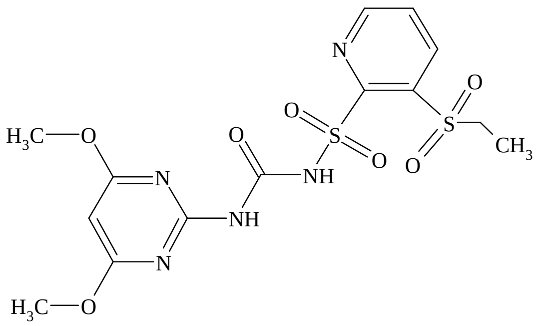
			
MU-466 2-sulfamoyl-N-methylnicotinamide	215,23 	Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant

5.3.3 Rimsulfuron

5.3.3.1 Identity, further information of Rimsulfuron

Table 5.3-6 Identity, further information of Rimsulfuron

Active substance (ISO common name)	Rimsulfuron
IUPAC	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
Function (e.g. fungicide)	Herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/02/2007
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. Member States must pay particular attention to the protection of non target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.
Confirmatory data	None Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for: - potential for accumulation of metabolites in soil under cold climatic conditions with respect to the protection of soil dwelling organisms - evaluation of run-off and drainage into surface water in the

	risk assessment of aquatic organisms
RMS	DE
Molecular formula	$C_{14}H_{17}N_5O_7S_2$
Molecular mass (g/mol)	431.45
Structural formula	

5.3.3.2 Physical and chemical properties of Rimsulfuron

Please refer to Table 4 of the Core Assessment, Part B, Section 5.

5.3.3.3 Metabolites of Rimsulfuron

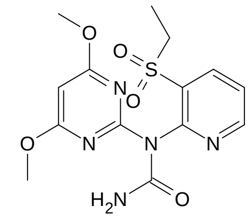
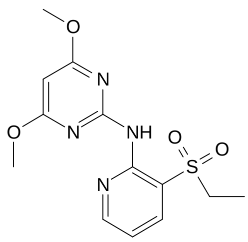
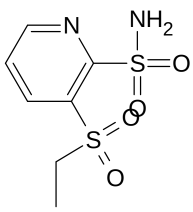
Environmental occurring metabolites of Rimsulfuron requiring further assessment according to the results of the assessment Rimsulfuron for EU approval are summarized in Table 5.3-2.

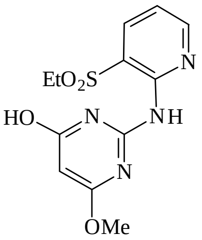
No new study on the fate and behaviour of Rimsulfuron or ARIGO has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/10528/2005 – 27/01/2006). Therefore no new risk assessment of these metabolites for aquatic organisms hence no exposure assessment is necessary. However regarding terrestrial organisms, the risk assessment of these metabolites for EU approval of Rimsulfuron is not considered sufficient enough for approval of plant protection products in Germany. Thus, PECsoil values of the metabolites IN-7094 and IN-E9260 were calculated for the intended uses of ARIGO in maize.

Additionally, the leaching potential into groundwater of the soil metabolites IN-70941, IN-70942 and IN-E9260 will be assessed for the application of ARIGO in its intended uses. Additionally, the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration will be performed for the soil metabolites of IN-70941, IN-70942 and IN-E9260.

Table 5.3-7: Metabolites of Rimsulfuron potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular formula/ Molecular weight	occurrence in compartments (Max. at day)	Status of Relevance (SANCO/10528/2005 – 27/01/2006)
IN-70941	 $C_{14}H_{17}N_5O_5S$ M = 367.39 g/mol	Soil, aerob: Laboratory studies: 54.1% max. at d 60 Field studies: 72% max. at d 92 (all European trials) & 30% max. at d 31 (German trials) Water of water/sediment study: 71.4% max. at d 3 Sediment of water/sediment study: max. 15.2% at d 7 aqueous photolysis: 24.6% max. at d 14 (pH 7)	Terrestrial organism: not relevant Aquatic organism: Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 3-4)[1)]
IN-70942	 $C_{13}H_{16}N_4O_4S$ M=324.36 g/mol	Soil, aerob: Laboratory studies: 23.5% max. at d 360 Field studies: 6.8% max. at d 92 (all European trials) & 5.8% max. at d 45 (German trials) Water of water/sediment study: 31.45% max. at d 14 Sediment of water/sediment study: max. 73.1% at d 100 aqueous photolysis: 8.4% max. ar d 21 (pH 7)	Terrestrial organism: not relevant Aquatic organism: Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 2)[1)]
IN-E9260	 $C_7H_{10}N_2O_4S_2$ M=250.29 g/mol	Soil, aerob: Laboratory studies: 18.9% max. at day 180 Field studies: 6.4% max at d 92 (all European trials) & 4.4% max. at d 14 (German trials)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3-4)[1)]

IN-JF999	 $C_{12}H_{14}N_4O_4S$ M=310.33 g/mol	Sediment of water/sediment study: 21.8% max. at d 65	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not applicable Groundwater: not applicable

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Mesotrione

No new studies have been submitted regarding route and rate of degradation in soil of mesotrione since EU approval. The DT_{50} values of the studies submitted for EU approval were normalized to 20°C and pF2 by the zRMS and are listed in Table 10 of the core assessment, part B, section 5. However, two of the soils investigeated from Tarr, 1997 are missing in the Table. Besides, our temperature and moisture normalization leads to slightly higher DT_{50} values than derived by the zRMS for most soils. Additionally, while the zRMS used only the DT_{50} value from the study Miller, 1997 for the soil silt loam, our approach ist generally to derive a geometric mean from all available DT_{50} values derived in one soil (three DT_{50} in this case). Thus, the DT_{50} values for mesotrione used for exposure an risk assessment in Germany are presented in Table 5.4-1.

Table 5.4-1 Summary of aerobic degradation rates for Mesotrione - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**		**Kinetic, Fit**	**Reference**
Wisconsin silt loam, Cyclohexane-Markierung	6.2	25	75% of 1/3 bar	15	48	20.4	18.3	First order, r^2: 0.99	Vispetto & Tovshteyn, 1997
Wisconsin silt loam, phenyl-Markierung	6.2	25	75% of 1/3 bar	12.1	-	16.5		First order, r^2: 0.99	Suba-Rao, 1996
Wisconsin Silt Loam, Phenyl Markierung	6.1	20	50% WHC	14	48	18.2		First order	Miller 1997
ERTC, Sandy Loam (USA)	6.4	20	50% WHC	12	39	8.5		1st order	Miller & Wilson, 1997

Garonne, Loam (France)	7.7	20	50% WHC	5.9	20	5.5	1st order	
Pickett Piece, Clay Loam (UK)	7.1	20	50% WHC	4.6	15	4.6	1st order	
Land O'Lakes (Clay Loam)	5.6	25	100% of 1/3 bar	22.0	73	35.3	1st order	Tarr, 1997
Danville (Silty Clay Loam)	5.6	25	100% of 1/3 bar	10.6	35	17.0	1st order	
Breese (Silt Loam)	5.5	25	100% of 1/3 bar	16.6	55	26.7	1st order	
Osceola (Loamy Sand)	4.6	25	100% of 1/3 bar	25.9	86	20.9	1st order	
Elk City (Loam)	5.3	25	100% of 1/3 bar	8.0	27	12.5	1st order	
Noblesville (Clay Loam)	5.0	25	100% of 1/3 bar	24.1	80	37.7	1st order	
Martinsville (Loam)	6.0	25	100% of 1/3 bar	8.5	28	11.4	1st order	
Delavan (Silt Loam)	6.1	25	100% of 1/3 bar	12.9	43	20.7	1st order	
New Holland (Clay Loam)	5.3	25	100% of 1/3 bar	19.1	63	30.2	1st order	
Clarence (Silty Clay Loam)	6.4	25	100% of 1/3 bar	14.4	48	23.1	1st order	
Valley Springs (Silty Clay Loam)	5.1	25	100% of 1/3 bar	15.8	53	25.4	1st order	
Champaign I (Silty Clay Loam)	5.0	25	100% of 1/3 bar	31.5	105	49.0	1st order	
Champaign II (Silty Clay Loam)	7.5	25	100% of 1/3 bar	8.2	27	13.2	1st order	
Aggregated DT_{50} (n=17)	**Coefficient of variation (%)**					57		
	Geometric mean (d)					17.7		

	Geometric mean, acidic soils, (pH < 6.5, n=14)	21.7	
	90th percentile (d)	36.3	

n.a.: not available

According to the Kendall test, the degradation of Mesotrione shows a pH dependency with slower degradation under acidic conditions. Thus, for German groundwater risk assessment, the geometric mean of the acidic soils (pH < 6.5) is used as endpoint for modelling.

No new studies have been submitted regarding route and rate of degradation in soil of the metabolite MNBA since EU approval. The DT_{50} values of the studies submitted for EU approval were normalized to 20°C and pF2 by the zRMS and are listed in Table 11 of the core assessment, part B, section 5.

No new studies have been submitted regarding route and rate of degradation in soil of the metabolite AMBA since EU approval. However, instead of using the FOMC degradation kinetics derived for EU approval, the zRMS derived first order kinetics for AMBA from soil degradation studies to be used for exposure assessment but no information was presented on the visual and statistical fit. Thus, since the metabolite shows a clear biphasic degradation kinetic in soil, for German exposure assessment the kinetics derived for EU approval were used instead and are thus presented in Table 5.4-2. For groundwater risk assessment single first order (SFO) DT50 values were derived by dividing the FOMC DT_{90} with 3.32 according to FOCUS degradation kinetics, 2006. The temperature and moisture normalization of the resulting DT_{50} values were performed according to FOCUS groundwater, 2000.

Table 5.4-2 Summary of aerobic degradation rates for AMBA - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Wisborough Green Clay	4.9	20	40% WHC	3	39	-	FOMC, α: 0.776, β:2.139	Marth, 1997
				11.75	-	5.6	$DT_{90, FOMC}$/ 3.32	
Wisconsin Silt Loam	6.4	20	40% WHC	6	308	-	FOMC, α: 0.443, β:1.710	
				92.7	-	66	$DT_{90, FOMC}$/ 3.32	
East Anglia sandy loam	7.9	20	40% WHC	2	63	-	FOMC, α: 0.479, β: 0.516	
				18.98		19	$DT_{90, FOMC}$/ 3.32	

Rivers Michigan USA loamy sand	6.7	20	40% WHC	1.83	55.75	-	FOMC, α: 0.216, β:0.644	Lay, 2000
				16.79		16	$DT_{90/\ FOMC}$: 3.32	
Aggregated DT_{50} (n=17)		**Coefficient of variation (%)**				101		
		Geometric mean (d)				18.3		
		90th percentile (d)				51.9		

Nicosulfuron

No new studies have been submitted regarding route and rate of degradation in soil of Nicosulfuron and its soil metabolites AUSN; UCSN; ASDM; ADMP; HMUD and MU-466. The proposed degradation pathway for Nicosulfuron in soil is given in the Figure below.

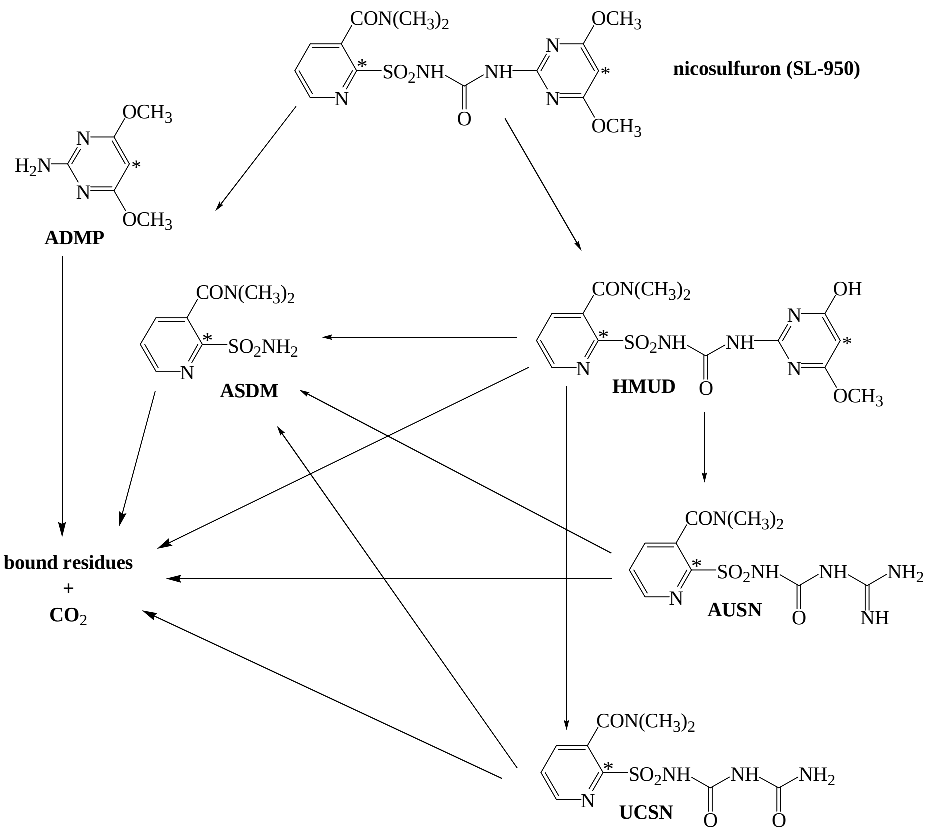


Table 5.4-3 Summary of aerobic degradation rates of Nicosulfuron - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Method of calculation
Les Evouettes, silt loam (pyridine level)	6.1	20 ,	54.6% MWHC	40.5	134*	33.2**	0.981	1st order nonlinear
Les Evouettes, silt loam (pyrimidine level)	6.1	20 ,	54.6% MWHC	33.1	110.1*	27.1**	0.993	1st order nonlinear
arithm. mean						30.1**		
Le Noron, loam (pyridine level)	5.3	20	46.3% MWHC	20.0	66.4*	13.3**	0.986	1st order nonlinear
Le Noron, loam (pyrimidine level)	5.3	20	46.3% MWHC	26.3	87.4*	17.5**	0.901	1st order nonlinear
arithm. mean						15.3**		
Speyer 2.1, sand (pyridine level)	6.0	20	20°C, 21.1% MWHC	35.1	116.6*	30.6**	0.989	1st order nonlinear
Speyer 2.1, sand (pyrimidine level)	6.0	20	20°C, 21.1% MWHC	46.3	154.0*	40.4**	0.974	1st order nonlinear
arithm. mean						35.5**		
Speyer 2.1, sandy loam (pyridine level)	6.6	20	31.4% MWHC	26.7	88.8*	20.3**	0.985	1st order nonlinear
Speyer 2.1, sandy loam (pyrimidine level)	6.6	20	31.4% MWHC	23.2	77.2*	17.7**	0.992	1st order nonlinear
arithm. mean						19.0**		
Pappelacker, loamy sand (pyrimidine level)	7.0	20	40% MWHC	7.0	23.4	5.7**	0.960	SFO
Karolinenhof, sand (pyrimidine level)	7.2	20	40% MWHC	13.2	43.9	12.6**	0.992	SFO
Otzberg, silt loam (pyrimidine level)	7.2	20	40% MWHC	18.9	62.8	14.3**	0.991	SFO

silty loam	7.1	20	50% MWHC	30.5	101	21.7***	0.932	SFO
silty loam	7.1	20	50% MWHC	22	162	15.7***	0,960	FOMC
Sandy loam	6.1	20	50% MWHC	59	196	46.4***	0.924	SFO
Sandy loam	6.1	20	50% MWHC	50	480	39.4***	0.947	FOMC
Sandy loam	5.4	20	50% MWHC	20	66	15.7***	9.972	SFO
Sandy loam	5.4	20	50% MWHC	16	92	12.5***	0.990	FOMC
summaryDT_{50}	coefficient of variation (%)					57	no significant correlation between DT50 and pH	
	geometric mean					**18.6**		
	90. percentile					36.6		

* Values from DAR (UK 2005); ** see core assessment; *** own calculation using default values; values in bold letters are used for calculation

Table 5.4-4 Summary of aerobic degradation rates of soil metabolites of Nicosulfuron - laboratory studies (see EFSA Conclusion; 2007 and core assessment)

HMUD	**Aerobic conditions**							
Soil type	**label**	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**ff**	**DT50 / 20°C pF2**	**St (r2)**	**Method of calculation**
Les Evouettes, silt loam	Pyridine	6.1	20 °C, 54.6% MWHC	30.8 / 102.2	0.00 752	25.2	0.983	ModelMaker based on SFO formation and decline from parent
Les Evouettes, silt loam	Pyrimidine	6.1	20 °C, 54.6% MWHC	27.4 / 90.0	0.00 786	22.4	0.930	ModelMaker based on SFO formation and decline from parent
geometric mean						**23.8**		
90.Percentile						24.9		
coefficient of variation%						8		
formation fraction (dRR) from parent					**0.442**			
The DT50 for HMUD are 2 values from 2 parent labels for 1 soil. Whereas for the other metabolites more than 1 soil was tested. The notifer calculated these using first-order kinetics in Modelmaker based on formation of HMUD and its subsequent degradation (HMUD formation fraction used was 0.00752 and 0.00786 respectively).								

values in bold letters are used for calculation

Table 5.4-5 Summary of aerobic degradation rates of the Metabolite ADMP of Nicosulfuron - laboratory studies

ADMP	Aerobic conditions					
Soil type	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**DT50 / 20°C pF2**	**St (r^2)**	**Method of calculation**
Collombey, loamy sand	7.6	20°C, 40% MWHC	2.9 / 9.5	2.4#	0.995	1st order nonlinear
Speyer 2.2, loamy sand	6.0	20°C, 40% MWHC	6.1 / 20.4	5.4#	0.980	1st order nonlinear
Les Evouettes, loam	7.3	20°C, 40% MWHC	11.3 / 37.7	7.3#	0.970	1st order nonlinear
sandy loam	7.1	20°C; 50% MWHC	19/ 63	15	0,936	SFO
loamy sand	5.0	20°C; 50% MWHC	18/60	16.2	0,880	SFO
sandy loam	6.3	20°C; 50% MWHC	3/10	2.4	0,995	SFO
silt loam	5.9	20°C; 50% MWHC	13/42	9.3	0,864	SFO
summaryDT_{50}	coefficient of variation (%)		67	no significant correlation between DT50 and pH		
	geometric mean		**6.5**			
	90. percentile		15.5			
	formation fraction (dRR) from parent		**0.214**			

see core assessment; values in bold letters are used for calculation

Table 5.4-6 Summary of aerobic degradation rates of the Metabolite ASDM of Nicosulfuron - laboratory studies

ASDM	Aerobic conditions					
Soil type	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**DT50 / 20°C pF2**	**St (r^2)**	**Method of calculation**
Collombey, loamy sand	7.6	20°C, 40% MWHC	90.5 / 300.8	73.6#	0.995	1st order nonlinear
Speyer 2.2, loamy sand	6.0	20°C, 40% MWHC	268.5 / 892.1	236.6#	0.933	1st order nonlinear
Les Evouettes, loam	7.3	20°C, 40% MWHC	114.8 / 381.4	73.8#	0.992	1st order nonlinear
Clay loam	7.2	20°C, 50% MWHC	476/1580	321.8	0,829	SFO
Sandy loam	7.0	20°C, 50% MWHC	278/ 923	218.8	0,955	SFO
Silt loam	5.9	20°C, 50%	(1130)/(3770)	804.6	(0,578)	(SFO)

		MWHC				
Sand	6.0	20°C, 50% MWHC	409/1360	409.0	0,839	SFO
Silt loam	6.3	20°C, 50% MWHC	484/1610	344.6	0,850	SFO
summaryDT_{50}	coefficient of variation (%)			75	no significant correlation between DT50 and pH	
	geometric mean			**237.9**		
	90. percentile			527.7		
	formation fraction (dRR) from parent			**0.214**		

see core assessment; values in bold letters are used for calculation

Table 5.4-7 Summary of aerobic degradation rates of the Metabolite AUSN of Nicosulfuron - laboratory studies

AUSN	**Aerobic conditions**					
Soil type	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**DT50 / 20°C pF2**	**St (r^2)**	**Method of calculation**
Collombey, loamy sand	7.6	20°C, 40% MWHC	73.8/245.1	60.0#	0.894	1st order nonlinear
Speyer 2.2, loamy sand	6.0	20°C, 40% MWHC	218.2/724.8	192.3#	0.907	1st order nonlinear
Les Evouettes, loam	7.3	20°C, 40% MWHC	101.4/336.9	65.2#	0.856	1st order nonlinear
Silty clay	7.5	20°C, 50% MWHC	(861)/ (2860)	566,5	0.502	(SFO)
Sandy loam	7.5	20°C, 50% MWHC	236/783	185,7	0.959	SFO
Loamy sand	5.5	20°C, 50% MWHC	790/2620	709,4	0.618	SFO
summaryDT_{50}	coefficient of variation (%)			92	no significant correlation between DT50 and pH	
	geometric mean			**195.7**		
	90. percentile			638		
	formation fraction (dRR) from HMUD			**0.687**		

see core assessment; values in bold letters are used for calculation

Table 5.4-8 Summary of aerobic degradation rates of the Metabolite UCSN of Nicosulfuron - laboratory studies

UCSN	**Aerobic conditions**					
Soil type	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**DT50 / 20°C pF2**	**St (r^2)**	**Method of calculation**
Collombey, loamy sand	7.6	20°C, 40% MWHC	126.2/419.3	102.6#	0.993	1st order nonlinear
Speyer 2.2, loamy sand	6.0	20°C, 40% MWHC	307.5/1021.7	271.0#	0.962	1st order nonlinear

Les Evouettes, loam	7.3	20°C, 40% MWHC	229.3/761.7	147.5#	0.942	1st order nonlinear
Silty clay	7.5	20°C, 50% MWHC	857/ 2850	563.9	0.736	SFO
Sandy loam	7.5	20°C, 50% MWHC	343/ 1140	269.9	0.989	SFO
Loamy sand	5.5	20°C, 50% MWHC	983/ 3270	882.7	0.792	SFO
summaryDT_{50}	coefficient of variation (%)			80	no significant correlation between DT50 and pH	
	geometric mean			**286.3**		
	90. percentile			723.3		
	formation fraction (dRR) from HMUD			**0.313**		

see core assessment; values in bold letters are used for calculation

Table 5.4-9 Summary of aerobic degradation rates of the Metabolite MU-466 of Nicosulfuron - laboratory studies

MU-466	Aerobic conditions					
Soil type	**pH**	**T°C; % Moisture**	**DT50 / DT90**	**DT50 / 20°C pF2**	**St (r^2)**	**Method of calculation**
UffholtzFrance (Soil I)silty clay loam	5.74	20°C, 40% MWHC	89.5 / 297	66.3#	0.943	1st order nonlinear
Speyer 2.1Germany (Soil II)sand	6.2	20°C, 40% MWHC	84 / 279	75.5#	0.975	1st order nonlinear
3A Germany (Soil III)loam	7.1	20°C, 40% MWHC	67.9 / 225.5	59.1#	1.000	1st order nonlinear
Fislis silt loam	7.3	20°C; pF2.5	81.4/ 270.4	68.3	0.9567	1st order
Bad Säckingen silt loam	5.68	20°C; pF2.5	231/767.4	193.8	0.8303	1st order
Speyer 2.3 sandy loam	6.4	20°C; pF2.5	117.3/389.7	98.4	0.9220	1st order
summaryDT_{50}	coefficient of variation (%)			54		
	geometric mean			**85.2**		
	90. percentile			145.7		
	formation fraction (dRR) from ASDM			**0.282**		

see core assessment; values in bold letters are used for calculation

Rimsulfuron

No new studies have been submitted regarding route and rate of degradation in soil of Rimsulfuron and its soil metabolites IN-70941, IN-70942 and In-E9260 since EU approval. However, a a new kinetic evaluation of all laboratory studies according to FOCUS degradation kinetics is available for this assessment (Huber, 2007). The study Huber, 2007 was, according to the zRMS (see Commenting

Table), also submitted for the Core Assessment and should of have been summarized there. Thus, only the resulting DT_{50} values are listed here but no detailed evaluation in added in Appendix 2.

The DT_{50} values for rimsulfuron used for exposure an risk assessment in Germany are presented in Table 5.4-10.

Table 5.4-10 Summary of aerobic degradation rates for Rimsulfuron - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Sassafras sandy loam	6.7	25	75% ⅓ bar MWHC	14	104	-	FOMC (α: 1.18, β:17.19) chi²: 9.5%	Naidu, 1989/ Huber, 2007
				31	-	20.8	SFO (FOMC DT_{50}/3.32)	
Sion Hill/ Loamy Sand	7.0	20	40% MWHC	23	78	17.7	SFO , chi²: 19.3%	Benwell, 1992/ Huber, 2007
Middlefield/ Sandy Loam	6.7	20	40% MWHC	3.2	158	-	HS (tb:3.84) chi²: 10.6	Benwell, 1992/ Huber, 2007
				73	-	49.1	SFO (HS slow phase)	
Speyer 2.2/ Loamy Sand	5.6	20	40% MWHC	26	87	20.0	SFO, chi²: 16.4%	Benwell, 1992/ Huber, 2007
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**				55		
		Geometric mean (d)				24.5		
		90th percentile (d)				40.6		

The DT_{50} values for IN-70941 used for exposure an risk assessment in Germany are presented in Table 5.4-11. Additionally 1 formation fraction was derived for IN-70941 from Huber, 2007 using the data of the laboratory study Naidu, 1989. The formation fraction is also listed in Table 5.4-11.

Table 5.4-11 Summary of aerobic degradation rates for the metabolite IN-70941 - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Lynge, Denmark/ Sandy Loam	5,4	20	40 - 50% MWHC	359	1194	262	SFO, r² : 0.913, chi²: 1.6%	McClanahn und Shaw, 2000b/ Huber, 2007
San Pietro, Italy/ Clay	7,9	20	40 - 50% MWHC	38	127	23,3	SFO, r² : 0.982, chi²: 4.3%	

Handorf, Germany/ Sandy Loam	5,8	20	40 - 50% MWHC	615	2045	450	SFO, r^2 : 0.722, chi^2:1.8%	
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**				87		
		Geometric mean (d)				140.1		
		90th percentile (d)				412.4		
Formation Fraction (as → met), n=1		0.57				Naidu, 1989/ Huber, 2007		

The DT_{50} values for IN-70942 used for exposure an risk assessment in Germany are presented inTable 5.4-12.

Table 5.4-12 Summary of aerobic degradation rates for the metabolite IN-70942 - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Lynge, Denmark/ Sandy Loam	5.4	20	40 - 50% MWHC	214	713	156	SFO, chi^2: 2.5%	McClanahn und Shaw, 2000c/ Huber, 2007
San Pietro, Italy/ Clay	7.9	20	40 - 50% MWHC	92	>1000	-	FOMC (α:0.29,β:9.47), chi^2: 2.6%	
				101		61.9	SFO (FOMC DT_{50}/3.32)	
Handorf, Germany/ Sandy Loam	5.8	20	40 - 50% MWHC	116	386	85	SFO, chi^2:3.3 %	
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**				49		
		Geometric mean (d)				93.6		
		90th percentile (d)				141.8		

The DT_{50} values for IN-E9260 used for exposure an risk assessment in Germany are presented in Table 5.4-13. Additionally 1 formation fraction was derived for IN-E9260 from Huber, 2007 using the data of the laboratory study Naidu, 1989. The formation fraction is also listed in Table 5.4-13.

Table 5.4-13 Summary of aerobic degradation rates for the metabolite IN-E9260 - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Lynge, Denmark/ Sandy Loam	5.4	20	40 - 50% MWHC (0 bar)	736	>1000	538	SFO, chi2: 1.0%	McClanahn und Shaw, 2000a/ Huber, 2007
San Pietro, Italy/ Clay	7.9	20	40 - 50% MWHC (0 bar)	252	832	155	SFO, r^2 : 0.710, chi^2: 4.7%	
Handorf, Germany/ Sandy Loam	5.8	20	40 - 50% MWHC (0 bar)	969	>1000	708	SFO, r^2 : 0.337, chi^2: 2.3	
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**				61		
		Geometric mean (d)				389		
		90th percentile (d)				674		
Formation Fraction (as → met), n=1		0.18				Naidu, 1989/ Huber, 2007		

5.4.1.2 Field studies

Mesotrione

No new field dissipation studies have been submitted for mesotrione since EU approval. The resulting dissipation half times of mesotrione are summarized in Table 22 of the core assessment, part B, section 5. Since the derived dissipation half times were not derived according to FOCUS degradation kinetics, 2006 and no temperature and moisture normalized DT_{50} values are available, the study results are not used for German exposure and risk assessment.

Nicosulfuron

No new field dissipation studies have been submitted for nicosulfuron since EU approval. A summary of results from field studies are given below in Table 5. 4-8.

Table 5.4-14 Field studies of nicosulfuron

Parent	**Aerobic conditions**								
Soil type (indicate if bare or cropped soil was used).	**Location (country or USA state).**	**% OC**	**pH**	**Depth (cm)**	**DT_{50} /d actual**	**DT_{90}/d actual**	**St. (r_2)**	**DT_{50} (d) Norm.**	**Method of calculation**
Sand (bare	Flackenhorst,	0.8	5.7	0-10	20.7	68.8	0.869	N/A	1st order

soil)	Germany								non-linear
Silty clay loam (bare soil)	Hünfelden, Germany	0.8	7.1	0-10	63.3#	210#	0.919#	N/A	1st order non-linear
Loam (bare soil)	St. Claire, N. France	1.5	5.3	0-5	12#	40#	0.949#	N/A	1st order non-linear
Clay loam, (bare soil)	Lanta, S. France	0.88	6.0	0-5	8.9#	29.7#	0.964#	N/A	1st order non-linear
Cropped soil (maize): Niederhofen and Schifferstadt (Germany), <0.01 mg/kg after 27/28 days, Emilia Romagna (Italy) calculation of DT_{50} not possible; Lombardia and Veneto, (Italy), DT_{50s} uncertain due to non-validated LOQ.									

values from listing of endpoints

Rimsulfuron

No new field dissipation studies have been submitted with Rimsulfuron since EU approval. However, a new kinetic evaluation of the field dissipation study LeNoir et al, 2002a according to FOCUS degradation kinetics including temperature and moisture normalizations of the derived DT_{50} values is available for this assessment (Huber, 2007). The study Huber, 2007 was according to the zRMS also submitted for the Core Assessment (see Commenting Table) and should of have been summarized there. Thus, only the resulting DT_{50} values are listed here but no detailed evaluation in added in Appendix 2.

The DT_{50} values of the field dissipation study for rimsulfuron are presented in Table 5.4-15.

Table 5.4-15 Field dissipation studies of Rimsulfuron

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Clay, Greenville (Mississippi)	7.0	66	8.8	29	1st order, r^2: 0.958/ r^2: 0.881	-	-	Naidu, 1991
Sandy Clay Loam, Madera (California)	7.7	66	8.1	27	1st order, r^2:0.988/ r^2: 0.991	-	-	
Clay, Rochelle (Illinois)	7.4	66	16.8	55.8	1st order, r^2: 0.946/ r^2: 0.936	-	-	
Silty Sand, Catalonia (Spain)	6.7		5.6	19	r^2: 0.95 (1st order)	3 (DT_{90} FOMC/ 3.32)	FOMC (α:0.879, β:0.88), χ^2: 19.4%	LeNoir et al, 2002a, Huber, 2007
Clayey Silt, Hessen (Germany)	6.6	10	10	33	r^2: 0.94, χ^2: 12%	5	SFO, χ^2: 14.1%	LeNoir et al, 2002b, Huber, 2007
Loamy Sand, Fyn (Denmark)	6.6	10	14	46	r^2: 0.95 (1st order)	7	SFO, χ^2: 15.8%	LeNoir et al, 2002c, Huber, 2007

At some locations field dissipation studies are fulfilling ctgb criteria, so that DT_{50} values can be used for PEC_{GW} modeling. The respective DT_{50} values are summarized in Table 5.4-16.

Table 5.4-16: Field degradation studies of Rimsulfuron fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Silty Sand, Catalonia (Spain)	6.7		5.6	19	r^2: 0.95 (1st order)	3 (DT_{90} FOMC/ 3.32)	FOMC (α:0.879, β:0.88), χ^2: 19.4%	LeNoir et al, 2002b, Huber, 2007
Clayey Silt, Hessen (Germany)	6.6	10	10	33	r^2: 0.94, χ^2: 12%	5	SFO, χ^2: 14.1%	LeNoir et al, 2002b, Huber, 2007
Loamy Sand, Fyn (Denmark)	6.6	10	14	46	r^2: 0.95 (1st order)	7	SFO, χ^2: 15.8%	LeNoir et al, 2002c, Huber, 2007
Aggregated DT_{50} (n=3)	**Minimum/ Maximum (d)**					3/ 7		

The DT_{50} values from the field dissipation study for the metabolite IN-70941 are presented in 5.4-17. The field dissipation studies are fulfilling ctgb criteria, so that DT_{50} values can be used for PEC_{GW} modeling.

5.4-17 Field dissipation studies of the metabolite IN-70941 fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT_{50} /DT_{90} (d)	f.f. (as →met)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Silty Sand, Catalonia (Spain)	6.7	10	435/ -	0.18	1st order, r^2: 0,95	277	SFO, χ^2: 14,9%	LeNoir et al, 2002b, Huber, 2007
Clayey Silt, Hessen (Germany)	6.6	10	41/ 135	0.39	1st order, χ^2: 23%	58	SFO, χ^2:19,6%	
Loamy Sand, Fyn (Denmark)	6.6	10	368/ 1221	0.60	1st order,	502	SFO, χ^2: 19,8%	
Aggregated DT_{50} (n=3)	**Coefficient of variation (%)**					80		
	Geometric mean					200.5		
	10th/ 90th percentile (d)					101.8/ 457		

Aggregated formation fraction as → met (n=3)	**Arithmetic mean**	0.49	
	Maximum	0.60	

Additional DT_{50} values from the field dissipation study were also derived for the metabolite IN-E9260. However, they didn't pass the statistical tests (chi2>15%, t-test not passed) and are thus not considered reliable. Thus, they are not used for exposure assessment of ARIGO in Germany ad are thus not presented here.

5.4.2 Adsorption/desorption

Mesotrione

No new studies have been submitted regarding the adsorption and desorption properties of mesotrione since EU approval. The derived adsorption parameters for mesotrione are summarized in Table 25 of the core assessment, part B, section 5.

However, in the study Row and Lane, 1997b only K_d and K_{doc} values and not K_f and K_{foc} values were derived. Since a sufficient number of 9 K_f and K_{foc} values is available for mesotrione, only these were used for German exposure and risk assessment.

The K_{foc} values of mesotrione were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). The statitistic results of the analysis are presented in Table 5.4-12.

5.4-18 Statistic values according to INPUT DECISION 3.2 for mesotrione for PEC_{GW} modelling (n = 9)

Does the active substance dissociate ?	yes, pKs = 3.12	
correlation K_{foc} and pH	Kendall-τ: -0.611 p-value: 0.029	Negativ significant dependency → use pH tool
correlation K_f and oc	Kendall-τ: 0.722 p-value: 0.005	positiv significant (p-Wert < significance level)
coefficient of variation K_{foc}	90	too high (> 60%)
coefficient of variation Kf	140	too high (> 100%)
Correlation K_f and other soil parameters (clay, CEC)	Not relevant	not relevant
K_{foc}/K_f for PEC_{GW}	Calculation of PECgw using the FOCUS PELMO pH tool with two randomly selected Kfoc of mesotrione	
1/n PECgw	0.976	arithmetic mean all soils
$K_{foc, Runoff}$ for PEC_{sw}	53	Arithmetic mean all soils

$K_{foc, mobility class}$ for PEC_{sw}	18	10^{th} percentile

No new studies have been submitted regarding the adsorption and desorption properties of the metabolite MNBA since EU approval. The derived adsorption parameters for MNBA are summarized in Table 26 of the core assessment, part B, section 5. Since only two valid K_{foc} and one valid K_d value are available for MNBA and the K_{foc} of the remaining soils are expected to be smaller, the approach of the zRMS was followed and the minimum Kfoc value of 3 was used for the German exposure and risk assessment.

No new studies have been submitted regarding the adsorption and desorption properties of the metabolite AMBA since EU approval. The derived adsorption parameters for MNBA are summarized in Table 27 of the core assessment, part B, section 5. In the study Hand, 1999a only K_d and K_{doc} values and not K_f and K_{foc} values were derived. However, due to the low numbers of adsorption parameters, these values were included in exposure and risk assessment in order to allow a sufficient statistic analysis of the available data. The K_{foc} values of AMBA were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). The statitistic results of the analysis are presented in Table 5.4-19.

Table 5.4-19 Statistic values according to INPUT DECISION 3.2 for the metabolite AMBA for PEC_{GW} modelling (n = 9)

Does the active substance dissociate ?	yes, pKs = 3.12	
correlation K_{foc} and pH	Kendall-τ: -0.817 p-value: 0.003	Negativ significant dependency → use pH tool
correlation K_f and oc	Kendall-τ: 0.8172 p-value: 0.002	positiv significant (p-Wert < significance level)
coefficient of variation K_{foc}	76	too high (> 60%)
coefficient of variation Kf	123	too high (> 100%)
Correlation K_f and other soil parameters (clay, CEC)	Not relevant	not relevant
K_{foc}/K_f for PEC_{GW}	Calculation of PECgw using the FOCUS PELMO pH tool with two randomly selected Kfoc of AMBA	
1/n PECgw	0.85	arithmetic mean of the 4 soils, for which Kf and Kfoc values were derived
K_{foc}/K_f for PEC_{SW}	63	Arithmetic mean all soils

Nicosulfuron

No new studies have been submitted regarding the adsorption and desorption properties of Nicosulfuron since EU approval. But in the Core assessment not all available valid adsorption/desorption values have been considered. During the course of national assessment for Nicosulfuron and its metabolites further more studies regarding the adsorption and desorption properties of them had been submitted. Therefore for the national addendum all available valid adsorption and desorption values for nicosulfuron and its metabolites have been considered and summarized in Table 5.4-20 to 5.4-33.

Table 5.4-20: K_f, K_{foc} and 1/n (Freundlich exponent) values for Nicosulfuron

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL g$^{-1)}$	1/n (-)	Reference
Sandy loam	0.65	6.6	0.16	24.6	0.89	Priester und Sheftic, 1988
Sandy loam	1.24	6.5	0.28	22.6	0.91	
Silt loam	2.53	5.4	1.73	68.4	0.90	
Silt loam	2.77	4.3	0.61	22.0	0.91	
Silty clay loam	2.3	7.4	0.93	41	0.908	Sarff, 2005
Sandy loam	0.93	7.5	0.32	35	0.884	
Loamy sand	1.3	5.5	0.32	24	0.852	
sand/loamy sand	0.48	6.0	0.05	10.02	0.9031	Schanne, 1991
sandy loam/loamy sand	2.55	6.0	0.2	7.93	0.9914	
silt loam	1.42	7.7	0.73	51.33	0.9987	
silt loam/ loam	1.40	6.1	0.19	13.65	0.9948	

Table 5.4-21: Statistic values according to INPUT DECISION 3.3 for Nicosulfuron for PEC_{GW} modelling

coefficient of variation K_{foc}	63 %	Input_Decision 3.3
coefficient of variation Kf	98 %	Input_Decision 3.3
positive significant correlation oc-Kf	tau: 0.514 p: 0.018	Input_Decision 3.3
arithm. mean Kfoc	**29.00**	Input_Decision 3.3
1/n PECgw	**0.922** (arithmetic mean)	Input_Decision 3.3

Table 5.4-22: K_f, K_{foc} and 1/n (Freundlich exponent) values for ADMP

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL g$^{-1)}$	1/n (-)	Reference
Loamy sand	2.1	6.4	1.22	58.1	0.85	Aikens, 2001
Loamy sand	0.5	5.2	2.26	452	0.81	
Silt loam	3.1	5.5	45.3	1460	0.71	

Sandy loam	0.7	7.8	0.859	123	0.79	
Loamy sand	2.29	7.0	1.200	52	0.84	Völkel, 1995
Loamy sand	1.17	7.7	0.700	60	0.82	
Sandy loam	1.57	7.8	0.800	51	0.92	
Silt loam	4.05	7.3	1.700	42	0.91	
Silt loam	1.2	5.8	2.35	196	0.82	Aikens, 2001

Table 5.4-23: Statistic values according to INPUT DECISION 3.3 for ADMP for PEC_{GW} modelling

coefficient of variation K_{foc}	167 %	
coefficient of variation Kf	234 %	
K_{foc}/K_f for PEC_{GW}	2 simulations : 1. Kremsmünster scenario (pH7.7-7.0)1.-5. horizon. arithm. mean of Kf (neutral and alkaline soils 2. Hamburg scenario 1-3 horizon arithm. mean of kf; 4-6 horizon Kf=0	Input_Decision 3.3
1/n PECgw	**0.83** (arithmetic mean)	
positive significant correlation Kf-pH	tau: -0.648 p-value: 0.021	Input_Decision 3.3
arithm. mean in general:	Kf: **6.27** Kfoc:**277**	Input_Decision 3.3
arithm mean pH 7.7-7.0	Kf: **1.0518** Kfoc:65.6	

Table 5.4-24: K_f, K_{foc} and 1/n (Freundlich exponent) values for ASDM

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Sandy loam	2.10	5.2	0.065	3.1	1.08	Sarff, 2004
Silt loam	3.86	4.7	0.50	13.1	0.988	
Silty clay loam	3.34	7	0.63	18.7	1.01	
Clay loam	1.07	7.3	0.16	14.8	1.05	
Loamy sand	2.29	7.0	0.05	2.30	0.8165	Flückiger, 1995
Loamy sand	1.17	7.7	0.08	6.74	0.8126	

Sandy loam	1.57	7.8	0.12	7.70	1.0669	
Silt loam	4.05	7.3	0.24	6.03	0.9401	
Silt loam	0.977	5.2	0.070	7.1	1.23	Sarff, 2004

Table 5.4-25: Statistic values according to INPUT DECISION 3.3 for ASDM for PEC_{GW} modelling

coefficient of variation K_{foc}	62 %	Input_Decision 3.3
coefficient of variation Kf	100 %	Input_Decision 3.3
K_{foc}/K_f for PEC_{GW}	Hamburg scenario 1-3 horizon arithm. mean of kf; 4-6 horizon Kf=0	Input_Decision 3.3
1/n PECgw	**0.999** (arithmetic mean)	
arithm. mean in general	**Kf: 0.21** **Kfoc:9.0**	Input_Decision 3.3

Table 5.4-26: K_f, K_{foc} and 1/n (Freundlich exponent) values for AUSN

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam	2.10	5.2	0.283	13.5	1.05	Sarff, 2004
Silt loam	3.86	4.7	2.43	63.1	1.03	
Silty clay loam	3.34	7	3.21	96.3	1.02	
Clay loam	1.07	7.3	0.999	93.4	1.01	
Loamy sand	2.29	7.0	0.30	13.0	0.9825	Völkel, 1995
Loamy sand	1.17	7.7	0.40	35.6	0.9167	
Sandy loam	1.57	7.8	0.60	39.0	0.9752	
Silt loam	4.05	7.3	0.90	22.3	0.9618	
Silt loam	0.977	5.2	0.376	38.5	1.04	Sarff, 2004

Table 5.4-27: Statistic values according to INPUT DECISION 3.3 for AUSN for PEC_{GW} modelling

coefficient of variation K_{foc}	69 %	
coefficient of variation Kf	99 %	

K_{foc}/K_f for PEC_{GW}	Kf-values: 1 – 3 Horizon: 1.06 (arithmetic mean) and 4 – 6 Horizon: 0	Input_Decision 3.3
1/n PECgw	**0.998 (**arithmetic mean)	
arithm mean (pH7.7-7.0)	Kf: **1.06** Kfoc: 46	

Table 5.4-28: K_f, K_{foc} and 1/n (Freundlich exponent) values for UCSN

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Sandy loam	2.10	5.2	0.0631	3.00	1.09	Sarff, 2004
Silt loam	3.86	4.7	0.298	7.72	1.01	
Silty clay loam	3.34	7	0.354	10.6	1.04	
Clay loam	1.07	7.3	0.098	9.17	1.09	
Silt loam	0.977	5.2	0.081	8.25	1.06	Sarff, 2004

Table 5.4-29: Statistic values according to INPUT DECISION 3.3 for UCSN for PEC_{GW} modelling

coefficient of variation K_{foc}	36 %	
coefficient of variation Kf	78 %	
K_{foc}/K_f for PEC_{GW}	Kf**: 0.18** K_{foc}: **8** (arithmetic mean)	Input_Decision 3.3
1/n PECgw	**1.058** (arithmetic mean)	

Table 5.4-30: K_d, K_{doc} and 1/n (Freundlich exponent) values for HMUD

Soil Type	OC (%)	pH (-)	Kd (mL g-1	Kdoc (mL g-1)	1/n (-)	Reference
sandy loam	2.3	5.6	0.12	5.07		
loam	1.28	7.37	0.14	10.75	-	
silty clay loam	2.67	5.42	0.02	0.88	-	
clay	2.94	7.23	0.19	6.98	-	
siltloam	2.11	5.70	0.08	2.83	-	

Table 5.4-31: Statistic values according to INPUT DECISION 3.3 for HMUD for PEC_{GW} modelling

coefficient of variation K_{doc}	-	Kd-values only available

coefficient of variation K_d	-	Kd-values only available
K_{doc} for PEC_{GW}	**2** (10. Perz., worst case)	Kd-values only available
1/n PECgw	**1.0** (default)	

Table 5.4-32: K_d, K_{doc} and 1/n (Freundlich exponent) values for MU-466

Soil Type	**OC (%)**	**pH (-)**	**K_d (mL g^{-1}**	**K_{doc} (mL $g^{-1)}$**	**1/n (-)**	**Reference**
sandy loam	2.3	5.6	0.07	3.05	-	
loam	1.28	7.37	0.14	10.73	-	
silty clay loam	2.67	5.42	0.04	1.32	-	
clay	2.94	7.23	0.43	16.08	-	
siltloam	2.11	5.70	0.17	6.50	-	

Table 5.4-33: Statistic values according to INPUT DECISION 3.3 for MU-466 for PEC_{GW} modelling

coefficient of variation K_{doc}	-	Kd-values only available
coefficient of variation K_d	-	Kd-values only available
K_{doc} for PEC_{GW}	**2** (10. Perz.. worst case)	Kd-values only available
1/n PECgw	**1.0** (default)	

For the Metabolites HMUD (IN-37740) and MU-466 only K_d – values were available and hence the K_{doc}values were taken in to account for the ground water simulations.

Rimsulfuron

No new studies have been submitted regarding the adsorption and desorption properties of Rimsulfuron since EU approval. The derived adsorption parameters for mesotrione are summarized in Table 41 of the core assessment. part B. section 5.

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany. Texte Umweltbundesamt 56. 2011). The statitistic results of the analysis are presented in Table 5.4-34.

Table 5.4-34: Statistic values according to INPUT DECISION 3.2 for Rimsulfuron for PEC_{GW} modelling (n = 4)

Does the active substance dissociate ?	yes. pKs = 4.0	

correlation K_{foc} and pH	Kendall-τ: 0.333 p-value: 0.734	No significant correlation
correlation K_f and oc	Kendall-τ: 0.548 p-value: 0.235	No significant correlation
coefficient of variation K_{foc}	41	sufficiently low (≤ 60%)
Correlation K_f and other soil parameters (clay. CEC)	Not relevant	not relevant
K_{foc}/K_f for PEC_{GW}	48	Arithmetic mean all soils
1/n PECgw	1.02	arithmetic mean all soils
K_{foc}/K_f for PEC_{SW}	48	Arithmetic mean all soils

No new studies have been submitted regarding the adsorption and desorption properties of the metabolite IN-07941 since EU approval. The derived adsorption parameters for mesotrione are summarized in Table 42 of the core assessment. part B. section 5.

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany. Texte Umweltbundesamt 56. 2011). The statitistic results of the analysis are presented in Table 5.4-29.

Table 5.4-35: Statistic values according to INPUT DECISION 3.2 for IN-07941 for PEC_{GW} modelling (n = 4)

Does the active substance dissociate ?	yes. pKs = 4.0	
correlation K_{foc} and pH	Kendall-τ: 0.000 p-value: 1.000	No significant correlation
correlation Kf and oc	Kendall-τ: 1.000 p-value: 0.045	positiv significant correlation
coefficient of variation Kfoc	62	too high (> 60%)/
Correlation Kf and other soil parameters (clay. CEC)	Not relevant	not relevant
Kfoc/Kf for PECGW	61	Arithmetic mean all soils
1/n PECgw	0.935	arithmetic mean all soils
Kfoc/Kf for PECSW	61	Arithmetic mean all soils

No new studies have been submitted regarding the adsorption and desorption properties of the metabolite IN-07942 since EU approval. The derived adsorption parameters for mesotrione are summarized in Table 43 of the core assessment. part B. section 5.

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany. Texte Umweltbundesamt 56. 2011). The statitistic results of the analysis are presented in Table 5.4-36.

Table 5.4-36: Statistic values according to INPUT DECISION 3.2 for IN-07942 for PEC_{GW} modelling (n = 4)

Does the active substance dissociate ?	yes. pKs = 4.0	
correlation Kfoc and pH	Kendall-τ: 0.000 p-value: 1.000	No significant correlation
correlation Kf and oc	Kendall-τ: 1.000 p-value: 0.045	positiv significant correlation
coefficient of variation Kfoc	18	sufficiently low (≤ 60%)
Correlation Kf and other soil parameters (clay. CEC)	Not relevant	not relevant
Kfoc/Kf for PECGW	194	Arithmetic mean all soils
1/n PECgw	0.845	arithmetic mean all soils
Kfoc/Kf for PECSW	194	Arithmetic mean all soils

No new studies have been submitted regarding the adsorption and desorption properties of the metabolite IN-E9260 since EU approval. The derived adsorption parameters for mesotrione are summarized in Table 44 of the core assessment. part B. section 5.

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany. Texte Umweltbundesamt 56. 2011). The statitistic results of the analysis are presented in Table 5.4-37.

Table 5.4-37: Statistic values according to INPUT DECISION 3.2 for IN-E9260 for PEC_{GW} modelling (n = 4)

Does the active substance dissociate ?	yes. pKs = 4.0	
correlation Kfoc and pH	Kendall-τ: 0.000 p-value: 1.000	No significant correlation
correlation Kf and oc	Kendall-τ: 1.000 p-value: 0.045	positiv significant correlation
coefficient of variation Kfoc	79	too high (> 60%)/
Correlation Kf and other soil parameters (clay. CEC)	Not relevant	not relevant
Kfoc/Kf for PECGW	40	Arithmetic mean all soils
1/n PECgw	0.99	arithmetic mean all soils
Kfoc/Kf for PECSW	40	Arithmetic mean all soils

5.4.3 Rate of degradation in water/sediment

Mesotrione

No new water/sediment study with mesotrione has been submitted since EU approval. The DT_{50} values of the water/sediment study reviewed in the DAR are summarized in Table 5.4-38.

Table 5.4-38: Degradation in water/sediment of mesotrione

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic. Fit	$DissT_{50}$/ $DissT9_0$ water	Kinetic. Fit	$DissT_{50}$/ $DissT_{90}$ sed.	Kinetic. Fit	Reference
Virginia Water	6.5/ 21	1st order	6.6/ 22	1st order	No deposition into the sediment	-	Cayne & Payne. 1999
Old Basing	3.9/ 13	1st order	3.9/ 13	1st order	No deposition into the sediment	-	

There is no potential for mesotrione to accumulate in the sediment.

Nicosulfuron

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Nicosulfuron (Sarff. 2004; Vercruysse. 2002) reviewed in the

The DT_{50} values of the water/sediment study are summarized in Table 5.4-383.

Table 5.4-39: Degradation in water/sediment of Nicosulfuron

Water/sediment system pH water / pH sediment	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic. Fit	$DissT_{50}$/ $DissT9_0$ water	Kinetic. Fit	$DissT_{50}$/ $DissT_{90}$ sed.	Kinetic. Fit	Reference
I)River(Rhine) no data / 6.9	49.8 / 165.4 21.9 / 72.7	SFO. 0.978 FOMC. 0.9	32 / 106 63.9* / 212*	SFO. 0.922 FOMC. 0.90	21.9*/ 72.7* no data	SFO. 0.9026 FOMC. no data	Vercruysse. 2002; * calculated using Modelmaker
II)Pond(Anwil) no data / 6.9	33.2 / 110 no data	SFO. 0.994 FOMC. no data	24.9 / 83 66.2* / 220*	SFO. 0.993 FOMC. 0.97	8.8 */ 29.3* no data	SFO. 0.9737 FOMC. no data	Vercruysse. 2002; * calculated using Modelmaker
I)Estany de Banyoles 8.2 / 7.8	83 / 276	SFO. 0.951	80 / 267	SFO. 0.960	no data	-	Sarff. 2004
II)Golden Lake 8.3 / 8.2	102 / 340	SFO. 0.944	82 / 274	SFO. 0.962	no data	-	Sarff. 2004
Mineralisation and non-extractable residues (source: study Sarff ; 2004)							

Water/sediment system	**Mineralisation after 100 d or end of study**	**non-extractable residues after 100 d or end of study**
I)River (Rhine)	0.6% (105 d)	28.3% (105 d)
II)Pond (Anwil)	0.6% (105 d)	46.1% (105 d)
I)Estany de Banyoles	0.2% (102 d)	17.5% (102 d)
II)Golden Lake	0.5% (102 d)	20% (102 d)
Distribution in water / sediment (active substance)	study 1: water: after 14d 57.4% / 56.9%. after 105d 19.3% / 8.1% Sediment: after 14d max. 24.0% / 17.9% after 105d 8.1% / 2.7% study 2: water: 53% on day 45; 33% on day102 Sediment: max. 25% on day 3; 10% on day 102 DT_{50} 8.8-21.9 days (calculated with Modelmaker r²=0.90-0.97) (source: list of endpoints	
Distribution in water / sediment (relevant metabolites) source: study of Vercruysse (2002); Sarff (2004) and listing of end points (2007)	HMUD: water : max. 22.3% on day 102 (increasing)) sediment : max. 6.8% on day 102(increasing until end of study) AUSN: water : 9.1 %AR on day 177 (study end) sedimen t: 2.4 %AR on day 105 UCSN: water : 5.4 %AR on day 177 sedimenr : 1.4 %AR on day 105 ASDM: water : 6.9 %AR on day 177 sediment : 4.4 %AR on day 62	

Table 5.4-40: Accumulation of active substance and relevant metabolites in the sediment

active substance	Nicosulfuron
accumulation potential in sediment	no ($DT_{90.\text{whole system}}$ < 1 year)
accumulation factor (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	No evidence for accumulation.v faccu = 0.091 (DT50whole system max. = 102d)

Rimsulfuron

No new water/sediment study with Rimsulfuron has been submitted. However. a new kinetic evaluation of the water/sediment study according to FOCUS degradation kinetics is available for this assessment (Huber. 2007). The study Huber. 2007 was also submitted for the Core Assessment and should of have been summarized there. Thus. only the resulting DT_{50} values are listed here but no detailed evaluation in added in Appendix 2.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-41.

Table 5.4-41: Degradation in water/sediment of Rimsulfuron

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic. Fit	$DissT_{50}$/ $DissT_{90}$ water	Kinetic. Fit	$DissT_{50}$/ $DissT_{90}$ sed.	Kinetic. Fit	Reference
I Blackiston Wildlife Refuge	1/ 3	SFO. chi^2: 23.3%	1/ 3	SFO. chi^2: 19.7%	n.c.		Trabue & Lydick. 2001/ Huber. 2007
II Mills Lawn Stream	10/33	SFO. chi^2: 4.6%	7/ 24	SFO. chi^2: 4.9%	n.c.		

There is no potential for Rimsulfuron to accumulate in the sediment.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PEC_{soil} calculation for ARIGO according to EU assessment considering 5 cm soil depth are given in the core assessment. part B. section 5. chapter IIIA 9.4 and IIIA 9.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent. Löffler. Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018. UBA. Berlin 1999). Generally for active substances with a $K_{f.oc}$ < 500 a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f.oc}$ > 500 a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

Due to the fast degradation of the active substance Mesotrione in soil (DT_{90} <365 d. SFO. laboratory data). the accumulation potential of Mesotrione does not need to be considered.

Due to the fast degradation of the active substance Nicosulfuron in soil (DT_{90} < 365 d. SFO. laboratoryand field data) the accumulation potential of Nicosulfuron does not need to be considered.

Due to the fast degradation of the active substance Rimsulfuron in soil (DT_{90} < 365 d. SFO. laboratory data) the accumulation potential of Rimsulfuron does not need to be considered. Due to the slow degradation of the metabolites IN-70941 and IN-E9260 of Rimsulfuron in soil (DT_{90} > 365 d, Kinetic, laboratory data), the accumulation potential of IN-70941 and IN-E9260 needs to be considered. Therefore PEC_{soil} for the metabolites IN-70941 and IN-E9260 used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for Mesotrione. Nicosulfuron and Rimsulfuron as presented in Table 5.5-1.

Table 5.5-1: Input parameters for ARIGO for PEC_{soil} calculation

Active substance	DT_{50}
Mesotrione	Not required
Nicosulfuron	Not required
Rimsulfuron	Not required

Metabolite IN-70941	412.4 d (90th percentile, laboratory data) – see Table 5.4-11
Metabolite IN-E9260	674 d (90th percentile, laboratory data) – see Table 5.4-13

Additional $PEC_{soil.act}$ was calculated for the formulation ARIGO for a soil depth of 2.5 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil.act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for Mesotrione. Nicosulfuron and Rimsulfuron and for the formulation ARIGO are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use of ARIGO in maize used for German risk assessment

plant protection product:		ARIGO				
use:		00-001				
Number of applications		1				
application rate:		330 g/ha ARIGO with 118.8 g/ha Mesotrione. 39.6 g/ha Nicosulfuron and 9.9 g/ha Rimsulfuron				
crop interception:		25%				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Mesotrione	89.1	2.5	0.2376	20	n.c.	n.c.
Nicosulfuron	29.7	2.5	0.0792	20	n.c.	n.c.
Rimsulfuron	7.425	2.5	0.0198	20	n.c.	n.c.
Metabolite IN-70941	3.45*	2.5	0.0092	20	0.0014	0.0106
Metabolite IN-E9260	0.825**	2.5	0.0022	20	0.0006	0.0028
ARIGO	247.5	2.5	0.66	20	n.c.	n.c.

n.c.: not calculated
* calculated as direct application of IN-70941 using the maximum observed occurrence of 54.1% in soil and the molecular correction factor 0.852
** calculated as direct application of IN-E9260 using the maximum observed occurrence of 18.9% in soil and the molecular correction factor 0.580

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of ARIGO for the intended for uses in maize using FOCUS Surface Water are given in the core assessment. part B. section 5. chapter IIIA 9.7 and IIIA 9.8.

For authorization in Germany. exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off. drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilisation

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Mesotrione is < 10^{-5} Pa. Hence the Mesotrione is regarded as non-volatile. Therefore exposure of surface water by Mesotrione due to deposition following volatilization does not need/ needs to be considered.

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Nicosulfuron is < 10^{-5} Pa. Hence the active substance Nicosulfuron is regarded as non-volatile. Therefore exposure of surface water by the active substance Nicosulfuron due to deposition following volatilization does not need to be considered.

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Rimsulfuron is < 10^{-5} Pa. Hence Rimsulfuron is regarded as non-volatile. Therefore. exposure of surface water by the Rimsulfuron due to deposition following volatilization does not need to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application. the exposure assessment via spray drift is based on the application rate in conjunction with the 90^{th} percentile of the drift values. For multiple applications. lower percentiles of the drift values for each application are applied. resulting in an overall 90^{th} percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of Mesotrione. Nicosulfuron and Rimsulfuron used for the PEC_{SW} calculations with EVA 2.1

Parameter	Active substance Mesotrione	Reference
vapour pressure at 20 °C (Pa)	<5.7 x 10^{-6}	See core assessment. section 5. Table 2
Solubility in water (mg/L)	160	See core assessment. section 5. Table 2
DT_{50} hydrolysis/photolysis (d)	1000	default
Parameter	**Active substance Nicosulfuron**	**Reference**
vapour pressure at 20 °C (Pa)	<8 x 10^{-10} Pa at 25°C	See core assessment. section 5. Table 3
Solubility in water (mg/L) at pH 7 and 25°C	pH 5.0: 0.25g/L at 20 °C pH 6.5: 7.5g/L at 20 °C pH 9.0: 76.4 g/L at 20 °C	See core assessment. section 5. Table 3
DT_{50} hydrolysis/photolysis (d)	1000	default
Parameter	**Active substance Rimsulfuron**	**Reference**
vapour pressure at 20 °C (Pa)	8.9 x 10^{-7}	See core assessment. section 5. Table 4
Solubility in water (mg/L)	7300	See core assessment. section 5. Table 4
DT_{50} hydrolysis/photolysis (d)	1000	default

The calculated PECsw values after exposure via spray drift for the active substance Mesotrione for the intended use 00-001 in maize (worst case application rate) are summarized in Table 5.6-2.

Table 5.6-2 PEC_{SW} for the active substance Mesotrione after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance			Mesotrione					
use no:			00-001					
application rate/number of applications / interval			1 x 118.8 g/ha					
scenario/percentile:			90^{th}/ agriculture					
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**common**	**90% red.**	**75% red.**	**50% red.**
0	100.00	39.60	-	-	39.60	3.96	9.90	19.80
1	2.77	1.10	-	-	1.097	0.11	0.27	0.55
5	0.57	0.23	-	-	0.226	0.02	0.06	0.11
10	0.29	0.11	-	-	0.115	0.01	0.03	0.06
15	0.20	0.08	-	-	0.079	0.01	0.02	0.04
20	0.15	0.06	-	-	0.059	0.01	0.01	0.03

The calculated PECsw values after exposure via spray drift for the active substance Nicosulfuron for the intended use 00-001 in maize (worst case application rate) are summarized in Table 5.6-3.

Table 5.6-3 PEC_{SW} for the active substance Nicosulfuron after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance			Nicosulfuron					
use no:			00-001					
application rate/number of applications / interval			1 x 39.6 g/ha					
scenario/percentile:			90^{th}/ agriculture.					
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**common**	**90% red.**	**75% red.**	**50% red.**
0	100.00	13.20	-	-	13.20	1.32	3.30	6.60
1	2.770	0.366	-	-	0.366	0.04	0.09	0.18
3	-		-	-				
5	0.570	0.075	-	-	0.075	0.01	0.02	0.04
10	0.290	0.038	-	-	0.038	0.00	0.01	0.02

15	0.200	0.026	-	-	0.026	0.00	0.01	0.01
20	0.150	0.020	-	-	0.020	0.00	0.00	0.01

The calculated PECsw values after exposure via spray drift for the active Rimsulfuron for the intended use 00-001 in maize are summarized in Table 5.6-4.

Table 5.6-4 PEC_{SW} for the active substance Rimsulfuron after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance		Rimsulfuron						
use no:		00-001						
application rate/number of applications / interval		1 x 9.9 g/ha						
scenario/percentile:		90^{th} percentile/ agriculture						
distance (m)	**PECsw via drift**		**PECsw via volatilisation**		**PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)**			
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**common**	**90% red.**	**75% red.**	**50% red.**
0	100.00	3.30	-	-	3.30	0.33	0.83	1.65
1	2.77	0.09	-	-	0.091	0.01	0.02	0.05
5	0.57	0.02	-	-	0.019	0.00	0.00	0.01
10	0.29	0.01	-	-	0.010	0.00	0.00	0.00
15	0.20	0.01	-	-	0.007	0.00	0.00	0.00
20	0.15	0.00	-	-	0.005	0.00	0.00	0.00

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substances Mesotrione. Nicosulfuron and Rimsulfuron in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The parameters for Mesotrione used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-5.

Table 5.6-5 Input parameters for Mesotrione used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	**Mesotrione**	**Reference**
$K_{foc.\ Runoff}$	53	arithmetic mean. see Table 5.4-11
$K_{foc.\ mobility\ class}$	18	10^{th} percentil. see Table 5.4-11
DT_{50} soil (d)	36.3	90^{th} percentile. see Table 5.4-1
Solubility in water (mg/L)	160	See core assessment. section 5. Table 2

The parameters for Nicosulfuron used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-6.

Table 5.6-6 Input parameters for Nicosulfuron used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Nicosulfuron	Reference
$K_{foc. Runoff}$	29 (arithm. mean)	Input Decision 3.3
$K_{foc. mobility class}$	29(arithm. mean)	Input Decision 3.3
DT_{50} soil (d)	36.6 (90. Perc. pF2; lab.)	Input Decision 3.3
Solubility in water (mg/L)	pH 6.5: 7.5g/l at 19.7°C	see core assessment. section 5. point 5.3.1.1

The parameters for Rimsulfuronused for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-7.

Table 5.6-7 Input parameters for Rimsulfuron used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Rimsulfuron	Reference
$K_{foc. Runoff}$	48	arithm. Mean. see Table 5.4-34
$K_{foc. mobility class}$	48	arithm. Mean. see Table 5.4-34
DT_{50} soil (d)	40.6	90^{th} percentile. see Table 5.4-10
Solubility in water (mg/L)	7300	See core assessment. section 5. Table 4

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Mesotrione for the intended for use 00-001 in maize are summarized in Table 5.6-8.

Table 5.6-8 PEC_{SW} of Mesotrione in an adjacent ditch due to surface run-off and drainage

Active substance: Mesotrione **Use no:** 00-001 **Application rate:** 1 x 118.8 g/ha **Interception (%)** 25		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini Gesamtaustrag}$) (µg/L)**
0	0.64	0.64
5	0.55	0.55
10	0.47	0.47
20	0.33	0.33
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.81	
Spring/summer	0.26	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Nicosulfuron for the intended for use in Maize (worst case application rate) are summarized in Table 5.6-9.

Table 5.6-9 PEC_{SW} of Nicosulfuron in an adjacent ditch due to surface run-off and drainage

Active substance: Nicosulfuron **Use no:** 00-001 **Application rate:** 39.6 g/ha (single application) **Interception (%)** 25%		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.16	0.16
5	0.14	0.14
10	0.12	0.12
20	0.08	0.08
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.27	
Spring/summer	0.09	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Rimsulfuron for the intended for use 00-001 in maize (worst case application rate) are summarized in Table 5.6-10.

Table 5.6-10 PEC_{SW} of Rimsulfuron in an adjacent ditch due to surface run-off and drainage

Active substance: Rimsulfuron **Use no:** 00-001 **Application rate:** 1 x 9.9 g/ha **Interception** 25%		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.04	0.04
5	0.04	0.04
10	0.03	0.03
20	0.02	0.02
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.07	
Spring/summer	0.02	

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of Mesotrione. Nicsulfuron and Rimsulfuron for the intended uses of ARIGO in maize according to EU assessment are given in the core assessment. part B. section 5. chapter IIIA 9.6.

For authorization in Germany. risk assessment for groundwater considers two pathways. (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany. Texte Umweltbundesamt 56. 2011) for tier 1 and tier 2 risk assessment. According to Hold et al. 2011. endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO 4.4.3.

In tier 3 risk assessment. results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenario used for PECgw modelling is summarized in Table 5.7-1. It covers the intended uses of ARIGO in maize according to Table 5.2-1.

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.1

use no	00-001
application rate	0.1188 kg/ha Mesotrione 0.0396 kg/ha Nicosulfuron 0.0099 kg/ha Rimsulfuron
Soil effective application rate	0.0891 k/ha Mesotrione 0.0297 g/ha Nicosulfuron 0.007425 kg/ha Rimsulfuron
crop (crop rotation)	None and every other year
date of application	7th of May
interception (%)	25
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Mesotrione

The endpoints used for groundwater modelling for Mesotrione and its metabolites MNBA and AMBA according to INPUT DECISION 3.2 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters related to Mesotrione for PEC_{GW} modelling

Parent	**Mesotrione**	**Remarks/Reference to core assessment. part B. section 5**
molecular weight (g/mol)	339.3	See Table 5.3-1
DT_{50} in soil (d)	21.5	Geometric mean. acidic soils. (pH < 6.5. n=14). see Table 5.4-1
K_{foc}	Calculation of PECgw using the FOCUS PELMO pH tool with two randomly selected K_{foc} of mesotrione (see Table 5.4-11). Used Kfoc values: 170 at pH 5.1 and 19 at pH 7.7	
pKa	3.12	See Table 2 of the core assessment. part B. section 5)
1/n	0.976	Arithmetic mean
Plant Uptake	0	default
Metabolite	**MNBA**	
molecular weight (g/mol)	245	See Table 5.3-2
Formation fraction as → MNBA	1.0	default
DT_{50} in soil (d)	4.7	Geometric mean laboratory studies at 20° and pF2. see Table 11 of the core assessment. part B. section 5
K_{foc}	3	Minimum (see Table 26 of the core assessment. part B. section 5)
1/n	0.976	Maximum
Plant Uptake	0	default
Metabolite	**AMBA**	
molecular weight (g/mol)	215	See Table 5.3-2
Formation fraction MNBA → AMBA	1.0	default
DT_{50} in soil (d)	18.3	Geometric mean laboratory studies at 20° and pF2. see Table 5.4-2
K_{foc}	Calculation of PECgw using the FOCUS PELMO pH tool with two randomly selected K_{foc} of MNBA (see Table 5.4-12). Used Kfoc values: 3.21 at pH 5.1 and 17.7 at pH 7.8	
pKa	3.12	Dissociation constant of parent
1/n	0.85	Minimum (see Table 27 of the core assessment. part B. section 5)
Plant Uptake	0	default

The results of the groundwater simulation for a yearly application of ARIGO are presented in Table 5.7-3.

Table 5.7-3 PEC$_{GW}$ at 1 m soil depth of Mesotrione and its metabolites MNBA and AMBA considered relevant for German exposure assessment for a yearly application of ARIGO

Use No.	Szenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3		
		Mesotrione	Metabolite MNBA	Metabolite AMBA
00-001	Hamburg	0.108	0.343	0.195

The results of the groundwater simulation for only one application of ARIGO every other year is presented in Table 5.7-3.

Table 5.7-4 PEC$_{GW}$ at 1 m soil depth of Mesotrione and its metabolites MNBA and AMBA considered relevant for German exposure assessment for one application of ARIGO every other year

Use No.	Szenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3		
		Mesotrione	Metabolite MNBA	Metabolite AMBA
00-001	Hamburg	0.038	0.170	0.077

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3. a groundwater contamination of the active substance Mesotrione in concentrations of ≥ 0.1 µg/L can not be excluded for a yearly application of ARIGO the intended use in maize. However. a groundwater contamination of the active substance Mesotrione in concentrations of ≥ 0.1 µg/L is not expected for only one application of ARIGO every other year the intended use in maize.

For the metabolite MNBA of Mesotrione a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the application in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

For the metabolite AMBA of Mesotrione a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for a yearly application of ARIGO in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3. For only one application every other year however. a groundwater concentration ≥ 0.1 µg/L for the metabolite AMBA can be excluded.

Nicosulfuron

The endpoints used for groundwater modelling for Nicosulfuron and its metabolites AUSN; UCSN; ASDM; ADMP; HMUD and MU-466… according to INPUT DECISION 3.3 are summarized in Table 5.7-2.

Table 5.7-5 Input parameters related to Nicosulfuron for PEC$_{GW}$ modelling

Parent	Nicosulfuron	Remarks/Reference to core assessment. part B. section 5

molecular weight (g/mol)	410.14	see Table 5.3-3
DT_{50} in soil (d)	18.6 (geometric mean pF2)	see Table 5.4-3
K_{foc}	29 (arithm mean)	see Table 5.4-20
1/n	0.922 (arithm mean)	see Table 5.4-20
plant uptake	0 and 0.5	
metabolite	**HMUD**	
molecular weight (g/mol)	336.4	see Table 5.3-5
Formation fraction	0.442 (from parent)	see Table 5.4-4
DT_{50} in soil (d)	23.8 (geomean pF2)	see Table 5.4-4
K_d	2 (10. perc. = worst case)	see Table 5.4-31
1/n	1.0 (default)	see Table 5.4-31
plant uptake	0 and 0.5	
metabolite	**AUSN**	
molecular weight (g/mol)	314.36	see Table 5.3-5
Formation fraction	0.687 (from HMUD)	see Table 5.4-7
DT_{50} in soil (d)	195.7 (geomean pF2)	see Table 5.4-7
K_f	1. - 3. Horizon: 1.06 (CV<100%) 4. - 6. Horizon: 0.00	see Table 5.4-27
1/n	0.998 (arithm mean)	see Table 5.4-27
plant uptake	0 and 0.5	
metabolite	**UCSN**	
molecular weight (g/mol)	315.3	see Table 5.3-5
Formation fraction	0.313 (from HMUD)	see Table 5.4-8
DT_{50} in soil (d)	286.3 (geomean pF2)	see Table 5.4-8
K_{foc}	8 (arithm. mean)	see Table 5.4-29
1/n	1.058 (arith. mean)	see Table 5.4-29
plant uptake	0 and 0.5	
metabolite	**ADMP**	
molecular weight (g/mol)	155.16	see Table 5.3-5
Formation fraction	0.214 (from parent)	see Table 5.4-5
DT_{50} in soil (d)	6.5 (geomean pF2)	see Table 5.4-5
K_{foc}	Hamburg 1.-3. Horizon (arithm mean 6.27) 4. - 6. Horizon 0	see Table 5.4-23
1/n	0.83 (arithm measn)	see Table 5..4-23
plant uptake	0 and 0.5	
metabolite	**ASDM**	

molecular weight (g/mol)	292.2	see Table 5.3-5
Formation fraction	0.214 (from parent)	see Table 5.4-6
DT_{50} in soil (d)	237.9 (geomean pF2)	see Table 5.4-6
K_{foc}	Hamburg 1.-3. Horizon 0.21 (arithm. mean) 4.-6. Horizon 0	see Table 5.4-25
1/n	0.999 (arithm. mean)	see Table 5.4-25
plant uptake	0 and 0.5	
metabolite	**MU-466**	
molecular weight (g/mol)	215.23	see Table 5.3-5
Formation fraction	0.282 (from ASDM)	see Table 5.4-9
DT_{50} in soil (d)	85.2 (geomean pF2)	see Table 5.4-9
K_d	2 (10. Perc. = worst case)	see Table 5.4-33
1/n	1.0 (default)	see Table 5.4-33
plant uptake	0 and 0.5	

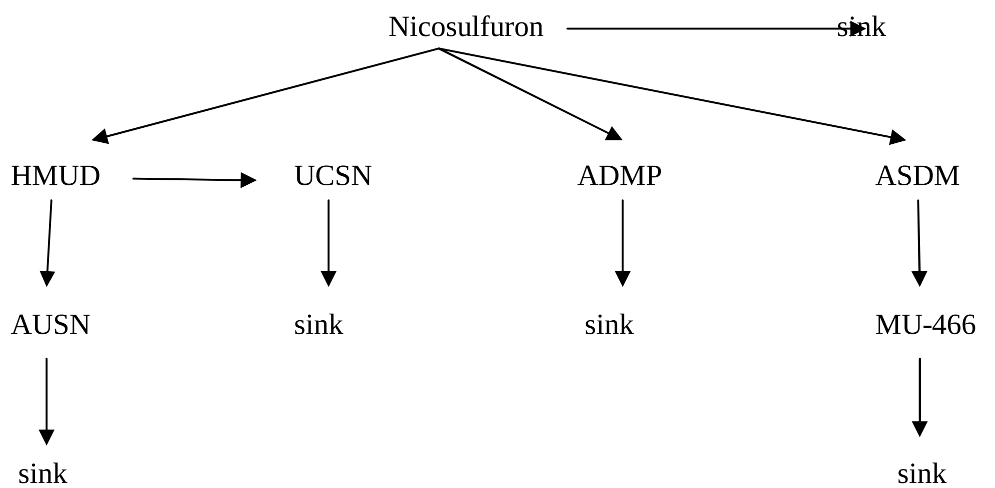
The results of 3 groundwater simulations are presented in Table 5.7-6.

Table 5.7-6 PEC_{GW} at 1 m soil depth of Nicosulfuron and its metabolites HMUD; UCSN; ADMP; ASDM; AUSN; MU-466 were considered to be relevant for German exposure assessment

Use No.	**Szenario**	**80^{th} Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0 ; application: every year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.184	1.493 1.422 0.001 2.082 1.445 0.001
Use No.	**Szenario**	**80^{th} Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0.5 ; application: every year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466

00-001	Hamburg	0.133	0.818 0.568 0.001 1.035 0.672 <0.001
Use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0.5 ; application: every other year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.059	0.398 0.276 <0.001 0.533 0.334 <0.001
Use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0 ; application: every other year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.082	0.676 0.702 <0.001 0.984 0.717 <0.001

Scheme used for FOCUSPELMO_5.5.3 - Simulation



According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3. a groundwater contamination of the active substance Nicosulfuron in concentrations of ≥ 0.1 µg/L cannot be excluded for the intended use in maize for a yearly application. However, a groundwater contamination of Nicosulfuron in concentrations of ≥ 0.1 µg/L can be excluded for one application every other year.

For the metabolites HMUD: UCSN: ASDM: AUSN of Nicosulfuron a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the application in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

In addition to the PECgw modelling experimental data from lysimeter studies are used to assess the leaching behaviour of the active substance Nicosulfuron.

Rimsulfuron

Groundwater modelling with Rimsulfuron was performed separately with laboratory degradation data derive potential groundwater concentrations for IN-70942 and IN-E9260 and as a higher tier modelling with field dissipation data to derive potential groundwater concentrations for Rimsulfuron and IN-90741.

The endpoints used for groundwater modelling for Rimsulfuron and its metabolites IN-90741. IN-90742 and IN-E9260 according to INPUT DECISION 3.1 are summarized in Table 5.7-2.

Table 5.7-7 Input parameters related to Rimsulfuron for PEC_{GW} modelling

Parent	**Rimsulfuron**	**Remarks/Reference to core assessment. part B. section 5**
molecular weight (g/mol)	431.45	See Table 5.3-6
DT_{50} in soil (d)	24.5	Geometric mean (laboratory. SFO. pF2. 20°C). see Table 5.4-10
	7	Maximum field studies (SFO. pF2. 20°C). seeTable 5.4-16
K_{foc}	48	Arithmetic mean. see Table 5.4-34
1/n	1.02	Arithmetic mean. see Table 5.4-34
Plant Uptake	0	default
Metabolite	**IN-90741**	
molecular weight (g/mol)	367.39	See Table 5.3-7
Formation fraction as → IN-70941	0.57	Arithmetic mean. formation fractions laboratory studies. see Table 5.4-11
	0.49	Arithmetic mean. formation fractions field studies. see 5.4-17
DT_{50} in soil (d)	71 d 412 d	10^{th} percentile for modelling entries of IN-90472. (laboratory. SFO. pF2. 20°C). see Table 5.4-11 90^{th} percentile for modelling entries of IN-

		90471 . (laboratory. SFO. pF2. 20°C). see Table 5.4-11
	102 d 457 d	10th percentile for modelling entries of IN-90472. (field studies .SFO. pF2. 20°C). see 5.4-17 90th percentile for modelling entries of IN-90471. (field studies. SFO. pF2. 20°C). see 5.4-17
K_{foc}	61	Arithmetic mean. see Table 5.4-35
1/n	0.935	Arithmetic mean. see Table 5.4-35
Plant Uptake	0	default
Metabolite	**IN-90742**	
molecular weight (g/mol)	324.36	See Table 5.3-7
Formation fraction IN-70941 → IN-70942	1	default
DT_{50} in soil (d)	94	Geometric mean. (laboratory. SFO. pF2. 20°C). see Table 5.4-12
K_{foc}	194	Arithmetic mean. see Table 5.4-36
1/n	0.845	Arithmetic mean. see Table 5.4-36
Plant Uptake	0	default
Metabolite	**IN-E9260**	
molecular weight (g/mol)	250.29	See Table 5.3-7
Formation fraction as → IN-E9260	0.18	Formation fractions laboratory studies. n=1. see Table 5.4-13
DT_{50} in soil (d)	389	Geometric mean. (laboratory. SFO. pF2. 20°C). see Table 5.4-13
K_{foc}	40	Arithmetic mean. see Table 5.4-37
1/n	0.99	Arithmetic mean. see Table 5.4-37
Plant Uptake	0	default

The results of the groundwater simulation for a yearly application of ARIGO are presented in Table 5.7-3.

Table 5.7-8 PEC_{GW} at 1 m soil depth of Rimsulfuron and its metabolite IN-70941. IN-70942 and IN-E9260 considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth ($\mu g\ L^{-1}$) modeled by FOCUS PELMO 5.5.3			
		Rimsulfuron	Metabolite IN-70941	Metabolite IN-70942	Metabolite IN-E9260
00-001	Hamburg	<0.001	0.777	0.032	0.255

The results of the groundwater simulation for only one application of ARIGO every other year is presented in Table 5.7-3.

Table 5.7-9 PEC$_{GW}$ at 1 m soil depth of Rimsulfuron and its metabolite IN-70941. IN-70942 and IN-E9260 considered relevant for German exposure assessment for one application of ARIGO every other year

Use No.	Szenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3			
		Rimsulfuron	Metabolite IN-70941	Metabolite IN-70942	Metabolite IN-E9260
00-001	Hamburg	<0.001	0.377	0.015	0.126

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3. a groundwater contamination of the active substance Rimsulfuron in concentrations of ≥ 0.1 µg/L is not expected for the intended use in maize.

For the metabolite IN-70942 of Rimsulfuron. a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

For the metabolites IN-70941 and IN-E9260 of Rimsulfuron. a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the application in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

5.7.1.2 Experimental data to the leaching behaviour of the active substances

Mesotrione

No lysimeter studies with Mesotrione are available.

Nicosulfuron

In case of the active substance Nicosulfuron exposure assessment is based additionally on results of 2 lysimeter studies (authors : Kurth; Report No. BAS-010/7-11 dated 1997 and Burgener et al.; Report No 321546 dated 1996.

Table 5.7-10 Data of the Lysimeter study 1

location	Schmallenberg			
crop	Maize			
sowing	22.05.95 and 13.05.96 winter wheat end of 1996			
application rate	1 x **40 g ai./ha** on 20.06.95			
stage of development	3 – 4 leaf stage (BBCH: 13-14)			
irrigation [mm]	600,5 (1995/96); 1039,3 (1996/97) and 75 (1997)			
Leachate [L]	1st year (06.95 until 06.96): 401,1 (Lys.13) and 455,9 (Lys. 16) 2nd year (06.96 until 06.97): 674,6 (Lys.13) and 699,7 (Lys. 16) sum: 1075,7 (Lys.13) und 1155,6 (Lys. 16)			
average concentration per year [µg/L]				
	Lysimeter 13		Lysimeter 16	
	1st year	2 nd year	1st year	2 nd year

Nicosulfuron	0.06	0.03	0.07	0.06
ASDM (IN-V9367)	**0.99**	**0.18**	**0.88**	**0.30**
AUSN (IN-HYY21)	**0.24**	**0.43**	**0.24**	**0.59**
UCSN (IN-GDC42)	**0.18**	0.03	**0.22**	0.07
MU-466 (IN-64859)	0.03	0.02	0.04	0.04

Table 5.7-10 Data of the Lysimeter study 2

location	Switzerland						
crop	Maize						
sowing	27.05.92 (Maize); 11.05.93 (Maize); summer wheat in summer 1994 and winter rye in autumn 1994						
application rate	[pyridine-^{14}C]Nicosulfuron: 60 g ai./ha on 19.06.92 (Lysimeter 12 and 14) and 1 x 60 g ai./ha on 07.06.93 (Lysimeter 14) [pyrimidine-^{14}C]Nicosulfuron: 60 g ai./ha on 16.06.92 (Lysimeter 15 and 16) and 1 x 60 g ai./ha on 02.06.93 (Lysimeter 15)						
stage of development	BBCH: 13 - 14 (3 – 4 leaves)						
irrigation [mm]	831.9 (1992/93); 1136 (1993/94) and 1118 (1994/95)						
Leachate [L]	[pyridine-^{14}C]Nicosulfuron: 1st year (08.92 until 06.93): 333.9 (Lys.12) and 335.0 (Lys. 14) 2nd year (06.93 until 05.94): 529.4 (Lys.12) and 514.6 (Lys. 14) 3rd year (07.94 until 07.95): 537.5 (Lys.12) and 521.6 (Lys. 14) sum: 1400,8 (Lys.12) und 1371.2 (Lys. 14) [pyrimidine-^{14}C]Nicosulfuron: 1st year (07.92 until 06.93): 303.4 (Lys.16) and 345.8 (Lys. 15) 2nd year (06.93 until 05.94): 485.1 (Lys.16) and 542.6 (Lys. 15) 3rd year (06.94 until 07.95): 434.2 (Lys.16) and 545.5 (Lys. 15) sum: 1222.7 (Lys.16) and 1433.9 (Lys. 15)						
average concentration per year [µg/L]							
[pyridine-^{14}C]Nicosulfuron:							
Lysimeter 12 (1 x 60 g ai./ha)							
	WS	ASDM (IN-V9367)	AUSN (IN-HYY21)	UCSN (IN-GDC42)	MU-466 (IN-64859)	DDTP	HMUD
1st year	0.15	2.24	0.54	0.36	0.15	0.02	n.d.
2 nd year	0.04	0.47	0.89	0.21	0.08	0.02	n.d.
3rd year	0.02	0.10	0.18	0.02	0.03	< 0.01	0.01
Lysimeter 14 (2 x 60 g ai./ha)							
1st year	0.13	2.70	0.85	0.20	0.14	0.01	n.d.
2 nd year	0.05	1.69	1.62	0.94	0.14	0.03	0.01
3rd year	0.03	0.34	0.68	0.06	0.07	n.d.	0.03
[pyrimidine-^{14}C]Nicosulfuron:							
Lysimeter 16 (1 x 60 g ai./ha)							
	WS	M4	M5	M7	M9	DDTP	HMUD
1st year	0.19	<0.01	0.02	0,03	<0,01	0,02	0,01
2 nd year	0.03	<0.01	0.01	0,01	<0,01	0,02	< 0,01
3rd year	<0.01	<0.01	<0,01	<0,01	<0,01	<0,01	<0,01
Lysimeter 15 (2 x 60 g ai./ha)							
1st year	0.17	<0.01	0.03	0.04	0.01	0.03	0.03
2 nd year	0.10	<0.01	0.04	0.01	<0.01	0.04	0.01
3rd year	0.01	<0.01	0.02	<0.01	<0.01	<0.01	<0.01

Table 5.7-11 Resultss of the FOCUSPELMO_5.5.3 - simulations in comparison to the lysimeter study results

	simulation results FOCUSPELMO_5.5.3			results of Lysimeter studies	
	1 x 39.6 g a.i./ha yearly application rate			1 x 40 g a.i./ha every other year	1 x 60 g a.i./ha every year
	pu*=0; every year [µg/L]	pu*=0.5; every year [µg/L]	pu*=0; every other year [µg/L]	[µg/L]	[µg/L]
Nicosulfuron	**0.184**	**0.133**	0.082	0,07	**0,19**
HMUD	**1.493**	**0.818**	**0.676**	--	0,03
AUSN	**1.445**	**0.672**	**0.717**	0,59 (2nd year)	1,62
ADMP	0.001	0.001	<0.001	--	--
UCSN	**1.422**	**0.568**	**0.702**	0,22	0,94
ASDM	**2.082**	**1.035**	**0.984**	0,99	2,7
MU-466	0.001	<0.001	<0.001	< 0,01	0,15

*pu = plant uptake

All available data for leaching of Nicosulfuron into ground water are considered in this national addendum. On the basis of the FOCUSPELMO-simulations and the results of the lysimeter studies it can be seen that an application of nicosulfuron at a rate of 40 g/ha every other year does not lead to a leaching of the active substance into groundwater at concentrations $\geq$ 0.1µg/L.
A limitation of the application of DPX-Q9H36 51WG that contains nicosulfuron is necessary to protect the ground water. Therefore an application of maximum 40g nicosulfuron /ha only every other year was assessed for application in Germany.
The metabolites HMUD, AUSN, UCSN and ASDM leach to ground water in concentrations $\geq$ 0.1µg/L.
Furthermore the results of a representative ground water monitoring have to be taken into account (see below).

The experimental data on the leaching behaviour of the active substance nicosulfuron show that the active substance nicosulfuron could leach into ground water at concentrations of ≥ 0.1µg/L in the intended uses in maize.

For the metabolites HMUD, AUSN, UCSN and ASDM of nicosulfuron concentrations of ≥ 0.1µg/L in groundwater cannot excluded.

Monitoring studies for nicosulfuron

Some results from interim reports of monitoring studies for a groundwater monitoring of nicosulfuron are available.

Interim report Fa. DuPont :

author:	Schneider M.; Zietz E.
study:	Groundwater Monitoring for Nicosulfuron and 6 metabolites in four representative regions in Germany 1st Interim Report, Study Period April 2010-March 2011
date:	2011-08-01
study No.:	IF-10/01407246
Method / Guidelines:	see publication Aden et al. (2002)
enterprise:	ZA 6258 / DuPont
period / start:	4 years / 04/2010

Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 20 representative locations in Germany were chosen. The limit of quantification (LOQ) was 0.1µg/L. Therefore a direct comparison to the simulation calculation results was impossible. The LOQ should be at least 0.05 µg/L or below this value. The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be 1.7µg/L on 4 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

Interim report Fa. ISK:

author:	Gezahegne, W.
study:	Groundwater Monitoring for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM in Germany in 2010-2013 Interim Report April 2010 - March 2011
date:	2012-03-02
study No.:	S10-1357; BVL 2290721
Method / Guidelines:	see publication Aden et al. (2002)
enterprise:	ZA 4409 / ISK
period / start:	4 years / 04/2010
Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application per year) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 21 representative locations in Germany were chosen. (LOQ = 0.05; estemated concentration of nicosulfuron: <0.015µg/L). The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be max. 0.61µg/L on 14 of 21 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

Rimsulfuron

No lysimeter studies with Rimsulfuron are available.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS-PELMO 5.5.3 show that concentrations of ≥ 0.1µg/L of the active substance Mesotrione in groundwater cannot be excluded for a yearly application of ARIGO the intended use in maize. However. a groundwater contamination of the active substance Mesotrione in concentrations of ≥ 0.1 µg/L can be excluded for only one application of ARIGO every other year the intended use in maize.

For the metabolite MNBA of Mesotrione. concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. However. the metabolites MNBA is classified as eco-toxicological not relevant for groundwater (see national addendum, part B. section 8).

For the metabolite AMBA of Mesotrione. concentrations of ≥ 0.1µg/L in groundwater cannot be excluded for a yearly application of ARIGO in the intended use in maize. However. for only one application every other year concentrations of ≥ 0.1µg/L in groundwater can be excluded for the metabolite AMBA.

Results of modelling with FOCUSPELMO 5.5.3 show that concentrations ≥ 0.1µg/L of the active substance Nicosulfuron in the intended use in maize cannot be excluded in case of a yearly application. However. a groundwater contamination of the active substance Nicosulfuron in concentrations of ≥ 0.1 µg/L can be excluded for only one application of ARIGO every other year for the intended use in maize.

The metabolites HMUD, UCSN, ASDM and AUSN can leach into groundwater in concentrations of ≥ 0.1µg/L. However the metabolites HMUD, UCSN, ASDM and AUSN are classified as eco-toxicological not relevant for groundwater (see national addendum, part B. section 8).

Results of modelling with FOCUS-PELMO 5.5.3 show that the active substance Rimsulfuron is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of ARIGO in maize.

For the metabolite IN-70942 of Rimsulfuron concentrations of ≥ 0.1µg/L in groundwater can be excluded. For the metabolites IN-70941 and IN-E9260 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. However. the metabolites IN-70941 and IN-E9260 are classified as eco-toxicological not relevant for groundwater (see national addendum, part B. section 8).

Consequences for authorization:

Use No. 00-001 NG 200, NG 326 and NG 327

5.7.2 Groundwater contamination by bank filtration due to surface water exposure via run-off and drainage

Mesotrione

The input parameters for Mesotrione used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-11.

Table 5.7-11 Input parameters for Mesotrione used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Mesotrione	Reference
$K_{foc.\ Runoff}$	53	arithmetic mean. see Table 5.4-11
$K_{foc.\ mobility\ class}$	18	10^{th} percentil. see Table 5.4-11
DT_{50} soil (d)	36.3	90^{th} percentile. see Table 5.4-1
Solubility in water (mg/L)	160	See core assessment. section 5. Table 2
Mobility class	3	Exposit 3.01 parameter

Reduction by bank filtration	90%	Exposit 3.01 parameter

The calculated PECgw for Mesotrione after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-12.

Table 5.7-12 PEC_{gw} for Mesotrione after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Mesotrione**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	118.8 g/ha/ 25% interception	0	0.005	autumn/winter/ early spring	0.006
		5	0.004		
		10	0.004	spring/summer	0.002
		20	0.003		
required labelling		None			

The soil metabolites MNBA and AMBA of Mesotrione are formed > 10 % and 2 x 5% (subsequent samples) respectively in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are summarized in Table 5.7-13. the results are given in Table 5.7-14 and Table 5.7-15.

Table 5.7-13: Input parameter for soil metabolites of MNBA and AMBA for EXPOSIT 3.01

Parameter	**Metabolite MNBA**	**Reference**
Molecular weight (g/mol)	215	See Table 5.3-2
Correction factor molecular weight	0.722	
Maximum occurrence in soil (%)	57.2	See Table 5.3-2
$K_{foc. Runoff}$	3.16	Minimum. see core assessment. section 5. Table 26
$K_{foc. mobility class}$	3.16	Minimum. see core assessment. section 5. Table 26
DT_{50} soil (d)[1)]	10	90th percentile (laboratory studies. 20°C. pF2). see core assessment. section 5. Table 11
Solubility in water (mg/L)	160	Solubility of parent. see core assessment. section 5. Table 2
Mobility class	1	
Reduction by bank filtration	100%	
Parameter	**Metabolite AMBA**	

Molecular weight (g/mol)	245	See Table 5.3-2
Correction factor molecular weight	0.634	
Maximum occurrence in soil (%)	9.7	See Table 5.3-2
$K_{foc.\ Runoff}$	63	Arithmetic mean. see Table 5.4-19
$K_{foc.\ mobility\ class}$	63	Arithmetic mean. see Table 5.4-19
DT_{50} soil (d)[1)]	51.9	90th percentile (laboratory studies. 20°C. pF2). see Table 5.4-2
Solubility in water (mg/L)	160	Solubility of parent. see core assessment. section 5. Table 2
Mobility class	3	
Reduction by bank filtration	90%	

1) only relevant for mobility class

Table 5.7-14: PEC_{gw} for soil metabolite AMBA of Mesotrione after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolite		**MNBA**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	49 g/ha. 25% interception	0	<0.001	autumn/winter/ early spring	<0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001
		20	<0.001		
required labelling		none			

Table 5.7-15: PEC_{gw} for soil metabolite MNBA of Mesotrione after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolite		**AMBA**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	6.2 g/ha. 25% interception	0	<0.001	autumn/winter/ early spring	<0.001 <0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001

		20	<0.001		
required labelling		none			

According modelling with EXPOSIT 3. groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Mesotrione due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded. According to modelling with EXPOSIT 3. groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of AMBA and MNBA due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can also be excluded.

Nicosulfuron

The input parameters for nicosulfuron used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-11.

Table 5.7-16 Input parameters for nicosulfuron used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	**nicosulfuron**	**Reference**
$K_{foc.\ Runoff}$	29	see Table 5.4-21
$K_{foc.\ mobility\ class}$	29	see Table 5.4-21
DT_{50} soil (d)	36.6 (90. perc. pF2)	see Table 5.4-3
Solubility in water (mg/L)	7500 (at pH6.5)	see Table 5.3-4
Mobility class	3	
Reduction by bank filtration	90%	

The calculated PECgw for nicosulfuron after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-12.

Table 5.7-17 PEC_{gw} for Nicosulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Nicosulfuron**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	39.6 g/ha	0	<0.001	autumn/winter/ early spring	0.002
	25%	5	<0.001		
		10	<0.001	spring/summer	0.001
		20	<0.001		
required labelling		none			

All metabolites of nicosulfuron do not show any ecotoxicological relevance. Therefore a simulation for the metabolites is not necessary.

Rimsulfuron

The input parameters for Rimsulfuron used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-11.

Table 5.7-18 Input parameters for Rimsulfuron used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Rimsulfuron	Reference
$K_{foc. Runoff}$	48	arithm. Mean. see Table 5.4-34
$K_{foc. mobility class}$	48	arithm. Mean. see Table 5.4-34
DT_{50} soil (d)	40.6	90^{th} percentile. see Table 5.4-10
Solubility in water (mg/L)	7300	See core assessment. section 5. Table 4
Mobility class	3	Exposit parameter
Reduction by bank filtration	90%	Exposit parameter

The calculated PECgw for Rimsulfuron after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-12.

Table 5.7-19 PEC_{gw} for Rimsulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Rimsulfuron**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-0012	9.9 g/ha. 25% interception	0	<0.001	autumn/winter/ early spring	<0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001
		20	<0.001		
required labelling		None			

The soil metabolites of Rimsulfuron (see Table 5.3-7) are formed 2 x > 5% in subsequent samples or > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are and summarized in Table 5.7-20. The results are given in Table 5.7-21.Table 5.7-22 and Table 5.7-23.

Table 5.7-20: Input parameter for soil metabolites of Rimsulfuron for EXPOSIT 3.01

Parameter	Metabolite IN-70941	Reference
Molecular weight (g/mol)	367.39	See Table 5.3-7
Correction factor molecular weight	0.852	
Maximum occurrence in soil (%)	54.1%	See Table 5.3-7

$K_{foc. Runoff}$	61	Arithmetic mean. see Table 5.4-35
$K_{foc. mobility class}$	61	Arithmetic mean. see Table 5.4-35
DT_{50} soil (d)[1)]	412	90^{th} percentile (laboratory studies. 20°C. pF 2). see Table 5.4-11
Solubility in water (mg/L)	7300	Solubility of parent. see core assessment. section 5. Table 4
Mobility class	3	
Reduction by bank filtration	90%	
Parameter	**Metabolite IN-70942**	
Molecular weight (g/mol)	324.36	See Table 5.3-7
Correction factor molecular weight	0.752	
Maximum occurrence in soil (%)	23.5%	See Table 5.3-7
$K_{foc. Runoff}$	194	Arithmetic mean. see Table 5.4-36
$K_{foc. mobility class}$	194	Arithmetic mean. see Table 5.4-36
DT_{50} soil (d)[1)]	142	90^{th} percentile (laboratory studies. 20°C. pF 2). see Table 5.4-12
Solubility in water (mg/L)	7300	Solubility of parent. See core assessment. section 5. Table 4
Mobility class	2	
Reduction by bank filtration	75%	
Parameter	**Metabolite IN-E9260**	
Molecular weight (g/mol)	250.29	See Table 5.3-7
Correction factor molecular weight	0.580	
Maximum occurrence in soil (%)	18.9%	See Table 5.3-7
$K_{foc. Runoff}$	40	Arithmetic mean. see Table 5.4-37
$K_{foc. mobility class}$	40	Arithmetic mean. see Table 5.4-37
DT_{50} soil (d)[1)]	674	90^{th} percentile (laboratory studies. 20°C. pF 2). see Table 5.4-13
Solubility in water (mg/L)	7300	Solubility of parent. See core assessment. section 5. Table 4
Mobility class	3	
Reduction by bank filtration	90%	

[1)] only relevant for mobility class

Table 5.7-21: PEC_{gw} for soil metabolite IN-70941 of Rimsulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolit		**IN-70941**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	4.56 g/ha. 25% interceptioin	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		None			

Table 5.7-22: PEC_{gw} for soil metabolite IN-70942 of Rimsulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolit		**IN-70942**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	1.75 g/ha. 25% interceptioin	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		None			

Table 5.7-23: PEC_{gw} for soil metabolite IN-E9260 of Rimsulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolit		**IN-E9260**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001	1.01 g/ha. 25% interceptioin	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		None			

According modelling with EXPOSIT 3. groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Rimsulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According to modelling with EXPOSIT 3. groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites IN-70941. IN-70942 and IN-E9260 of Rimsulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None

Appendix 2 List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant). Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
KIIA7.12	Schneider M.; Zietz E.	2011	Groundwater Monitoring for Nicosulfuron and 6 metabolites in four representative regions in Germany 1st Interim Report, Study Period April 2010-March 2011	Y	Du Pont	(interim report)
KIIA7.12	Gezahegne , W.	2012	Groundwater Monitoring for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM in Germany in 2010-2013 Interim Report April 2010 - March 2011	Y	ISK	(interim report)

*

1) accepted (study valid and considered for evaluation)

2) not accepted (study not valid and not considered for evaluation)

3) not considered (study not relevant for evaluation)

4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)

5) supplemental (additional information. alone not sufficient to fulfil a data requirement. considered for evaluation)

Appendix 3 Detailed evaluation of studies relied upon

Report only studies. which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

KIIIA1 9 Fate and Behaviour in the Environment

KIIA7.12 Schneider et al. 2011

Reference:	
Author	Schneider M.; Zietz E.
Report:	Groundwater Monitoring for Nicosulfuron and 6 metabolites in four representative regions in Germany 1st Interim Report, Study Period April 2010-March 2011
Date:	2011-08-01
Guideline(s):	see publication Aden et al. (2002)
Deviations:	interim report
GLP:	Y
Acceptability:	Y
Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 20 representative locations in Germany were chosen. The limit of quantification (LOQ) was 0.1µg/L. Therefore a direct comparison to the simulation calculation results was impossible. The LOQ should be at least 0.05 µg/L or below this value. The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be 1.7µg/L on 4 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

KIIA7.12 Gezahegne, W.; 2012

Reference:	
Author	Gezahegne, W.
Report:	Groundwater Monitoring for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM in Germany in 2010-2013 Interim Report April 2010 - March 2011
Date:	2012-03-02
Guideline(s):	see publication Aden et al. (2002)
Deviations:	interim report
GLP:	Y
Acceptability:	Y

Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 20 representative locations in Germany were chosen. The limit of quantification (LOQ) was 0.1µg/L. Therefore a direct comparison to the simulation calculation results was impossible. The LOQ should be at least 0.05 µg/L or below this value. The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be 1.7µg/L on 4 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

Appendix 4 Table of Intended Uses in Germany (according to BVL 19/01/2012)

PPP (product name/code)	**ARIGO/ DPX-Q9H36 51WG**	**Formulation type:**	**Water dispersible granule**
active substance 1	**Mesotrione**	**Conc. of as 1:**	**360 g/kg**
active substance 2	**Nicosulfuron**	**Conc. of as 2:**	**120 g/kg**
active substance 2	**Rimsulfuron**	**Conc. of as 3:**	**30 g/kg**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	g. kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Maize	F	annual monocotyledonous weeds annual dicotyledonous weeds	spray	After emergence. BBCH 12 18	a) 1 b) 1	a) 0.33 kg/ha b) 0.33 kg/ha	a) 118.8 g/ha Mesotrione. 39.6 g/ha Nicosulfuron. 9.9 g/ha Rimsulfuron b) 118.8 g/ha Mesotrione. 39.6 g/ha Nicosulfuron. 9.9 g/ha Rimsulfuron	200 - 400		

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: DPX-Q9H36 51WG

Active Substances:

Mesotrione 360 g/kg

Nicosulfuron 120 g/kg

Rimsulfuron 30 g/kg

Central Zone
Zonal Rapporteur Member State: Czech Republik

NATIONAL ADDENDUM - Germany

Applicant: E. I. Dupont de Nemours and Company
Date: January 2013

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

This document presents the national addendum for Germany and should be read in conjunction with the core assessment for section 6. The national addendum addresses national requirements differing from the standard EU modelling and risk assessment procedures. It refers moreover to specific management and risk mitigation practices that can be implemented in Germany.

6.1 Proposed use pattern and considered metabolites

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment in Germany is presented in Table 6.1-1. A list of all intended uses in Germany is given in Appendix 3. The individual use numbers for Germany stated in Table 5.2-1 and Appendix 3 of this document have been assigned from the German Federal Office of Consumer Protection and Food Safety (BVL) for administrative purposes.

Table 6.1-1: Critical use pattern of DPX-Q9H36 51WG (ARIGO)

Group/ use No	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Maize BBCH 12	Spray/ Agriculture	1 application Time: 7th of may 25% interception	118.8 g/ha Mesotrione 39.6 g/ha Nicosulfuron 9.9 g/ha Rimsulfuron	89.1 g/ha Mesotrione 29.7 g/ha Nicosulfuron 7.425 g/ha Rimsulfuron

6.1.2 Consideration of metabolites

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU reviews of nicosulfuron (SANCO/3780/07 – rev2, 2008 respectively EFSA Scientific Report 2007; 120, 1-91) and rimsulfuron (SANCO/10528/2005 – rev. 2, 2006 respectively EFSA Scientific Report 2005; 45; 1-61) as well as in the core dossier for the central zone. Mesotrione metabolites were only considered in the core dossier for the central zone (no metabolite assessment in SANCO/1416/2001 – Final, 2003). The metabolites of mesotrione, nicosulfuron, and rimsulfuron have been assessed as ecotoxicologically not relevant. Therefore, the metabolites will not be considered further in the risk assessment.

Further information on metabolites is provided in Part B, Section 5 and Part B, Section 8.

6.2 Effects on Birds

Please refer to the core dossier for the central zone.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

For the short-term risk assessment (acute toxicity) please refer to the core dossier for the central zone.

For the long-term risk refinement for the active ingredient mesosulfuron of the formulation DPX-Q9H36 51WG the cMS does not accept the endpoint from the 28-day study of Lees (2000) of 2.4 mg/kg bw/d since the study duration was not long enough to cover all live stages of rat (for detailed information please see the rational below).

Relevant toxic endpoints for the long-term risk assessment for mammals are given in the following table (see also core dossier):

Table 6.3-1: Toxicity of the active substances rimsulfuron, nicosulfuron and mesotrione to mammals

Species	Substance	Exposure: Duration System	Results: Toxicity	Reference: Author Date Code	ICS-Nr.
Rat	Rimsulfuron	Multi-generation study 2 years	NOAEL : 11.8 mg/kg bw/d[1)] Reduced body weight	Keller D.A. 1993 HLR 559-90	76058
Rat	Nicosulfuron	2 Generations	NOAEL : 3861 mg/kg bw/d[2)] Reproduction	Willoughby 1992 91/ISK130/0054	74135
Rat	Mesotrione	3 Generations	NOEL = 0.3 mg/kg bw/d (2.5 ppm)[3)] Offspring survival, ocular effects	Milburn, G. 1997 CTL/P/5147	77113
Mouse	Mesotrione	20 weeks	NOEL = 2 mg/kg bw/d (=10 ppm)[4)] Increased liver weight, reduced body weight (offspring)	Moxon, M. 1997 CTL/P/5531	77114

[1)] EFSA Scientific Report 2005; 45; 1-61 for rimsulfuron

[2)] EFSA Scientific Report 2007; 120, 1-91 for nicosulfuron

[3)] Study listed in core dossier

[4)] DAR for Mesotrione (1999)

Please find in the following the rational for the use of the NOAEL = 2.0 mg/kg bw/d (Moxon, 1997) as relevant toxic endpoint for the risk assessment:

The applicant suggests the refinement of the ecotoxicologcial endpoint. Instead of the NOEL of 0.3 mg/kg bw/d for rats (Milburn, 1997) a NOAEL of 2.4 mg/kg bw/d, derived from a 28-day study on rats (Lees, 2000), was suggested.

As justification the rapid degradation of mesotrione and the specific sensitivity of rats to mesotrione was given. The sensitivity to mesotrione observed for rats was not observed for rabbit or mouse.

Lees, 2000: According to the EFSA Guidance Document 1438 (2009) the long-term risk assessment is based on an evalutation of effects observed during a long-term exposure of test organisms. Furthermore, a multi-generation study has to cover all (potentially sensitive) life stages of the test organisms. In shorttermstudies not all life stages are considered and, therefore, it can not be excluded that a sensitive life stage is omitted. Thus, despite the rapid degradation of mesotrione, the acceptability criterium of TER ≥ 5 respectively 2 (modified acceptability criterium specific for Germany) can not be applied to the ecotoxicological endpoint derived from short-term studies or studies with shortened exposure, if the mode of action of the substance is not fully known. Sensitive life stages may vary depending on the active substance and the mode of action and it can not be excluded that a sensitive life stage was omitted. Therefore, the Federal Environment Agency (UBA) does not agree to use the 28-day NOAEL of 2.4 mg/kg bw/d (Lees, 2000) as relevant endpoint for long-term risk assessment. However, from this study it can be derived that the increase of the tyrosine levels in male rats (and potential impairment of the liver) is in direct proportionality to the exposure to mesotrione and that the effect is reversible.

Milburn, 1997: Statistically significant reduction of pup survival was observed in the F1 generation at the concentration of 10 ppm (see DAR for mesotrione (1999), Vol 3, B.6.6.1). At the concentration of 100 ppm this effect was less pronounced (no statistic significance) but was increasing again at the highest test concentration of 2500 ppm (statistically significant reduction compared to control). Furthermore, increased organ weights and ocular effects caused by tyrosinaemia were observed at a concentration of 10 ppm. Effects on organ weights and eye effects were considered to have no relevance for reproduction according to the BfR report for Annex I inclusion of mesotrione. According to the DAR (DAR, Vol 3, B.6.6.1 – Conclusion), effects on reproduction (decreased litter size) at 0.3 mg/kg bw/d were reversible based on results obtained for recovery sub-groups. Therefore, in the DAR, a NOAEL of 100 ppm was considered appropriate for ecotixicological risk evaluation and was used for Annex I inclusion of mesotrione (DAR Vol 3, B.9.3, p. 281). However, at 100 ppm statistically significant effects on the body weight of the F1 and F2CT(continuous treatment) generation were observed.

Moxon 1997: From this study a NOAEL of 2 mg/kg bw/d (= 10 ppm) was derived. At the (next higher) test concentration of 50 ppm the tyrosin levels of the F1 and F2A generation were significantly increased (at maximum18-fold, F2A generation - males). An increase of the tyrosin level is reversible, however, it can not be excluded that thereby caused effects may affect reproduction of wild life as it is not known to which extent (besides cloudy eyes) the tyrosinaemia affects sensory organs and influences e.g. foraging success. Furthermore, organ weights of pups and adults were increased at the test concentration of 50 ppm and at all higher test concentrations.

From the available data it can be derived that the effects observed at lower treatment levels are reversiblefor rats (Lees 2000 and Milburn 1997) and it was assumed that these effects are not relevant forpopulations. Furthermore, the active substance mesotrione rapidly degrades (DT_{50} for mesotrione inimmature maize <12 hours, White 2001).The German Federal Environment Agency (UBA) assumes the NOAEL of 2 mg/kg bw/d, derived from the multi-generation study with mice (Moxon 1997), to be sufficiently protective to regulate also the observed effects (increased tyrosin levels and ocular effects) for rats at concentrations below 2 mg/kg bw/d. The NOAEL of 2 mg/kg bw/d was also used by BfR for the assessment of the human toxicology in the process of Annex I inclusion of mesotrione.

Tier 1 risk assessment

For the Tier 1 risk assessment, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009. Annex I). The risk assessment is driven by the active ingredient mesotrione of the formulation DPX-Q9H36 51WG.

The relevant short-cut values for scenarios evaluated are summarized in the following table.

Table 6.3-2: Mammal generic focal species for the intended use of the formulation DPX-Q9H36 51WG and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
00-001	Maize BBCH 12-18	Small insectivorous mammal “shrew”	4.2
		Small herbivorous mammal “vole”	72.3
		Small omnivorous mammal “mouse”	7.8

The outcome of the Tier 1 risk assessment step is presented in the following table.

Table 6.3-3: Reproductive mammal risk assessment of DPX-Q9H36 51WG (Tier 1)

Substance	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
Mesotrione	"Shrew"	0.1188	0.53	4.2	1	0.264	2.0	7.6
	"Vole"			72.3	1	4.55		**0.44**
	"Mouse"			7.8	1	0.45		4.4
TERs shown in bold fall below the relevant trigger.								

Based on the refined Tier 1 assessment step, the calculated TER value for the generic focal species "shrew" (*Sorex araneus*) achieve the acceptability criterium TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects.

For generic focal species *Microtus arvalis* ("vole") and *Apodemus sylvaticus* ("mouse") the acceptability criterium TER ≥ 5 is not achieved. In cases where the relevant model species for assessment of the risk from the intended uses of DPX-Q9H36 51WG is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the 'worst case' for agricultural areas in Europes' central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in populations creating the necessity for control measures). Hence, a TER ≥ 2 in the long-term exposure scenario for the generic focal species "mouse" may be accepted as sufficient according to Bundesanzeiger (Official Gazette, 2010): Bekanntmachung über die Umsetzung des EFSA-Guidance Document zur Risikobewertung für Vögel und Säuger (BVL 10/02/14). Nr.94. p.2228-2229 ff. (29.06.2010). Public domain.

For the generic focal species "vole" (*Microtus arvalis*) even the modified acceptability criterium TER ≥ 2 is not achieved. This indicates an unacceptable risk for mammals due to the intended use of DPX-Q9H36 51WG in maize according to the label. Further refinement is necessary.

As a further refinement step, a refined DT_{50} of 0.5 days for residue levels in immature maize is used and the refined 21 day TWA residue factor (f_{twa}) was calculated in accordance with the core dossier.

Table 6.3-4: Refinement of reproductive risk assessment according to EFSA Journal (2009) for *Microtus arvalis* exposed to mesotrione

Application rate (kg/ha)	Species / Diet	MAF	TWA	Short cut Value (Mean RUD)	DDD	Endpoint (mg/kg bw/day)	TER
0.1188	vole *Microtus arvalis* 25% weeds 50% weed seeds 25% ground arthropods	1	0.034	72.3	0.295	2.0	**6.8**

A TER(mix) was calculated with the following formula:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s.}_i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

For nicosulfuron and rimsulfuron the screening step assessment resulted in long-term TER values of 2524 and 31.05, respectively (see core dossier for the central zone).

TER (mix) = 5.6

Based on the further refined Tier 1 assessment step, the calculated TER(mix) value for the long-term risk resulting from an exposure of mammals to mesotrione, nicosulfuron, and rimsulfuron according to the GAP of the formulation DPX-Q9H36 51WG achieves the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of DPX-Q9H36 51WG in maize according to the label.

Drinking water exposure

In case of early post-emergence uses as intended for DPX-Q9H36 51WG mammals might be exposed via drinking water from leaves or puddles. The active ingredients mesosulfuron, nicosulfuron and rimsulfuron are less sorptive substances (Koc < 500 L/kg), according to the new Guidance Document (EFSA, 2009), and calculations of drinking water exposure and TER are necessary for the active ingredient mesotrione since the ratio of effective application rate (118.8 g mesotrione/ha) to the relevant endpoint (2.0 mg/kg bw/d) exceeds 50. For nicosulfuron and rimsulfuron the ratio application rate to endpoint does not exceed 50.

The assessment of the risk to mammals exposed to the active ingredient mesotrione of the formulation DPX-Q9H36 51WG via drinking water is based on the evaluation of *Apodemus sylvaticus* (21.7 g bw, drinking water intake rate: 5.1 mL/d, drinking water uptake: 0.24 L/kg bw/d).

Table 6.3-5: Assessment of the risk for *Apodemus sylvaticus* from an exposure to Mesotrione through drinking water uptake from leaves or puddles

Parameter		**comments**
Application rate [g/ha]	118.8	
DT_{50} soil [d]	36.3	
Water application rate [L/ha]	200	Worst case
Koc [L/kg]	122	See Core dossier Section 5, mean value
LD50 (mg/kg bw/d)	>5000	
NOEL (mg/kg bw/d)	2.0	
TER_{acute} (Leaf scenario)	>351	
TER_{acute} (Puddle scenario)	>355991	
TER_{lt} (Puddle scenario)	142	

Based on the calculation of the risk arising from drinking water exposure, the calculated TER values for mammals exposed to the active substance mesotrione according to the GAP of the formulation DPX-Q9H36 51WG achieve the acceptability criteria TER ≥ 10 for acute effects and TER ≥ 5 for long-term effects.

6.4 Effects on Aquatic Organisms

6.4.1 Toxicity

Please refer to the core dossier for the central zone.

However, for nicosulfuron the endpoint E_yC_{50} = 0.0011 mg/L (*Lemna gibba*) was used instead of the EC_{50} = 0.0017 mg/L (*Lemna gibba*) given in the core dossier.

Species	**Substance**	**Exposure:** **Duration System**	**Results: Toxicity**	**Reference: Author Date, Code**	**ICS-Nr**
Lemna gibba	Nicosulfuron techn.	7 d Semi-static	E_yC_{50} : 0.0011 mg/L Frond numbers[1)] NOEC : 0.000087 mg/L real	Bätscher, R. 2008 B81461	73954

[1)] Study newer than DAR (2005) or EFSA Scientific Report (2007) for nicosulfuron and providing the lowest endpoint for nicosulfuron

6.4.2 Exposure

DPX-Q9H36 51WG is formulated as wettable granule containing mesotrione, nicosulfuron, and rimsulfuron as active substances. According to the GAP table of intended uses (see Appendix 3) the application of the formulation is considered to take place in maize once per year at BBCH 12-18. The formulation is applied as aqueous spray (200-400 L water/ha) in conjunction with the surfactant 004873-00 DU PONT TREND (DPX-KG691, 0.3 L/ha) and will be used against annual monocotyledonous and dicotyledonous weeds in maize.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When DPX-Q9H36 51WG is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application and by run-off and drainage.

In addition to the FOCUS based evaluation presented in the core dossier, an aquatic risk assessment is presented based on the two German evalution models: EXPOSIT 3.0 and DRIFTOX 4.0. The risk evaluations are based on the most sensitive aquatic endpoints: E_bC_{50} = 0.0077 mg ai/L (*L. gibba*) for mesotrione, E_bC_{50} = 0.0011 mg ai/L (*L. gibba*) for nicosulfuron, and E_bC_{50} = 0.0046 mg ai/L (*L. minor*) for rimsulfuron. Furthermore, the toxic endpoint for the formulation DPX-Q9H36 51WG for aquatic plants was considered: E_bC_{50} = 0.0062 mg product/L (*L. gibba*).

The calculation of concentrations in surface water via spray drift is based on data by Rautmann and Ganzelmeier. The vapour pressure of the active substances mesotrione, nicosulfuron and rimsulfuron are below 1×10^{-5} Pa. Thus, the active substances are regarded as non-volatile and a calculation of inputs resulting from volatilization is not necessary.

The input parameters for EXPOSIT 3.0 used for modelling surface water exposure via run-off and drainage in an adjacent ditch are summarized in dRR NA Part B, Section 5.6.

6.4.3 Toxicity to Exposure ratios

The risk for aquatic organisms exposed to mesotrione, nicosulfuron, and rimsulfuron was assessed according to the intended use of the formulation DPX-Q9H36 51WG.

The initial maximum PEC_{SW} values resulting from run-off, drainage, and drift were compared to the relevant toxicity endpoints. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoints are the test results for aquatic plants (Lemna) as given above. The ratio endpoint/’corresponding safety factor’ is higher for all other organisms.

In the following tables PECsw and the resulting TER values are presented for the intended use of the formulation DPX-Q9H36 51WG as given in Table 6.1-1.

6.4.3.1 TER values for the entry into surface water via spraydrift

Table 6.4-1: TER-values regarding the exposure to the formulation DPX-Q9H36 51WG via spraydrift scenario "agriculture" (Model: DRIFTOX 4.0)

Compound:			**DPX-Q9H36 51WG**			
Crop / Application rate:			**Agriculture; 1 x 330 g product/ha**			
Growth stage and season			**-**			
Indication:			**00-001 (maize)**			
PEC-selection:			**actual**			
Drift-Percentile:			**90th percentile of drift probabilities**			
Buffer zone	**Entry via spraydrift**		**PECsw [µg prod/L]; conventional and drift reducing technique**			
[m]	**[%]**	**[µg/L]**	**0% conv.**	**90% red.**	**75% red.**	**50% red.**
0	**100.0**	110.00	110.00	-	-	-
1	**2.770**	3.0470	3.0470	0.3047	0.7618	1.5235
5	**0.570**	0.6270	0.6270	0.0627	0.1568	0.3135
10	**0.290**	0.3190	0.3190	0.0319	0.0798	0.1595
15	**0.200**	0.2200	0.2200	0.0220	0.0550	0.1100
20	**0.150**	0.1650	0.1650	0.0165	0.0413	0.0825

Relevant toxicity endpoint: E_bC_{50} = 0.0062 mg product/L (*L. gibba*) Relevant TER: 10				
Buffer zone [m]	**TER**			
0	0.056	-	-	-
1	2.0	**20**	8.1	4.1
5	9.9	99	**40**	**20**
10	**19**	194	78	39
15	28	282	113	56
20	38	376	150	75
Risk mitigation measures	**NW 605 (1 m: 90% red. ; 5 m: 75% red. / 50% red.) NW 606 (10 m)**			

6.4.3.2 TER values for the entry into surface water via run-off and drainage

Table 6.4-2: TER-values regarding the exposure to the active ingredient mesosulfuron via run-off and drainage (EXPOSIT 3.01)

Compound:	**Mesotrione**	
Application rate:	**Agriculture; 1 x 118.8 g a.s./ha; 25 % interception**	
Indication	**00-001 (maize)**	
PEC-selection:	**actual**	
Relevant toxicity endpoint:	**E_bC_{50} = 0.0077 mg a.s./L**	
Relevant TER:	**10**	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.64	12
5	0.55	14
10	0.47	16
20	0.33	23
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	not relevant	not relevant
Spring/summer	0.26	29
Risk mitigation measures	**none**	

Table 6.4-3: TER-values regarding the exposure to the active ingredient nicosulfuron via run-off and drainage (EXPOSIT 3.01)

Compound:	**Nicosulfuron**	
Application rate:	**Agriculture; 1 x 39.6 g a.s./ha; 25 % interception**	
Indication	**00-001 (maize)**	
PEC-selection:	**actual**	
Relevant toxicity endpoint:	**E_bC_{50} = 0.0011 mg a.s./L**	
Relevant TER:	**10**	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.16	**6.8**
5	0.14	**7.8**
10	0.12	**9.1**
20	0.08	13
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	not relevant	not relevant
Spring/summer	0.09	13
Risk mitigation measures	**NW 706**	

Table 6.4-4: TER-values regarding the exposure to the active ingredient rimsulfuron via run-off and drainage (EXPOSIT 3.01)

Compound:	**Rimsulfuron**	
Application rate:	**Agriculture; 1 x 9.9 g a.s./ha; 25 % interception**	
Indication	**00-001 (maize)**	
PEC-selection:	**actual**	
Relevant toxicity endpoint:	**E_bC_{50} = 0.0046 mg a.s./L**	
Relevant TER:	**10**	
Run-off		
Buffer zone [m]	**PEC [µg/L]**	**TER**
0	0.04	112
5	0.04	130
10	0.03	151
20	0.02	216
Drainage		
Time of application	**PEC [µg/L]**	**TER**
Autumn/winter/early spring	not relevant	not relevant
Spring/summer	0.09	209
Risk mitigation measures	**none**	

From the TER values of the active ingredients TER(mix) values (20-m-buffer-zone assumed) were calculated for the formulation DPX-Q9H36 51WG based on the following rational:

Calculating an EC_{50}(mix) of the active ingredients mesotrione, nicosulfuron, and rimsulfuron assuming effect additivity, the endpoint of the Lemna study performed with the formulation DPX-Q9H36 51WG (EC_{50} = 0.0062 mg product/L, corresponding to 0.00316 mg active ingredients/L) is well 'predicted' respectively described with EC_{50}(mix) = 0.0031 mg/L.

The following formula was used to derive the surrogate EC_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$EC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as:

X(mesotrione) = 360 g mesotrione /kg / (360 g mesotrione /kg + 120 g nicosulfuron /kg + 30 g rimsulfuron /kg)

X(nicosulfuron) = 120 g nicosulfuron /kg / (360 g mesotrione /kg + 120 g nicosulfuron /kg + 30 g rimsulfuron /kg)

X(rimsulfuron) = 30 g rimsulfuron /kg / (360 g mesotrione /kg + 120 g nicosulfuron /kg + 30 g rimsulfuron /kg)

LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

A dose and effect additivity of the three active ingredients can be assumed and the TER(mix) was calculated as follows:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s.}_i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i* respecting a **buffer zone of 20 m**

TER(mix) run off = 8.3

TER(mix) drainage = 8.6

Based on the calculated concentrations of the formulation DPX-Q9H36 51WG (spray drift) respectively its active ingredients mesotrione, nicosulfuron, and rimsulfuron (run-off and drainage) in surface water (PEC_{SW} according to DRIFTOX 4.0 and EXPOSIT 3.01), the calculated TER(mix) values for the risk resulting from an exposure of aquatic organisms to DPX-Q9H36 51WG according to the GAP of the formulation do not achieve the acceptability criterium TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. However, due to the steep concentration-effect-relationship observed in the *Lemna* study with the formulation DPX-Q9H36 51WG with the NOEC only 3.2 times lower than the EC_{50} of DPX-Q9H36 51WG, the slight deviations of the TER(mix) = 8.3 and TER(mix) = 8.6 from the proposed acceptability criterium of 10 indicate an acceptable risk for aquatic organisms.

According to the results of the TER calculations, the implementation of risk mitigation measures will be necessary to reduce the exposure of aquatic organisms to DPX-Q9H36 51WG.

6.4.4 Accumulation in aquatic non-target organisms

Please refer to the core dossier for the central zone.

6.4.5 Risk assessment –overall conclusions for aquatic organisms

The risk to aquatic organisms following exposure to DPX-Q9H36 51WG via spraydrift is not acceptable without drift reducing measures and buffer zones. The risk for the entry routes run-off and drainage is also not acceptable without buffer zones for the intended use of DPX-Q9H36 51WG.

Due to the toxicity of the active ingredients as well as the formulation, the following labels must be indicated:

NW 605: When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones (see Table 6.4-5) must be kept from surface waters. In addition to the minimum buffer zone provided for by state law, § 6 (2) 2nd sentence of the 'PflSchG' (German Plant Protection Act) must be observed for the drift reduction classes marked with "*".

NW 606: The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro.

NW 706: Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters- there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 20 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.

The following table summarises the risk mitigation measures necessary for the respective intended uses.

Table 6.4-5: Summary of Risk mitigation measures to be implemented for the use of DPX-Q9H36 51WG

uses no.	Risk mitigation measures	Buffer zone / technique	Risk acceptable
00-001	NW 605	* m / 90% red. 5 m / 75% red. or 50% red.	Yes
	NW 606	10 m / conventional	
	NW 706	20 m / conventional	

6.5 Effects on Bees

The acute risk to honey bees from use of DPX-Q9H36 51WG was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (EPPO 2003) as follows:

$$Hazard\ Quotient = \frac{Maximum\ application\ rate\ (g\ formulation/ha)}{Acute\ LD_{50}\ (\mu g\ formulation/bee)}$$

Hazard quotients were calculated for oral exposure (Q_{ho}) and contact exposure (Q_{hc}) to DPX-Q9H36 51WG (see table below). A hazard quotient of less than 50 indicates a low risk to bees in the field.

Test substance	Exposure route	LD_{50} (µg /bee)	Maximum single application rate (g/ha)	Hazard quotient (HQ)	HQ assessment trigger
Mesotrione	Oral	= >11	120	10.9	< 50
	Contact	= >100	120	1.2	
Nicosulfuron	Oral	>1000 mg a.s./L in diet*	40	-	
	Contact	76	40	0.52	
Rimsulfuron	Contact	100	10	0.1	
Rimsulfuron 25 WG + IN-KG691 surfactant	Oral	41.1	10	0.24	
	Contact	27.9	10	0.36	
DPX-Q9H36 51WG + IN-KG691 surfactant	Oral	>209.6	330	1.6	
	Contact	190.9	330	1.7	

All hazard quotients (HQ) are considerably less than 50, indicating that DPX-Q9H36 51WG applied at the maximum use rate in maize poses low risk to bees.

Consequences for authorization:

NB6641

For further information please refer to the core dossier of the zRMS.

6.6 Effects on Arthropods Other Than Bees

The applicant has submitted data on the effects of DPX-Q9H36 51WG on non-target terrestrial arthropods (please refer to the core dossier for the central zone). According to the herbicidal effects of the formulation the effect values for non-target terrestrial arthropods are substantially higher than the effects determined for non-target plants. The latter are, therefore, relevant for the risk assessment for terrestrial biocoenosis. A quantitative risk assessment for non-target terrestrial arthropods is for that reason not conducted in this national addendum.

6.7 Effects on Earthworms and other Non-target Soil Organisms

6.7.1 Toxicity

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to the plant protection product DPX-Q9H36 51WG containing mesotrione, nicosulfuron, and rimsulfuron whenever contamination of soil may occur as a result of the intended use.

For studies that are listed in the EU Lists of Endpoints for mesotrione, nicosulfuron, and rimsulfuron please refer to the core dossier for the central zone.

Here only study endpoints used for the risk assessment different from the EU Lists of Endpoints for the active substances are provided as well as the studies with the formulation DPX-Q9H36 51WG which were not part of the EU review.

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna following exposure to mesotrione, nicosulfuron, and rimsulfuron and DPX-Q9H36 51WG with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Earthworm – acute toxicity					
Eisenia fetida	DPX-Q9H36 51WG (“Arigo”) + DPX-KG691 (surfactant) [ratio of formulation and surfactant: 1:0.9]	14 d acute	LC50 >1000 mg/kg soil dw [1)] Mortality	Lührs, U. 2009 DuPont-27680	78856
Eisenia foetida	Mesotrione	14 d acute	LC50 > 2000 mg/kg soil dw [2)]	Bembridge, J., Jackson, D. 1996 Report No. RJ 2225B	39328
Eisenia fetida	ADMP (Nicosulfuron-Metabolite)	14 d acute	LC50 : 1088 mg/kg soil dw [3)] Mortality 10 % Sphagnum peat	Schmidt, T. 2008 B81505	73959
Eisenia fetida	IN-HYY21 (AUSN), 90.3%	14 d acute	LC50 > 1000 mg/kg soil dw [4)] Mortality	Lührs, U. 2004 DuPont 12760	65343
Eisenia fetida	IN-GDC42, = UCSN 98.0 %	14 d acute Quarz sand	LC50 > 1000 mg/kg soil dw [4)] Mortality	Lührs, U. 2004 DuPont 14031	65344
Earthworm – reproduction toxicity					
Eisenia fetida	DPX-Q9H36 51WG (“Arigo”) +	56 d Reproduction	NOEC <31.25 mg/kg soil dw [1)]	Lührs, U. 2009	78857

	DPX-KG691 (surfactant); ratio of formulation and surfactant 1:0.9		Reproduction EC20 : 22.95 mg/kg soil dw	DuPont-27678 RV1	
Eisenia fetida	Nicosulfuron-Metabolite IN-V9367, = ASDM 99.7%	56 d Reproduction Quarz sand	NOEC : 1000 mg/kg soil dw 5) Reproduction, mortality, body weight, behaviour	Lührs, U. 2003 DuPont 12116	65348
Eisenia fetida	Nicosulfuron-Metabolite IN-HYY21 (AUSN), 90.3 %	56 d Reproduction	NOEC : 1000 mg/kg soil dw 5) Reproduction, mortality, body weight, behaviour	Lührs, U. 2004 DuPont 12346	65350
Eisenia fetida	Nicosulfuron-Metabolite IN-GDC42, = UCSN 98.0%	56 d Reproduction Quarz sand	NOEC : 1000 mg/kg soil dw 5) Reproduction, mortality, body weight, behaviour	Lührs, U. 2004 DuPont 14030	65349
Other non-target soil organisms – reproduction toxicity					
Folsomia candida	IN-70941	28 d Lab Reproduction	NOEC >= 0.183 5) mg/kg soil dw	Nienstedt, K. M. and Novent, O. 2001 1033.019.641	48555
Folsomia candida	IN-70942, 99,5% a.i.	28 d Lab Reproduction	NOEC >= 0.183 5) mg/kg soil dw	Nienstedt, K. M. and Novent, O. 2001 1033.016.641	48558
Folsomia candida	IN-E9260, 99,8% a.i.	28 d Lab Reproduction	NOEC >= 0.183 5) mg/kg soil dw	Nienstedt, K. M. and Novent, O. 2001 1033.017.641	48559

1) New study submitted by the applicant

2) DAR for Mesotrione (1999)

3) Study newer than DAR for Nicosulfuron

4) Study not included in Nicosulfuron LoEP (2007). The study included in the List of Endpoints is considered invalid in Germany, because the study has not been performed according to guideline (number of replicates)

5) This study was conducted with a higher concentration than the one listed in the LoEP

The log K_{OW} values for the active ingredients mesotrione, nicosulfuron, and rimsulfuron are below the agreed trigger value of 2. There is no data available concerning the relevant metabolites, however it is assumed that their log K_{OW} values are around the same values as the parent compounds. Therefore, no correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils and a resulting lower bioavailability of the active substance to soil organisms.

Overall, the acute toxicity of the active ingredients mesotrione, nicosulfuron, and rimsulfuron as well as the toxicity of their soil relevant metabolites towards tested soil fauna is low. All LC_{50} values were >1000 mg/kg soil dw. In the chronic toxicity tests the lowest endpoints were obtained for the rimsulfuron metabolites IN-70941, IN-70942, and IN-E9260 (NOEC: 0.18 mg/kg soil dw, see core dossier) and for the formulation DPX-Q9H36 51W (NOEC < 31.25 mg/kg soil dw, EC_{20} = 22.95 mg/kg soil dw (EC_{20} calculated by cMS)).

6.7.2 Exposure

For the calculations of predicted environmental concentrations in soil (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the formulation DPX-Q9H36 51W and its active substances mesotrione, nicosulfuron, and rimsulfuron are presented in the table below.

Calculations considered the maximum application rate of 330 g formulation/ha and a minimum of 25 % foliar interception for applications to Maize at BBCH growth stage 12.

All calculations assumed an even distribution of the substances in the top 2.5 cm horizon with a soil bulk density of 1.5 g/mL. Accumulation in the soil profile due to the persistence of mesotrione, nicosulfuron, and rimsulfuron does not need to be considered.

Table 6.7-2: Maximum predicted environmental concentrations in soil PEC_S[1)] for mesotrione, nicosulfuron, rimsulfuron and DPX-Q9H36 51WG following application in the intended use 00-001

plant protection product:		**DPX-Q9H36 51WG**				
use:		**00-001**				
Number of applications/intervall		**1**				
application rate:		**330 g product/ha with 118.8 g mesotrione/ha, 39.6 g nicosulfuron /ha and 9.9 g rimsulfuron/ha**				
crop interception:		**25 %**				
Active substance / formulation	**soil relevant application rate (g/ha)**	**Soil $depth_{act}$ (cm)**	**PEC_{act}[1)] (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Mesotrione	89.1	2.5	0.2376	20	n.c.	n.c.
Nicosulfuron	29.7	2.5	0.0792	20	n.c.	n.c.
Rimsulfuron	7.425	2.5	0.0198	20	n.c.	n.c.
DPX-Q9H36 51W	247.5	2.5	0.66	20	n.c.	n.c.
IN-70941 (Rimsulfuron metabolite)	3.45*	2.5	0.0092	20	0.0014	0.0106
IN-E9260 (Rimsulfuron metabolite)	0.825**	2.5	0.0022	20	0.0006	0.0028

n.c.: not calculated since not relevant ($DT_{90\ soil}$ < 365 d)

1) PEC_{act} = maximum annual soil concentration for a soil depth of 2.5 cm

PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops)

PEC_{accu} = accumulated soil concentration

* calculated as direct application of IN-70941 using the maximum observed occurrence of 54.1% in soil and the molecular correction factor 0.852

** calculated as direct application of IN-E9260 using the maximum observed occurrence of 18.9% in soil and the molecular correction factor 0.580

The rimsulfuron metabolites IN-70941, IN-70942 and IN-E9260, and nicosulfuron metabolites ASDM, AUSN, HMUD and UCSN were formed in concentrations >10 % AR in soil. For details please see Section 5, Part 9.1. PEC values for the nicosulfuron soil metabolites were not calculated since the metabolites were relatively untoxic to soil fauna and were not assumed relevant in the EU review of nicosulfuron. TER values were, thus, based on a PEC value assuming 100 % formation of metabolites from the parent nicosulfuron as a worst case assumption. As worst-case scenario for the rimsulfuron metabolites PEC values were calculated for the mainly formed and most persistent metabolites (IN-70941 and IN-E9260) since the toxicity endpoints of all soil relevant rimsulfuron metabolites were identical.

6.7.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.7-3: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of DPX-Q9H36 51WG according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Mesotrione	1x 330 g/ha ARIGO with 118.8 g/ha Mesotrione, 39.6 g/ha Nicosulfuron and 9.9 g/ha Rimsulfuron	Acute	> 2000	0.2376	> 8418	10
MNBA (Mesotr. metabolite)		Acute	> 1000	0.2376*	> 4209	10
Nicosulfuron		Acute	> 1000	0.0792	> 12626	10
ADMP (Nicosulf. metabolite)		Acute	1088	0.0792*	13737	10
ASDM / AUSN / USCN		Acute/Long-term	1000	0.0792*	12626	10/5
HMUD		Acute	>1250	0.0792*	> 15783	10
Rimsulfuron		Acute	> 1000	0.0198	> 50505	10
IN-70941 / IN-70492 / IN-E9260		Long-term	0.18	0.0106**	17	5
DPX-Q9H36 51W		Acute	> 1000	0.66	> 1515	10
		Long-term	22.95[#]	0.66	35	5
Collembola (*Folsomia candida*)						
IN-70941 / IN-70492 / IN-E9260	1x 330 g/ha ARIGO	Long-term	0.18	0.0106**	17	5
ASDM / AUSN / USCN		Long-term	100	0.0792*	1263	5

* worst case presumption based on 100 % formation

** worst case presumption based on PECaccu for IN-70941

[#] This is an EC_{20} value, no real NOEC could be determined in the study.

Based on the predicted concentrations of mesotrione, nicosulfuron, rimsulfuron, rimsulfuron metabolites, and DPX-Q9H36 51WG in soil, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to DPX-Q9H36 51WG according to the GAP achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of DPX-Q9H36 51WG in maize according to the label.

6.7.4 Residue content of earthworms

The log Kow values of mesotrione, nicosulfuron, and rimsulfuron are < 3. Thus, mesotrione, nicosulfuron, and rimsulfuron are not deemed to bioaccumulate in earthworms. Therefore, studies determining residue contents in earthworms are not necessary.

6.8 Effects on Soil Microbial Activity

6.8.1 Toxicity

Please refer to the core dossier for the central zone.

6.8.2 Exposure

Please see PEC values of chapter 6.7.2 .

6.8.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation DPX-Q9H36 51WG and its active substances mesotrione, nicosulfuron, and rimsulfuron in soil are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure, indicating that the proposed use of DPX-Q9H36 51WG poses an acceptable risk to soil microorganisms.

6.9 Effects on Non-Target Plants

6.9.1 Toxicity

Please see also the core dossier for the central zone.

The relevant endpoints for the risk assessment are given in the following table.

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure to DPX-Q9H36 51WG plus isodecylalcohol ethoxylated (DPX-KG691) surfactant

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Seedling emergence					
Beta vulgaris (sugarbeet) *Zea mays (corn)* *Avena sativa (oat)* *Allium cepa (common onion)* *Sorghum bicolor (sorghum)* *Cucumis sativa (cucumber)* *Brassica napus (oilseed rape)* *Pisum sativum (pea)* *Glycine max (soybean)* *Lycopersicon esculentum (tomato)*	DPX-Q9H36 51WG / Mesotrione, Nicosulfuron, and Rimsulfuron plus isodecylalcohol ethoxylated (DPX-KG691) surfactant	Seedling emergence test under greenhouse conditions (21 days)	ER_{50} = 5.84 g DPX-Q9H36 51WG/ha plus IN-KG691 surfactant (sugarbeet)	Porch, J.R., Kendall, T.Z., 2009 [1)] (DuPont-27674)	80361
Vegetative vigour					
Beta vulgaris (sugarbeet) *Zea mays (corn)* *Avena sativa (oat)* *Allium cepa (common onion)* *Sorghum bicolor (sorghum)* *Cucumis sativa (cucumber)* *Brassica napus (oilseed rape)* *Pisum sativum (pea)* *Glycine max (soybean)* *Lycopersicon esculentum (tomato)*	DPX-Q9H36 51WG / Mesotrione, Nicosulfuron, and Rimsulfuron plus isodecylalcohol ethoxylated (DPX-KG691) surfactant	Vegetative vigour	ER_{50} = 2.88 g DPX-Q9H36 51WG/ha plus IN-KG691 surfactant (sugarbeet)	Porch, J.R., Kendall, T.Z., 2009 [1)] (DuPont-27670)	80360

The risk assessment will be based on the ER_{50} for the most sensitive species (sugar beet; vegetative vigour test; ER_{50} = 2.88 g product/ha). Moreover, it is proposed to reduce the safety factor (TER trigger) in the German approach, if ≥10 plant species are tested in the non-target plant studies.

Besides the deterministic approach, the applicant has provided a probabilistic risk assessment for non-target plants since data for more than six species were available. The cMS Germany has (partly) not accepted this approach for the following reasons:

- a censoring of “greater than” data was ignored by the applicant in the SSD, which means that these values were plotted as actual results (e.g. >333 g/ha were plotted as 333 g/ha). The cMS does not support this approach in principal since SSDs should clearly represent actual toxicity (effect) value distributions.
- The shape of the SSD for the seedling emergence is not found to adequately fit the EC_{50} data points. Therefore, it is not considered justified to derive a HR_5 on that basis. For instance, this is shown by the fact that the derived HR_5 (n=10) for seedling emergence data is higher by a factor of 2.83 than the EC_{50} for the most sensitive plant species (16.55 vs. 2.88 g/ha).
- Consequently, a TER trigger of 1 as stated by the applicant is not accepted by the cMS for the reasons given above.
- From the cMS’ point of view, a corrected HC_5 of 2.71 g product/ha (using eight data points in the vegetative vigour SSD) may potentially be used for the probalistic risk assessment. However, this value is not considererd here since this approach would have no impact on the outcome of the risk assessment.

6.9.2 Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

PER off-field= Maximum in-field PER (including MAF) x %drift

The resulting maximum off-field predicted environmental rates (PER off-field) are summarized in the following table:

Table 6.9-2: Maximum off-field predicted environmental rates of DPX-Q9H36 51WG following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.77 % drift)	Maximum PERoff-field at 5m (0.57% drift)
(g DPX-Q9H36 51WG/ha)		
330	9.14	1.88

6.9.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.9-3: Summary of risk assessment for non-target terrestrial plants exposed to DPX-Q9H36 51WG

Active substance/product:	DPX-Q9H36 51WG plus isodecylalcohol ethoxylated (DPX-KG691) surfactant							
Use pattern/gap:	00-001 (1 x 0.33 kg/ha)							
MAF:	1							
Spray drift scenario:	agriculture (90th percentile)							
Interception*:	25							
Distance (m)	Drift		Volatilisation/ Deposition		$PER_{off-field}$(g/ha) (incl. Volatilisation, Interception)			
	(%)	(g/ha)	(%)	(g/ha)	without technique.	90% Red.	75% Red.	50% Red.
1	2.77	9.14	-	-	9.14	0.91	2.29	4.57
5	0.57	1.88	-	-	1.88	0.19	0.47	0.94
relevant toxicity:	ER_{50} = 2.88 g product/ha, *Beta vulgaris* (vegetative vigour)							
relevant TER:	5							
Distance (m)					TER-values (calculated)			
1					0.32	3.15	1.26	0.63
5					1.53	**15.31**	**6.12**	3.06
Risk mitigation:	**NT 108 (75% drift reduction, 5 m buffer zone)**							

Based on the predicted rates of DPX-Q9H36 51WG in off-field areas, the TER values describing the risk for non-target plants following exposure to mesotrione, nicosulfuron, and rimsulfuron /DPX-Q9H36 51WG according to the GAP of the formulation DPX-Q9H36 51WG achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of DPX-Q9H36 51WG in maize according to the label in conjunction with the proposed risk mitigation measures.

The following risk mitigation measures will have to be implemented to reduce the exposure of non-target terrestrial plants to DPX-Q9H36 51WG:

- no-spray buffer zone of 5 m and the use of 75% drift reducing nozzles (NT 108).

Appendix 1 Detailed evaluation of studies relied upon

A2-1 Active substance

KIIA 8.6 Effects on aquatic plants

Reference:	OECD K II A 8.6/01
Report	R. Bätscher, 2008, Toxicity of nicosulfuron technical to the aquatic higher plant *Lemna gibba* in a 7-day growth inhibition test, supplemented with testing for recoveryof growth , B81461
Guideline(s):	Yes OECD 221
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by cMS	No

<u>Comments of cMS</u>

Study Comments:	Study is accaptable.
Agreed Endpoints:	E_yC_{50} (frond numbers): 0.0011 mg/L

Appendix 2 Table of Intended Uses justification and GAP tables (according to BVL 19/01/2012)

GAP rev. (1), date: 2013-01-23

PPP (product name/code)	Arigo (007526-00/00)	Formulation type:	WG
active substance 1	Rimsulfuron	Conc. of as 1:	30 g/kg
active substance 2	Nicosulfuron	Conc. of as 2:	120 g/kg
active substance 3	Mesotrione	Conc. of as 3:	360 g/kg

Applicant:	DuPont de Nemour	professional use	X
Zone(s):	central zone	non professional use	☐
Verified by MS:	yes		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season]	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Maize ZEAMX	F	annual monocotyledonous weeds TTTMS annual dicotyledonous weeds TTTDS	spraying	BBCH 12 - 18; post-emergence	a) 1 b) 1	a) 0.33 b) 0.33	Rimsulfuron a) 0.01 b) 0.01 Nicosulfuron a) 0.04 b) 0.04 Mesotrione a) 0.119 b) 0.119	200 - 400	XF	WH9161 WP734 WH960 mandatory tank mix with DU PONT TREND (004873-00/00) a) 0.3 L/ha b) 0.3 L/ha

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: ARIGO

Reg. No.: 007526-00/00.

Active Substances: 30 g/kg Rimsulfuron, 120 g/kg Nicosulfuron, 360 g/kg Mesotrione

Central Zone

Zonal Rapporteur Member State: CZ

National Addendum Germany

Applicant: DUPONT de NEMOURS AND COMPANY

Date: July 2012

Evaluator: Julius Kühn-Institut

Date: 2012-10-05

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Refer to Registration Report from July 2012 for further information.

Recent registration situation/history of the PPP

Refer to Registration Report from July 2012 for further information.

Information on the active ingredients (Uptake and mode of action)

Refer to Registration Report from July 2012 for further information.

Information on crops and pests

Refer to Registration Report from July 2012 for further information.

Information on the intended uses

AWG-No.	**007526-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Maize (ZEAMX)
Crop stage(s) (BBCH)	12 to 18
Pest(s)/target(s)/aim(s)	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS)
Area of use	Outdoors
Time of treatment	After emergence
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	330 g/ha in 200 to 400 l water/ha
Combination partner	In mix with: 004873-00 DU PONT TREND (0.3 L/ha)

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Refer to Registration Report from July 2012 for further information.

IIIA1 6.1.2 Minimum effective dose tests

Refer to Registration Report from July 2012 for further information.

IIIA1 6.1.3 Efficacy tests

For some weeds which are described in the label as being controlled well, only a few or no efficacy results exist. Furthermore it should be noted that some maize varieties respond to sulfonylureas very sensitively. So the restriction WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is proposed.

IIIA1 6.1.4 Effects on yield and quality

Refer to Registration Report from July 2012 for further information.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Refer to Registration Report from July 2012 for further information.

IIIA1 6.1.4.2 Effects on the processing procedure

Refer to Registration Report from July 2012 for further information.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Refer to Registration Report from July 2012 for further information.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Damage to the maize crop cannot be excluded. The restriction WP734 (Damage is possible to the crop.) is proposed.

IIIA1 6.2.2 Adverse effects on health of host animals

Refer to Registration Report from July 2012 for further information.

IIIA1 6.2.3 Adverse effects on site of application

Refer to Registration Report from July 2012 for further information.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial arthropods

No effect on non-target organisms was recorded in any efficacy or selectivity trials (Points IIIA 6.1.3 and IIIA 6.1.4), which were conducted with DPX-Q9H36 51WG.

For evaluating the effects on relevant beneficial arthropods according German criteria we refer to the results of the toxicity tests on relevant beneficial arthropods summarized in Registration Report Part B, Section 6, Point IIIA 10.5., Appendix 2, table 79 and 80 (July 2012) and compare them with the proposed field rates in Germany.

The toxicity to non-target arthropods has been investigated by carrying out a Tier 1 test on *Aphidius rhopalosiphi* and a Tier 1 test on *Typhlodromus pyri* with the blend formulation DPX-

Q9H36 51WG (Mesotrione 50WG, Nicosulfuron 75WG and Rimsulfuron 25SG) plus IN-KG691 surfactant on artificial substrate (glass).

In the test with *Typhlodromus pyri* the highest tested rate of DPX-Q9H36 51WG, 0.33 kg/ha, plus 0.2 l/ha surfactant caused a corrected mortality of 4% and a reduction of fecundity by 13% (DuPont-27676).

In the test with *Aphidius rhopalosiphi* the highest tested rate of DPX-Q9H36 51WG, 0.33 kg/ha, plus 0.2 l/ha surfactant caused no mortality and a reduction of parasitisation rate by 6% (DuPont-27679).

On the basis of the results of these valid tests the following classification can be concluded:

The product is classified as not harmful for populations of relevant predatory mites and spiders.
The test product is classified as not harmful for populations of the parasitic wasp *Aphidius rhopalosiphi.*

Classification according IOBC:
Laboratory tests on inert substrates

< 30%	= harmless
30 – 79%	= moderately harmful
≥ 80%	= harmful

Effects on soil quality

Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms, collembolan and organic matter breakdown

All the acute/chronic TERs are above the relevant trigger values of 10/5 indicating a low and acceptable acute/chronic risk to earthworms of the active substances and the relevant soil degradation products following treatment with DPX-Q9H36 51WG in accordance with the intended worst-case use pattern and according to the GAP.

No study identified significant mortality or reproduction effects (28 days studies) on collembolan and the long-term TER values for the soil dwelling collembolan species *Folsomia candida* are above the trigger of 5. Thus, no risk to soil non-target macro-organisms is expected.

The conducted litterbag studies have shown that the product does not inhibit nitrogen transformation. Thus, after application the product DPX-Q9H36 51WG is not expected to affect organic matter breakdown in soil.

Overall conclusion with respect to effects on soil macro-organisms

It is concluded that the proposed use of the herbicide ARIGO 51 WG (DPX-Q9H36, 360 g/kg mesotrione + 120 g/kg nicosulfuron + 30 g/kg rimsulfuron) will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Effects on soil non-target micro-organisms exposed to ARIGO

At the end of 28 days, deviations in nitrate formation rate and respiration rates at concentration up to 4,44 mg DPX-Q9H36 51WG/kg soil d.w. compared to the control were <25%.

Risk assessment for soil microflora functions
For the proposed use of ARIGO an acceptable risk to soil microbial activity can be concluded.

The following restriction is proposed:

(NN100)
The product is classified as non-harmful for populations of relevant beneficial arthropods.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Refer to Registration Report from July 2012 for further information.

IIIA1 6.2.6 Impact on succeeding crops

Because of the persistence in soil and the biological activity of the active substances the restriction WH960 (The risk of replanting has to be indicated on the package and in the instructions of use. Particularly the endangered succeeding crops have to be declared and measures for a risk management have to be described.) is proposed.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Refer to Registration Report from July 2012 for further information.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Due to a medium to high resistance risk, the restriction WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.

IIIA1 6.3 Economics

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

Refer to Registration Report from July 2012 for further information.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Refer to Registration Report from July 2012 for further information.

IIIA1 6.7 List of test facilities including the corresponding certificates

Refer to Registration Report from July 2012 for further information.

Appendix 1: List of data submitted in support of the evaluation

Refer to Registration Report from July 2012 for further information.
No additional studies submitted.

Appendix 2: GAP table

Rimsulfuron

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/ synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Maize (ZEAMX)	F	Annual monocotyledonous weeds TTTMS, Annual dicotyledonous weeds TTTDS,	spraying	12 - 18; After emergence	a) 1 b) 1	a) 0.33 b) 0.33	a) 0.01 b) 0.01	200 - 400	XF	Mandatory tank mix with DU PONT TREND (004873-00/00) a) 0.3 L/ha b) 0.3 L/ha

Nicosulfuron

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/ synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Maize (ZEAMX)	F	Annual monocotyledonous weeds TTTMS, Annual dicotyledonous weeds TTTDS,	spraying	12 - 18; After emergence	a) 1 b) 1	a) 0.33 b) 0.33	a) 0.04 b) 0.04	200 - 400	XF	Mandatory tank mix with DU PONT TREND (004873-00/00) a) 0.3 L/ha b) 0.3 L/ha

Mesotrione

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/ synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]	g, kg a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Maize (ZEAMX)	F	Annual monocotyledonous weeds TTTMS, Annual dicotyledonous weeds TTTDS,	spraying	12 - 18; After emergence	a) 1 b) 1	a) 0.33 b) 0.33	a) 0.119 b) 0.119	200 - 400	XF	Mandatory tank mix with DU PONT TREND (004873-00/00) a) 0.3 L/ha b) 0.3 L/ha

REGISTRATION REPORT
Part B

Section 8 Assessment of the relevance of metabolites in groundwater
Detailed summary of the risk assessment

Product code: DPX-Q9H36 51WG

Active Substances:

Mesotrione	**360 g/kg**
Nicosulfuron	**120 g/kg**
Rimsulfuron	**30 g/kg**

Central Zone
Zonal Rapporteur Member State: Czech Republic

NATIONAL ADDENDUM – Germany

Applicant:	**E. I. du Pont de Nemours and Company**
Date:	**January 2013**

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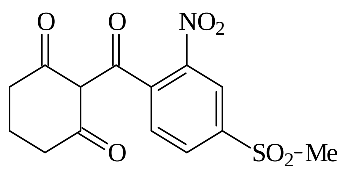
Sec 8 ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 Introduction

8.1.1 Mesotrione

The active substance Mesotrione has been approved according to Regulation (EC) No 1107/2009.

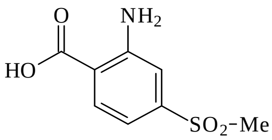
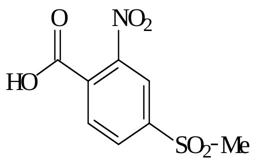
Table 8.1-1: Identity, further information on Mesotrione

Active substance (ISO common name)	**Mesotrione**
IUPAC	2-(4-Mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
Function (e.g. fungicide)	Herbicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/10/2003
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.
Confirmatory data	None
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	content pure: 360.0 g/kg; content techn.: 391.3 g/kg
Molecular formula	$C_{14}H_{13}NO_7S$
Molecular mass	339.3
Structural formula	

Environmental occurring metabolites of Mesotrione according to the results of the assessment of Mesotrione for EU approval are summarized in Part B, National Addendum- Germany, Section 5, Table 5.3-2.

The soil metabolites of Mesotrione for wich the leaching potentials into groundwater was assessed are summarised in Table 8.1-2.

Table 8.1-2: Metabolites of Mesotrione relevant for groundwater exposure assessment

Metabolite	Structural formula/ Molecular weight	Maximum occurence in compartements	Status of relevance (SANCO/1416/2001 – 14/04/2003)
AMBA (2-Amino-4-methylsulfonyl-benzoesäure)	 M = 215 g/mol	Soil, aerob: 9.4 & 9.7% max. at day 18 & 23 (subsequent samples) Water of water/sediment studies: 11.5% at day 14 Sediment of water/sediment studies: 7.9 & 7.0% at day 56 & 69 (subsequent samples)	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed (Step 2)[1)]
MNBA (4-Methylsulfonyl-2-nitro-benzoesäure)	 M = 245 g/mol	Soil, aerob: 57.2% at day 28 Water of water/sediment studies: 7.4% at day 3 (1 x >5%) Sediment of water/sediment studies: 0.6% max at day 3	Aquatic organism: Water: not assessed Sediment: not applicable Terrestrial organism: not assessed Groundwater: not assessed (Step 2)[1)]

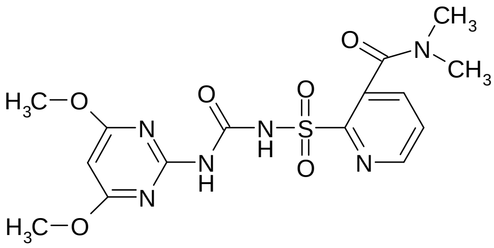
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

8.1.2 Nicosulfuron

The active substance Nicosulfuron has been approved according Regulation (EC) No 1107/2009.

Table 8.1-3: Identity, further information on Nicosulfuron

Active substance (ISO common name)	Nicosulfuron
IUPAC	2-(4,6-Dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)- *N,N*-dimethylnicotinamid
Function	herbicide
Status under Reg. (EC) No 1107/2009	approved; Annex I (91/414/EWG) yes
Date of approval	29.03.2008 / SANCO/3780/07 – rev. 1 (22 January 2008)
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: - the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, - the protection of aquatic plants and must ensure that the

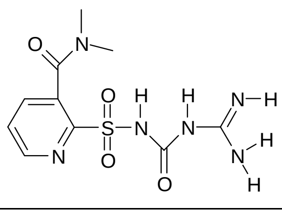
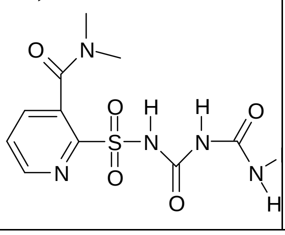
	conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, - the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, - the protection of groundwater and surface water under vulnerable soil and climatic conditions.
Confirmatory data	none
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	content pure: 120.0 g/kg; content techn.: 131.9 g/kg
Molecular formula	$C_{15}H_{18}N_6O_6S$
Molecular mass	410.14
Structural formula	

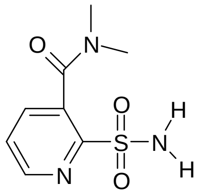
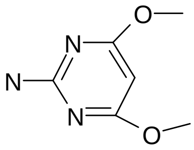
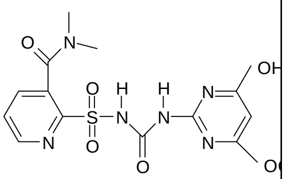
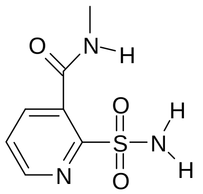
Environmental occurring metabolites of Nicosulfuron according to the results of the assessment of Nicosulfuron for EU approval are summarized in Part B, national addendum, Section 5, Table 5.3-5.

No new laboratory studies on the degradation of Nicosulfuron in soil have been performed.

The leaching potential of soil metabolites of Nicosulfuron is summarised in Table 8.1-2.

Table 8.1-4: Metabolites of Nicosulfuron relevant for groundwater exposure assessment

Metabolite	**Molecular weight (g/mol)/ Structural formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance**
AUSN (IN-HYY21) (2-(3-amidinoureidosulfonyl)-N,N-imethylnicotinamide)	314,36 	soil; aerob; max 34.9% on day 120. Water; max. 5.9% on day 102, increasing Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: Soil: not relevant Groundwater: relevant
UCSN (IN-GDC42) (N,N-dimethyl-2-ureidocarbonyl-sulfamoylnicotinamide)	315,3 	soil; aerob; max. 11% on day238 Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: Soil: not relevant Groundwater: relevant

ASDM (IN;-V9367) N,N-dimethyl-2-sulfamoyl-nicotinamide	229,2 	soil; aerob; max. 21.5% on day 85 water; 6.9% on day 177; increasing	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: Soil: not relevant Groundwater: relevant
ADMP IN-J0290 2-amino-4,6-dimethoxypyrimidine	155,16 	soil; aerob; max. 7.2% on day 31	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant
HMUD (IN-37740) 2-(4-hydroxy-6-methoxypyrimidin-2-ylcarbamoylsulfamoyal)-N,N-dimethylnicotinamide	336,4 	soil; aerob; max. 18.5% on day 56 water; max. 22.3% on day 102; increasing sediment; max. 6.8% on day 102 indreasing to the end of study	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant
MU-466 2-sulfamoyl-N-methylnicotinamide	215,23 	Lysimeter; >0.1µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant

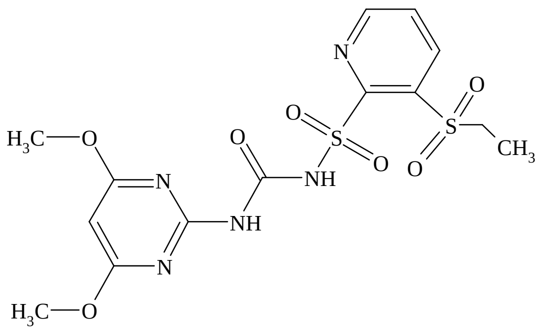
1) According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

8.1.3 Rimsulfuron

The active substance rimsulfuron has been approved according to Regulation (EC) No 1107/2009.

Table 8.1-5: Identity, further information on Rimsulfuron

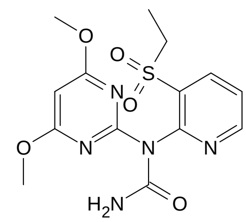
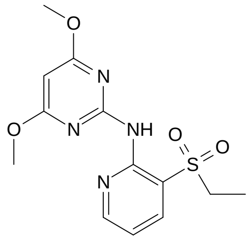
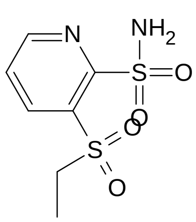
Active substance (ISO common name)	Rimsulfuron
IUPAC	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
Function (e.g. fungicide)	Herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/02/2007
Conditions of approval	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions

	of the review report on rimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. Member States must pay particular attention to the protection of non target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.
Confirmatory data	None Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for: - potential for accumulation of metabolites in soil under cold climatic conditions with respect to the protection of soil dwelling organisms - evaluation of run-off and drainage into surface water in the risk assessment of aquatic organisms
RMS	DE
Molecular formula	$C_{14}H_{17}N_5O_7S_2$
Molecular mass (g/mol)	431.45
Structural formula	

Environmental occurring metabolites of Rimsulfuron according to the results of the assessment of Rimsulfuron for EU approval are summarized in Part B, National Addendum- Germany, Section 5, Table 5.3-2.

The soil metabolites of Rimsulfuron for wich the leaching potentials into groundwater was assessed are summarised in Table 8.1-6.

Table 8.1-6: Metabolites of Rimsulfuron relevant for groundwater exposure assessment

Metabolite	Structural formula/ Molecular formula/ Molecular weight	occurrence in compartments (Max. at day)	Status of Relevance (SANCO/10528/2005 – 27/01/2006)
IN-70941	 $C_{14}H_{17}N_5O_5S$ M = 367.39 g/mol	Soil, aerob: Laboratory studies: 54.1% max. at d 60 Field studies: 72% max. at d 92 (all European trials) & 30% max. at d 31 (German trials) Water of water/sediment study: 71.4% max. at d 3 Sediment of water/sediment study: max. 15.2% at d 7 aqueous photolysis: 24.6% max. at d 14 (pH 7)	Terrestrial organism: not relevant Aquatic organism: Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 3-4)[1)]
IN-70942	 $C_{13}H_{16}N_4O_4S$ M=324.36 g/mol	Soil, aerob: Laboratory studies: 23.5% max. at d 360 Field studies: 6.8% max. at d 92 (all European trials) & 5.8% max. at d 45 (German trials) Water of water/sediment study: 31.45% max. at d 14 Sediment of water/sediment study: max. 73.1% at d 100 aqueous photolysis: 8.4% max. ar d 21 (pH 7)	Terrestrial organism: not relevant Aquatic organism: Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 2)[1)]
IN-E9260	 $C_7H_{10}N_2O_4S_2$ M=250.29 g/mol	Soil, aerob: Laboratory studies: 18.9% max. at day 180 Field studies: 6.4% max at d 92 (all European trials) & 4.4% max. at d 14 (German trials)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3-4)[1)]

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

8.2 Exclusion of degradation products of no concern

8.2.1 Mesotrione

None.

8.2.2 Nicosulfuron

None.

8.2.3 Rimsulfuron

None.

8.3 Quantification of potential groundwater contamination (Step 2)

8.3.1 Mesotrione

8.3.1.1 Exposure assessment for Germany

PEC_{GW} calculations after leaching from soil for the Mesotrione and its metabolites (see Table 8.1-2) were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, National Addendum, Section 5).

Following uses of ARIGO were considered (see Table below). Details of the input parameters for the active substance and the metabolites are given in Part B, National Addendum, Section 5, chapter 5.7.1.1.

Table 8.3-1: Input parameters related to application of ARIGO for PECgw modelling

use no	00-001
application rate	0.1188 kg/ha Mesotrione
Soil effective application rate	0.0891 k/ha Mesotrione
crop (crop rotation)	Every other year
date of application	7th of May
interception (%)	25
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

The result of the PECgw calculation with FOCUS PELMO 5.5.3 for the intended use of ARIGO in maize according to use no 00-001 are summarised in Table 8.3-2.

Table 8.3-2: PEC_{GW} at 1 m soil depth of Mesotrione and its metabolites MNBA and AMBA considered relevant for German exposure assessment for one application of ARIGO every other year

Use No.	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3		
		Mesotrione	Metabolite MNBA	Metabolite AMBA
00-001	Hamburg	0.038	0.170	0.077

The PECgw values for the AMBA was calculated to be ≤0.1 µg/L. The PECgw values for the MNBA was calculated to be >0.1 µg/L.

8.3.1.2 Conclusions

The metabolites that are relevant according to Step 2 of this assessment are summarized in Table 8.3-3.

Table 8.3-3: Summary of PECgw of soil metabolites of Mesotrione for its intended uses of ARIGO in maize (simulation with FOCUS PELMO 5.5.3)

Metabolite	PEC gw	Maximum concentration in ground water	Status of relevance
MNBA	> 0.1 µg/L	0.170 µg/L	relevant (Step 2)
AMBA	≤ 0.1 µg/L	0.077 µg/L	not relevant (Step 2)

A relevance assessment for the metabolite MNBA is required.

8.3.2 Nicosulfuron

8.3.2.1 Exposure assessment for Germany

PEC_{GW} calculations after leaching from soil for the active substance Nicosulfuron and its metabolites were performed using the simulation model FOCUS PELMO 5.5.3 (see Section 5).

Following uses of ARIGO were considered (see Table below). Details of the input parameters for the active substance and the metabolites are given in Part B, National Addendum, Section 5, chapter 5.7.1.1.

Table 8.3-4 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.1

use no	00-001
application rate	0.0396 kg/ha Nicosulfuron
Soil effective application rate	0.0297 g/ha Nicosulfuron
crop (crop rotation)	None and every other year
date of application	7th of May
interception (%)	25
soil moisture	100 % FC
Q10-factor	2.58

moisture exponent	0.7
simulation period (years)	26

The result of the PECgw calculation with FOCUS PELMO 5.5.3 for the intended use of ARIGO in maize according to use no 00-001 are summarised in Table 8.3-5.

Table 8.3-5: PEC$_{GW}$ at 1 m soil depth of Nicosulfuron and its metabolites HMUD; UCSN; ADMP; ASDM; AUSN; MU-466 were considered to be relevant for German exposure assessment

Use No.	**Scenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0 ; application: every year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.184	1.493 1.422 0.001 2.082 1.445 0.001
Use No.	**Scenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0.5 ; application: every year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.133	0.818 0.568 0.001 1.035 0.672 <0.001
Use No.	**Scenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3 plant uptake: 0.5 ; application: every other year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.059	0.398 0.276 <0.001 0.533 0.334

			<0.001
Use No.	**Scenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3** **plant uptake: 0 ; application: every other year**	
		Nicosulfuron	**Metabolite** HMUD: UCSN: ADMP: ASDM: AUSN: MU-466
00-001	Hamburg	0.082	0.676 0.702 <0.001 0.984 0.717 <0.001

For the metabolites HMUD; UCSN; ASDM; AUSN; groundwater concentration of ≥ 0.1 µg/L cannot be excluded (simulation model FOCUSPELMO 5.5.3; plant uptake factor = 0 as worst case and application every other year).

In addition to the Tier 1 PEC_{GW} modeling, a higher tier leaching assessment using experimental data from lysimeter studies for the active substance Nicosulfuron is available. The results are given in the Tables below.

Table 8.3-6: Data of the Lysimeter study 1

location	Schmallenberg			
crop	Maize			
sowing	22.05.95 and 13.05.96 winter wheat end of 1996			
application rate	1 x **40 g ai./ha** on 20.06.95			
stage of development	3 – 4 leaf stage (BBCH: 13-14)			
irrigation [mm]	600.5 (1995/96); 1039.3 (1996/97) and 75 (1997)			
Leachate [L]	1st year (06.95 until 06.96): 401.1 (Lys.13) and 455,9 (Lys. 16) 2nd year (06.96 until 06.97): 674.6 (Lys.13) and 699.7 (Lys. 16) sum: 1075.7 (Lys.13) und 1155.6 (Lys. 16)			
average concentration per year [µg/L]				
	Lysimeter 13		Lysimeter 16	
	1st year	2 nd year	1st year	2 nd year
Nicosulfuron	0.06	0.03	0.07	0.06
ASDM (IN-V9367)	**0.99**	**0.18**	**0.88**	**0.30**
AUSN (IN-HYY21)	**0.24**	**0.43**	**0.24**	**0.59**
UCSN (IN-GDC42)	**0.18**	0.03	**0.22**	0.07
MU-466 (IN-64859)	0.03	0.02	0.04	0.04

Table 8.3-7: Data of the Lysimeter study 2

location	Switzerland
crop	Maize
sowing	27.05.92 (Maize); 11.05.93 (Maize); summer wheat in summer 1994 and winter rye in autumn 1994
application rate	[pyridine-^{14}C]Nicosulfuron: 60 g ai./ha on 19.06.92 (Lysimeter 12 and 14) and 1 x 60 g ai./ha on 07.06.93

	(Lysimeter 14) [pyrimidine-^{14}C]Nicosulfuron: 60 g ai./ha on 16.06.92 (Lysimeter 15 and 16) and 1 x 60 g ai./ha on 02.06.93 (Lysimeter 15)
stage of development	BBCH: 13 - 14 (3 – 4 leaves)
irrigation [mm]	831.9 (1992/93); 1136 (1993/94) and 1118 (1994/95)
Leachate [L]	[pyridine-^{14}C]Nicosulfuron: 1st year (08.92 until 06.93): 333.9 (Lys.12) and 335.0 (Lys. 14) 2nd year (06.93 until 05.94): 529.4 (Lys.12) and 514.6 (Lys. 14) 3rd year (07.94 until 07.95): 537.5 (Lys.12) and 521.6 (Lys. 14) sum: 1400.8 (Lys.12) and 1371.2 (Lys. 14) [pyrimidine-^{14}C]Nicosulfuron: 1st year (07.92 until 06.93): 303.4 (Lys.16) and 345.8 (Lys. 15) 2nd year (06.93 until 05.94): 485.1 (Lys.16) and 542.6 (Lys. 15) 3rd year (06.94 until 07.95): 434.2 (Lys.16) and 545.5 (Lys. 15) sum: 1222.7 (Lys.16) and 1433.9 (Lys. 15)

average concentration per year [µg/L]							
[pyridine-^{14}C]Nicosulfuron:							
Lysimeter 12 (1 x 60 g ai./ha)							
	as	ASDM (IN-V9367)	AUSN (IN-HYY21)	UCSN (IN-GDC42)	MU-466 (IN-64859)	DDTP	HMUD
1st year	0.15	2.24	0.54	0.36	0.15	0.02	n.d.
2 nd year	0.04	0.47	0.89	0.21	0.08	0.02	n.d.
3rd year	0.02	0.10	0.18	0.02	0.03	< 0.01	0.01
Lysimeter 14 (2 x 60 g ai./ha)							
1st year	0.13	2.70	0.85	0.20	0.14	0.01	n.d.
2 nd year	0.05	1.69	1.62	0.94	0.14	0.03	0.01
3rd year	0.03	0.34	0.68	0.06	0.07	n.d.	0.03
[pyrimidine-^{14}C]Nicosulfuron:							
Lysimeter 16 (1 x 60 g ai./ha)							
	as	M4	M5	M7	M9	DDTP	HMUD
1st year	0.19	<0.01	0.02	0.03	<0.01	0.02	0.01
2 nd year	0.03	<0.01	0.01	0.01	<0.01	0.02	< 0.01
3rd year	<0.01	<0.01	<0,01	<0.01	<0.01	<0.01	<0.01
Lysimeter 15 (2 x 60 g ai./ha)							
1st year	0.17	<0.01	0.03	0.04	0.01	0.03	0.03
2 nd year	0.10	<0.01	0.04	0.01	<0.01	0.04	0.01
3rd year	0.01	<0.01	0.02	<0.01	<0.01	<0.01	<0.01

On the basis of the FOCUSPELMO-simulations and the results of the lysimeter studies it can be seen that an application of nicosulfuron at a rate of 40 g/ha **every other year** does not lead to a leaching of the active substance into groundwater in concentrations ≥ 0.1µg/L.
A limitation of the application of DPX-Q9H36 51WG that contains nicosulfuron is necessary to protect the groundwater. Therefore an application of maximum 40 g nicosulfuron /ha **only every other year** was assessed for application in Germany.
The metabolites HMUD, AUSN, UCSN and ASDM leach to ground water in concentrations ≥ 0.1µg/L.
Furthermore the results of a representative groundwater monitoring have to be taken into account (see below).

Table 8.3-8 Monitoring study Fa. DuPont (Interim Report)

author:	Schneider M.; Zietz E.
study:	Groundwater Monitoring for Nicosulfuron and 6 metabolites in four representative regions in Germany 1st Interim Report, Study Period April 2010-March 2011
date:	2011-08-01
study No.:	IF-10/01407246
Method / Guidelines:	see publication Aden et al. (2002)
enterprise:	ZA 6258 / DuPont
period / start:	4 years / 04/2010
Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 20 representative locations in Germany were chosen. The limit of quantification (LOQ) was 0.1µg/L. Therefore a direct comparison to the simulation calculation results was impossible. The LOQ should be at least 0.05 µg/L or below this value. The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be 1.7µg/L on 4 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

Table 8.3-9 Monitoring study Fa. ISK (Interim Report)

author:	Gezahegne, W.
study:	Groundwater Monitoring for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM in Germany in 2010-2013 Interim Report April 2010 - March 2011
date:	2012-03-02
study No.:	S10-1357; BVL 2290721
Method / Guidelines:	see publication Aden et al. (2002)
enterprise:	ZA 4409 / ISK
period / start:	4 years / 04/2010

Assessment of the study:	The aim of the study is to show that the concentration of nicosulfuron (max. 33.75 g/ha - application every other year on the same field) in ground water is below 0.1µg/L. Furthermore, the concentration of the non toxic metabolites of nicosulfuron should be below 10µg/L. Results: 45g/ha nicosulfuron (interception 25%; only one application per year) do not leache in the first year to ground water in concentrations higher than 0.1µg/L. 21 representative locations in Germany were chosen. (LOQ = 0.05; estemated concentration of nicosulfuron: <0.015µg/L). The concentration of metabolites of nicosulfuron ASDM, AUSN, UCSN and MU-466 were estimated to be max. 0.61µg/L on 14 of 21 locations. The concentration is clearly below 10µg/L. But note the conditions: 45g/ha nicosulfuron (interception 25%; only one application per year, results after 1 year).

8.3.3 Rimsulfuron

8.3.3.1 Exposure assessment for Germany

PEC_{GW} calculations after leaching from soil for the Rimsulfuron and its metabolites (see Table 8.1-6) were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, National Addendum, Section 5).

Following uses of ARIGO were considered (see Table below). Details of the input parameters for the active substance and the metabolites are given in Part B, National Addendum, Section 5, chapter 5.7.1.1.

Table 8.3-10 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.1

use no	00-001
application rate	0.0099 kg/ha Rimsulfuron
Soil effective application rate	0.007425 kg/ha Rimsulfuron
crop (crop rotation)	None and every other year
date of application	7th of May
interception (%)	25
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

The result of the PECgw calculation with FOCUS PELMO 5.5.3 for the intended use of ARIGO in maize according to use no 00-001 are summarised in Table 8.3-11.

Table 8.3-11 PEC_{GW} at 1 m soil depth of Rimsulfuron and its metabolite IN-70941. IN-70942 and IN-E9260 considered relevant for German exposure assessment for one application of ARIGO every other year

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3			
		Rimsulfuron	Metabolite IN-70941	Metabolite IN-70942	Metabolite IN-E9260
00-001	Hamburg	<0.001	0.377	0.015	0.126

The PECgw values for the IN-70942 was calculated to be ≤0.1 µg/L. The PECgw values for the IN-70941 and IN-E9260 were calculated to be >0.1 µg/L.

8.3.3.2 Conclusions

The metabolites that are relevant according to Step 2 of this assessment are summarized in Table 8.3-3.

Table 8.3-12: Summary of PECgw of soil metabolites of Rimsulfuron for its intended uses of ARIGO in maize (simulation with FOCUS PELMO 5.5.3)

Metabolite	PEC gw	Maximum concentration in ground water	Status of relevance
IN-70942	≤ 0.1 µg/L	0.015 µg/L	Not relevant (Step 2)
IN-70941	> 0.1 µg/L	0.377 µg/L	relevant (Step 2)
IN-E9260	>0.1 µg/L	0.126 µg/L	relevant (Step 2)

8.4 Hazard Assessment: Identification of relevant metabolites (Step 3)

8.4.1 Screening for biological activity

8.4.1.1 Mesotrione-metabolite MNBA

Information on the biological (herbicidal) activity of MNBA can be found in the screening study by Shribbs, J.M. (1997; ref. no. RAD1818/28; ICS-Lit. 27670; cited in Bartley, G., 2000; ref. no. RAD1818). MNBA was tested up to 4000 g ai/ha pre and post-emergence in herbicidal screening. Tested species included a wide variety of grass and broadleaf species. MNBA had no herbicidal activity on any of the tested species following pre and post-emergence application. In addition, it has been demonstrated in the study by Elcombe, B.M. & Meadowcroft, S. (1998; report-no. CTL/R/1367) that MNBA does not inhibit HPPD which is the mode of action of the active substance.

8.4.1.2 Nicosulfuron-metabolites

The herbicidal activity of ASDM, AUSN, UCSN and HMUD has been assessed in vegetative vigour studies by Yoshi, H. (1993; Doc. no. AD 931102-H-01; ICS-Lit. no. 42671) and Yoshii, H. (1996; Doc. no. AD 960119-H-01; ICS-Lit. no. 42667). No herbicidal activity could be demonstrated for each metabolite up to an application rate of 100 g/ha.

8.4.1.3 Rimsulfuron-metabolites

In a screening test the metabolites IN-70941, IN-7092, and IN-E9260 were evaluated for herbicidal activity (Leva & Rardon, 2001). The metabolites had no herbicidal activity up to an application rate of 50 g/ha (IN-70941and IN-7092) respectively 400 g/ha (IN-E9260).

8.4.2 Screening for genotoxicity

8.4.2.1 Mesotrione-metabolite MNBA

Submitted studies for the mesotrione-metabolite revealed that MNBA does not present any structural genotoxic alerts. Results of the Ames test did not indicate any mutagenic potential of MNBA. Moreover, in vitro/in vivo studies demonstrated no clastogenic potential (please refer to the conclusion of the Federal Institute for Risk Assessment (BfR)).

8.4.2.2 Nicosulfuron-metabolites

Results obtained from the toxicological studies did not indicate any genotoxic potential of the metabolites ASDM, AUSN, UCSN and HMUD (please refer to the conclusion of the Federal Institute for Risk Assessment (BfR)).

8.4.2.3 Rimsulfuron-metabolites

Please refer to the conclusion of the Federal Institute for Risk Assessment (BfR).

8.4.3 Screening for toxicity

Please refer to the conclusion of the Federal Institute for Risk Assessment (BfR).

8.5 Exposure assessment – threshold of concern approach (Step 4)

Please refer to the assessment and the conclusions of the Federal Institute for Risk Assessment (BfR).

8.6 Refined risk assessment for non-relevant metabolites (Step 5)

8.6.1 Refined toxicological risk assessment for non-relevant metabolites

Please refer to the assessment and the conclusions of the Federal Institute for Risk Assessment (BfR).

8.6.2 Refined ecotoxicological risk assessment for non-relevant metabolites

8.6.2.1 Mesotrione-metabolite MNBA

The PEC_{GW} for MNBA was calculated to be 0.17 µg/L. The EC_{50} for Daphnia magna is 130000 µg MNBA/L.

Thereof, a TER of 764706 results for crustacean in groundwater which is well above the acceptability criterium of TER ≥ 100.

For groundwater becoming surface water again the resulting $PEC_{(sw)}$ is generally presumed to arise to a tenth of the PEC_{GW} value (0.017 µg/L). The most sensitive aquatic endpoint, which is available for MNBA, was obtained for algae (E_bC_{50} = 38000 µg/L, *P. subcapitata*). A TER of 2235294 results which is far above the acceptability criterium of TER ≥ 10.

8.6.2.2 Nicosulfuron-metabolites

For PEC_{GW} values for ASDM, AUSN, UCSN and HMUD please see also Table 8.3-4.

Substance	PEC_{GW} [µg/L]	Acute toxicity endpoint crustacean [µg/L]	$TER_{crustacean}$	PEC_{GW}/10 ("$PEC_{(SW)}$") [µg/L]	Most sensitive aquatic toxicity endpoint [µg/L]	$TER_{(SW)}$
ASDM	2.082	954000	458213	0.2082	>120000 (*Lemna*)	>576369
AUSN	1.445	>100000	>69204	0.1445	>120000 (*Lemna*)	>830450
UCSN	1.422	>100000	>70323	0.1422	>120000 (*Lemna*)	>843882
HMUD	1.493	>100000	>66979	0.1493	665 (*Lemna*)	4454

(SW) : ground water becoming surface water

TER values well achieve the acceptability criterium of TER ≥ 100 respectively TER ≥ 10.

8.6.2.3 Rimsulfuron-metabolites

Substance	PEC_{GW} [µg/L]	Acute toxicity endpoint crustacean [µg/L]	$TER_{crustacean}$	PEC_{GW}/10 ("$PEC_{(SW)}$") [µg/L]	Most sensitive aquatic toxicity endpoint [µg/L]	$TER_{(SW)}$
IN-70941	0.377	95000	251989	0.0377	1200 (*Lemna*)	31830
IN-E9260	0.126	184000	1460317	0.0126	>100000 (Algae)	>7936508

(SW) : ground water becoming surface water

8.6.2.4 Conclusion

The metabolites MNBA, ASDM, AUSN, UCSN, HMUD, IN-70941, and IN-E9260 are ecotoxicologically not relevant for groundwater (crustacean) and not relevant for aquatic organisms if groundwater becomes surface water again. All TER values were well above the acceptability criterium of TER ≥ 100 (acute data) respectively TER ≥ 10 (chronic data).

Appendix 1 Table of Intended Uses in Germany (according to BVL 19/01/2012)

PPP (product name/code)	**ARIGO/ DPX-Q9H36 51WG**	**Formulation type:**	**Water dispersible granule**
		Conc. of as 1:	**360 g/kg**
active substance 1	**Mesotrione**	**Conc. of as 2:**	**120 g/kg**
active substance 2	**Nicosulfuron**	**Conc. of as 3:**	**30 g/kg**
active substance 3	**Rimsulfuron**		

1	2	3	4	5	6	7	8	10	11
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application ra**	
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. tota rate per crop/season
00-001	DE	Maize	F	annual monocotyledonous weeds annual dicotyledonous weeds	spray	After emergence. BBCH 12 18	a) 1 b) 1	a) 0.33 kg/ha b) 0.33 kg/ha	a) 118.8 g/ Mesotrione 39.6 g/ha Nicosulfuro 9.9 g/ha Rimsulfuro b) 118.8 g/ Mesotrione 39.6 g/ha Nicosulfuro 9.9 g/ha Rimsulfuro