Renewal Assessment Report

Dimethenamid-P

BAS 656 12 H

Volume 3 – B.9 Ecotoxicology data and assessment of risks for non-target species

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B Summary, evaluation and assessment of the data and information

B.9 Ecotoxicology data and assessment of risks for non-target species

A search for open literature which included papers in peer-reviewed journals and reports from government and other agencies in the EU and several other countries was performed by the applicant. The literature search was done via databases such as PubMed, Agricola, and SciFinder using the key-word "dimethenamid" or "dimethenamid-P" and the CAS Numbers 87674-68-8 and 163515-14-8, respectively. The initial search was a net cast as wide as possible to ensure complete coverage of the literature. The references were then reviewed and, on the basis of the title and the abstract, a subset was retained for use in the characterisation. Priority was given to papers published since 2003 and, where possible, copies of these were obtained for more detailed review. No additional open-literature studies concerning ecotoxicology of dimethenamid-P were found helpful for risk assessment purposes.

Study summaries of all listed studies are provided below.

The final results of all acceptable studies regarding the fate and behaviour of dimethenamid-P and its metabolites in water and soil are summarised in Volume 1 under 2.9.

B.9.1 Effects on birds and other terrestrial vertebrates

B.9.1.1 Effects on birds

No new studies were required or submitted for the renewal assessment. Studies were already submitted and accepted in the Monograph of dimethenamid-P, prepared in the context of the inclusion of the active substance in Annex I of Council Directive 91/414/EEC, 1999 and the EU Review Report Dimethenamid-P, July 2003, (SANCO/1402/2001).

B.9.1.2 Effects on terrestrial vertebrates other than birds

The risk assessment for terrestrial vertebrates, namely small mammals is based on the same toxicity data that is used for assessing the risk to humans – see chapter B.6 of this RAR.
Table B.9.2-1 below gives the relevant mammalian toxicity end points for dimethenamid-P for use in the ecotoxicological risk assessment, as taken from the current official end points for the active substance.

For a comprehensive study evaluation, see chapter B.6.

B.9.2 Risk assessment for birds and other terrestrial vertebrates

According to current guidance, a specific risk assessment for short-term risks from dietary uptake is not triggered for dimethenamid-P, since there are no indications for delayed action or accumulation of the compound leading to mortality on a short-term time scale.

Table B.9.2-1: Proposed avian and mammalian toxicity endpoints for use in risk assessment

Species	Test substance	Time scale	End point (mg/kg bw per day)	Reference
Birds				
Colinus virginianus	Dimethenamid-P	Acute	LD_{50} = 1068 mg/kg bw	[redacted] 03.06.1996 131-187; BASF RegDoc #1996/5419 *[1)]
Colinus virginianus	Dimethenamid-racemate	Long-term	NOEC = 900 ppm NOEL = 114 mg as/kg bw/d [3)]	[redacted] *et al.* 06.05.1994 131-177; BASF RegDoc # 1994/11900 *[1)]
Mammals				
Rat	Dimethenamid-P	Acute	LD_{50} = 429 mg/kg bw (male) LD_{50} = 531 mg/kg bw (female) LD_{50} = **466 mg/kg** bw (sexes combined)	[redacted] 17.07.1996 94-1404; BASF RegDoc # 1996/11087*[1)]
Rat	Dimethenamid-racemate Keto-enol process Undiluted, no carrier	Acute	LD_{50} = 397 mg/kg bw 90 % at 600 mg/kg bw 10 % at 300 mg/kg bw 0 % at 150 mg/kg bw	[redacted] 1991 1991/11940; BASF RegDoc# 1991/11940 [4)]
Rat	BAS 656 08 H	Acute	500 mg/kg bw < LD_{50} < 2000 mg/kg bw	[redacted] 2006 BASFDoc#2006/1026825[4)]
Rat	Dimethenamid-racemate	Long-term (2-generation-study)	NOAEL = 500 mg as/kg diet NOAEL = **33.3** mg/kg bw/day [3)]	[redacted] 17.05.1989 2012065; BASF Doc# 1990/11140 *[2) 4)]

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003.
1) For summary and evaluation of the study please refer to Dimethenamid-P_RAR_11_Volume_3CA_B-9.
2) For summary and evaluation of the study please refer to Dimethenamid-P_RAR_08_Volume_3CA_B-6.
3) Daily Dose [mg/kg b.w./d] calculated based on study data for food consumption and body weight.
4) Endpoint from EFSA Scientific Report (2005) 53, 1-73, Conclusion on the peer review of dimethenamid.

B.9.2.1 Risk for birds and mammals from dietary exposure

The first-tier risk assessment for birds and mammals is performed by calculating TER values based on dietary exposure according to the scenarios as provided by the current EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009). The relevant crop groups for the outdoor applications of the formulation BAS 656 12 H as well as the corresponding shortcut values for estimating the daily dietary dose of dimethenamid-P from uptake of contaminated food and, finally, the resulting TER values for birds are summarised in Table B.9.2-2 for acute and Table B.9.2-3 for long-term/reproductive toxicity, respectively. TER values for mammals are summarised in Table B.9.2-4 for acute and Table B.9.2-5 for long-term/reproductive toxicity, respectively. Only the respective worst-case generic focal species are listed, since their TER values are already above the pertinent acceptability criteria.

The uses have been grouped for the scenarios Maize (Maize and Sugar Maize), Bare Soil (BBCH < 10 for Soybean, Sunflower, Sugar Beet in BBCH 00-09, and Sugar Beet BBCH 12-18 in terms of a risk envelope covering the uses Sugar Beet in BBCH 16-18, and Sugar Beet in BBCH 12-18 splitted in 2 or 3 applications.

Table B.9.2-2: Avian risk assessment for dietary exposure to dimethenamid-P and to the formulation BAS 656 12 H (acute toxicity, screening and tier 1: worst-case generic focal species)

Crop and application timing	Applic. rate	Scenario	Indicator species	Shortcut value × MAF	Daily dietary dose (mg as/kg bw/d)	TER
Dimethenamid-P acute toxicity: LD_{50} = 1068 mg as/kg bw						
Screening assessment						
Maize/Sugar Maize BBCH 00-09	1 × 0.864 kg as/ha	Bare soil	Small granivorous bird	24.7	21.3	50
Soybean BBCH 00-09						
Sunflower BBCH 00-09						
Sugar Beet BBCH 00-09						
Maize/Sugar Maize BBCH 10-16	1 × 0.864 kg as/ha	Maize	Small omnivorous bird	158.8	137.2	**7.8**
Sugar Beet BBCH 12-18[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small omnivorous bird	158.8	114.3	**9.3**
Tier 1 assessment						
Maize/Sugar Maize BBCH 10-29	1 × 0.864 kg as/ha	Maize	Medium granivorous bird 100 % seed	6.6	5.702	187
Maize/Sugar Maize BBCH 10-19			Small insectivorous bird 100 % soil dwelling arthropods	10.5	9.072	118
Maize/Sugar Maize BBCH 10-29			Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	24	20.736	52
Maize/Sugar Maize BBCH 10-29			Medium herbivorous/ granivorous bird 100 % leaves	55.6	48.038	22
Maize/Sugar Maize BBCH 10-19			Small insectivorous bird 50 % ground arthropods 50 % foliar arthropods	26.8	23.155	46
Sugar Beet BBCH 10-19[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small insectivorous bird 100 % soil dwelling arthropods	10.9	6.9	136
Sugar Beet BBCH 10-19[1)] (spring)			Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	24.0	17.28	62

TER values shown in **bold** fall below the relevant trigger.

[1)] covering the uses Sugar Beet in BBCH 16-18, and Sugar Beet in BBCH 12-18 splitted in 2 or 3 applications

Table B.9.2-3: Avian risk assessment for dietary exposure to dimethenamid-P and to the formulation BAS 656 12 H (long-term/reproductive toxicity, screening and tier 1: worst-case generic focal species)

Crop and application timing	Applic. rate	Scenario	Indicator species	Shortcut value × MAF	Daily dietary dose (mg as/kg bw/d)	TER
Dimethenamid-P chronic toxicity: LD_{50} /10 = 106.8 mg/kg bw/d*						
Screening assessment						
Maize/Sugar Maize BBCH 00-09 Soybean BBCH 00-09 Sunflower BBCH 00-09 Sugar Beet BBCH 00-09	1 × 0.864 kg as/ha	Bare soil	Small granivorous bird	11.4	5.22	20.1
Maize/Sugar Maize BBCH 10-16	1 × 0.864 kg as/ha	Maize	Small omnivorous bird	64.8	29.67	**3.6**
Sugar Beet BBCH 12-18[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small omnivorous bird	64.8	24.73	**4.3**
Tier 1 assessment						
Maize/Sugar Maize BBCH 10-29	1 × 0.864 kg as/ha	Maize	Medium granivorous bird 100 % seed	3	1.374	78
Maize/Sugar Maize BBCH 10-19			Small insectivorous bird 100 % soil dwelling arthropods	5.7	2.610	41
Maize/Sugar Maize BBCH 10-29			Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	10.9	4.991	21
Maize/Sugar Maize BBCH 10-29			Medium herbivorous/ granivorous bird 100 % leaves	22.7	10.395	10
Maize/Sugar Maize BBCH 10-19			Small insectivorous bird 50 % ground arthropods 50 % foliar arthropods	11.3	5.174	21
Sugar Beet BBCH 10-19[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small insectivorous bird 100 % soil dwelling arthropods	5.9	2.25	47.4
Sugar Beet BBCH 10-19[1)] (spring)			Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	10.9*	4.15	25.7

TER values shown in **bold** fall below the relevant trigger.

SV: shortcut value; MAF_{90}: multiple application factor (90[th] percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

1) covering the uses Sugar Beet in BBCH 16-18, and Sugar Beet in BBCH 12-18 splitted in 2 or 3 applications

* LD_{50} /10, see also EFSA/2009/1438, page 35.

Table B.9.2-4: Mammalian risk assessment for dietary exposure to dimethenamid-P and to the formulation BAS 656 12 H (acute toxicity, screening and tier 1: worst-case generic focal species)

Crop and application timing	Applic. rate	Scenario	Indicator species	Shortcut value × MAF	Daily dietary dose (mg as/kg bw/d)	TER
Dimethenamid-P acute toxicity: LD_{50} = 466 mg as/kg bw						
Screening assessment						
Maize/Sugar Maize BBCH 00-09	1 × 0.864 kg as/ha	Bare soil	Small granivorous mammal	14.4	12.442	37.5
Soybean BBCH 00-09						
Sunflower BBCH 00-09						
Sugar Beet BBCH 00-09						
Maize/Sugar Maize BBCH 10-16	1 × 0.864 kg as/ha	Maize	Small herbivorous mammal	136.4	117.85	**4.0**
Sugar Beet BBCH 12-18[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small herbivorous mammal	118.4	85.25	**5.5**
Tier 1 assessment						
Maize/Sugar Maize BBCH 10-19	1 × 0.864 kg as/ha	Maize	Small insectivorous mammal 100 % ground arthropods	7.6	6.57	71.0
Maize/Sugar Maize BBCH 10-29			Small herbivorous mammal All maize shoots + later grass	136.4	117.85	**4.0**
Maize/Sugar Maize BBCH 10-29			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	17.2	14.86	31.4
Sugar Beet BBCH 10-19[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small insectivorous mammal 100 % ground arthropods	7.6	5.47	85.2
Sugar Beet BBCH 10-39[1)]			Large herbivorous mammal 100 % crop leaves	35.1	25.27	18.4
Sugar Beet BBCH 10-39[1)]			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	17.2	12.384	37.6

Crop and application timing	Applic. rate	Scenario	Indicator species	Shortcut value × MAF	Daily dietary dose (mg as/kg bw/d)	TER
Formulation BAS 6556 08 acute toxicity: 500 < LD_{50} < 2000 mg as/kg bw/d						
Screening assessment						
Maize/Sugar Maize BBCH 00-09	1 × 1.356 kg as/ha*	Bare soil	Small granivorous mammal	14.4	19.53	>25.6
Soybean BBCH 00-09						
Sunflower BBCH 00-09						
Sugar Beet BBCH 00-09						
Maize/Sugar Maize BBCH 10-16	1 × 1.356 kg as/ha*	Maize	Small herbivorous mammal	136.4	184.86	**>2.7**
Sugar Beet BBCH 12-18[1)]	1 × 1.130 kg as/ha	Sugar Beet	Small herbivorous mammal	118.4	133.79	**> 3.74**
Tier 1 assessment						
Maize/Sugar Maize BBCH 10-19	1 × 1.356 kg as/ha*	Maize	Small insectivorous mammal 100 % ground arthropods	7.6	10.306	>48.5
Maize/Sugar Maize BBCH 10-29			Small herbivorous mammal All maize shoots + later grass	136.4	184.96	**>2.7**
Maize/Sugar Maize BBCH 10-29			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	17.2	23.323	>21.4
Sugar Beet BBCH 10-19[1)]	1 × 1.130 kg as/ha*	Sugar Beet	Small insectivorous mammal 100 % ground arthropods	7.6	8.588	>58.2
Sugar Beet BBCH 10-39[1)]			Large herbivorous mammal 100 % crop leaves	35.1	39.663	>12.6
Sugar Beet BBCH 10-39[1)]			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	17.2	19.436	>25.7

TER values shown in **bold** fall below the relevant trigger.

[1)] covering the uses Sugar Beet in BBCH 16-18, and Sugar Beet in BBCH 12-18 splitted in 2 or 3 applications

* Taking into account the density of BAS 656 112 H of 1.13 g/cm^3

Table B.9.2-5: Mammalian risk assessment for dietary exposure to dimethenamid-P and to the formulation BAS 656 12 H (long-term/reproductive toxicity, screening and tier 1: worst-case generic focal species)

Crop and application timing	Applic. rate	Scenari o	Indicator species	Shortcut value × MAF	Daily dietary dose (mg as/kg bw/d)	TER
dimethenamid-P chronic toxicity: NOAEL = 33.3 mg as/kg bw/d						
Screening assessment						
Maize/Sugar Maize BBCH 00-09	1 × 0.864 kg as/ha	Bare soil	Small granivorous mammal	6.6	3.022	11.1
Soybean BBCH 00-09						
Sunflower BBCH 00-09						
Sugar Beet BBCH 00-09						
Maize/Sugar Maize BBCH 10-16	1 × 0.864 kg as/ha	Maize	Small herbivorous mammal	72.3	53.1	**1.0**
Sugar Beet BBCH 12-18[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small herbivorous mammal	48.3	16.6	**2.0**
Tier 1 assessment						
Maize/Sugar Maize BBCH 10-19	1 × 0.864 kg as/ha	Maize	Small insectivorous mammal 100 % ground arthropods	4.2	1.923	17.3
Maize/Sugar Maize BBCH 10-29			Small herbivorous mammal All maize shoots + later grass	72.3	33.11	**1.0**
Maize/Sugar Maize BBCH 10-29			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	7.8	3.57	9.3
Sugar Beet BBCH 10-19[1)]	1 × 0.720 kg as/ha	Sugar Beet	Small insectivorous mammal 100 % ground arthropods	4.2	1.6	20.8
Sugar Beet BBCH 10-39[1)]			Large herbivorous mammal 100 % crop leaves	14.3	5.46	6.1
Sugar Beet BBCH 10-39[1)]			Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	7.8	2.98	11.2

TER values shown in **bold** fall below the relevant trigger.
SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
1) covering the uses Sugar Beet in BBCH 16-18, and Sugar Beet in BBCH 12-18 splitted in 2 or 3 applications

Values in bold indicate where further refinements are required. For avian acute and long-term risk assessment TER values are above the relevant trigger value. For mammalian risk assessment, most TER values are above the trigger value, except for the scenario “small herbivorous mammal” in Maize/Sugar Maize BBCH 10-29 indicating the need for higher tier risk assessment for the uses 2 and 4.

Higher tier risk assessment

The tier 1 assessment indicates that there may be an acute risk to small herbivorous mammals (generic focal species voles) following the use of dimethenamid-P in Maize/Sugar Maize BBCH 10-16.

The applicant has not provided data for refinement for voles in Maize/Sugar Maize BBCH 10-16 but instead does not consider this generic focal species as relevant for a higher tier risk assessment concerning maize at early post-emergence for the following reasons:
First, in the applicant's opinion arable crops not constitute the vole's primary habitat. Second, in the view of the applicant voles are not present in maize fields at early post-emergence.

1) In the view of the applicant do arable crops not constitute the vole's primary habitat

The ecology of the species suggests that arable crops such as maize do not constitute the common vole's primary habitat. Instead, the common vole prefers undisturbed vegetation such as meadows, set-a-side land, flower strips, grassy field verges, alfalfa and clover fields. Furthermore, common vole populations naturally display cyclical changes, and a strong ability to recover from decimation, contributing to its pest status in European countries.

Conclusion

It is assumed that vole prefers undisturbed vegetation. On the other hand it is also shown to use cereal fields as habitat. From the studies provided, it cannot be excluded that voles are present in early maize. No information was provided, proving that vole populations present in the area avoid fields with young maize plants and do not feed on maize early post emergence (BBCH 10 – 19). Therefore, the statement of the applicant cannot be used to suspend the scenario common vole from higher tier risk assessment for maize early post emergence.

2) In the view of the applicant voles are not present in maize fields at early post-emergence

i) Generic field monitoring on maize and beet fields in Austria (Wolf 2005, BASF DocID 2005/1031348)

Live trapping of small mammals (with individual marking and subsequent recaptures) was conducted in a mixed arable landscape in Austria to identify those species that use early maize fields as part of their natural home range. Five maize and five sugar beet fields were chosen as primary study plots. The experimental phase started some weeks before drilling of maize and sugar beet (19.03.2004) and was completed approximately 2 months later (19.05.2004) Furthermore, the portion of time in early maize of the relevant species was investigated by radio telemetry.

The table below summarises the trapping results in and around maize fields during the time period of drilling to early post-emergence. The common vole, the field vole and the European pine vole were never captured on maize and sugar beet fields (Table B.9.2-6).

Table B.9.2-6 Mammal trapping results in maize (Wolf 2005) in Austria

Species	Result (captures/1000 trap nights)			% in field
	Field	Surrounding	Total	
Wood mouse (*Apodemus sylvaticus*)	4.5	32.1	36.5	12.3
Yellow-necked mouse (*Apodemus flavicollis*)	0.0	6.4	6.4	0.0
Common vole (*Microtus arvalis*)	0.0	12.8	12.8	0.0
Field vole (*Microtus agrestis*)	0.0	12.8	12.8	0.0
European pine vole (*Microtus subterraneus*)	0.0	24.4	24.4	0.0
European water vole (*Arvicola terrestris*)	0.0	1.3	1.3	0.0
Common shrew (*Sorex araneus*)	0.0	1.3	1.3	0.0

Additionally, four common voles (*Microtus arvalis*) were radio-tracked for a period of approximately 24 h, respectively. Only one out of the four individuals had maize fields within its home range. However, this individual did not use the maize field as foraging ground. In fact, none of the four voles was found to use the maize fields as foraging ground.

The objective of this study was to obtain information on crop use and diet of farmland birds and mammals in an agricultural environment in Austria. The information generated in this study can be used in the assessment of risks from plant protection products to terrestrial vertebrates in the frame of Regulation (EC) 1107/2009 and EFSA/2009/1438. The study focused on one bird (skylark) and one mammal (wood mouse) species but information on other species were also collected. In the present summary, only results of the small mammals are included.

Material and Methods

The study was conducted in mixed arable land in the 'Tullner Feld' to the west of Vienna in Austria. This region is a typical area of maize and sugar beet cultivation in Europe. Five maize and five sugar beet fields were chosen as primary study plots. The experimental phase of the study started some weeks before drilling of maize and sugar beet (19.03.2004) and was completed approximately 2 months later (19.05.2004).

The relevance of maize and sugar beet fields as well as the adjacent surrounding for small mammals was investigated. The presence of small mammal species and their abundance in different habitats was determined by live trapping (capture - mark - recapture method). Live trapping of mammals was conducted on 4 study plots in the study area to generate a list of small mammal species, occurring in plain field, drilled and germinated maize and sugar beet fields. Two of the study plots (plot 1 and 2) contained maize and the other 2 study plots (plot 4 and 7) contained sugar beet fields. In each field 45 'Ugglan' live traps were installed. 15 traps were set up in the surrounding along the border of the field to capture individuals, potentially using the field and the surrounding structure. 15 traps were set up from the border inside the field, to represent a gradient of closeness to the border. 15 traps were set up in the centre of the field. The trapping effort was twice inside the field than in the surrounding. Additionally 17 traps were installed in 2 potential good rodent habitats (plot Z2 and Z7) close to the study plots 2 and 7, to increase the possibility to trap animals, which suit for telemetry. In May on 2 additional maize fields (plot 3 and 6) 45 traps were set in the same order as in the other plots to improve the trapping data and to trap animals for telemetry.

Suitable adult individuals caught in the live traps were supplied with radio collars. Animals were regarded as suitable if they were heavy enough. The collar (~ 2 g) should not weight more than 10 % of the body mass. Those individuals, species and number were dependent on the trapping success, were tracked 1 – 4 times for approximately 24 h periods. During the tracking session each change of location, habitat and behaviour together with time and GPS position was recorded. In addition, GPS position was taken every 15 to 20 minutes, even if no change was noticed. These data allowed to calculate the portion of time an animal spent in a specific habitat type (e.g. maize field) and, furthermore, to calculate the size and shape of the total home range of the tracking session. The potential foraging time (PT) is the time when an individual is active and the behaviour foraging cannot be excluded. Nocturnal mice such as wood mouse and yellow-necked mouse have their active period from dusk till dawn. For voles with short-time rhythmic activity patterns, such as common voles, the whole 24h-telemetry period was regarded as active period, because the determination of active and inactive period was not reliable.

Results and discussion
Live trapping

In 7040 trap nights 377 trap events occurred and 120 animals of 9 species were individually marked. The recapture rate of all species was low. The average recapture rate for wood mice was 2.1, yellow-necked mice 4.9, pygmy field mouse 9.5, common vole 2, field vole 0.2, pine vole 0.1, house mouse 1.3, water vole and common shrew 0. In total 16 voles and mice died. Six animals (1.6 % from all handling events) died during the handling procedure and ten individuals were found dead in a trap or nearby. In the fields the trapping effort was twice as high as in the surrounding, to get comparable results they were related to trappings per 1000 trap nights.

The trapping data of wood mouse in spring in agricultural landscape showed that the habitat field (22 % of all trappings) was not preferred by the population. In early spring the uncultivated plain fields were attractive for the wood mouse (60 % of the trappings). The leavings of the previous crop caused the attractiveness of such plain fields. They were lying on the surface of the field. This easy detectable food source attracted the wood mouse even when no hide was available. After drilling and germination the attractiveness of fields decreased for the wood mouse. Only 18 % of the trappings were inside the sugar beet field and 12 % inside maize fields. This effect was due to the field cultivation. The preparation for the drilling and the drilling itself eroded the leavings of the last harvest in the soil.

The common vole in spring was trapped in agricultural fields only rarely (0.6 % of all trappings), that showed that fields in spring were avoided; on maize and sugar beet fields the common voles was never trapped.

The results are taken from Tables 23, 24 and 25 on page 82 and 83 of the study report.

Table B.9.2-7: Trapping of mammals in different fields in the Austrian agricultural landscape studied by Wolf (2005)

		Trapping efficiency (trappings/1000 trap nights)			% of captures in field
Habitat	**Species**	**Field**	**Surrounding**	**Total**	
plain field	*Apodemus sylvaticus*	10.4	6.9	17.4	60.0
	Apodemus flavicollis	0.0	25.0	25.0	0.0
	Mus musculus	2.1	5.6	7.6	27.3
	Microtus arvalis	0.7	87.5	88.2	0.8
	Microtus agrestis	0.0	1.4	1.4	0.0
sugar beet	*Apodemus sylvaticus*	11.5	53.0	64.5	17.8
	Microtus arvalis	0.0	8.6	8.6	0.0
maize	*Apodemus sylvaticus*	4.5	32.1	36.5	12.3
	Apodemus flavicollis	0.0	6.4	6.4	0.0
	Microtus arvalis	0.0	12.8	12.8	0.0
	Microtus agrestis	0.0	12.8	12.8	0.0
	Microtus subterraneus	0.0	24.4	24.4	0.0
	Arvicola terrestris	0.0	1.3	1.3	0.0
	Sorex araneus	0.0	1.3	1.3	0.0
Agricultural field	*Apodemus sylvaticus*	8.6	30.5	39.1	22.1
	Apodemus flavicollis	0.0	10.5	10.5	0.0
	Arvicola terrestris	0.0	0.5	0.5	0.0
	Microtus agrestis	0.0	5.0	5.0	0.0
	Microtus arvalis	0.2	35.9	36.2	0.6
	Microtus subterraneus	0.0	8.6	8.6	0.0
	Mus musculus	0.7	1.8	2.5	27.3
	Sorex araneus	0.0	0.5	0.5	0.0

Radio tracking

To calculate the potential foraging time, continuous radio tracking data of 16 individual rodents (eight wood mice, four yellow-necked mice and four common voles) in 25 radio tracking sessions were used.

Agricultural fields

To calculate the potential foraging time (PT) in agricultural landscape the average of all tracking session of one species was calculated. In spring the crop stages of the fields change very fast from plain field to drilled field and to germinated field. Still the summarisation of the different field stages gives a good overview of small mammal behaviour in spring. All the different crop states have similar attributes, nearly no cover that means no hiding places against avian predation. Fifteen tracking sessions of eight wood mouse individuals contain field habitats in their home range. The wood mouse spent 52.7 % of the potential foraging time on agriculture field with a range of 4.3 – 100.0 %. Four common voles were radio tracked one time each, only one individual used the habitat field for 0.14 % of the PT. The average of the four tracking sessions was 0.04 %. The yellow-necked mouse with five tracking sessions of four individuals did not use the habitat field

Plain fields

The potential foraging time was calculated from 6 tracking session. Four wood mice, one yellow-necked mouse and one common vole individual, each were radio tracked once. The wood mice spent on average 16.6 %, with a range of 5.3 – 43.8 %, of the PT on plain fields. The yellow-necked mouse and the common vole did no spent any time on the plain field.

Sugar beet

The potential foraging time in sugar beet was calculated from 17 tracking sessions. Eleven tracking sessions of five wood mice individuals, four tracking sessions of three yellow-necked mice and two tracking sessions of two common vole individuals. The average PT of wood mouse in sugar beet was 33.3 % with a range from 0.0 – 100.0 %. The yellow-necked mouse and the common vole did not enter the sugar beet field (PT = 0.0 %).

Also the PT of small mammals of the different crop stages was calculated. After drilling and before germination, three tracking session of three wood mouse and two tracking sessions of two yellow-necked mice individuals contain drilled sugar beet in their home range. The average PT of wood mice was 38.2 % inside the drilled sugar beet with a range 6.1 – 98.0 %. The yellow-necked mice did not use the drilled sugar beet (PT = 0.0 %). After the sugar beet seed were germinated eight tracking sessions of five wood mice, two tracking session of one yellow-necked mouse and two tracking sessions of two common vole individuals include germinated sugar beet in their home range. The average PT inside the germinated sugar beet for wood mouse was 31.5 % with a range of 0.0 – 100.0 %. The yellow-necked mouse and the common vole did not use the germinated sugar beet (PT = 0.0 %).

Maize field

The potential foraging time in maize was calculated from seven tracking sessions. Five tracking sessions of three wood mice, one tracking session of yellow-necked mouse and one tracking session of common vole individuals included maize in their home range. For the wood mouse the average PT was 1.4 % with a range from 0.0 – 3.8 %. The yellow-necked mouse and the common vole did not use the maize field (PT = 0.0 %).

The PT of the different crop stages of maize was calculated. After drilling two tracking sessions of one wood mouse and one tracking session of yellow-necked mouse include maize in their home range. Both the wood mouse and the yellow-necked mouse never entered the maize field after drilling. The part of PT in drilled maize was 0.0 %. After the maize germinated, three tracking session of two wood mice and one tracking sessions of common vole individuals included germinated maize in their home range. The average PT in germinated maize for wood mice was 2.3 % with a range of 0.0 - 3.8 %. The common vole did not enter the germinated maize (PT = 0.0 %).

Table B.9.2-8 Potential foraging time of small mammals trapped in the study of Wolf (2005)

Each tracking session with the appropriate habitat in the MCP was used for the PT analyses of this habitat.									
		PT [%]							
species	**individual**	**plain field**	**drilled maize**	**germinated maize**	**sum maize**	**drilled sugar beet**	**germinated sugar beet**	**sum sugar beet**	**agricultural field**
Apodemus flavicollis	1	-	-	-	-	0.0	-	0.0	0.0
	2	-	0.0	-	0.0	-	0.0	0.0	0.0
	2	-	-	-	-	-	0.0	0.0	0.0
	3	0.0	-	-	-	0.0	-	0.0	0.0
	mean	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0
	90 %tile	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0
Apodemus sylvaticus	5		-	-	-	98.0	-	98.0	100.0
	5	-	-	-	-	-	90.1	90.1	93.5
	5	-	-	-	-	-	100.0	100.0	100.0
	5	-	-	-	-	-	54.0	54.0	100.0
	6	9.8	-	-	-	-	-	-	9.8
	7	-	-	0.0	0.0	-	4.3	4.3	4.3
	8	-	-	-	-	-	-	-	70.0
	9	7.7	-	-	-	6.1	-	6.1	24.9
	9	-	-	-	-	-	0.0	0.0	98.1
	10	43.8	-	-	-	-	-	-	64.0
	11	5.3	-	-	-	10.5	-	10.5	15.8
	11	-	-	-	-	-	-	-	-
	11	-	-	3.8	3.8	-	1.6	1.6	5.4
	11	-	-	3.1	3.1	-	1.9	1.9	5.1
	12	-	0.0	-	0.0	-	0.0	0.0	82.0
	12	-	0.0	-	0.0	-	-	-	17.4
	mean	16.6	0.0	2.3	1.4	38.2	31.5	33.3	52.7
	90 %tile	33.6	0.0	3.7	3.5	80.5	93.1	98.0	100.0
Microtus arvalis	13	0.0	-	-	-	-	-	-	0.1
	14	-	-	-	-	-	0.0	0.0	0.0
	15	-	-	-	-	-	-	-	0.0
	16	-	-	0.0	0.0	-	0.0	0.0	0.0
	mean	0.0	-	0.0	0.0	-	0.0	0.0	0.0
	90 %tile	0.0	-	0.0	0.0	-	0.0	0.0	0.1

Finding

According to the results of trapping and radio tracking the wood mouse has been the species of concern. The live trapping revealed that the uncultivated plain field was most attractive, which was due to the leavings of the previous crops on the surface. These leavings were an easy food source. After the field cultivation began and the leavings were eroded in the soil, the attractiveness of sugar beet and of maize decreased. The average potential foraging time (PT) based on radio tracked wood mouse was in sugar beet 33 % and for plain field 17 %. Maize (1.4 %) was scarcely part of the PT. The common vole was rarely captured on agricultural fields and never in maize fields. Also the PT data revealed that maize and sugar beet fields were never used as foraging ground by common voles.

Conclusion

The study Wolf (2005) intended to show that out of four radio-tracked common voles no individual used maize fields as a foraging area. However, as the applicant summarises the study, only one of these four voles had maize fields in its home range. Hence, the other three voles did not have the possibility to choose or not choose to forage on maize fields. Therefore, these three voles cannot be used to decide if voles are a focal species on maize. For the remaining vole maize fields made up only 11.7 % of its home range, which is very little. Additionally, common voles undergo strong population cycles. In some years only a small number of voles are present and in other years common voles are numerous. It is unclear, what the abundance of common voles in this particular year in this particular region had been. Therefore, the study cannot be used for risk assessment.

ii) Generic field monitoring on maize fields in France (Funkenhaus & Giessing (2010)
Live trapping as well as diurnal and nocturnal monitoring were conducted in an arable landscape in France from 27 April to 27 May 2009 in order to identify the mammal species that use maize field after drilling (BBCH0), after emergence of maize seedlings (BBCH 10-11) and after emergence of leaves BBCH 12 – 16.

Table B.9.2-9 summarises the trapping and monitoring results in and around maize fields during the time period of drilling to early post-emergence.

Table B.9.2-9: Mammal trapping and monitoring results in maize (Funkenhaus & Giessing 2010) in France

Small mammal trapping			
Species	**Mean trapping efficiency [captures/100 trap nights]**		**Captures in the field [% of total captures]**
	Field (based on 1 116 trapnights)	Off-crop (based on 372 trapnights)	
Wood mouse (*Apodemus sylvaticus*)	0.35	15.40	6.56
Greater white-toothed shrew (*Crocidura russula*)	0.00	6.60	0.00
Common vole (*Microtus arvalis*)	0.00	1.04	0.00

Diurnal and nocturnal mammal monitoring				
Thermographic scan sampling				
Species	Abundance [ind./ha]	Foraging Individuals [%]	FOscan [%]	FOfield [%]
Wood mouse (*Apodemus sylvaticus*)	0.31	57.14	3.43	100
European brown hare (*Lepus europaeus*)	0.04	45.83	9.80	75
European rabbit (*Oryctolagus cuniculus*)	0.02	46.15	5.39	50
Diurnal scan sampling				
European brown hare (*Lepus europaeus*)	0.004	61.11	2.63	40

Three small mammal species occurred in off-crop habitats adjacent to maize fields: the wood mouse (*Apodemus sylvaticus*), the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*). Notably, common voles were never captured in maize fields. Instead, only the wood mouse was captured and observed inside maize fields.

The aim of this generic study was to obtain information about occurrence of wild mammals in maize fields in Southern Europe in order to define the focal species in this crop between drilling and BBCH growth stage 16.

Material and Methods
The study was conducted in Southern France in a typical maize growing region south of Toulouse in the departments Haute-Garonne and Ariège (region Midi-Pyrénées).

The study was conducted in spring 2009. The occurrence of mammals in drilled maize fields was assessed by small mammal live trapping and scan sampling. The live trapping of small mammals was carried out according to a ‘Capture-Mark-Recapture (CMR)’ design and was used to generate a list of small mammal species and their abundance in freshly drilled maize fields.

Trapping was carried out from 27 April until 27 May 2009 on four different maize fields with a trapping effort of 1 488 trapnights per field, with 25 % of the traps set up in the adjacent off-crop habitat. In order to identify and quantify the occurrence of nocturnal mammals in maize fields 'thermographic scan sampling' observations were carried out in four fields, using a thermographic camera which is suitable for the detection of nocturnal mammals. To quantify the abundance and to characterise the behaviour of diurnal mammals on drilled maize fields, ten study fields were observed by scan sampling for mammal activity. With the purpose to obtain more detailed information about the foraging behaviour of mammals on maize fields (period: after drilling until BBCH 16), individual mammals with a focus on medium-sized herbivores (hares) were visually observed. Live trapping, thermographic scan sampling, diurnal scan sampling and monitoring of foraging behaviour was done at three different times according to crop stages of the maize plants: shortly after drilling (BBCH 0), after emergence of maize seedlings (BBCH 10-11) and after emergence of leaves (BBCH 12-16).

Results and discussion

The most abundant small mammal species according to the trapping data was the wood mouse (*Apodemus sylvaticus*). Besides the wood mouse, the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*) were captured. Regarding the trapping data the common vole and the white-toothed shrew were never captured in the maize fields. The wood mouse was occasionally captured inside maize field but mainly in the off-crop habitat.

The diurnal and nocturnal monitoring showed that besides the wood mouse, the European brown hare (*Lepus europaeus*) and the European rabbit (*Oryctolagus cuniculus*) were the relevant species monitored as potentially foraging during thermographic scan sampling sessions. The hare was the only mammal species observed during daylight scan sampling. Overall mammals showed low abundances.

Table B.9.2-10: Overview of key results of small mammal trapping in maize (Funkenhaus & Giessing 2010) in France

Species	**Mean trapping efficiency [captures/100 trapnights]**		**Captures in the field [% of total captures]**
	Field (based on 1 116 trapnights)	**Off-crop (based on 372 trapnights)**	
Wood mouse (*Apodemus sylvaticus*)	0.35	15.40	6.56
Greater white-toothed shrew (*Crocidura russula*)	0.00	6.60	0.00
Common vole (*Microtus arvalis*)	0.00	1.04	0.00

Diurnal and nocturnal mammal monitoring				
Thermographic scan sampling				
Species	Abundance [ind./ha]	Foraging Individuals [%]	FOscan [%]	FOfield [%]
Wood mouse (*Apodemus sylvaticus*)	0.31	57.14	3.43	100
European brown hare (*Lepus europaeus*)	0.04	45.83	9.80	75
European rabbit (*Oryctolagus cuniculus*)	0.02	46.15	5.39	50
Diurnal scan sampling				
European brown hare (*Lepus europaeus*)	0.004	61.11	2.63	40

Finding

Three small mammal species occurred in off-crop habitats adjacent to maize fields: the wood mouse (*Apodemus sylvaticus*), the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*). Only the wood mouse was found inside maize fields and then only in very small numbers after emergence of maize. In addition to the wood mouse, the European brown hare (*Lepus europaeus*) and the European rabbit (*Oryctolagus cuniculus*) were also observed in maize fields.

Conclusion

In the study of Funkenhaus and Giessing (2010), small mammals were captured and recaptured in maize fields and in off-crop areas adjacent to maize fields. Within 992 trap nights after the emergence of the maize plants only three common voles were captured. All of these three voles were captured in the off-crop areas adjacent to one particular maize field. Hence, no voles occurred in the maize fields and no voles occurred in the off-crop areas except one. It is unclear, what the abundance of voles in that region and time was. Only if it had been shown that common voles were abundant in a population size typical for the region and time of the year, it would have been possible to show that nevertheless common voles avoided maize fields. With the data presented, it cannot be excluded that common voles were not abundant in this region and year. Therefore, the study cannot be used to suspend the scenario common vole from higher tier risk assessment for maize early post emergence. The study cannot be used for risk assessment.

Submitted public literature

In addition to the proprietary industry studies, the following four studies strongly support the notion that the common vole is not a relevant focal species in maize:

Truszkowski (1982) investigated the density of the common vole population in a capture-recapture field study in an agricultural landscape in Poland. The study area comprised over 3100 ha, 2150 ha of which were arable land. Root crops (potatoes, beet) and maize formed 19.7 % of the study area. No information on comprising maize fields only is given. The density of the common vole population was monitored over a period of five years (i.e. from 1971-1976). Population density was estimated by flushing common voles from their burrows with water in spring (April, May), summer (July, August) and autumn (October, November). In each season 5-10 capture events (i.e. flushing) were undertaken on each field. In total, 5420 common voles were caught during the five-year period on almost 550 fields of different crops. Lucerne, clover and grass plantations are the common voles' preferred habitat. In contrast to that, root crops (potatoes, beet) and maize were characterised by zero or nearly zero voles, suggesting that maize, beet and potato crops are not the preferred habitat of the common vole.

Conclusion

The study shows that in the agricultural landscape in Poland of the 1970th maize fields are not the preferred habitat of voles. In contrast voles showed high abundance in lucerne. Since the agricultural conditions changed a lot in the meantime in Europe (more maize fields, less lucerne fields, larger fields) the study does not provide information on vole abundance under current agricultural conditions. Therefore, the study cannot be used to suspend the scenario common vole from higher tier risk assessment for maize early post emergence.

Further, Zejda & Nesvadbova (2000) investigated the entire terrestrial small mammal community in a six year field study conducted between 1983 and 1989 in arable land in Moravia (Czech Republic). The size of the study area was 46 km². Arable land comprised 91 %, including 23 % maize fields (15 % grown for grains; 8 % grown for silage) and 17 different habitat types in total. Snap traps were used to capture voles (20 traps each placed 5 m apart, total length of trap line: 100 m). In a 3 – monthly interval, traps were set in a capture period for 48 or 72 hours and were inspected after 24 hours. In total, 1368 common voles were captured in the study area over a six year period. In spring the abundance of *Microtus arvalis* was very low; it mainly occurred in wastelands and banks, but also in winter wheat, alfalfa crops, woods and windbreaks, most likely because these areas remain undisturbed until the trapping period and therefore, the burrow system of the vole prevails. Few common voles were captured in spring, none of them inside the maize fields.

Conclusion

The study shows that in the agricultural landscape in southern Moravia (Czech Republic) of the 1980th maize fields are not the preferred habitat of voles. Since the agricultural conditions changed a lot in the meantime in Europe (more maize fields, less alfalfa fields, larger fields) the study does not provide information on vole abundance under current agricultural conditions. Therefore, the study cannot be used to suspend the scenario common vole from higher tier risk assessment for maize early post emergence.

Briner et al. (2005) performed a two year telemetry study (from the year 2000-2001; each year from spring to autumn) with automatic radio tracking of common voles in a six-year old wildflower strip near Bern, Switzerland. Adjacent crops were to maize and wheat fields in 2000 and adjacent to maize and sugar beet fields in 2001. With fixed receivers and antennas in the field and a PC-based system controller common voles were tagged, (1-5 days) and the tracking interval was 60 s, each with more than 100 data points per day. Voles were captured using Longworth traps and transmitters affixed around the neck while under light anaesthesia. Of the 118 individual voles tagged, 40 had transmitters which worked for at least 24 hours and could be analysed. Data from March-July was used to analyse the above ground activity of the voles. Activity (scored as active or inactive) was recorded every 15 minutes.The voles captured had 100 % of the core areas of the home ranges within the wildflower stripe and none was tracked in the maize fields. Home range sizes were stable between consecutive days with a median overlap of 87.5 %. Additionally, common voles were live-trapped biweekly and individually marked with ear tags. Population abundance was assessed by the minimum number known to be alive. The collected data show, that the voles developed high population densities of up to 650 individuals/ha within a wildflower strip, but did not expand into the adjacent crop areas.

Conclusion

The study shows that the wildflower strip provides sufficient food and cover for the voles not to venture into the crop. It does not provide information on populations that may live within the crop. Therefore the study cannot be used for risk assessment.

Janova et al., (2011) determined the attractiveness of traditional crops (alfalfa, barley, wheat) and maize, rape and sunflower fields for small mammals. Data were collected from 2004-2005 in a study area of approximately 40 x 12 km in South Moravia (Czech Republic). The rest of pre-crops were cleared off at the end of summer and the fields were ploughed – which leads to the moving of small rodents to adjacent habitat. Trap lines began about 50 m apart from the borders of the field to avoid edge effects. Snap trapping was used to catch small mammals and between 6 and 13 different fields of each crop were sampled in each year (in total, 49 and 63 fields were sampled in 2004 and 2005, respectively). Mammals were caught twice a year, at the beginning of the vegetative season and before the harvest. In more detail, maize was sampled in late May (height: 20-30 cm; state: 30 % cover) and at the end of August (height: 12-200 cm; state: nearly ripe). In total only 4 and 14 common voles were caught in all crops spring 2004 and 2005, respectively. None of them was caught in maize fields in spring. At harvest time the number of voles increased. In total 113 and 158 common voles were caught in all crops spring 2004 and 2005, respectively, 2 and 6 thereof were caught in maize fields. The authors conclude that herbivorous species (especially the common vole) do not live in crops which do not have green leaves near the ground (e.g. sunflower, maize), while mobile granivorous species can inhabit all types of crop. In summary, the study showed that maize had no importance at all for common voles, but instead, maize was a favoured habitat for the wood mice.

Conclusion

The study shows that in the area observed the voles might not re-enter up to the center of newly established maize fields at about BBCH 30. It does not provide information on populations that may live within the crop nor whether young leaves of emerging maize (BBCH 09-16) are attractive for voles. Therefore the study cannot be used for risk assessment.

Overall conclusion of RMS on higher tier statement of the applicant:

According to the Guidance Document EFSA/2009/1438 the common vole (*Microtus arvalis)* is the representative species for the small herbivorous mammal.

It is assumed that voles prefer undisturbed vegetation and avoid exposed uncovered areas. On the other hand voles are known to use cereal fields as habitat. From the studies provided, it can be concluded that maize fields at early post emergence are not the preferred habitat of voles. However, it cannot be excluded that voles are present in maize at this stage. No information was provided, proving that vole populations present in the area avoid fields with young maize plants and do not feed on maize early post emergence (BBCH 10 – 19). At time of application, the vegetation in field (non-crop as well as young maize plants) might provide cover and attractive food for the vole. After application, when the non-crop plant species are extinct, only the young maize plants remain as food source in this area. At this time voles start building up their populations. To show that the intended use in maize does not cause a risk for voles, data proving that voles do not feed on young maize plants (BBCH 10-19) are lacking. Concerning the long-term risk assessment, it could be assumed that the scenario of voles feeding on young maize plants sprayed one single time might not be relevant for a long time scale taking also into account that the food source (weeds - at least initially - and young maize plants) and cover will not be available. Reproduction cycles of voles are short and so the next generation could also be exposed to the residues. No information is available whether DT_{50} of dimethenamid-P on young maize plants is sufficiently lower than the default value used in Tier 1. Therefore, it is unclear whether exposure is reduced in the respective period.

Overall, the scenario common vole cannot be excluded from higher tier risk assessment for maize early post emergence and therefore unacceptable acute and chronic risks remain for the uses 2 and 4.

B.9.2.2 Risk for birds and mammals from exposure to contaminated drinking water

In addition to their diet, birds and mammals may also be exposed to dimethenamid-P via drinking water. Only the scenario of puddles formed on soil needs to be considered in this case. As pointed out in the EFSA Guidance document, specific calculations of exposure and TER values are only necessary when the ratio of effective application rate (in g as/ha) to the relevant endpoint (in mg as/kg bw/d) exceeds 50 in the case of less sorptive (K_{OC} < 500 L/kg) or 3000 in the case of more sorptive (KOC ≥ 500 L/kg) substances. For dimethenamid-P, the K_{OC} is 227 L/kg. The ratio of highest application rate (864 g as/ha) to lowest relevant avian endpoint (LD_{50}/10 = 106.8 mg as/kg bw/d) is 8.1; therefore, the risk for birds can be considered acceptable without the need for further calculations. The ratio of highest application rate (864 g as/ha) to lowest relevant mammalian endpoint (NOEL = 33.3 mg as/kg bw/d) is 26; therefore, the risk for mammals can be considered acceptable without the need for further calculations.

B.9.2.3 Risk assessment for metabolites

Plant material may serve as potential food item for herbivorous / granivorous birds and mammals. Several metabolites of dimethenamid-P have been detected in plant metabolism studies.

The metabolites M27 (sulfonate) and M30 (sulfoxide of thioactic acid) were found in edible crop parts up to 7.4 % and 17.9 % of parent level. Both metabolites also occurred in laying hens, rats and mice.

Since mammalian testing does not indicate that they are more toxic than the parent, it can be concluded that the risk to mammals will be covered by the parent compound and no further quantitative risk assessment is conducted.

B.9.2.4 Bioaccumulation and food chain behaviour for birds and mammals

According to the EFSA Guidance Document, substances with a log $P_{OW} \geq 3$ are likely to possess a potential for bioaccumulation that might result in unacceptable risks for organisms at higher trophic levels. Hence, a specific risk assessment (‘secondary poisoning’) must be performed for these substances. The log P_{OW} for dimethenamid-P is 1.89, therefore an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

B.9.2.5 Overall conclusions

Dietary risk assessment

TER values for birds were calculated, taking into account the relevant toxicity data for dimethenamid-P and calculated exposure levels for dietary exposure, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects as well as the acceptability criterion TER ≥ 5 for long-term/reproductive effects, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. The results of the assessment indicate an acceptable risk for birds due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

TER values mammals were calculated, taking into account the relevant toxicity data for dimethenamid-P and the formulation BAS 656 08 H and calculated exposure levels for dietary exposure, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects as well as the acceptability criterion TER ≥ 5 for long-term/reproductive effects, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1 in the intended uses 1, 3, 5 - 10 but not in the intended uses 2 and 4. The results of the assessment indicate an acceptable risk for mammals due to the intended use of BAS 656 12 H in maize (uses 1 and 3), sugar maize, soybean, sunflower, and beets according to the label. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of BAS 656 12 H in maize (uses 2 and 4) according to the label.

Risk assessment for exposure via drinking water

The ratio of highest application rate to lowest relevant endpoint for birds and mammals were calculated, taking into account the relevant toxicity data for dimethenamid-P and calculated exposure levels for exposure via drinking water, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The calculated ratios are below the trigger of 50 for less sorptive (KOC < 500 L/kg) substances. The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

Risk assessment for exposure via secondary poisoning

The log P_{OW} for dimethenamid-P is 1.89, therefore an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

B.9.3 Effects on aquatic organisms

B.9.3.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

KCP 10.2.1/1 (study evaluated in the initial monograph, 2000)

Author:	[redacted]
Title:	Report BAS 656 07 H: Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792) in a static system (96 hours)
Date:	25.03.1999
Doc ID:	12F0085/985026; WAT1999-495; (BASF RegDoc# 1999/10372)
Guidelines:	EPA 72-1; OECD 203
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 656 07 H (Frontier X2), batch no. 98001; purity: 64.0 w % (see certificate of Analytical BASF corporation of February 1998).
Test species:	Rainbow trout (*Oncorhynchus mykiss*), about 5 months old at test start; body length 6.37 cm (6.0 – 6.9 cm); body weight 2.43 g (2.0 – 3.4 g).
Test design:	Static test system (96 hours); 9 test item concentrations and a (water) control, 10 fish per aquarium (loading 0.2 g fish/L) and per concentration; assessment of mortality and symptoms of toxicity within 1 hour after start of exposure and after 24, 48, 72 and 96 hours after start of exposure.
Endpoints:	LC_{50}, NOEC, mortality and sub-lethal effects.
Test concentrations:	Negative control, 1.0, 1.47, 2.15, 3.16, 4.64, 6.81, 10.0, 14.70, 21.50 mg BAS 656 07 H /L (nominal).
Test conditions:	Glass aquaria with a stainless steel frame, volume of water: 100 L; one aquarium for each test group; temperature: 12 - 13 °C; pH about 8.0; dissolved oxygen concentration >60 % of saturation throughout the test; total hardness: 250 mg $CaCO_3$/L; photoperiod: 16 h light : 8 h dark
Analytics:	The test concentrations were determined by HPLC.
Statistics:	Descriptive statistics; probit analysis for calculation of the LC_{50}; determination of NOEC by visual interpretation of mortality and clinical observation data.

Results and Discussion

Analytical measurements: The analytical results varied between 99 % and 100 % of the nominal concentrations.

Biological results: Rainbow trout in the negative control, 1.0, 1.47 and 2.15 mg/L treatment group appeared normal and healthy throughout the test. After 96 hours of exposure, mortality in the 6.81, 10.0, 14.7 and 21.5 mg BAS 656 07 H /L treatments was 20, 90, 100 and 100 %, respectively. The LC_{50} value with 95 % confidence limits at 96 hours was calculated from the mortality data and the results are shown in Table B.9.3-1.

Table B.9.3-1: Acute toxicity (96 h) of BAS 656 07 H on rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] (nominal)	**control**	**1.0**	**1.47**	**2.15**	**3.16**	**4.64**	**6.81**	**10.0**	**14.7**	**21.5**
Mortality after 96 hours [%]	0	0	0	0	0	0	20	90	100	100
Symptoms *	none	none	none	none	C10	C10	C8	K1	n.d.	n.d.
Endpoints [mg BAS 656 07 H/L (nominal)]										
LC_{50} (96 h)	7.94 (95 % confidence limits: 6.84 – 9.23)									
NOEC (96 h)	2.15									

n.d. = not determined (all fish dead); C = swimming near water surface; K = convulsions
* number behind symbol for symptom = number of affected fish

Conclusions

In a static acute toxicity study with rainbow trout the LC_{50} (96 h) of BAS 656 07 H was 7.94 mg as/L based on nominal concentrations. The NOEC (96 h) was determined to be 2.15 mg as/L (nominal).

KCP 10.2.1/2 (study evaluated in the initial monograph, 2000)

Author:	Jatzek, J.
Title:	Determination of the acute effect of BAS 656 07 H on the swimming ability of the water flea *Daphnia magna* STRAUS according to GLP, EN 45001 and ISO 9002.
Date:	24.03.1999
Doc ID:	99/0083/50/1; WAT1999-496; (BASF RegDoc# 1999/10316)
Guidelines:	OPPTS 850.1010; OECD 202
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 656 07 H (Frontier X2), batch no. 98001; purity: 64.0 %.
Test species:	Water flea (*Daphnia magna*), daphnid neonates used in the test were less than 24-hours old.
Test design:	Static test system (48 hours), 8 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility after 3, 6, 24 and 48 hours.
Endpoints:	LC_{50}, NOEC, mortality and sub-lethal effects.
Test concentrations:	Negative control, 0.78, 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg BAS 656 07 H (nominal)
Test conditions:	Test tubes (glass) with flat bottom (nominal volume 20 mL); test volume: 10 mL; Water temperatures were within the 20±2 °C. Dissolved oxygen concentrations ranged from 8.2 to 8.7 mg/L in all tested replicates. Measurements of pH ranged from 8.0 to 8.2.
Analytics:	Analytical verification of the test item was conducted using gas chromatography coupled with atomic emission detection (GC/AED). All samples were enriched by solid-phase micro extraction (SPME) which is directly connected to the GC/AED system.
Statistics:	For the statistical calculation of the EC_{50} the moving average method was used.

Results and Discussion

Analytical measurements: The analytical results varied between 105.7 % and 115.1 % of the nominal concentrations.

Biological results: At test termination, no immobility occurred in the control group, one daphnid in the 12.5 mg/L treatment group was immobile and in the three highest treatment groups (25, 50 and 100 mg/L) all daphnids were immobile. EC_{50} values and 95 % confidence limits for 48 hours were calculated or estimated from the mortality/immobility data, and are shown in Table B.9.3-2.

Table B.9.3-2: Effect of BAS 656 07 H on *Daphnia magna* immobility

Concentration [mg/L] (nominal)	**control**	**0.78**	**1.56**	**3.13**	**6.25**	**12.5**	**25**	**50**	**100**
Immobility (48 h) [%]	0	0	0	0	0	5	100	100	100
Symptoms	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Endpoints [mg BAS 656 07 H /L (nominal)]								
EC_{50} (48 h)	17.1 (95 % confidence limits: 16 – 18.3)								
EC_0 (48 h)	12.5								

n.d. = not determined (symptoms not reported in the study)

Conclusions

The 48-hour EC_{50} value for daphnids exposed to BAS 656 07 H was 17.1 mg/L. The 95 % confidence limits were 16.0 and 18.3 mg BAS 656 07 H/L.

KCP 10.2.1/3 (study evaluated in the initial monograph, 2000)

Author:	Reuschenbach, P.
Title:	Determination of the inhibitory effect of BAS 656 07 H on the cell multiplication of unicellular algae according to GLP, EN 45001 and ISO 9002.
Date:	26.03.1999
Doc ID:	99/0083/60/1; WAT1999-497; BASF RegDoc# 1999/10315
Guidelines:	OPPTS 850.5400; OECD 201
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 656 07 H (Frontier X2), batch no. 98001; purity: 64.0 %.

Test species: *Scenedesmus subspicatus* (= *Desmodesmus subspicatus*), the test strain was obtained at regular intervals from SAG (Collection of algal cultures in Göttingen) and is kept in liquid culture in the laboratory of ecology at BASF AG Ludwigshafen.

Test design: Static system (72 hours), 10 test concentrations plus control group, three replicates per treatment; daily cell density measurement via the parameter chlorophyll-a fluorescence; initial cell density: 10^4 cells/mL.

Endpoints: EC_{50} and NOEC with respect to growth rate and biomass after exposure over 72 hours.

Test concentrations: Negative control, 0.00098, 0.0019, 0.0078, 0.0156, 0.0313, 0.0625, 0.125, 0.25, 1 and 10 mg BAS 656 07 H (nominal)

Test conditions: Test chambers were sterile, 250-mL Erlenmeyer flasks containing 100 mL of test solution. The test chambers were shaken continuously. Temperature was within 20 ±1 °C; pH ranged from 7.9 to 8.1; light intensity: 60-120 µE/m²s at a wave length of 400 - 700 nm. Test parameter: *in vivo* chlorophyll-a-fluorescence (pulsed excitation with light flashes having a wave length of 435 nm).

Analytics: Analytical verification of the test item was conducted using gas chromatography coupled with atomic emission detection (GC/AED). All samples were enriched by solid-phase micro extraction (SPME) which is directly connected to the GC/AED system.

Statistics: Descriptive statistics; calculation of EC_{50}; determination of NOEC.

Results and Discussion

Analytical measurements: Samples collected at 0 Hours had measured values that ranged from 79.9 to 108.9 % of nominal values, while measured values for samples taken at 72 hours ranged from 75.5 to 102.1 %. Nominal concentrations were used in the calculations of EC_{50} values.

Biological results:
The EC_{50} (72 h) of the reference substance potassium dichromate was 0.36 mg/L (Date of the last reference control experiment: 29-Jan-1999; project no. 97/0242/60/13). The cell multiplication factor in the untreated control was 143 after 72 hours. NOEC and EC_{50} values with 95 % confidence limits at 72 hours are shown in Table B.9.3-3.

Table B.9.3-3: Effect of BAS 656 07 H on the growth of green alga *Scenedesmus subspicatus* (= *Desmodesmus subspicatus*)

Concentration [mg as/L] (nominal)	**0.00098**	**0.0019**	**0.0078**	**0.0156**	**0.0313**	**0.0625**	**0.125**	**0.25**	**1.0**	**10**
% Inh. in 3 d (growth rate)	1.2	3.3	3.8	6.6	11.8	28.4	48.2	69.3	100	100
% Inh. in 3 d (biomass)	5.2	13.7	12.7	20.4	33.7	58.6	77.0	88.6	99.4	100
Endpoints [mg BAS 656 07 H/L (nominal)]										
E_rC_{10} (3 d)	0.0245 (95 % confidence limits: not calculated)									
E_rC_{50} (3 d)	0.1327 (95 % confidence limits: not calculated)									
E_bC_{10} (3 d)	0.0014 (95 % confidence limits: not calculated)									
E_bC_{50} (3 d)	0.0492 (95 % confidence limits: not calculated)									
NOEC (3 d)	0.00098									

Conclusions

In a 120-hour algae test with *Scenedesmus subspicatus* (= *Desmodesmus subspicatus*), the E_bC_{50} for BAS 656 07 H/L was determined to be 0.0492 mg as/L and the E_rC_{50} was 0.1327 mg/L, based on nominal concentrations. The NOEC was 0.00098 mg/L (nominal).

KCP 10.2.1/4 (study evaluated in the initial monograph, 2000)

Author:	Dohmen, G.P.
Title:	Effects of BAS 656 07 H on the Aquatic Plant *Lemna gibba*.
Date:	26.03.1999
Doc ID:	58944;WAT1999-498; BASF RegDoc# 1999/10314
Guidelines:	ASTM E1415-91 Subdiv. J 123-2; OPPTS 850.4400 (draft, April 1996)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 656 07 H (Frontier X2), batch no. 98001; purity: 64.0 % (w/w).
Test species:	Duckweed (*Lemna gibba* G3), plants from axenic stock culture (with regular transfer to fresh nutrient medium) are used to inoculate the flasks in this test.
Test design:	Static test over 7 days; 6 test item concentrations plus control group, 3 replicates for the test item treatments and 6 replicates for the control; 3 plants with 4 fronds and 1 plant with 3 fronds, total number of fronds at test initiation: 15 per replicate; assessment of growth and other effects on days 3, 5 and 7.
Endpoints:	EC_{10} and EC_{50} with respect to growth rate and yield after exposure over 7 days.
Test concentrations:	Control, 0.001, 0.003, 0.01, 0.032, 0.1 and 0.316 mg BAS 656 07 H/L (nominal).
Test conditions:	400 mL glass beakers, test volume 160 mL, 20x-AAP nutrient medium, pH 7.50 at test initiation; water temperature: 23 °C - 26 °C, continuous light at 5900 lux.
Analytics:	Analytical verification of the test item was conducted using gas chromatography coupled with atomic emission detection (GC/AED). All samples were enriched by solid-phase micro extraction (SPME) which is directly connected to the GC/AED system.
Statistics:	Descriptive statistics, EC_{50} calculation using probit analysis

Results and Discussion

Analytical measurements: Analytical verification of test item concentrations was conducted at every concentration except for the two lowest test levels which were below the LOQ; here the respective stock solution was measured instead. Measured concentrations at test initiation ranged from 98.5 % to 115.1 % of nominal with a mean of value of 105.2 % of nominal. At test termination the measured concentrations ranged from 106.6 % to 111.2 %, confirming in general the nominal values. Therefore the following biological results are based on nominal concentrations.

Biological results: BAS 656 07 H had a negative impact on the growth of *Lemna gibba* at concentrations of 0.003 mg/L and higher. The highest test concentration caused an inhibition in growth rate of 66.3 % and a corresponding inhibition in frond numbers of 88.5 %. At concentrations of 0.01 mg/L and higher the fronds were smaller as compared to the controls; at 0.1 mg/L and 0.316 mg/L fronds became chlorotic and roots were shorter.

The duckweed population in the control vessels showed sufficient growth, increasing from 11 fronds per vessel to an average of 222 fronds per vessel, corresponding to a 20.2 x multiplication. The dry weight increased from 2.1 mg to an average of 28.9 mg per vessel in the control at test termination. No morphological effects on algae were observed in the control group and at any of the test item concentrations tested. Effects on the growth of *Lemna gibba* are summarised in Table B.9.3-4.

Table B.9.3-4: Effect of BAS 656 07 H on the growth of duckweed *Lemna gibba*

Concentration [mg/L] (nominal)	**0.001**	**0.003**	**0.01**	**0.032**	**0.1**	**0.316**
Inhibition after 7 d [%] (growth rate)	1.9	20.9	27.2	51.3	60.9	66.3
Inhibition after 7 d [%] (frond number)	5.1	44.9	54.3	79.3	85.6	88.5
	Endpoints [mg BAS 656 07 H/L] (nominal)					
E_rC_{50} (7 d)	0.054 (95 % confidence limits: 0.038 – 0.075)					
E_bC_{50} (7 d)	0.0085 (95 % confidence limits: 0.0069 – 0.0104)					
NOEC (7 d)	0.003 (based on frond size)					

Conclusions

In a 7-day aquatic plant test with *Lemna gibba*, the E_bC_{50} for BAS 656 07 H/L was determined to be 0.0085 mg/L and the E_rC_{50} was 0.054 mg/L (nominal). The NOEC was 0.003 mg/L (nominal).

B.9.3.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Marine or estuarine organisms

Studies on marine or estuarine species are not required according to the relevant EU documents and no studies have been conducted with the formulation BAS 656 12 H on marine or estuarine organisms. The contamination of estuarine and marine environments is considered to be minimal compared to freshwater habitats adjacent to agricultural land according to the use pattern, the potential route of contamination and the dissipation of the active substance. Thus, the risk to those habitats is covered by the risk assessment for freshwater ecosystems.

Marine sediment invertebrates

Studies on marine or estuarine species are not required according to the relevant EU documents and no studies have been conducted with the formulation BAS 656 12 H on marine or estuarine organisms. The contamination of estuarine and marine environments is considered to be minimal compared to freshwater habitats adjacent to agricultural land according to the use pattern, the potential route of contamination and the dissipation of the active substance. Thus, the risk to those habitats is covered by the risk assessment for freshwater ecosystems.

Microcosm or mesocosm study

No microcosm or mesocosm study has been performed with the formulated product BAS 656 12 H or dimethenamid-P, since the data available are sufficient for risk assessment.

Residue data in fish

The log P_{OW} of the active substance dimethenamid-P was determined to be <2 (BASF DocID 1998/5071). Hence, the accumulation potential of dimethenamid-P in aquatic organisms is considered to be low.

Thus, residues of dimethenamid-P in fish are of no concern and no accumulation in the food chain is to be expected.

Chronic toxicity to fish and aquatic invertebrates

The results obtained in the acute studies on *O. mykiss* and *D. magna* with the formulated product BAS 656 12 H are in good agreement with the results expected from the data with the active substance dimethenamid-P (see above). This demonstrates that the formulation does not cause significant unexpected (additional) toxicity to fish and daphnids. No synergisms or additional toxicity is thus expected to occur due to co-formulants. Therefore, the studies conducted with the active substances can be used to assess the chronic risk resulting from BAS 656 12 H applications according to the proposed uses. No further testing with the product is indicated.

Accumulation in aquatic non-target organisms

Bioaccumulation of the active substance dimethenamid-P under natural conditions is not expected to occur (see "Residue data in fish" above); additional studies are not required or necessary to determine bioaccumulation in aquatic non-target organisms.

B.9.3.3 Further testing on aquatic organisms

No further studies submitted.

B.9.4 Risk assessment for aquatic organisms

In Volume 1, section 2.9.2, an overview of the available toxicity endpoints for aquatic organisms is presented.

B.9.4.1 Lower tier acute and chronic risk assessment

The acute and long-term TER values calculated by the RMS for dimethenamid-P are presented in the tables below.

Table B.9.4-1: Maximum PEC_{SW} values (FOCUS Step 1 and 2) and TER values for dimethenamid-P following one application of dimethenamid during March-May in maize, soybeans and sunflowers [1 x 864 g as/ha]

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
Step 1							
	243.39	**10.68**	**0.49**	**13.15**	**2.79**	**0.03**	**0.02**
Step 2 *							
N. Europe	43.14	**60.27**	**2.78**	**74.17**	15.76	**0.15**	**0.14**
S. Europe	79.99	**32.51**	**1.50**	**40.01**	**8.50**	**0.08**	**0.07**
Step 2 +							
N. Europe	33.93	**76.63**	**3.54**	**94.31**	20.04	**0.19**	**0.18**
S. Europe	61.56	**42.23**	**1.95**	**51.98**	11.05	**0.11**	**0.10**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger
* based on a single application in pre-emergence maize/soybeans/sunflowers
+ based on a single application in post-emergence maize

The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger values of 10 and 100 based on FOCUS Step 1 and 2 calculations for application in maize, soybeans and sunflowers, indicating high aquatic risk. Therefore, additional TER calculations considering more realistic Step 3 PEC_{SW} values are presented for these crop scenarios in the tables below.

Table B.9.4-2: Maximum PEC_{SW} values (FOCUS Step 1 and 2) and TER values for dimethenamid-P following one application of dimethenamid during March-May/June-September in sugar beets [1 x 720 g as/ha]

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
Step 1							
	202.83	**12.82**	**0.59**	**15.78**	**3.35**	**0.03**	**0.03**
Step 2 *							
N. Europe	29.81	**87.22**	**4.03**	107.34	22.81	**0.22**	**0.20**
S. Europe	54.37	**47.82**	**2.21**	**58.85**	12.51	**0.12**	**0.11**
Step 2 +							
N. Europe	29.81	**87.22**	**4.03**	107.34	22.81	**0.22**	**0.20**
S. Europe	42.09	**61.77**	**2.85**	**76.02**	16.15	**0.16**	**0.14**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger
* based on a single application in sugar beets between March-May
+ based on a single application in sugar beets between June-September

The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger values of 10 and 100 based on FOCUS Step 1 and 2 calculations for application in sugar beets, indicating high aquatic risk. Therefore, additional TER calculations considering more realistic Step 3 PEC_{SW} values are presented for these crop scenarios in the tables below.

Table B.9.4-3: Maximum PEC_{SW} values (FOCUS Step 3) and TER values for dimethenamid-P following one application in maize [1 x 864 g as/ha]

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	***Oncorhynchus mykiss***	***Americamysis bahia***	***Daphnia magna***	***Monoraphidium griffithii***	***Lemna gibba***
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
Step 3, pre-emergence							
D3/ditch	4.524	574.71	26.53	707.34	150.31	**1.46**	**1.32**
D4/pond	0.212	12264.15	566.04	15094.34	3207.55	31.13	28.25
D4/stream	3.721	698.74	32.25	859.98	182.75	**1.77**	**1.61**
D5/pond	0.215	12093.02	558.14	14883.72	3162.79	30.70	27.86
D5/stream	4.025	645.96	29.81	795.03	168.94	**1.64**	**1.49**
D6/ditch	4.578	567.93	26.21	699.00	148.54	**1.44**	**1.31**
R1/pond	0.33	7878.79	363.64	9696.97	2060.61	20.00	18.15
R1/stream	10.478	248.14	11.45	305.40	64.90	**0.63**	**0.57**
R2/stream	7.504	346.48	15.99	426.44	90.62	**0.88**	**0.80**
R3/stream	16.982	153.10	**7.07**	188.43	40.04	**0.39**	**0.35**
R4/stream	46.07	**56.44**	**2.60**	**69.46**	14.76	**0.14**	**0.13**
Step 3, post-emergence							
D3/ditch	4.528	574.20	26.50	706.71	150.18	**1.46**	**1.32**
D4/pond	0.226	11504.42	530.97	14159.29	3008.85	29.20	26.50
D4/stream	3.954	657.56	30.35	809.31	171.98	**1.67**	**1.51**
D5/pond	0.24	10833.33	500.00	13333.33	2833.33	27.50	24.96
D5/stream	3.636	715.07	33.00	880.09	187.02	**1.82**	**1.65**
D6/ditch	4.532	573.70	26.48	706.09	150.04	**1.46**	**1.32**
R1/pond	0.655	3969.47	183.21	4885.50	1038.17	**10.08**	**9.15**
R1/stream	11.503	226.03	10.43	278.19	59.12	**0.57**	**0.52**
R2/stream	9.647	269.51	12.44	331.71	70.49	**0.68**	**0.62**
R3/stream	25.173	103.29	**4.77**	127.12	27.01	**0.26**	**0.24**
R4/stream	28.803	**90.27**	**4.17**	111.10	23.61	**0.23**	**0.21**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger

Based on FOCUS Step 3, an acceptable risk has been demonstrated for 3 out of 11 FOCUS scenarios in the maize pre-emergence use (D4/pond, D5/pond and R1/pond), whereas only 2 FOCUS scenarios are acceptable in the maize post-emergence use (D4/pond and D5/pond).
The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger values of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaining FOCUS scenarios in maize, indicating high risk to algae and macrophytes, driving the risk assessment. Therefore, TER-calculations based on FOCUS Step 4 including risk mitigating measures are presented for these crop scenarios in the tables below.

Table B.9.4-4: Maximum PEC_{SW} values (FOCUS Step 3) and TER values for dimethenamid-P following one pre-emergence application in soybeans, sunflowers and sugar beets [1 x 864 g a.s./ha] and one post-emergence application in sugar beets [1 x 720 g a.s./ha], respectively

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
Step 3, Soybeans, 864 g/ha, pre-emergence							
R3/stream	23.084	112.63	**5.20**	138.62	29.46	**0.29**	**0.26**
R4/stream	13.805	188.34	**8.69**	231.80	49.26	**0.48**	**0.43**
Step 3, Sugar beets, 864 g/ha, pre-emergence							
D3/ditch	4.524	574.71	26.53	707.34	150.31	**1.46**	**1.32**
D4/pond	0.219	11872.15	547.95	14611.87	3105.02	30.14	27.35
D4/stream	3.727	697.61	32.20	858.60	182.45	**1.77**	**1.61**
R1/pond	1.972	1318.46	60.85	1622.72	344.83	**3.35**	**3.04**
R1/stream	20.477	126.97	5.86	156.27	33.21	**0.32**	**0.29**
R3/stream	38.356	67.79	3.13	83.43	17.73	**0.17**	**0.16**
Step 3, Sugar beets, 720 g/ha, post-emergence							
D3/ditch	3.772	689.29	31.81	848.36	180.28	**1.75**	**1.59**
D4/pond	0.192	13541.67	625.00	16666.67	3541.67	34.38	31.20
D4/stream	3.16	822.78	37.97	1012.66	215.19	**2.09**	**1.90**
R1/pond	0.279	9319.00	430.11	11469.53	2437.28	23.66	21.47
R1/stream	3.597	722.82	33.36	889.63	189.05	**1.83**	**1.67**
R3/stream	5.7	456.14	21.05	561.40	119.30	**1.16**	**1.05**
Step 3, Sunflowers, 864 g/ha, pre-emergence							
D5/pond	0.215	12093.02	558.14	14883.72	3162.79	30.70	27.86
D5/stream	3.745	694.26	32.04	854.47	181.58	**1.76**	**1.60**
R1/pond	0.355	7323.94	338.03	9014.08	1915.49	18.59	16.87
R1/stream	9.407	276.39	12.76	340.17	72.29	**0.70**	**0.64**
R3/stream	43.354	**59.97**	**2.77**	**73.81**	15.68	**0.15**	**0.14**
R4/stream	37.897	**68.61**	**3.17**	**84.44**	17.94	**0.17**	**0.16**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger

The table above shows that no acceptable risk has been demonstrated for the use in soybeans.
However, acceptable risks have been demonstrated for 2 FOCUS scenarios in sugar beets (D4/pond and R1/pond) and in sunflowers (D5/pond and R1/pond), respectively.
The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger values of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaining FOCUS scenarios, indicating high risk to aquatic organisms. Therefore, TER-calculations based on FOCUS Step 4 including risk mitigating measures are presented for these crop scenarios in the tables below.

Table B.9.4-5: Maximum PEC_{SW} values (FOCUS Step 4) and TER values for dimethenamid-P following one application [1 x 864 g as/ha] in maize pre-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence maize: 5 m drift mitigation							
D3/ditch	1.483	1753.20	80.92	2157.79	458.53	**4.45**	**4.04**
D4/pond	0.187	13903.74	641.71	17112.30	3636.36	35.29	32.03
D4/stream	1.577	1648.70	76.09	2029.17	431.20	**4.19**	**3.80**
D5/pond	0.19	13684.21	631.58	16842.11	3578.95	34.74	31.53
D5/stream	1.706	1524.03	70.34	1875.73	398.59	**3.87**	**3.51**
D6/ditch	1.535	1693.81	78.18	2084.69	443.00	**4.30**	**3.90**
R1/pond	0.314	8280.25	382.17	10191.08	2165.61	21.02	19.08
R1/stream	10.478	248.14	11.45	305.40	64.90	**0.63**	**0.57**
R2/stream	7.504	346.48	15.99	426.44	90.62	**0.88**	**0.80**
R3/stream	16.982	153.10	**7.07**	188.43	40.04	**0.39**	**0.35**
R4/stream	46.07	**56.44**	**2.60**	**69.46**	14.76	**0.14**	**0.13**
step 4 pre-emergence maize: 10 m drift mitigation							
D3/ditch	0.786	3307.89	152.67	4071.25	865.14	**8.40**	**7.62**
D4/pond	0.137	18978.10	875.91	23357.66	4963.50	48.18	43.72
D4/stream	0.842	3087.89	142.52	3800.48	807.60	**7.84**	**7.11**
D5/pond	0.139	18705.04	863.31	23021.58	4892.09	47.48	43.09
D5/stream	0.911	2854.01	131.72	3512.62	746.43	**7.24**	**6.58**
D6/ditch	0.838	3102.63	143.20	3818.62	811.46	**7.88**	**7.15**
R1/pond	0.282	9219.86	425.53	11347.52	2411.35	23.40	21.24
R1/stream	10.478	248.14	11.45	305.40	64.90	**0.63**	**0.57**
R2/stream	7.504	346.48	15.99	426.44	90.62	**0.88**	**0.80**
R3/stream	16.982	153.10	**7.07**	188.43	40.04	**0.39**	**0.35**
R4/stream	46.07	**56.44**	**2.60**	**69.46**	14.76	**0.14**	**0.13**
step 4 pre-emergence maize: 20 m drift mitigation							
D3/ditch	0.409	6356.97	293.40	7823.96	1662.59	16.14	14.65
D4/pond	0.09	28888.89	1333.33	35555.56	7555.56	73.33	66.56
D4/stream	0.44	5909.09	272.73	7272.73	1545.45	15.00	13.61
D5/pond	0.093	27956.99	1290.32	34408.60	7311.83	70.97	64.41
D5/stream	0.476	5462.18	252.10	6722.69	1428.57	13.87	12.58
D6/ditch	0.46	5652.17	260.87	6956.52	1478.26	14.35	13.02
R1/pond	0.253	10276.68	474.31	12648.22	2687.75	26.09	23.68
R1/stream	10.478	248.14	11.45	305.40	64.90	**0.63**	**0.57**
R2/stream	7.504	346.48	15.99	426.44	90.62	**0.88**	**0.80**
R3/stream	16.981	153.11	**7.07**	188.45	40.04	**0.39**	**0.35**
R4/stream	46.07	**56.44**	**2.60**	**69.46**	14.76	**0.14**	**0.13**

FOCUS Scenario / water body	**PEC global max (µg/L)**	**Fish acute**	**Fish ELS**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Aquatic plant**
		Oncorhyn-chus mykiss	***Oncorhyn chus mykiss***	***Americamysis bahia***	***Daphnia magna***	***Monorap hidium griffithii***	***Lemna gibba***
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence maize: 10 m drift + runoff mitigation							
D3/ditch	0.786	3307.89	152.67	4071.25	865.14	**8.40**	**7.62**
D4/pond	0.137	18978.10	875.91	23357.66	4963.50	48.18	43.72
D4/stream	0.842	3087.89	142.52	3800.48	807.60	**7.84**	**7.11**
D5/pond	0.139	18705.04	863.31	23021.58	4892.09	47.48	43.09
D5/stream	0.911	2854.01	131.72	3512.62	746.43	**7.24**	**6.58**
D6/ditch	0.838	3102.63	143.20	3818.62	811.46	**7.88**	**7.15**
R1/pond	0.164	15853.66	731.71	19512.20	4146.34	40.24	36.52
R1/stream	4.442	585.32	27.01	720.40	153.08	**1.49**	**1.35**
R2/stream	3.362	773.35	35.69	951.81	202.26	**1.96**	**1.78**
R3/stream	6.946	374.32	17.28	460.70	97.90	**0.95**	**0.86**
R4/stream	20.86	124.64	**5.75**	153.40	32.60	**0.32**	**0.29**
step 4 pre-emergence maize: 20 m drift + runoff mitigation							
D3/ditch	0.409	6356.97	293.40	7823.96	1662.59	16.14	14.65
D4/pond	0.09	28888.89	1333.33	35555.56	7555.56	73.33	66.56
D4/stream	0.44	5909.09	272.73	7272.73	1545.45	15.00	13.61
D5/pond	0.093	27956.99	1290.32	34408.60	7311.83	70.97	64.41
D5/stream	0.476	5462.18	252.10	6722.69	1428.57	13.87	12.58
D6/ditch	0.46	5652.17	260.87	6956.52	1478.26	14.35	13.02
R1/pond	0.095	27368.42	1263.16	33684.21	7157.89	69.47	63.05
R1/stream	2.266	1147.40	52.96	1412.18	300.09	**2.91**	**2.64**
R2/stream	1.75	1485.71	68.57	1828.57	388.57	**3.77**	**3.42**
R3/stream	3.498	743.28	34.31	914.81	194.40	**1.89**	**1.71**
R4/stream	10.909	238.34	11.00	293.34	62.33	**0.61**	**0.55**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger.

Based on FOCUS step 4 scenarios including risk mitigating measures, the number of safe scenarios considerably increases. TER values for all scenarios indicate an acceptable risk to aquatic organisms except R1-4/stream scenarios when considering 20 m drift and runoff mitigation.

Table B.9.4-6: Maximum PEC_{SW} values (FOCUS Step 4) and TER values for dimethenamid-P following one application [1 x 864 g as/ha] in maize post-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monorap hidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 post-emergence maize: 5 m drift mitigation							
D3/ditch	1.484	1752.02	80.86	2156.33	458.22	**4.45**	**4.04**
D4/pond	0.198	13131.31	606.06	16161.62	3434.34	33.33	30.25
D4/stream	1.683	1544.86	71.30	1901.37	404.04	**3.92**	**3.56**
D5/pond	0.212	12264.15	566.04	15094.34	3207.55	31.13	28.25
D5/stream	1.542	1686.12	77.82	2075.23	440.99	**4.28**	**3.88**
D6/ditch	1.506	1726.43	79.68	2124.83	451.53	**4.38**	**3.98**
R1/pond	0.632	4113.92	189.87	5063.29	1075.95	10.44	**9.48**
R1/stream	11.503	226.03	10.43	278.19	59.12	**0.57**	**0.52**
R2/stream	9.647	269.51	12.44	331.71	70.49	**0.68**	**0.62**
R3/stream	25.173	103.29	**4.77**	127.12	27.01	**0.26**	**0.24**
R4/stream	28.803	**90.27**	**4.17**	111.10	23.61	**0.23**	**0.21**
step 4 post-emergence maize: 10 m drift mitigation							
D3/ditch	0.792	3282.83	151.52	4040.40	858.59	**8.33**	**7.56**
D4/pond	0.145	17931.03	827.59	22068.97	4689.66	45.52	41.31
D4/stream	0.902	2882.48	133.04	3547.67	753.88	**7.32**	**6.64**
D5/pond	0.159	16352.20	754.72	20125.79	4276.73	41.51	37.67
D5/stream	0.825	3151.52	145.45	3878.79	824.24	**8.00**	**7.26**
D6/ditch	0.813	3198.03	147.60	3936.04	836.41	**8.12**	**7.37**
R1/pond	0.589	4414.26	203.74	5432.94	1154.50	11.21	10.17
R1/stream	11.503	226.03	10.43	278.19	59.12	**0.57**	**0.52**
R2/stream	9.647	269.51	12.44	331.71	70.49	**0.68**	**0.62**
R3/stream	25.173	103.29	**4.77**	127.12	27.01	**0.26**	**0.24**
R4/stream	28.803	**90.27**	**4.17**	111.10	23.61	**0.23**	**0.21**
step 4 post-emergence maize: 20 m drift mitigation							
D3/ditch	0.416	6250.00	288.46	7692.31	1634.62	15.87	14.40
D4/pond	0.095	27368.42	1263.16	33684.21	7157.89	69.47	63.05
D4/stream	0.471	5520.17	254.78	6794.06	1443.74	14.01	12.72
D5/pond	0.109	23853.21	1100.92	29357.80	6238.53	60.55	54.95
D5/stream	0.434	5990.78	276.50	7373.27	1566.82	15.21	13.80
D6/ditch	0.437	5949.66	274.60	7322.65	1556.06	15.10	13.71
R1/pond	0.55	4727.27	218.18	5818.18	1236.36	12.00	10.89
R1/stream	11.503	226.03	10.43	278.19	59.12	**0.57**	**0.52**
R2/stream	9.647	269.51	12.44	331.71	70.49	**0.68**	**0.62**
R3/stream	25.173	103.29	**4.77**	127.12	27.01	**0.26**	**0.24**
R4/stream	28.803	**90.27**	**4.17**	111.10	23.61	**0.23**	**0.21**

FOCUS Scenario / water body	**PEC global max (µg/L)**	**Fish acute**	**Fish ELS**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Aquatic plant**
		Oncorhyn-chus mykiss	***Oncorhynchus mykiss***	***Americamysis bahia***	***Daphnia magna***	***Monoraphidium griffithii***	***Lemna gibba***
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
step 4 post-emergence maize: 10 m drift + runoff mitigation							
D3/ditch	0.792	3282.83	151.52	4040.40	858.59	**8.33**	**7.56**
D4/pond	0.145	17931.03	827.59	22068.97	4689.66	45.52	41.31
D4/stream	0.902	2882.48	133.04	3547.67	753.88	**7.32**	**6.64**
D5/pond	0.159	16352.20	754.72	20125.79	4276.73	41.51	37.67
D5/stream	0.825	3151.52	145.45	3878.79	824.24	**8.00**	**7.26**
D6/ditch	0.813	3198.03	147.60	3936.04	836.41	**8.12**	**7.37**
R1/pond	0.305	8524.59	393.44	10491.80	2229.51	21.64	19.64
R1/stream	5.208	499.23	23.04	614.44	130.57	**1.27**	**1.15**
R2/stream	4.247	612.20	28.26	753.47	160.11	**1.55**	**1.41**
R3/stream	11.382	228.43	10.54	281.15	59.74	**0.58**	**0.53**
R4/stream	13.093	198.58	9.17	244.41	51.94	**0.50**	**0.46**
step 4 post-emergence maize: 20 m drift + runoff mitigation							
D3/ditch	0.416	6250.00	288.46	7692.31	1634.62	15.87	14.40
D4/pond	0.095	27368.42	1263.16	33684.21	7157.89	69.47	63.05
D4/stream	0.471	5520.17	254.78	6794.06	1443.74	14.01	12.72
D5/pond	0.109	23853.21	1100.92	29357.80	6238.53	60.55	54.95
D5/stream	0.434	5990.78	276.50	7373.27	1566.82	15.21	13.80
D6/ditch	0.437	5949.66	274.60	7322.65	1556.06	15.10	13.71
R1/pond	0.17	15294.12	705.88	18823.53	4000.00	38.82	35.24
R1/stream	2.723	954.83	44.07	1175.17	249.72	**2.42**	**2.20**
R2/stream	2.2	1181.82	54.55	1454.55	309.09	**3.00**	**2.72**
R3/stream	5.948	437.12	20.17	538.00	114.32	**1.11**	**1.01**
R4/stream	6.863	378.84	17.49	466.27	99.08	**0.96**	**0.87**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger.

Based on FOCUS step 4 scenarios including risk mitigating measures, the number of safe scenarios considerably increases. TER values for all scenarios indicate an acceptable risk to aquatic organisms except R1-4/stream scenarios when considering 20 m drift and runoff mitigation.

Table B.9.4-7: Maximum PEC_{SW} values (Focus Step 4) and TER values for dimethenamid-P following one application [1 x 864 g as/ha] in soybeans pre-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monorap hidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence soybeans: 5 m drift mitigation							
R3/stream	23.084	112.63	**5.20**	138.62	29.46	**0.29**	**0.26**
R4/stream	13.805	188.34	**8.69**	231.80	49.26	**0.48**	**0.43**
step 4 pre-emergence soybeans: 10 m drift mitigation							
R3/stream	23.084	112.63	**5.20**	138.62	29.46	**0.29**	**0.26**
R4/stream	13.805	188.34	**8.69**	231.80	49.26	**0.48**	**0.43**
step 4 pre-emergence soybeans: 20 m drift mitigation							
R3/stream	23.084	112.63	**5.20**	138.62	29.46	**0.29**	**0.26**
R4/stream	13.805	188.34	**8.69**	231.80	49.26	**0.48**	**0.43**
step 4 pre-emergence soybeans: 10 m drift + runoff mitigation							
R3/stream	10.548	246.49	11.38	303.38	**64.47**	**0.63**	**0.57**
R4/stream	6.285	413.68	19.09	509.15	108.19	**1.05**	**0.95**
step 4 pre-emergence soybeans: 20 m drift + runoff mitigation							
R3/stream	5.539	469.40	21.66	577.72	122.77	**1.19**	**1.08**
R4/stream	3.295	789.07	36.42	971.17	206.37	**2.00**	**1.82**
TER criterion		100	10	100	10	10	10

The table above shows that no safe use has been demonstrated in the FOCUS step 4 scenarios including risk mitigating measures for the pre-emergence uses in soybeans, indicating high risks to aquatic organisms.

Table B.9.4.4-6: Maximum PEC$_{SW}$ values (FOCUS Step 4) and TER values for dimethenamid-P following one pre-emergence application [1 x 864 g a.s./ha] in sugar beet

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence sugar beet: 5 m Drift mitigation							
D3/ditch	1.483	1753.20	80.92	2157.79	458.53	**4.45**	**4.04**
D4/pond	0.189	13756.61	634.92	16931.22	3597.88	34.92	31.69
D4/stream	1.578	1647.66	76.05	2027.88	430.93	**4.18**	**3.80**
R1/pond	1.948	1334.70	61.60	1642.71	349.08	**3.39**	**3.07**
R1/stream	20.477	126.97	**5.86**	156.27	33.21	**0.32**	**0.29**
R3/stream	38.356	**67.79**	**3.13**	**83.43**	17.73	**0.17**	**0.16**
step 4 pre-emergence sugar beet: 10 m Drift mitigation							
D3/ditch	0.787	3303.68	152.48	4066.07	864.04	**8.39**	**7.61**
D4/pond	0.144	18055.56	833.33	22222.22	4722.22	45.83	41.60
D4/stream	0.847	3069.66	141.68	3778.04	802.83	**7.79**	**7.07**
R1/pond	1.912	1359.83	62.76	1673.64	355.65	**3.45**	**3.13**
R1/stream	20.477	126.97	**5.86**	156.27	33.21	**0.32**	**0.29**
R3/stream	38.356	**67.79**	**3.13**	**83.43**	17.73	**0.17**	**0.16**
step 4 pre-emergence sugar beet: 20 m Drift mitigation							
D3/ditch	0.409	6356.97	293.40	7823.96	1662.59	16.14	14.65
D4/pond	0.0978	26584.87	1226.99	32719.84	6952.97	67.48	61.25
D4/stream	0.445	5842.70	269.66	7191.01	1528.09	14.83	13.46
R1/pond	1.875	1386.67	64.00	1706.67	362.67	**3.52**	**3.19**
R1/stream	20.477	126.97	**5.86**	156.27	33.21	**0.32**	**0.29**
R3/stream	38.356	**67.79**	**3.13**	**83.43**	17.73	**0.17**	**0.16**
step 4 pre-emergence sugar beet: 10 m Drift + runoff mitigation							
D3/ditch	0.787	3303.68	152.48	4066.07	864.04	**8.39**	**7.61**
D4/pond	0.144	18055.56	833.33	22222.22	4722.22	45.83	41.60
D4/stream	0.847	3069.66	141.68	3778.04	802.83	**7.79**	**7.07**
R1/pond	0.836	3110.05	143.54	3827.75	813.40	**7.89**	**7.17**
R1/stream	9.340	278.37	12.85	342.61	72.81	**0.71**	**0.64**
R3/stream	17.504	148.54	**6.86**	182.82	38.85	**0.38**	**0.34**
step 4 pre-emergence sugar beet: 20 m Drift + runoff mitigation							
D3/ditch	0.409	6356.97	293.40	7823.96	1662.59	16.14	14.65
D4/pond	0.0978	26584.87	1226.99	32719.84	6952.97	67.48	61.25
D4/stream	0.445	5842.70	269.66	7191.01	1528.09	14.83	13.46
R1/pond	0.436	5963.30	275.23	7339.45	1559.63	15.14	13.74
R1/stream	4.898	530.83	24.50	653.33	138.83	**1.35**	**1.22**
R3/stream	9.188	282.98	13.06	348.28	74.01	**0.72**	**0.65**

TER criterion		100	10	100	10	10	10

Based on FOCUS step 4 scenarios including risk mitigating measures, the number of safe scenarios increases. TER values for all D scenarios and R1/pond indicate an acceptable risk to aquatic organisms except the R stream scenarios (R1 and R3), when considering 20 m Drift and runoff mitigation.

Table B.9.4-9: Maximum PEC_{SW} values (Focus Step 4) and TER values for dimethenamid-P following one application [1 x 720 g as/ha] in sugar beet post-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	***Oncorhynchus mykiss***	***Americamysis bahia***	***Daphnia magna***	***Monoraphidium griffithii***	***Lemna gibba***
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
step 4 post-emergence sugar beet: 5 m drift mitigation							
D3/ditch	1.237	2101.86	97.01	2586.90	549.72	**5.34**	**4.84**
D4/pond	0.169	15384.62	710.06	18934.91	4023.67	39.05	35.44
D4/stream	1.346	1931.65	89.15	2377.41	505.20	**4.90**	**4.45**
R1/pond	0.265	9811.32	452.83	12075.47	2566.04	24.91	22.60
R1/stream	3.597	722.82	33.36	889.63	189.05	**1.83**	**1.67**
R3/stream	5.7	456.14	21.05	561.40	119.30	**1.16**	**1.05**
step 4 post-emergence sugar beet: 10 m drift mitigation							
D3/ditch	0.657	3957.38	182.65	4870.62	1035.01	10.05	9.12
D4/pond	0.125	20800.00	960.00	25600.00	5440.00	52.80	47.92
D4/stream	0.723	3596.13	165.98	4426.00	940.53	**9.13**	**8.28**
R1/pond	0.237	10970.46	506.33	13502.11	2869.20	27.85	25.27
R1/stream	3.597	722.82	33.36	889.63	189.05	**1.83**	**1.67**
R3/stream	5.7	456.14	21.05	561.40	119.30	**1.16**	**1.05**
step 4 post-emergence sugar beet: 20 m drift mitigation							
D3/ditch	0.345	7536.23	347.83	9275.36	1971.01	19.13	17.36
D4/pond	0.084	30952.38	1428.57	38095.24	8095.24	78.57	71.31
D4/stream	0.38	6842.11	315.79	8421.05	1789.47	17.37	15.76
R1/pond	0.211	12322.27	568.72	15165.88	3222.75	31.28	28.39
R1/stream	3.597	722.82	33.36	889.63	189.05	**1.83**	**1.67**
R3/stream	5.7	456.14	21.05	561.40	119.30	**1.16**	**1.05**
step 4 post-emergence sugar beet: 10 m drift + runoff mitigation							
D3/ditch	0.657	3957.38	182.65	4870.62	1035.01	10.05	**9.12**
D4/pond	0.125	20800.00	960.00	25600.00	5440.00	52.80	47.92
D4/stream	0.723	3596.13	165.98	4426.00	940.53	**9.13**	**8.28**
R1/pond	0.14	18571.43	857.14	22857.14	4857.14	47.14	42.79
R1/stream	1.631	1594.11	73.57	1961.99	416.92	**4.05**	**3.67**
R3/stream	2.603	998.85	46.10	1229.35	261.24	**2.54**	**2.30**

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monorap hidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 post-emergence sugar beet: 20 m drift + runoff mitigation							
D3/ditch	0.345	7536.23	347.83	9275.36	1971.01	19.13	17.36
D4/pond	0.084	30952.38	1428.57	38095.24	8095.24	78.57	71.31
D4/stream	0.38	6842.11	315.79	8421.05	1789.47	17.37	15.76
R1/pond	0.081	32098.77	1481.48	39506.17	8395.06	81.48	73.95
R1/stream	0.854	3044.50	140.52	3747.07	796.25	**7.73**	**7.01**
R3/stream	1.366	1903.37	87.85	2342.61	497.80	**4.83**	**4.39**
TER criterion		100	10	100	10	10	10

Based on FOCUS step 4 scenarios including risk mitigating measures, the number of safe scenarios increases. TER values for all D scenarios and R1/pond indicate an acceptable risk to aquatic organisms except the R stream scenarios (R1 and R3), when considering 20 m drift and runoff mitigation.

Table B.9.4-10: Maximum PEC_{SW} values (Focus Step 4) and TER values for dimethenamid-P following one application [1 x 864 g as/ha] in sunflower pre-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monorap hidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
Step 4 pre-emergence sunflower: 5 m drift mitigation							
D5/pond	0.19	13684.21	631.58	16842.11	3578.95	34.74	31.53
D5/stream	1.584	1641.41	75.76	2020.20	429.29	**4.17**	**3.78**
R1/pond	0.339	7669.62	353.98	9439.53	2005.90	19.47	17.67
R1/stream	9.407	276.39	12.76	340.17	72.29	**0.70**	**0.64**
R3/stream	43.354	59.97	2.77	73.81	15.68	**0.15**	**0.14**
R4/stream	37.897	68.61	3.17	84.44	17.94	**0.17**	**0.16**
Step 4 pre-emergence sunflower: 10 m drift mitigation							
D5/pond	0.14	18571.43	857.14	22857.14	4857.14	47.14	42.79
D5/stream	0.845	3076.92	142.01	3786.98	804.73	**7.81**	**7.09**
R1/pond	0.308	8441.56	389.61	10389.61	2207.79	21.43	19.45
R1/stream	9.407	276.39	12.76	340.17	72.29	**0.70**	**0.64**
R3/stream	43.354	59.97	2.77	73.81	15.68	**0.15**	**0.14**
R4/stream	37.897	68.61	3.17	84.44	17.94	**0.17**	**0.16**
Step 4 pre-emergence sunflower: 20 m drift mitigation							
D5/pond	0.094	27659.57	1276.60	34042.55	7234.04	70.21	63.72
D5/stream	0.441	5895.69	272.11	7256.24	1541.95	14.97	13.58
R1/pond	0.279	9319.00	430.11	11469.53	2437.28	23.66	21.47
R1/stream	9.407	276.39	12.76	340.17	72.29	**0.70**	**0.64**
R3/stream	43.354	59.97	2.77	73.81	15.68	**0.15**	**0.14**
R4/stream	37.897	68.61	3.17	84.44	17.94	**0.17**	**0.16**
Step 4 pre-emergence sunflower: 10 m drift + runoff mitigation							
D5/pond	0.14	18571.43	857.14	22857.14	4857.14	47.14	42.79
D5/stream	0.845	3076.92	142.01	3786.98	804.73	**7.81**	**7.09**
R1/pond	0.174	14942.53	689.66	18390.80	3908.05	37.93	34.43
R1/stream	3.958	656.90	30.32	808.49	171.80	**1.67**	**1.51**
R3/stream	19.801	131.31	6.06	161.61	34.34	**0.33**	**0.30**
R4/stream	16.627	156.37	7.22	192.46	40.90	**0.40**	**0.36**

FOCUS Scenario / water body	**PEC global max (µg/L)**	**Fish acute**	**Fish ELS**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Aquatic plant**
		Oncorhyn-chus mykiss	***Oncorhynchus mykiss***	***Americamysis bahia***	***Daphnia magna***	***Monoraphidium griffithii***	***Lemna gibba***
		LC_{50} (µg/L)	**NOEC (µg/L)**	**LC_{50} (µg/L)**	**NOEC (µg/L)**	**E_yC_{50} (µg/L)**	**E_bC_{50} (µg/L)**
		2600	120	3200	680	6.60	5.99
Step 4 pre-emergence sunflower: 20 m drift + runoff mitigation							
D5/pond	0.094	27659.57	1276.60	34042.55	7234.04	70.21	63.72
D5/stream	0.441	5895.69	272.11	7256.24	1541.95	14.97	13.58
R1/pond	0.1	26000.00	1200.00	32000.00	6800.00	66.00	59.90
R1/stream	2.014	1290.96	59.58	1588.88	337.64	**3.28**	**2.97**
R3/stream	10.394	250.14	11.55	307.87	65.42	**0.63**	**0.58**
R4/stream	8.594	302.54	13.96	372.35	79.12	**0.77**	**0.70**
TER criterion		100	10	100	10	10	10

Based on FOCUS step 4 scenarios including risk mitigating measures, the number of safe scenarios considerably increases. TER values for all scenarios indicate an acceptable risk to aquatic organisms except the R stream scenarios when considering 20 m drift and runoff mitigation.

Metabolites of dimethenamid-P

The acute and long-term TER values for the metabolites of dimethenamid-P are presented in the tables below.

Table B.9.4-11: Fish acute TER values for the metabolites M656H003, M656H023 and M656H027 using the worst-case FOCUS Step 1 $PEC_{SW,max}$ values

Test substance	**Test organism**	**96 h LC_{50} [µg/L]**	**Crop**	**FOCUS Step**	**$PEC_{SW, max}$ [µg/L]**	**TER_A**	**Trigger value**
M656H003	*O. mykiss*	60800	maize (pre- & post-emergence), soybeans, sunflowers	1	0.997	60983	100
			sugar beets (post-emergence)	1	0.831	73165	100
M656H023	*O. mykiss*	> 87000	maize (pre- & post-emergence), soybeans, sunflowers	1	38.220	> 2276	100
			sugar beets (post-emergence)	1	31.849	> 2732	100
M656H027	*O. mykiss*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	42.686	> 2343	100
			sugar beets (post-emergence)	1	35.572	> 2811	100

The TER_A values for the dimethenamid-P metabolites M656H003, M656H023 and M656H027 exceed the required trigger value of 100 based on worst-case FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-12: Acute TER values for *D. magna* exposed to metabolites M656H003, M656H023, M656H027 and M656H031 using the worst-case FOCUS Step 1 $PEC_{SW,\ max}$ values

Test substance	Test organism	48 h EC_{50} [µg/L]	Crop	FOCUS Step	$PEC_{sw,\ max}$ [µg/L]	TER_A	Trigger value
M656H003	*D. magna*	> 101600	maize (pre- & post-emergence), soybeans, sunflowers	1	0.997	> 101906	100
			sugar beets (post-emergence)	1	0.831	> 122262	100
M656H023	*D. magna*	> 95000	maize (pre- & post-emergence), soybeans, sunflowers	1	38.220	> 2486	100
			sugar beets (post-emergence)	1	31.849	> 2983	100
M656H027	*D. magna*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	42.686	> 2343	100
			sugar beets (post-emergence)	1	35.572	> 2811	100
M656H031	*D. magna*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	24.857	> 4023	100
			sugar beets (post-emergence)	1	20.714	> 4828	100

The TER_A values for the metabolites M656H003, M656H023, M656H027 and M656H031 exceed the required trigger value of 100 based on worst-case FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-13: TER values for algae[1)] exposed to major metabolites using worst-case FOCUS Step 1 $PEC_{SW, max}$ values

Test substance	Test organism	72 h E_bC_{50} [µg/L]	Crop	FOCUS Step	$PEC_{SW, max}$ [µg/L]	TER	Trigger value
M656H003	*D. subspicatus*	68500	maize (pre- & post-emergence), soybeans, sunflowers	1	0.997	68706	10
			sugar beets (post-emergence)	1	0.831	82431	10
M656H023	*P. subcapitata*	> 94000	maize (pre- & post-emergence), soybeans, sunflowers	1	38.220	> 2459	10
			sugar beets	1	31.849	> 2951	10
M656H027	*P. subcapitata*	> 208000	maize (pre- & post-emergence), soybeans, sunflowers	1	42.686	> 4873	10
			sugar beets (post-emergence)	1	35.572	> 5847	10
M656H031	*P. subcapitata*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	24.857	> 4023	10
			sugar beets (post-emergence)	1	20.714	> 4828	10

1) Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters, the lowest (most sensitive) endpoint is used in the TER calculations.

The TER values for the dimethenamid-P metabolites M656H003, M656H023, M656H027 and M656H031 exceed the required trigger value of 10 based on FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-14: TER values for the aquatic plant *Lemna gibba*[1)] exposed to metabolites M656H031, M656H062, M656PH043 and M656H055 using worst-case FOCUS Step 1 $PEC_{SW, max}$ values

Test substance	Test organism	7 d E_yC_{50} [µg/L]	Crop	FOCUS Step	$PEC_{SW, max}$ [µg/L]	TER_{LT}	Trigger value
M656H031	*L. gibba*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	24.857	4023	10
			sugar beets (post-emergence)	1	20.714	> 4828	10
M656H062	*L. gibba*	> 54570	maize (pre- & post-emergence), soybeans, sunflowers	1	243.394 #	> 224	10
			sugar beets (post-emergence)	1	202.828 #	> 269	10
M656PH043	*L. gibba*	> 100000	maize (pre- & post-emergence), soybeans, sunflowers	1	243.394 #	> 411	10
			sugar beets (post-emergence)	1	202.828 #	> 493	10
M656H055	*L. gibba*	> 143000	maize (pre- & post-emergence), soybeans, sunflowers	1	243.394 #	> 588	10
			sugar beets (post-emergence)	1	202.828 #	> 705	10

1) Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters, the lowest (most sensitive) endpoint is used in the TER calculations.
For the metabolites M656H062 (tested with Reg. No. 403 121; for details see above), M656PH043 and M656H055, the

worst-case Step 1 PEC value for the active substance is used for TER calculations (for justifications see above)

The TER_{LT} values for the dimethenamid-P metabolites M656H031, M656H062, M656PH043 and M656H055 exceed the required trigger value of 10 based on FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

B.9.4.2 Refined risk assessment

Since additional laboratory toxicity tests are available for the most sensitive organisms group “primary producers” (algae/macrophytes) a tier 2 effect assessment is performed below.

According to the EFSA Aquatic Guidance Document (EFSA, 2013) it is recommended to preferably apply the species sensitivity distribution (SSD) approach if more than eight algae/macrophyte endpoints are available. Nevertheless, the geomean approach could also be applied if, for example, the SSD is deemed inappropriate (e.g. goodness-of-fit tests not passed).

The present SSD analysis for algae and macrophytes, respectively, differs from the applicant in the following way:

- The median HC_5 (based on EC_{50} data) for both algae and macrophytes is calculated and used separately in the risk assessment as the presence of sediment in all macrophyte studies may have affected bioavailability, and thus, toxicity when compared to sediment-free algal test systems.
- Only E_bC_{50} or E_yC_{50} values were considered in the present risk assessment as the proposed change from biomass/yield to growth rate endpoints would lead to a significant decrease of the protection level for both algae and macrophytes if no specific corrections in the assessment factors were made (for further details, see Vol.1, chapter 2.9.2, algae and macrophytes).
- Geometric mean of measured test concentrations were considered in studies with recovery < 80 % of nominal over the entire study period.
- Geometric mean (instead of arithmetic mean) EC_{50} values were used if more than one study is available for the same species.
- In accordance with the EFSA GD (2013), unbound values (“greater-than” values) in the SSD were excluded from the SSD unless “greater-than” values corresponded to the highest toxicity value.
- Several algae tests were excluded from the SSD analysis as the validity criterion (cv % for section-by-section specific growth rate ≤ 35 %) were not met (see Volume 3CA B-9 for further details).

The SSD analysis presented below was performed with the software ETX 2.0 (Van Vlaardingen et al., 2004).

<u>**SSD for algae (Tier 2B):**</u>

Table B.9.4-15: Species sensitivity distribution (SSD) for algae

Data no	Toxicity data [µg/L]	Species
1	6.6	*Monoraphidium griffithii*
2	9.7	*Ankistrodesmus bibraianus*
3	13.9	*Pseudokirchneriella subcapitata* (geometric mean, n=2)
4	18.3	*Desmodesmus subspicatus*
5	85.4	*Chlamydomonas reinhardtii*
6	111	*Planktosphaeria botryoides*
7	127	*Schroederia setigera*
8	154	*Navicula pelliculosa*
9	368	*Neochloris aquatica*

Table B.9.4-16: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.466** **n: 9**
0.1	0.631	Accepted	
0.05	0.752	Accepted	
0.025	0.873	Accepted	
0.01	1.035	Accepted	

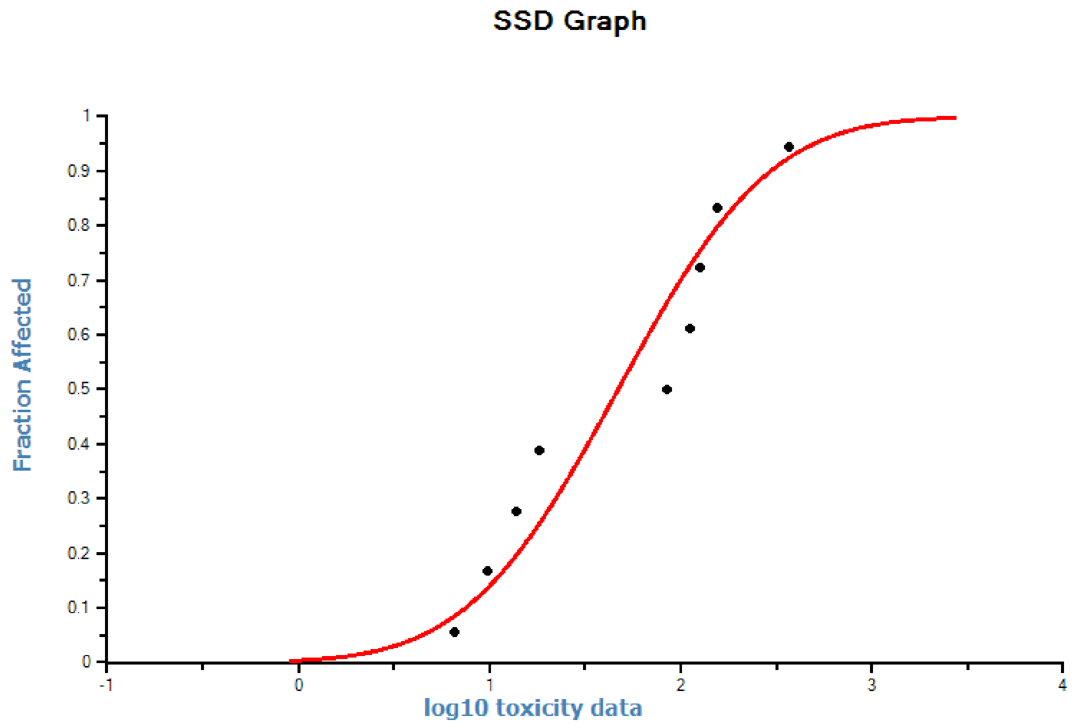

Figure B.9.4-1: **SSD graph for algae**

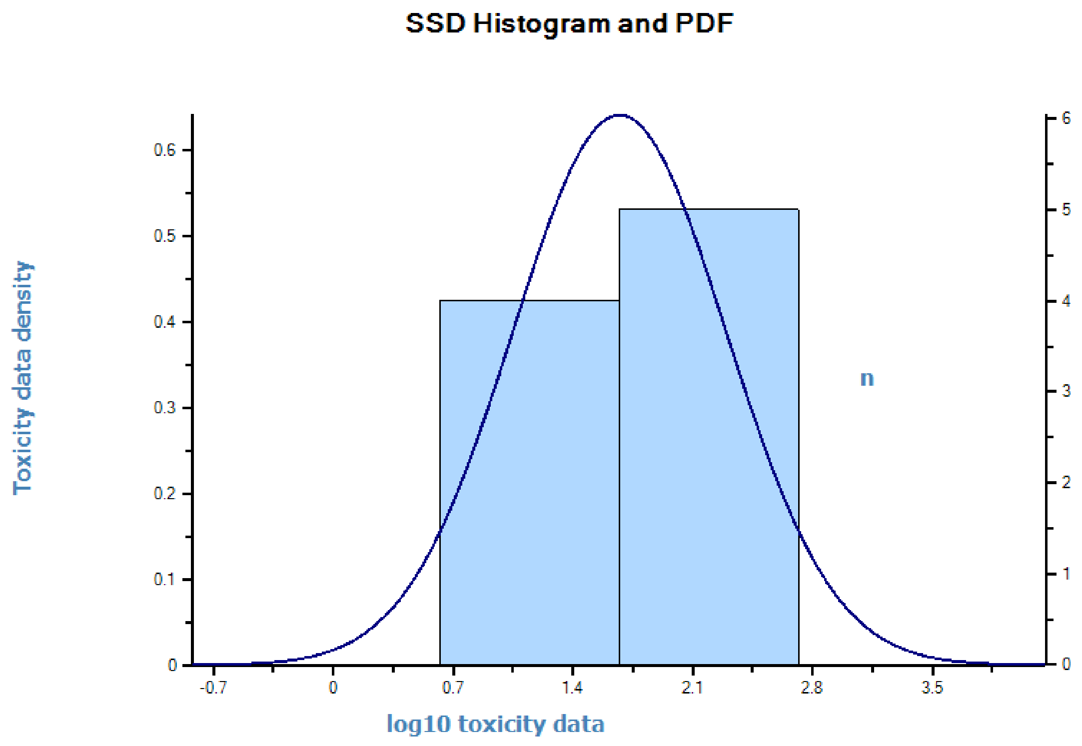

Figure B.9.4-2: SSD histogram for algae

Table B.9.4-17: Parameters of the normal distribution

Name	Value	Description
mean	1.672	mean of the log toxicity values
s.d.	0.623	sample standard deviation
n	9	sample size

Table B.9.4-18: HC_5 results

Name	Value [µg/L]	log10 (Value)	Description
LL HC_5	0.609	-0.216	lower estimate of the HC5
HC_5	**4.051**	**0.608**	**median estimate of the HC5**
UL HC_5	11.360	1.055	upper estimate of the HC5
sprHC_5	18.667	1.271	spread of the HC5 estimate

SSD for macrophytes (Tier 2B):

Table B.9.4-19: Species sensitivity distribution (SSD) for aquatic plants

Data no	Toxicity data [µg/L]	Species [1)]
1	13.3	*Ceratophyllum demersum*
2	25.5	*Lemna gibba* [2)]
3	33.5	*Ludwigia palustris*
4	86.5	*Crassula recurva*
5	88.4	*Myriophyllum spicatum*
6	104	*Veronica beccabunga*
7	109	*Glyceria maxima*
8	154	*Iris pseudoacorus*
9	174	*Potamogeton crispus*
10	206	*Mentha aquatica*
11	208	*Elodea densa*
12	373	*Sparganium erectum*
13	>1314	*Acorus calamus*

[1)] *Vallisneria spiralis* E_yC_{50} >269 µg/L was excluded from the SSD analysis as it is not recommended to include unbound values (greater-than or lower-than values) in the SSD (see EFSA GD, 2013).
[2)] The *Lemna* study with sediment was used in order to increase comparability among the remaining macrophyte endpoints.

Table B.9.4-20: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.318** **n: 13**
0.1	0.631	Accepted	
0.05	0.752	Accepted	
0.025	0.873	Accepted	
0.01	1.035	Accepted	

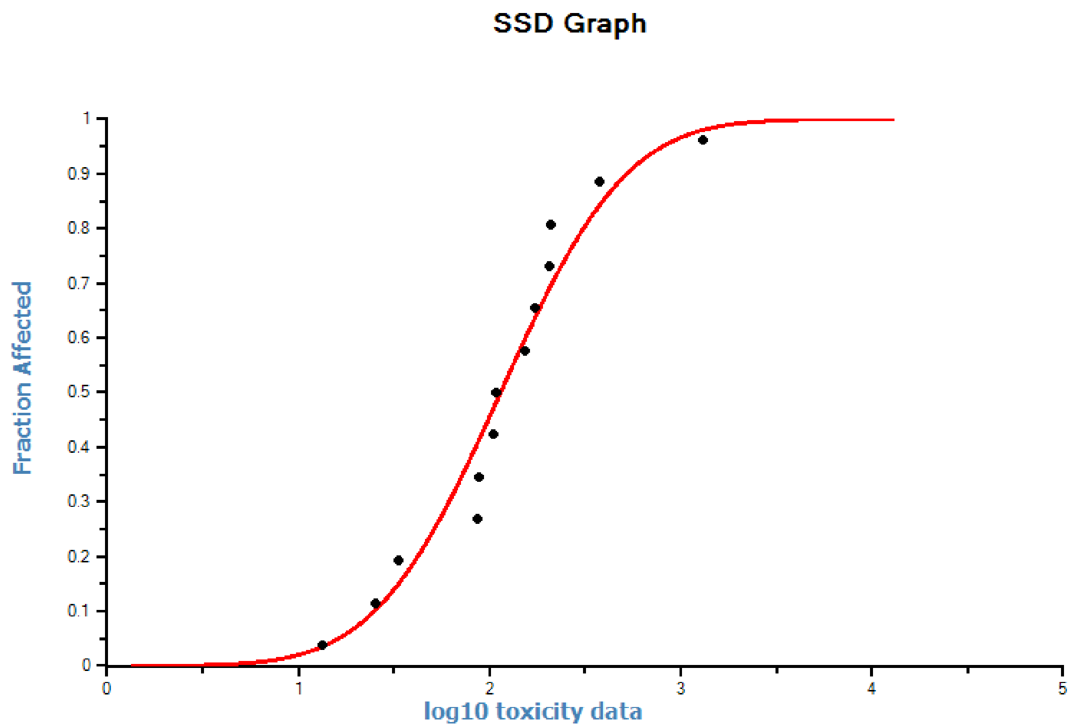

Figure B.9.4-3: SSD graph for macrophytes

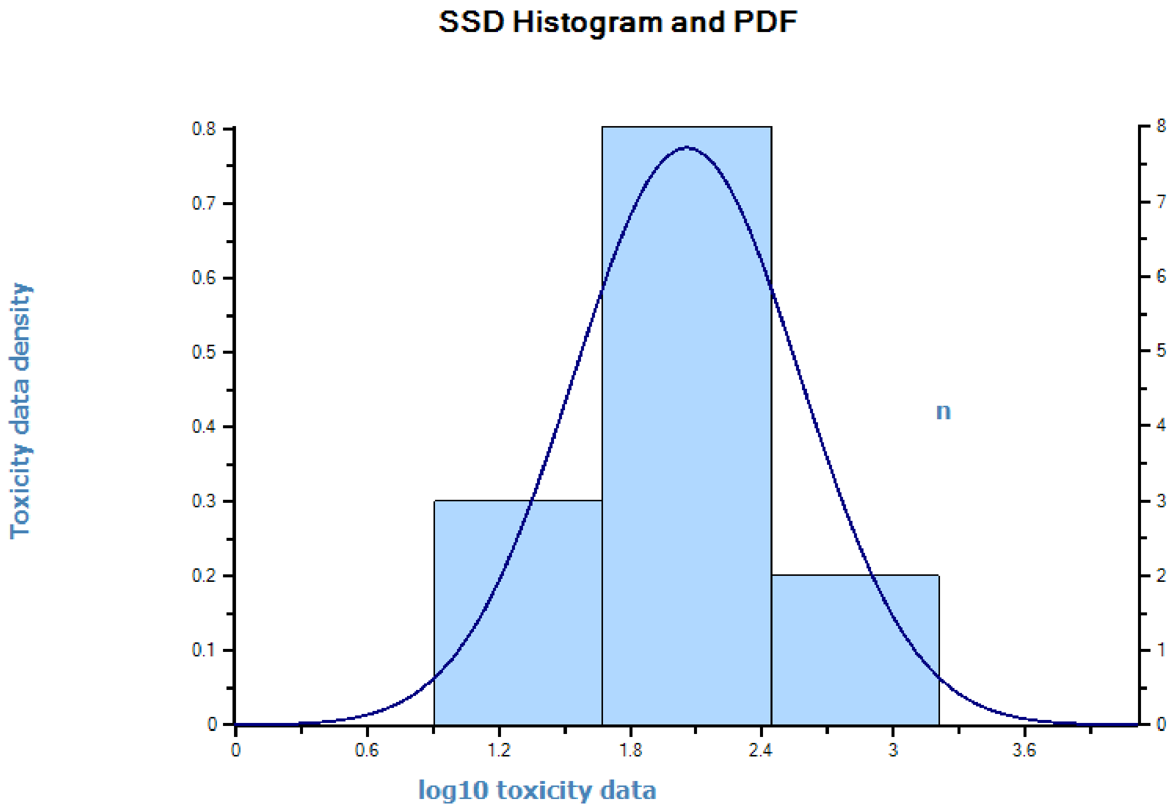

Figure B.9.4-4: SSD histogram for macrophytes

Table B.9.4-21: Parameters of the normal distribution

Name	Value	Description
mean	2.057	mean of the log toxicity values
s.d.	0.515	sample standard deviation
n	13	sample size

Table B.9.4-22: HC_5 results

Name	Value [µg/L]	log10 (Value)	Description
LL HC_5	4.808	0.682	lower estimate of the HC5
HC_5	**15.43**	**1.188**	**median estimate of the HC5**
UL HC_5	31.64	1.500	upper estimate of the HC5
sprHC_5	6.581	0.818	spread of the HC5 estimate

Conclusion on the SSD analysis:
HC_5 values were 4.05 and 15.4 µg as/L for algae and macrophytes, respectively. For the risk assessment, the lowest corresponding **RAC of 1.35 µ as g/L** will be used, taking into account an AF of 3 for primary producers in accordance with the EFSA GD (2013).

Refined Risk Assessment:
The TER values calculated by the RMS for the respective representative uses are presented in the tables below.

Table B.9.4-23: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one application [1 x 864 g as/ha] in pre-emergence and post-emergence maize

FOCUS Scenarios	Algae SSD- RAC [µg as/L]	FOCUS Step 4 – maize (pre-emergence)		FOCUS Step 4 – maize (post-emergence)	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m drift mitigation					
D3/ditch	1.35	1.483	**0.91**	1.484	**0.91**
D4/pond		0.187	7.22	0.198	6.82
D4/stream		1.577	**0.86**	1.683	**0.80**
D5/pond		0.19	7.11	0.212	6.37
D5/stream		1.706	**0.79**	1.542	0.88
D6/ditch		0.535	2.52	1.506	**0.90**
R1/pond		0.314	4.30	0.632	2.14
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.982	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
10 m drift mitigation					
D3/ditch	1.35	0.786	1.72	0.792	1.70
D4/pond		0.137	9.85	0.145	9.31
D4/stream		0.842	1.60	0.902	1.50
D5/pond		0.139	9.71	0.159	8.49
D5/stream		0.911	1.48	0.825	1.64
D6/ditch		0.838	1.61	0.813	1.66
R1/pond		0.282	4.79	0.589	2.29
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.982	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
20 m drift mitigation					
D3/ditch	1.35	0.409	3.30	0.416	3.25
D4/pond		0.09	15.00	0.095	14.21
D4/stream		0.44	3.07	0.471	2.87
D5/pond		0.093	14.52	0.109	12.39
D5/stream		0.476	2.84	0.434	3.11
D6/ditch		0.46	2.93	0.437	3.09
R1/pond		0.253	5.34	0.55	2.45
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.981	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
10 m drift + runoff mitigation					
D3/ditch	1.35	0.786	1.72	0.792	1.70
D4/pond		0.137	9.85	0.145	9.31
D4/stream		0.842	1.60	0.902	1.50
D5/pond		0.139	9.71	0.159	8.49
D5/stream		0.911	1.48	0.825	1.64
D6/ditch		0.838	1.61	0.813	1.66
R1/pond		0.164	8.23	0.305	4.43
R1/stream		4.442	**0.30**	5.208	**0.26**
R2/stream		3.362	**0.40**	4.247	**0.32**
R3/stream		6.946	**0.19**	11.382	**0.12**
R4/stream		20.86	**0.06**	13.093	**0.10**

FOCUS Scenarios	Algae SSD- RAC [µg as/L]	FOCUS Step 4 – maize (pre-emergence)		FOCUS Step 4 – maize (post-emergence)	
		$PEC_{sw. max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw. max}$ [µg/L]	TER (RAC/PEC)
20 m drift + runoff mitigation					
D3/ditch	1.35	0.409	3.30	0.416	3.25
D4/pond		0.09	15.00	0.095	14.21
D4/stream		0.44	3.07	0.471	2.87
D5/pond		0.093	14.52	0.109	12.39
D5/stream		0.476	2.84	0.434	3.11
D6/ditch		0.46	2.93	0.437	3.09
R1/pond		0.095	14.21	0.17	7.94
R1/stream		2.266	**0.60**	2.723	**0.50**
R2/stream		1.75	**0.77**	2.2	**0.61**
R3/stream		3.498	**0.39**	5.948	**0.23**
R4/stream		10.909	**0.12**	6.863	**0.20**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on the TER values above, unacceptable/high risks are identified for the R1-4/stream scenarios ($PEC_{sw;max} > RAC_{sw;ch}$).

Table B.9.4.24: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one application [1 x 864 g as/ha] in pre-emergence soybeans

FOCUS Scenarios	Algae SSD-RAC [µg as/L]	FOCUS Step 4 – pre-emergence soybeans	
		$PEC_{sw. max}$ [µg/L]	TER (RAC/PEC)
5 m drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
10 m drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
20 m drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
10 m drift + runoff mitigation			
R3/stream	1.35	10.548	**0.13**
R4/stream		6.285	**0.21**
20 m drift + runoff mitigation			
R3/stream	1.35	5.539	**0.24**
R4/stream		3.295	**0.41**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on the TER values above, unacceptable/high risks are identified for all R3-4/stream scenarios ($PEC_{sw;max} > RAC_{sw;ch}$).

Table B.9.4.4-7: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one pre-emergence application [1 x 864 g a.s./ha] in sunflower

FOCUS Scenarios	Algae SSD-RAC [µg a.s./L]	FOCUS Step 4 – pre-emergence sunflower	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation			
D5/pond	1.35	0.190	7.11
D5/stream		1.584	**0.85**
R1/pond		0.339	3.98
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**
10 m Drift mitigation			
D5/pond	1.35	0.140	9.64
D5/stream		0.845	1.60
R1/pond		0.308	4.38
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**
20 m Drift mitigation			
D5/pond	1.35	0.094	14.36
D5/stream		0.441	3.06
R1/pond		0.279	4.84
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**
10 m Drift + runoff mitigation			
D5/pond	1.35	0.140	9.64
D5/stream		0.845	1.60
R1/pond		0.174	7.76
R1/stream		3.958	**0.34**
R3/stream		19.801	**0.07**
R4/stream		16.627	**0.08**
20 m Drift + runoff mitigation			
D5/pond	1.35	0.094	14.36
D5/stream		0.441	3.06
R1/pond		0.100	13.50
R1/stream		2.014	**0.67**
R3/stream		10.394	**0.13**
R4/stream		8.594	**0.16**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on the TER values above, unacceptable/high risks ($PEC_{sw;max} > RAC_{sw;ch}$) are identified for all R1-3/stream scenarios in sunflowers (pre-emergence).

Table B.9.4.4-8: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one pre-emergence application [1 x 864 g a.s./ha] in sugar beets and one post-emergence application [1 x 720 g a.s./ha] in sugar beets, respectively.

FOCUS Scenarios	Algae SSD-RAC [µg a.s./L]	FOCUS Step 4 – pre-emergence sugar beet		FOCUS Step 4 – post-emergence sugar beet	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation					
D3/ditch	1.35	1.483	**0.91**	1.237	1.09
D4/pond		0.189	7.14	0.169	7.99
D4/stream		1.578	**0.86**	1.346	1.00
R1/pond		1.948	**0.69**	0.265	5.09
R1/stream		20.477	**0.07**	3.597	**0.38**
R3/stream		38.356	**0.04**	5.7	**0.24**
10 m Drift mitigation					
D3/ditch	1.35	0.787	1.72	0.657	2.05
D4/pond		0.144	9.38	0.125	10.80
D4/stream		0.847	1.59	0.723	1.87
R1/pond		1.912	**0.71**	0.237	5.70
R1/stream		20.477	**0.07**	3.597	**0.38**
R3/stream		38.356	**0.04**	5.7	**0.24**
20 m Drift mitigation					
D3/ditch	1.35	0.409	3.30	0.345	3.91
D4/pond		0.0978	13.80	0.084	16.07
D4/stream		0.445	3.03	0.38	3.55
R1/pond		1.875	**0.72**	0.211	6.40
R1/stream		20.477	**0.07**	3.597	**0.38**
R3/stream		38.356	**0.04**	5.7	**0.24**
10 m Drift + runoff mitigation					
D3/ditch	1.35	0.787	1.72	0.657	2.05
D4/pond		0.144	9.38	0.125	10.80
D4/stream		0.847	1.59	0.723	1.87
R1/pond		0.836	1.61	0.14	9.64
R1/stream		9.34	**0.14**	1.631	**0.83**
R3/stream		17.504	**0.08**	2.603	**0.52**
20 m Drift + runoff mitigation					
D3/ditch	1.35	0.409	3.30	0.345	3.91
D4/pond		0.0978	13.80	0.084	16.07
D4/stream		0.445	3.03	0.38	3.55
R1/pond		0.436	3.10	0.081	16.67
R1/stream		4.898	**0.28**	0.854	1.58
R3/stream		9.188	**0.15**	1.366	**0.99**

Based on the TER values above, unacceptable/high risks (PECsw;max > RACsw;ch) are identified for all R2-3/stream scenarios in sugar beet (pre-emergence) and for all R3/stream scenarios in sugar beet (post-emergence), respectively.

Tier 2C: The refined exposure laboratory test AF approach

In support of the higher tier risk assessment, the applicant has submitted refined exposure laboratory tests ("time-to-effect/event" (TTE) studies) on the sensitive aquatic plant species *L. gibba* and *C. demersum* as well as on two alga species *P. subcapitata* and *M. griffithii* with dimethenamid-P using exposure duration derived from exposure scenarios representative for moving water bodies like streams and ditches (see Table below).

Table B.9.4-27: Summary of the results of the time-to-effect/event studies on aquatic primary producers and the proposed use for refined risk assessment of dimethenamid-P

Test organism	Exposure scenario	E_rC_{50} / $E_{y/b}C_{50}$ (duration) [µg as/L] *	TTE-AUC [µg as/L*d] #	AF	covered peak conc. (duration) [µg as/L] *	covered peak AUC [µg as/L*d]
M. griffithii	single peak exposure over 6 & 24 h (+ 72 h growth phase)	> 2400 / > 2400 (6 h)	> 600	10	≤ 240 (6 h)	≤ 60.0
		> 1200 / > 1200 (24 h)	> 1200	10	≤ 120 (24 h)	≤ 120
P. subcapitata	single peak exposure over 6 & 24 h (+ 72 h growth phase)	> 1200 / 1200 (6 h)	> 300	10	≤ 120 (6 h)	≤ 30.0
		> 1200 / 388 (24 h)	120 / 388	10	≤ 38.8 (24 h)	≤ 38.8
L. gibba	Scenario A: single peak exposure over 12, 24 & 36 h (+ 7 d growth phase)	> 500 (12 h)	> 250	10	≤ 50 (12 h)	≤ 25.0
		> 500 (24 h)	> 500	10	≤ 50 (24 h)	≤ 50.0
		458 / 253 (36 h)	687 / 380	10	≤ 25.3 (36 h)	≤ 38.0
	Scenario B: two consecutive peaks with decreasing conc. separated by a 13 h non-exposure period (+ 7 d growth phase)	> 500-350-100-0-180-100 (5-4-3-13-6-3 h)	--	--	n.c.	n.c.
		≥ 250-175-50-0-90-50 (5-4-3-13-6-3 h)	--	--	n.c.	n.c.
C. demersum	single peak exposure over 24 & 48 h (+ 7 d growth phase)	> 3000 (24 h)	> 3000	10	≤ 300 (24 h)	≤ 300
		> 3000 (48 h)	> 6000	10	≤ 300 (48 h)	≤ 600

TTE = Time-To-Effect/Event; AF = Assessment Factor; n.c. = not calculated
# For details on AUC (= Area Under the Curve) calculation and its use for refined risk assessment see text below.
* Only valid for respective short-term exposure peaks (duration given in brackets).

Generally, the aim of TTE-studies is to mimic short exposure durations, which might result from running water bodies like streams or ditches in order to demonstrate that these exposure patterns elicit lower impacts on sensitive aquatic primary producers in comparison to long-term exposure durations simulated in the standard studies (Tier 1). In the present case, the results of the TTE studies simulating realistic short pulse exposure scenarios suggest that exposure durations strongly influence the toxicity of dimethenamid-P to aquatic primary producers.

According to the applicant, the results of these studies may directly be used for TER calculation since exposure patterns in the studies are comparable to the predicted exposure patterns that should be representative for streams and ditches used for calculation of PECs as proposed by the ELink workshop (Brock et al., 2009).

In order to define if the peak concentrations of short-term exposure profiles for dimethenamid-P are covered by the results of the TTE studies, for each exposure peak higher than a critical threshold level, a detailed characterisation of the exposure profile in the relevant FOCUS surface water stream scenarios has been performed by the applicant in the dossier using the Exposure Pattern Analysis Tool

(EPAT; Wang, 2010). This was done by comparing Area-under-the-curve concentrations (AUC) derived for respective peak durations from the simulated exposure profiles to the AUCs obtained from the TTE-studies.

However, EPAT-generated PEC values in conjunction with TTE studies are shown to be unsuitable for the higher tier assessment for several reasons:

i) The underlying concept of EPAT, for which no EU guidance is available so far, does not consider multiple years of application and consequently, an overall worst case concentration pattern for each scenario could not be defined (for further information, see also conclusions in chapter B.8.5 annex point KCP 9.2., Acceptability of PECsw and PECsed values – dimethenamid-P‘).
ii) Furthermore, an increase of effects over time (“carry-over of effects”) occurred in the TTE studies during the growth phase (see chapter B.9.5 annex point KCA 8.2.7/1 for more information) which supports the conclusion that repeated exposures are not ecotoxicologically independent.

Overall, it can be concluded that considerable uncertainties remain with regard to both the TTE-derived toxicity values and exposure modelling approaches such as EPAT, and therefore, the respective risk refinement approaches were not further presented in the renewal assessment report.

Conclusion on the aquatic risk assessment:
Based on the results above, taking into account SSD analysis for primary producers, no safe use has been identified for the use in soybeans. However, acceptable risk for aquatic organisms ($PEC_{sw;max} < RAC_{sw;ch}$) is supported for the intended uses in maize, sugar beets and sunflowers.

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees

BAS 656 12 H is an emulsifiable concentrate formulation (EC) supported for renewing the approval of dimethenamid-P (BAS 656 H) containing 720 g dimethenamid-P/L. Effects on honeybees of BAS 656 12 H were tested with technical dimethenamid-P (BAS 656 H).

B.9.5.1.1 Acute toxicity (KCP 10.3.1.1)

Acute oral (KCA 10.3.1.1.1) and contact (KCA 10.3.1.1.2) toxicity

Report:	B 9.3.1.1/1 Zenker K., 2011 Acute toxicity of BAS 656-H (Reg.No. 363 851, Dimethenamid-P) to the honeybee *Apis mellifera* L. under laboratory conditions 2010/1126065
Guidelines:	OECD 213 (1998), OECD 214 (1998)
GLP:	yes
Validity	Acceptable

For further information please refer to CA 9.3.1.1/1.

Report:	B 9.5.1.1/1 Sack D., 1999 Effect of BAS 656 07 H on the honeybee (*Apis mellifera* L.) in laboratory trials

	BASF DocID 99/10373
Guidelines:	OECD 213 (1998), OECD 214 (1998)
GLP:	yes
Validity:	Not acceptable

This study has been reported during the first EU review of dimethenamid-P, therefore only a brief summary and the endpoints are presented below.

Executive Summary

The acute contact and oral toxicity of BAS 656 07 H (batch 98001) was investigated in a 1aboratory test according to "Bulletin OEPP/EPPO Bulletin 22 (1992), no.170". A limit test and a multiple dose test have been conducted.

Limit tests (200 µg/bee):
The reference substance BAS 152 11 I, a formulation containing 400 g dimethoate/L, resulted in a LD_{50} (24 h/48 h) of 0.30 µg/bee and a LD_{50} (72 h) of 0.29 µg/bee in the oral test. The contact test resulted in a LD_{50} (24 h) of 0.41 µg/bee and a LD_{50} (48 h/72 h) of 0.39 µg/bee.
The test substance had slight effects in the contact test and in the oral test. After 24 h until the trials end, many bees are badly damaged (locked wet and moved only their legs, unable to reach the feeding tube).
The LD_{50}, (48 h) was reported to be > 200 µg/bee in the contact and > 124.76 µg/bee (highest dose consumed) in the oral test.
However, there is no specifying regarding the number of bees which has been badly damaged till the end of the trial. Therefore, no LD_{50} values can be calculated and the study has to be valued as not valid.

Multiple dose tests (12.5, 25, 50, 100, 150 and 200 µg/bee):
The reference substance BAS 152 11 I, a formulation containing 400 g dimethoate/L, resulted in a LD_{50} (24 h) of 0.42 µg/bee and a LD_{50} (48 h) of 0.38 µg/bee in the contact test. In the oral test the reference substance BAS 152 11 L resulted in a LD_{50} (24 h) of 0.29 µg/bee and a LD_{50} (48 h) of 0.26 µg/bee.
The test substance had slight effects in the contact test and in the oral test. After 24 h until the trials end, many bees are badly damaged (locked wet and moved only their legs, unable to reach the feeding tube).
The LD_{50}, (48 h) was reported to be > 200 µg/bee in the contact and > 103.3 µg/bee (highest dose consumed) in the oral test.

Conclusion
This study has already been evaluated for the first EU review of dimethenamid-P. However, form the current point of view the study is not considered valid and acceptable for the new risk assessment of dimethenamid-P any more. This decision was taken based on the high number of bees that have been sub-lethal affected and not recovered until the end of the test (48 hours). Regarding those facts the duration of the test would have to be extended at least up to 72 hours. This omission led to an uncertainty regarding the LD_{50} (48 h) values which might be different compared to LD_{50} values calculated after 72 hours. In addition, the RMS detected some errors regarding the calculation of the LD_{50} values.

B.9.5.1.2 Chronic toxicity (KCP 10.3.1.2)

Further tests are not required since laboratory studies with BAS 656 12 H show no unacceptable risk to honeybees.

B.9.5.1.3 Effects on honeybee brood (KCP 10.3.1.3)

Further tests are not required since BAS 656 12 H is not an IGR. However, the active substance dimethenamid-P was tested for its toxicity via oral uptake of honeybee larvae (please refer to Kleebaum K. 2014, CA 9.3.1.3/1).

B.9.5.1.4 Sublethal effects (KCP 10.3.1.4)

Further tests are not required since laboratory studies with BAS 656 12 H show no unacceptable risk to honeybees.

B.9.5.1.5 Cage and tunnel tests (KCP 10.3.1.5)

Further tests are not required since laboratory studies with BAS 656 12 H show no unacceptable risk to honeybees.

B.9.5.1.6 Field tests (KCP 10.3.1.6)

Further tests are not required since laboratory studies with BAS 656 12 H show no unacceptable risk to honeybees.

B.9.5.1.7 Summary of effects on honeybees

Due to the results of laboratory tests BAS 656 12 H is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. The sensitivity of adult bees and larvae to BAS 656 H is comparable, and it is likely that BAS 656 12 H is less toxic to larvae.

B.9.5.1.8 Risk assessment for honeybees

Toxicity

Table B.9.5-1 presents a summary of all studies submitted for the risk assessment. Further details regarding studies with BAS 656 H and BAS 656 07 H are provided in section B.9.5.1.1.

Table B.9.5-1: Toxicity to bees of BAS 656 H

Test substance	Test species	Endpoint	Value	Reference
Dimethenamid-P (BAS 656 H)	adult honeybees	24 h acute oral LD_{50}	> 1000 µg as/bee	Donat H.J, 1986 1986/11170
		24 h acute contact LD_{50}	94 µg as/bee	
	adult honeybees	48 h acute oral LD_{50}	118.8 µg as/bee	Zenker K., 2011** Study no. 2010/1126065
		48 h acute contact LD_{50}	93.8 µg as/bee	
	honeybee larvae	96 h oral LD_{50} 96 h oral LC_{50}	69.6 µg as/larva 2.054 g as/kg food	Kleebaum K., 2014** Study no. 2013/1132510
	bumblebee	48 h acute oral LD_{50}	> 158 µg as/bumblebee	Roehlig U., 2014** Study no. 2013/1275562
		48 h acute contact LD_{50}	> 200 µg as/bumblebee	
BAS 656 07 H*	adult honeybees	48 h acute oral LD_{50}	(>200 µg product/bee)	Sack D., 1999 Study no. 49231
		48 h acute contact LD_{50}	(>103.3 µg product/bee)	

* not valid: BAS 656 07 H (a similar formulation to BAS 656 12 H) was one of the representative formulations supported for the first EU review of dimethenamid-P (further details provided in section B.9.5.1.1).
** new study submitted for the re-evaluate of dimethenamid-P (BAS 656 H)

Exposure

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst honeybees are foraging for food. However, as the crops are not flowering during application time, they are of low attractiveness to foraging honeybees. However, in order to consider a worst-case scenario, the maximum recommended use rates are used for the risk assessment.

Table 9.5-2: Proposed use pattern of BAS 656 12 H

Crop	Application time (BBCH growth stage)	Number of applications	Application rate per treatment	
			Dimethenamid-P [g as/ha]	BAS 656 12 H [L/ha]
corn	00 – 09 10 – 16	1	864	1.2
soybean, sunflower	00 – 09		864	1.2
sugar beet	12 – 18		720	1.0 [1)]

[1)] Can be applied in split as well (up to 3 times).

Hazard quotients

The acute risk to honeybees from the use of BAS 656 12 H was assessed using the maximum single application rate and the respective LD_{50} values to calculate hazard quotients (HQ) (*EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*)) as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

HQs for honeybees were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to BAS 656 12 H. An HQ < 50 indicates low risk to honeybees in the field. For bumblebees no risk assessment scheme currently exists.

Table B.9.5-3: Risk to honeybees and bumblebees from exposure to BAS 656 12 H using the worst-case application rate

Test substance	Application rate [g as/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
BAS 656 12 H*	864	48 h acute, oral	118.8 µg as/bee	7.3	50
		48 h acute, contact	93.8 µg as/bee	9.2	
bumblebee					
Dimethenamid-P (BAS 656 H)	864	48 h oral	> 158 as/bee	-- [1)]	
		48 h contact	> 200 as/bee		

* tested as technical dimethenamid-P (Zenker K., 2011; 2010/1126065)
[1)] Currently, no risk assessment scheme for bumblebee exists.

Due to the results of laboratory tests BAS 656 12 H is considered to be practically non-toxic to bees. All HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field.

Regarding bumblebees no risk assessment scheme is available. However, the endpoints obtained for acute oral and acute contact exposure to BAS 656 H (dimethenamid-P) on bumble bees, compared to the data available for honey bees, do not indicate higher sensitivity to dimethenamid-P.

Conclusion
The proposed uses of BAS 656 12 H according to good agricultural practice present a low risk to honeybees and bumblebees and will not adversely affect honeybees or honeybee colonies as well as bumblebee colonies.

B.9.5.2 Effects on non-target arthropods other than bees

No studies on the toxicity of terrestrial arthropods of the representative formulation BAS 656 12 H were submitted. One new study on the acute toxicity of the formulation BAS 656 08 H to *Aphidius rhapalosiphi* was submitted with the renewal dossier and is summarised below.

To increase the transparency and comprehensibility of the overall assessment, summaries of the studies assessed with the initial evaluation of dimethenamid-P have been added by the RMS. No new evaluation of the previously submitted studies was performed.

B.9.5.2.1 Standard laboratory testing for non-target arthropods

KCP 10.3.2.1/1 Kühner, 1998a (study evaluated in the initial monograph, 2000)

Author:	Kühner, C.
Title:	BAS 656 07 H: Toxicity to the aphid parasitoid, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) in the laboratory
Date:	14.12.1998
Doc ID:	98303/01-NLAp; ANA1999-149; BASF RegDoc# 98/11333
Guidelines:	IOBC
GLP:	Yes
Validity:	Acceptable

Material and Methods

Testspecies: *Aphidius rhopalosiphi*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; Dimethenamid-P 64 %
Developmental stage: Adult
Substrate: Glas
Route of exposure: deposit
Duration of exposure: 48 h

Results and Discussion

Rate tested	Mortality	Sublethal Effects
1.4 L/ha	100 %	-/-

Remarks Deviation:1) humidity was app. 90 % for short time.
2) demineralised water was used for the control

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} < 1.4 L prod/ha (100 % mortality).

KCP 10.3.2.1/2 Kühner, 1998b (Study evaluated in the initial monograph, 2000)

Author: Kühner, C.
Title: BAS 656 07 H: Toxicity to the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) in the laboratory
Date: 18.11.1998
Doc ID: 98303/01-NLTp; ANA1999-146; BASF RegDoc# 98/11279
Guidelines: IOBC
GLP: Yes
Validity: Acceptable

Material and Methods

Testspecies: *Typhlodromus pyri*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; dimethenamid-P 64 %
Developmental stage: Nymph
Substrate: Glas
Route of exposure: deposit
Duration of exposure: 14 d

Results and Discussion

Rate tested	Mortality	Sublethal Effects	Overall Effects
0.0084 L/ha	0 %	11 % (Fertility)	11 %
0.14 L/ha	1 %	23 % (Fertility)	24 %
1.4 L/ha	11 %	27 % (Fertility)	35 %

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & ER_{50} ≥ 1.4 L prod/ha.

KCP 10.3.2.1/3 Kühner, 1998c (study evaluated in the initial monograph, 2000)

Author: Kühner, C.
Title: BAS 656 07 H: Toxicity to the green lacewing, *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) in the laboratory
Date: 14.12.1998

Doc ID: 98303/02-NLCc; ANA1999-148; BASF RegDoc# 98/11334
Guidelines: IOBC
GLP: Yes
Validity: Acceptable

Material and Methods

Testspecies: *Chrysopa carnea*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; dimethenamid-P 64 %
Developmental stage: Larvae
Substrate: Glas
Route of exposure: deposit
Duration of exposure: until emergence of adults

Results and Discussion

Rate tested	Mortality	Sublethal Effects	Overall Effects
1.4 L/ha	5 %	0 % (Fertility)	5 %

Remarks Deviation: 1) Temp. 19/26 °C and humidity 80 % for short time
2) demineralised water was used for control

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & ER_{50} ≥ 1.4 L prod/ha.

KCP 10.3.2.1/4 Kühner, 1998d (study evaluated in the initial monograph, 2000)

Author: Kühner, C.
Title: BAS 656 07 H: Toxicity to the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) in the laboratory
Date: 20.11.1998
Doc ID: 98303/01-NLPc; ANA1999-147; BASF RegDoc# 98/11278
Guidelines: BBA
GLP: Yes
Validity: Acceptable

Material and Methods

Testspecies: *Poecilus cupreus*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; Dimethenamid-P 64 %
Developmental stage: Adult
Substrate: Quarzsand
Route of exposure: overspray+oral
Duration of exposure: 14 d

Results and Discussion

Rate tested	Mortality	Sublethal Effects	Overall Effects
1.4 L/ha	0 %	11 % (Food Uptake)	

Remarks Deviation: 1) humidity 90 % for short time

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & ER_{50} ≥ 1.4 L prod/ha.

KCP 10.3.2.1/5 Kemmeter, 1999 (study evaluated in the initial monograph, 2000)

Author: Kemmeter, F.
Title: BAS 656 07 H: Toxicity to the staphylinid beetle, *Aleochara bilineata* GYLL. (Coleoptera, Staphylinidae) in the laboratory
Date: 22.07.1999
Doc ID: 99010/01-NLAb; ANA1999-277; BASF RegDoc# 1999/10856
Guidelines: IOBC
GLP: Yes
Validity: Acceptable

Material and Methods

Testspecies: *Aleochara bilineata*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; Dimethenamid-P 64 %
Developmental stage: Lifecycle
Substrate: Quarzsand
Route of exposure: deposit
Duration of exposure: 30 d

Results and Discussion

Rate tested	Mortality	Sublethal Effects	Overall Effects
1.4 L/ha	3 %	3 % (Fertility)	

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & $ER_{50} \geq 1.4$ L prod/ha.

KCP 10.3.2.1/6 Schmitzer, 1999 (study evaluated in the initial monograph, 2000)

Author: Schmitzer, S.
Title: Effects of BAS 656 07 H on the wolf spider *Pardosa spec*. (Araneae, Lycosidae) in the laboratory
Date: 29.06.1999
Doc ID: 5672065; ANA1999-276; BASF RegDoc# 1999/10751
Guidelines: BBA
GLP: Yes
Validity: Acceptable

Material and Methods

Testspecies: *Pardosa spp.*
Substance tested: Formulation: BAS 656 07 H (EC) BBA Reg.-No. 4789; dimethenamid-P 64 %
Developmental stage: Adult
Substrate: Quarzsand
Route of exposure: overspray
Duration of exposure: 14 d

Results and Discussion

Rate tested	Mortality	Sublethal Effects	Overall Effects
1.4 L/ha	0 %	+6 % (Food Uptake)	

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & $ER_{50} \geq 1.4$ L prod/ha.

KCP 10.3.2.1/7 Fussell, 2003 (new study, submitted with renewal dossier)

Author:	Fussell, S.
Title:	A rate-response laboratory test to determine the effects of BAS 656 08 H on the parasitic wasp, *Aphidius rhapalosiphi* (Hymenoptera, Braconidae)
Date:	24.03.2003
Doc ID:	BASF-03-8; BASF RegDoc# 2003/1006351
Guidelines:	Mead-Briggs M. et al. (2000)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 656 08 H, batch no. 2001-1; content of as: dimethenamid-P (BAS 656P H, Reg. no. 363 851): 711.4 g/L (nominal: 720.0 g/L); density: 1.127 g/cm³.

Test species: *Aphidius rhopalosiphi* (parasitoids); adults less than 48 h old; source: PK Nützlingszuchten, Welzheim, Germany.

Test design: Exposure of the wasps was reached via air-dried residues on treated glass plates. Based on the results of an initial range-finding test, 7 treatment groups (5 test item rates, water treated control, reference item) were tested. For each treatment, 4 replicates were set up. Each replicate contained 10 wasps. Assessment of mortality was done at 2, 24 and 48 hours. After 48 h, surviving wasps were confined individually over untreated barley plants infested with host cereal aphids. Assessments were made for control and for the three highest treatment rates of the test item with < 50 % mortality. The adult wasps were removed after 24 h and the plants left for a further 11 days before the number of aphid mummies that had developed was assessed.

Endpoint: LR_{50}, effects on reproduction.

Reference item: Perfekthion (dimethoate, nominal 400 g/L).

Test rates: Control (deionised water), 19.75, 29.63, 44.44, 66.67 and 100 mL BAS 656 08 H/ha. The reference item was applied at an application rate of 0.25 mL/ha. All substances were applied in 200 L/ha water. The substances were sprayed onto glass plates via laboratory spraying equipment and air dried afterwards.

Test conditions: Exposure of adults: temperature: 19 °C – 21 °C; relative humidity: 62 % – 92 %; photoperiod: 16 h light: 8 h dark; light intensity: 500 – 1400 lux; Reproduction assessment: temperature: 19 °C – 22 °C; photoperiod: 16 h light: 8 h dark; light intensity: 4880 – 6930 lux; food: solution of honey and water (1 : 3 (v/v)).

Statistics: Descriptive statistics. Probit analysis for determination of LR_{50}; ANOVA ($\alpha = 0.05$).

Results and Discussion

The LR_{50} value was determined to be 66.3 mL BAS 656 08 H/ha.

After 48 hours, the mortality in the test item treatments ranged between 15 % and 98 % in comparison to 5 % in the control, resulting in corrected mortalities between 11 % and 98 %. Effects on reproduction ranged from 0 % to -16 % in 29.63 and 44.44 mL/ha. No statistically significant differences compared to the control were observed at any tested rates regarding reproduction assessment (ANOVA, $\alpha = 0.05$). The results are summarised in Table B.9.5-4.

Table B.9.5-4: Effects on *Aphidius rhopalosiphi* exposed to BAS 656 08 H under worst-case laboratory conditions

Treatment	Rate [1)] [mL/ha]	Mortality [2)] [%]	Corrected Mortality [3)] [%]	Effects on reproduction [4)] [%]
Control	--	5	--	--
BAS 656 08 H	19.75	15	11	--
	29.63	25	21	0
	44.44	25	21	-16
	66.67	20	16	-7
	100	98	98	--
	Endpoint [mL BAS 656 08 H/ha]			
LR_{50}	66.3			

1) Application rate in 200 L water/ha.
2) Mortality after 48 hours of exposure to BAS 656 08 H on glass plates.
3) Corrected mortality according to Abbott (1925).
4) A negative value indicates an increase relative to the control.

The reference item caused 100.0 % corrected mortality after 48 hours.

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & ER_{50} = 66.3 mL prod/ha.

B.9.5.2.2 Extended laboratory testing, aged residues studies with non-target arthropods

KCP 10.3.2.2/1 Schuld, 1999 (study evaluated in the initial monograph, 2000)

Author: Schuld, M.
Title: BAS 656 07 H: Toxicity to the aphid parasitoid, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae)
Date: 09.06.1999
Doc ID: 99010/01-NEAp; ANA1999-275, BASF RegDoc# 1999/10669
Guidelines: IOBC
GLP: Yes
Validity: Acceptable

Material and Methods

Substance tested: Formulation BAS 656 07 H (EC); dimethenamid-P 64 %
Developmental stage: Adult
Substrate: nat. Substrate (Barley); 3 D
Route of exposure: deposit + oral
Duration of exposure: 48 h

Results and Discussion

Rate tested	Mortality	Sublethal Effects
0.14 L/ha	0 %	23 % (Parasitation Capacity)
1.4 L/ha	0 %	46 % (Parasitation Capacity)

Conclusions

The study is acceptable. Agreed endpoint: LR_{50} & ER_{50} ≥ 1.4 L prod/ha.

B.9.5.2.3 Semi-field studies with non-target arthropods

No studies submitted, not required.

B.9.5.2.4 Field studies with non-target arthropods

No studies submitted, not required.

B.9.5.2.5 Other routes of exposure for non-target arthropods

No studies submitted, not required.

B.9.6 Risk assessment for arthropods

BAS 656 12 H was not the representative formulation for the first EU review of dimethenamid-P. It is an emulsifiable concentrate formulation (EC) containing 720 g dimethenamid-P/L. A set of studies using the formulations BAS 656 07 H and BAS 656 08 H, each containing 720 g dimethenamid-P/L was submitted for the initial assessment of dimethenamid-P. It is concluded that the results of those studies can also be used to assess the toxicity of the active substance dimethenamid-P and the formulation BAS 656 12 H to terrestrial arthropods. BAS 656 12 H is the representative formulation supporting the application for renewing the approval of dimethenamid-P. Both formulations, BAS 656 07 H as well as BAS 656 08 H, were found to be similar to BAS 656 12 H and can be used for the risk assessment of BAS 656 12 H.

Table B.9.6-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Test substance	Exposure System	Results	Reference
Tier I				
Typhlodromus pyri (protonymphs)	BAS 656 07 H [1)]	Laboratory test glass plates, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kühner, C. 18.11.1998 GAB 98303/01-NLTp (BASF 98/11279)*
Aphidius rhopalosiphi (adults)	BAS 656 08 H [2)]	Laboratory test glass plates, 2D	LR_{50} = 0.0663 L prep./ha	Fussell, S. 24.03.2003 BASF-03-8 2003/1006351
Aphidius rhopalosiphi (adults)	BAS 656 07 H [1)]	Laboratory test glass plates, 2D	LR_{50} < 1.400 L/ha (100 % mortality)	Kühner, C. 14.12.1998 GAB 98303/01-NLAP (BASF 98/11333)*
Tier II				
Aphidius rhopalosiphi (adults)	BAS 656 07 H [1)]	Extended laboratory test, barley seedlings, 3D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Schuld, M. 09.06.1999 GAB 99010/01-NEAP (BASF 99/10669)
Aleochara bilineata	BAS 656 07 H [1)]	laboratory test, Quartz sand, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kemmeter, F. 22.07.1999 GAB 99010/01-NLAb (BASF 99/10856)*
Chrysoperla carnea	BAS 656 07 H [1)]	laboratory test, Glass plate, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kühner, C. 14.12.1998 GAB 98303/02-NLCc (BASF 98/11334)*
Poecilus cupreus	BAS 656 07 H [1)]	laboratory test, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kühner, C. 20.11.1998 GAB 98303/01-NLPc (BASF 98/11278)*
Pardosa sp.	BAS 656 07 H [1)]	laboratory test, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Schmitzer, S. 29.06.1999 5672065 (BASF 99/10751)*

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
[1)] Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H).
[2)] Study was carried out with BAS 656 08 H (a similar formulation to BAS 656 12 H).

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

B.9.6.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for non-target arthropods from all other intended uses in groups 2-10 (see Vol. 1, 1.5.1).

The risk for non-target arthropods exposed in-field to BAS 656 12 H was assessed by comparing the environmental rate ($PER_{in-field}$) to the lowest lethal rate (LR_{50}) estimated in toxicity tests with non-target arthropods. With regard to extended laboratory tests, lethal and sublethal effects of less than 50 % are considered acceptable, provided that the tests covered the appropriate field rate. For *T. pyri,* *P. cupreus, C. Carne, A. bilineata*, and *Paradosa sp.* only laboratory tests on inert substrate were available. The correction factor is intended to cover uncertainty with regard to species sensitivity, the default value is 10 when the two standard species are tested (Tier 1). The default value in higher tier testing is 5 when higher-tier studies on the ‘affected species and two additional species with different biology are conducted. Since only one species was tested in extended laboratory studies with BAS 656 12 H, the correction factor used in tier II risk assessment should remain 10.

Table B.9.6-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	1-6 covering also uses 7-9)		
Active substance/product	BAS 656 12 H		
Application rate	1 × 1.200 (L prep./ha)		
MAF	1		
Test species Tier I	**LR_{50} (lab.) [L/ha]**	**$PER_{in\text{-}field}$ [L/ha]**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>1.400	1.200	0.86
Aphidius rhopalosiphi	0.0663		**18**
Additional test species	**Rate with ≤ 50 % effect [L/ha]**	**$PER_{in\text{-}field}$ [L/ha]**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aleochara bilineata	1.400	1.200	yes
Chrysoperla carnea	1.400	1.200	yes
Poecilus cupreus	1.400	1.200	yes
Pardosa sp.	1.400	1.200	yes
Test species Higher-tier	**Rate with ≤ 50 % effect [L/ha]**	**$PER_{in\text{-}field}$ [L/ha]**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	1.400	1.200	yes

HQ values shown in **bold** are above the relevant trigger.

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

B.9.6.1.1 Risk assessment for off-field exposure

Table B.9.6-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	1-6 (covering also uses 7-9)
Active substance/product	BAS 656 12 H
Application rate (g/ha)	1 × 1.200 (L prep./ha)
MAF	1
vdf	10[1)]* with 2D test setups and 1[2)] with 3D test setups

Test species Tier I	**LR_{50} (lab.) [mL/ha]**	**Drift rate**	**$PER_{off\text{-}field}$ [mL/ha]**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>1400	33.24	3.32 [1)]	10	0.024
Aphidius rhopalosiphi	66.3		3.32 [1)]	10	0.5
Additional test species	**Rate with ≤ 50 % effect [mL/ha]**	**Drift rate**	**$PER_{off\text{-}field}$ [mL/ha]**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Aleochara bilineata	1400	33.24	3.32 [1)]	10	yes
Chrysoperla carnea	1400		3.32 [1)]	10	yes
Poecilus cupreus	1400		3.32 [1)]	10	yes
Pardosa sp.	1400		3.32 [1)]	10	yes
Test species Higher-tier	**Rate with ≤ 50 % effect** [mL/ha]	**Drift rate**	**PERoff-field** [mL/ha]	**CF**	**corr. PERoff-field below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	1400	33.24	33.24 [2)]	5	yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* For formal reasons, the numerical value of 10 from the ESCORT 2 is taken, although doubts on its reliability are already mentioned in the Guidance Document on Terrestrial Ecotoxicology. In the opinion of the RMS, experimental data only support a vdf of 5 for a standard assessment. However, the changed value would not affect the overall outcome of the risk assessment.

B.9.6.1.2 Risk mitigation measures

No risk mitigation needed.

B.9.6.2 Overall conclusions

In-field

Based on the calculated rates of BAS 656 12 H in in-field areas, the calculated HQ values describing the risk resulting from an exposure of non-target arthropods to BAS 656 12 H according to the GAP of the formulation BAS 656 12 H achieve the acceptability criteria HQ ≤ 2 (Tier 1) and “PER below rate with ≤ 50 % effect” (higher Tier), 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 arthropods due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

Off-field

Based on the calculated rates of BAS 656 12 H in off-field, the calculated HQ values describing the risk resulting from an exposure of non-target arthropods to BAS 656 12 H according to the GAP of the formulation BAS 656 12 H achieve the acceptability criteria HQ ≤ 2 (Tier 1) and "PER below rate with ≤ 50 % effect" (higher Tier), 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 arthropods due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

B.9.7 Effects on non-target soil meso- and macrofauna

B.9.7.1 Earthworms

Under commission regulation 283/2013 acute toxicity data with earthworms are no longer required. Nonetheless, one new study on the acute toxicity of the representative formulation BAS 656 12 H to earthworms was submitted with the renewal dossier and is summarised below. Also, one new study on the toxicity of the representative formulation BAS 656 12 H to collembola was submitted with the renewal dossier and is summarised below.

To increase the transparency and comprehensibility of the overall assessment, summaries of the studies assessed with the initial evaluation of dimethenamid-P have been added by the RMS. No new evaluation of the previously submitted studies was performed.

B.9.7.1.1 Earthworms – acute effects

KCP 10.4.1/1 Krieg, 1999 (study evaluated in the initial monograph, 2000)

Author:	Krieg, W.
Title:	Effect of BAS 656 07 H on the mortality of the earthworm *Eisenia foetida*.
Date:	02.03.1999
Doc ID:	49224; ARW1999-47; BASF RegDoc# 99/10267
Guidelines:	OECD 207
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 656 07 H formulated product, batch # 98001, dimethenamid-P: 64 %.

Test species: Earthworm (*Eisenia fetida*), adult worms (with clitellum and weight > 250 mg), less than one year old; in-house culture.

Test design: 14-d exposure in treated artificial soil; different concentrations of the test substance are mixed homogeneously into the soil which is filled in glass vessels before the earthworms are introduced on top of the soil; 4 replicates/concentration with 10 worms each; assessment of worm mortality and behavioural effects after 7 and 14 d, measurement of weight change as sublethal parameter after 14 d; chloroacetamide as reference substance.

Test rates: Control, 100, 177.8, 316.5, 563.4, and 1000 mg BAS 656 07 H/kg dry soil.

Test conditions: Artificial soil according to OECD 207 (with a content of peat: 10 %); pH 6.3; water content at test initiation: 28.0 g per 100 g soil (dry weight); temperature: 19 °C - 21 °C; continuous illumination.

Statistics: Analysis of variance, Dunnet's test, Spearman-Karber, and TOXSTAT 3.4 (PC software).

Results and Discussion

BAS 656 07 H caused mortality of the earthworms with 100 % dead worms at 1000 mg/kg soil, the highest concentration tested. Reduction in worm biomass was measured in all test variants including the untreated control. No particular behavioural or morphological changes were observed.

Table B.9.7-1: Effect of BAS 656 07 H on earthworm *(Eisenia foetida)* mortality and biomass (14 d)

BAS 656 07 H [mg/ kg dry soil]	**Control**	**100**	**177.8**	**316.5**	**563.4**	**1000**
Mortality (28 d) [%]	2.5	0.0	0.0	0.0	40	100
Weight change (28 d) [%]	-9.24	-7.10	-3.95	-8.09	-22.24	--

Conclusion

The study is acceptable.
Agreed endpoint: LC_{50} = 596.3 mg prod./kg dry soil), corresponding to 387 mg as/kg dw; NOEC = 316.5 mg BAS 656 07 H/kg dry soil (mortality, biomass). The test substance was incorporated in artificial soil (10 % peat).

B.9.7.1.2 Earthworms – sub-lethal effects

KCP 10.4.1/2 Friedrich, 2010a (new study, submitted with renewal dossier)

Author: Friedrich, S.
Title: Sublethal toxicity of BAS 656 12 H to the earthworm *Eisenia fetida* in artificial soil with 5 % peat
Date: 07.12.2010
Doc ID: 10 10 48 085 S; BASF RegDoc# 2010/1068962
Guidelines: OECD 222 (2004)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 656 12 H, batch no. FRE-000601; content of as: dimethenamid-P (BAS 656P H, Reg. no. 363 851): 720 g/L (722.7 g/L analysed); density: 1.119 g/cm³.

Test species: Earthworm (*Eisenia fetida*), adult worms (with clitellum and weight of 253 - 457 mg), approximately 3 months old; source: "W. Neudorff GmbH KG" followed by in-house culture.

Test design: 56-day test in treated artificial soil according to OECD 222 (5 % peat). Different concentrations of the test item were incorporated into the soil. 6 treatment groups (5 test item rates, control) were set up with 8 replicates for the control and 4 replicates for the test item group, each with 10 worms. Assessment of worm mortality, behavioural effects and weight change was done after 28 days of exposure, after additional 28 days (56 days after application) the reproduction rate was determined.

Endpoints: Mortality, weight change, feeding activity and reproduction rate.

Reference item: Nutdazim 50 FLOW (carbendazim, SC 500). The effects of the reference item were investigated in a separate study.

Test rates: Control, 31, 62, 124, 249 and 497 mg BAS 656 12 H/kg dry soil corresponding to 20, 40, 80, 160 and 320 mg as/kg dry soil.

Test conditions: Artificial soil according to OECD 222 (with a content of peat: 5 %); pH 5.99 - 6.14 at test initiation, pH 5.39 - 5.90 at test termination; water content at test initiation: 57.8 % to 58.2 % of maximum water holding capacity (WHC), 57.1 % to 58.0 % of maximum WHC at test termination; temperature: 18.0 °C - 22.8 °C; photoperiod: 16 hours light : 8 hours dark; light intensity: 680 lux; feeding with horse manure.

Statistics: Descriptive statistics. Fisher’s Exact test with Bonferroni correction for mortality, Dunnett’s t-test for weight change and reproduction (α = 0.05), Probit analysis for determination of LC_{50}.

Results and Discussion

BAS 656 12 H showed statistically significant effects on mortality in the two highest test concentrations, *i.e.* 160 and 320 mg as/kg dry soil (Fisher’s Exact test with Bonferroni correction, α = 0.05, one-sided greater). The mortality of adult worms ranged between 0 % and 100 % in the treatment groups and was 0 % in the control group. Statistically significant effects on worm weight of *Eisenia fetida* were determined at tested concentrations of 80 and 160 mg as/kg dry soil (Dunnett’s t-test, α = 0.05, one-sided smaller). The weight change of adult worms was between -30.2 % and 41.2 % in the treatment group and 44.0 % in the control group. The reproduction rate was statistically significantly different compared to the control at the concentrations of 40, 80, 160 and 320 mg as/kg dry soil (Dunnett’s t-test, α = 0.05, one-sided smaller). In the highest test concentration (320 mg as/kg dry soil), no data of weight change and reproduction could be determined as the mortality was 100 %.

The feeding activity of adult worms was reduced at 80, 160 and 320 g as/kg dry soil, compared to the control treatment. The results are summarised in the following table.

Table B.9.7-2: Effects of BAS 656 12 H on earthworm (*Eisenia fetida*) in a 56-day reproduction study

BAS 656 12 H [mg as/ kg dry soil]	**Control**	**20**	**40**	**80**	**160**	**320**
Mortality (28 d) [%]	0	0	0	0	17.5 **	100 **
Weight change (28 d) [%]	44.0	41.2	35.5	22.0 *	-30.2 *	--
Number of juveniles (56 d)	61.3	54.0	16.0 *	0 *	0 *	--
Reproduction (56 d) [% of control]	100	88.2	26.1	0	0	--
	Endpoints [mg as/kg dry soil]					
$NOEC_{weight\ change}$ (28 d)	40					
$NOEC_{reproduction}$ (56 d)	20					

* = statistically significantly different compared to the control (Dunnett’s -t-test, α = 0.05, one-sided smaller).
** = statistically significantly different compared to the control (Fisher’s Exact test with Bonferroni correction, α = 0.05, one-sided greater).

Conclusion

The study is acceptable.
Agreed endpoint: NOEC = 20 mg as/kg dw (reproduction), corresponding to 31 mg BAS 656 12 H/kg dry soil. LC_{50} = 192.9 mg as/kg dry soil. The test substance was incorporated in artificial soil (5 % peat).

B.9.7.1.3 Earthworms – field studies

No studies submitted, not required.

B.9.7.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

B.9.7.2.1 Species level testing

KCP 10.4.2.1/1 Friedrich, 2010b (new study, submitted with the renewal dossier)

Author:	Friedrich, S.
Title:	Effects of BAS 656 12 H on the reproduction of the collembolans *Folsomia candida*
Date:	11.11.2010; amended 30.09.2013
Doc ID:	10 10 48 086 S; BASF RegDoc# 2010/1068966 + Amendment BASF RegDoc# 2013/1335427
Guidelines:	OECD 232 (2009), ISO 11267 (1999)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 656 12 H, FRE-000601; content of as: dimethenamid-P (BAS 656P H, Reg. no. 363 851): 720 g/L (722.7 g/L analysed); density: 1.119 g/cm³.

Test species: Collembola (*Folsomia candida)*, age: 9 - 12 days; source: in-house culture.

Test design: 28-day test in treated artificial soil according to OECD 232 and ISO 11267; different concentrations of the test item were homogenously mixed into artificial soil (5 % peat) and filled in glass vessels before collembolans were introduced on top of the soil. 6 treatment groups (5 test item concentrations, control) were set up with 4 replicates for the test item treatments and 8 replicates for the control, each containing 10 collembolans.
Assessment of adult mortality and reproduction and behavioural effects was carried out after 28 days.

Endpoints: Mortality and reproduction rate after 28 days (NOEC, LC_{50}, EC_{50}).

Reference item: Boric acid (100 % analysed) The effects of the reference item were investigated in a separate study.

Test rates: Control, 18.75, 37.5, 75, 150 and 300 mg BAS 656 12 H/kg dry soil.

Test conditions: Artificial soil according to OECD 232 (with a reduced peat content of 5 %); pH 6.14 - 6.18 at test initiation, pH 5.97 - 6.21 at test termination; water content at test initiation 58.7 % - 58.9 % of maximum water holding capacity (WHC) and 57.5 - 58.2 % of maximum WHC at test termination; temperature: 18.5 °C - 21.7 °C; photoperiod: 16 h light : 8 h dark; light intensity: 750 lux; food: approximately 2 mg dry yeast at the start of the test and after 14 days.

Statistics: Descriptive statistics; Fisher-Exact Binominal Test for mortality ($\alpha = 0.05$, one-sided greater), Dunnett's t-test for reproduction ($\alpha = 0.05$, one-sided smaller), Probit analysis for determination of LC_{50} and EC_{50}.

Results and Discussion

A mortality of 5.0 % was observed in the control group compared to 2.5 % - 92.5 % mortality in the test item treatments. Statistically significant effects on mortality were observed at 75, 150 and 300 mg test item/kg dry soil (Fisher`s Exact Binominal Test, α = 0.05, one-sided greater). The mean reproduction in the untreated control reached 505.1 juveniles. The mean reproduction rates in the test item treatments ranged from 57.5 - 488.8 juveniles. Statistically significant effects on the number of juveniles compared to the control group were recorded at 37.5, 75, 150 and 300 mg BAS 656 12 H /kg dry soil (Dunnett's t-test, α = 0.05, one-sided smaller). The results are summarised in the following table.

Table B.9.7-1: Effect of BAS 656 12 H on collembola (*Folsomia candida*) in a 28-day reproduction study

BAS 656 12 H [mg/kg dry soil]	**Control**	**18.75**	**37.5**	**75**	**150**	**300**
Mortality [%]	5.0	2.5	5.0	35.0 *	55.0 *	92.5 *
No. of juveniles (day 28)	505.1	488.8	413.8 **	245.5 **	100.3 **	57.5 **
Reproduction in [%] of control	100	96.8	81.9	48.6	19.8	11.4
	Endpoints [mg/kg dry soil]					
$NOEC_{reproduction}$	18.75					
EC_{50}	76.5					
LC_{50}	120.8					

* Statistically significant differences compared to the control (Fisher's Exact Binominal test, α = 0.05, one-sided greater)
** Statistically significant differences compared to the control (Dunnett's t-test, α = 0.05, one-sided smaller).

Conclusion

The study is acceptable.
Agreed endpoint: NOEC = 18.75 mg/kg dw (reproduction). The LC_{50} and EC_{50} values were determined to be 120.8 and 76.5 mg BAS 656 12 H/kg dry soil, respectively. The test substance was incorporated in artificial soil (5 % peat).

B.9.7.2.2 Higher tier testing

No studies submitted, not required.

B.9.8 Risk assessment for non-target soil meso- and macrofauna

Table B.9.8-1: Proposed toxicity endpoints of soil meso- and macrofauna for use in risk assessment

Species	Test substance	Exposure System	Results	Reference
Earthworm acute				
Eisenia foetida	Dimethenamid-racemate	Acute, 14 d; 10 % peat	LC_{50} = 294.4 mg/kg dw	Van Dijk, A. 22.06.1988 204614*
Eisenia foetida	M 23	Acute, 14 d; 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ > 632 mg/kg dw[2)]	Krieg, W. 19.03.1998 47842*
Eisenia foetida	M 27	Acute, 14 d; 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ > 632 mg/kg dw[2)]	Krieg, W. 20.03.1998 47843*
Eisenia fetida	M 31	Acute, 14 d; 10 % peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr.}$ > 500 mg/kg dw[2)]	Krome, K. 26.09.2008 RRA 12620
Eisenia foetida	BAS 656 07 H [1)]	Acute, 14 d; 10 % peat	LC_{50} = 596.3 mg/kg dw (corresponding to 387 mg as/kg dw) [3)]	Krieg, W. 02.03.1999 49224 (BASF 99/10267)*
Earthworm chronic				
Eisenia foetida	Dimethenamid-P	Chronic; 5 % peat	NOEC = 25.4 mg as/kg dw Reproduction, biomass, mortality	Friedrich S. 06.11.2007 12 10 48 093 S; BASF RegDoc# 2012/1129456
Eisenia foetida	M 23	Chronic; 5 % peat	NOEC = 8.32 mg as/kg dw [5)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37431022; BASF RegDoc# 2007/1037731
Eisenia foetida	M 27	Chronic; 5 % peat	NOEC = 10.56 mg as/kg dw [5)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37421022; BASF RegDoc# 2007/1037732
Eisenia fetida	M 31	Chronic; 5 % peat	NOEC = 100 mg as/kg dw [5)] Reproduction, biomass, mortality	Lührs, U. 08.01.2009 46551022; BASF RegDoc# 2008/1070910
Eisenia foetida	BAS 656 12 H	Chronic; 5 % peat	NOEC = 80 mg as/kg dw (mortality); NOEC = 40 mg as/kg dw (biomass); **NOEC = 20 mg as/kg dw** (corresponding to 31 mg prod./kg dw) [4)] (reproduction)	Friedrich, S. 07.12.2010 10 10 48 085 S; BASF RegDoc# 2010/1068962

Species	**Test substance**	**Exposure System**	**Results**	**Reference**
Mesofauna chronic				
Folsomia candida	Dimethenamid-P	Chronic; incorporated, 5 % peat	**NOEC = 12.5 mg as/kg dw** mortality NOEC = 25 mg as/kg dw reproduction EC_{50} = 41.6 mg as/kg dw reproduction LC_{50} = 118.3 mg as/kg dw Mortality	Friedrich, S. 29.03.2011 11 10 48 015 S; BASF RegDoc# 2011/1000481S
Hypoaspis aculeifer	Dimethenamid-P	Chronic; incorporated, 5 % peat	NOEC = 1000 mg as/kg dw (mortality) NOEC = 500 mg as/kg dw (reproduction)	Schulz, L. 05.11.2012 12 10 48 097 S; BASF RegDoc# 2012/1129457
Folsomia candida	M 23	Chronic; incorporated, 5 % peat	NOEC = 200 mg as/kg dw [5)] (mortality, reproduction)	Friedrich, S. 18.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129536
Hypoaspis aculeifer	M 23	Chronic; incorporated, 5 % peat	NOEC = 200 mg as/kg dw (mortality) **NOEC = 100 mg as/kg dw** (reproduction)	Schulz, L. 20.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129538
Folsomia candida	M 27	Chronic; incorporated, 5 % peat	**NOEC = 200 mg as/kg dw** [5)] (mortality, reproduction)	Friedrich, S. 26.11.2012 12 10 48 105 S; BASF RegDoc# 2012/1129537
Hypoaspis aculeifer	M 27	Chronic; incorporated, 5 % peat	NOEC = 200 mg as/kg dw [5)] (mortality, reproduction)	Schulz, L. 20.12.2012 12 10 48 102 S; BASF RegDoc# 2012/1129539
Folsomia candida	M 31	Chronic; incorporated, 5 % peat	**NOEC = 200 mg as/kg dw** [5)] Mortality & reproduction	Friedrich, S. 13.01.2011 10 10 48 110 S; BASF RegDoc# 2011/1000222
Hypoaspis aculeifer	M 31	Chronic; incorporated, 5 % peat	NOEC = 500 mg as/kg dw [5)] (mortality, reproduction)	Schulz, L. 06.01.2014 13 10 48 113 S; BASF RegDoc# 2013/1103674
Folsomia candida	BAS 656 12 H	Chronic; incorporated, 5 % peat	NOEC = 18.75 mg prod./kg dw (reproduction) (corresponding to 12.1 mg as/kg dw) [4)]	Friedrich, S. 11.11.2010 10 10 48 086 S; BASF RegDoc# 2010/1068966 + Amendment BASF RegDoc# 2013/1335427

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003

1) Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H from the EU review of dimethenamid-P).

2) According to the EPPO risk assessment scheme the toxicity data from tests with artificial soil are divided by the factor of 2 because $logP_{OW}$ for the active substance is greater than 2 (No study on log P_{OW} of the metabolite has been provided by the applicant. According to the applicant´s dossier the log P_{OW} is >2).

3) Based on a nominal content of 720 g dimethenamid-P/L in BAS 656 07 H and a density of 1.11 g/cm^3.

4) Based on a nominal content of 720 g dimethenamid-P/L in BAS 656 12 H and a density of 1.119 g/cm^3.

5) Highest concentration testet.

The evaluation of the risk for earthworms and other soil macro-organisms was performed in

accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section B.8 (Environmental fate), Chapter 8.5.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for dimethenamid-P and its metabolite M 27 but for the metabolites M 23 and M 31.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for non-target arthropods from all other intended uses in groups 2-10 (see B.9.2).

The results of the risk assessment are summarised in the following table.

Table B.9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	**1-9**		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Dimethenamid-P	294.4	1.152	256
BAS 656 07 H	298.2 mg/kg dw[2]) (corresponding to 193.5 mg as/kg dw)	1.152	168
M 23	> 1264	0.1533*	8245
M 27	> 1264	0.179	7061
M 31	> 1000	0.1276*	7837
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lta} (criterion TER ≥ 5)**
Dimethenamid-P	25.4	1.152	22
BAS 656 12 H	20 mg as/kg dw	1.2 L/ha (corresponding to 1.152 mg as/kg dw)**	17
M 23	8.32	0.1533*	54
M 27	10.56	0.179	59
M 31	100	0.1534*	652
Chronic effects on other soil macro- and mesofauna, *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dimethenamid-P	12.5	1.152	11
BAS 656 12 H	18.75 mg prod./kg dw (corresponding to 12.1 mg as/kg dw)	1.2 L/ha (corresponding to 1.152 mg as/kg dw)	11
M 23	200	0.1533*	1304
M 27	200	0.179	1117
M 31	200	0.1534*	1303
Chronic effects on other soil macro- and mesofauna; *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dimethenamid-P	500	1.152	434
M 23	100	0.1533*	652
M 27	200	0.179	1117
M 31	500	0.1534*	3259

TER values shown in **bold** fall below the relevant trigger.
* PECsoil accu (pease refer to Section B.8 (Environmental fate), Chapter 8.5.2.
**Taking into account the density of BAS 656 12 H of 1.13 g/cm^3

B.9.8.1 Overall conclusions

Earthworms

TER values for earthworms were calculated, taking into account the relevant toxicity data for dimethenamid-P / BAS 656 12 H and calculated exposure concentrations in soil, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects and the acceptability criterion TER ≥ 5 for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

Other organisms of the soil macro- and mesofauna

TER values for other organisms of the soil macro- and mesofauna were calculated, taking into account the relevant toxicity data for dimethenamid-P / BAS 656 12 H and calculated exposure concentrations in soil, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The calculated TER values do achieve the acceptability criterion TER ≥ 5 for chronic effects (as adopted from the risk assessment for earthworms) on other organisms of the soil macro- and mesofauna, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for other organisms of the soil macro- and mesofauna due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

B.9.9 Effects on soil nitrogen transformation

No studies on the effect of the representative formulation BAS 656 12 H to soil nitrogen transformation were submitted with the renewal dossier. No studies with the active substance only were submitted. The study submitted in the initial monograph conducted with the racemate of dimethenamid was not considered valid in the initial monograph because no nitrification occurred. The risk assessment was based on a study submitted with BAS 656 07 H, a similar formulation to BAS 656 12 H which was the representative formulation of the initial assessment of dimethenamid-P.

To increase the transparency and comprehensibility of the overall assessment, the summary of the study with BAS 656 07 H, assessed with the initial evaluation of dimethenamid-P, has been added by the RMS. No new evaluation of the previously submitted study was performed.

KCP 10.5/1 Krieg, 1999 (study evaluated in the initial monograph, 2000)

Author:	Krieg, W.
Title:	Effects of BAS 656 07 H on the nitrogen turnover in soil.
Date:	1999
Doc ID:	49223; BMF1999-48; BASF RegDoc# 99/10134
Guidelines:	BBA part VI; 1990
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 656 07 H formulated product, batch # 98001, dimethenamid-P: 64 %.

Test system: Biologically active German agricultural soils: 1) loamy sand soil A (pH 6.8, 1.1 % org. C; Limburgerhof, Landwirtschaftliche Versuchsstation); 2) loamy sand soil B (pH

7.5, 1.7 % org. C; Limburgerhof, Bruch West).

Test design: NH_4-nitrogen formed from organically bound nitrogen and $N0_3$-nitrogen from the nitrification process was determined by using an ammonia-electrode and a nitrate-electrode, respectively; total incubation period 28 days.

Test rates: Control, 1.87 µL BAS 656 07 H per kg soil (= single application rate; corresponding to a field application rate of 1.4 L BAS 656 07 H per ha) and 9.33 µL BAS 656 07 H per kg soil (= 5-fold application rate; corresponding to an field application rate of 7.0 L BAS 656 07 H per ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3); Untreated control and positive control = N-Serve (nitrapyrin); 3 replicates/concentration.

Test conditions: Soil moisture: 43 - 44 % of its water holding capacity. Both soils were amended with lucerne meal (0.5 % of soil dry weight). Soil samples were incubated at 20 ± 2° C while stored in glass bottles. Sampling scheme: 0, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the measurement.

Statistics: Standard procedures.

Results and Discussion

No significant influences of the product on nitrogen turnover were observed in either soil and at either application rate. At the end of the study, after 28 days, the nitrate values of the treated variants deviated by less than 2 % from the untreated controls.

Table B.9.9-1: Effect on nitrogen turnover in a loamy sand soil A and a loamy sand soil B exposed to BAS 656 07 H after 28 days

Soil	% deviation from control	
	1.87 µL BAS 656 07 H per kg dry soil	9.33 µL BAS 656 07 H per kg dry soil
Loamy sand soil A	+1.7	+0.4
Loamy sand soil B	-0.5	-0.5

+ stimulation; - inhibition

Conclusion

The study is acceptable.
1.87 µL BAS 656 07 H per kg soil (= single application rate; corresponding to a field application rate of 1.4 L BAS 656 07 H per ha; 0.99 kg as/ ha) and 9.33 µL BAS 656 07 H per kg soil (= 5-fold application rate; corresponding to an field application rate of 7.0 L BAS 656 07 H per ha (4.93 kg as/ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3) caused no effects > 1.7 % on nitrogen turnover in a loamy sand soil.

B.9.10 Risk assessment for soil nitrogen transformation

The risk assessment is based on the SANCO/10329/2002 guidance document for terrestrial ecotoxicology. The outcome of the soil micro-organism test is directly assessed in terms of risk. According to Annex VI of 91/414/EEC the critical level is ± 25 % between treatment groups and controls after 100 days. The toxicity end points to be used in the risk assessment are displayed in table B.9.10-1.

Table B.9.10-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	28 d; loamy sand; clay silt	The study was evaluated in the initial DAR: Not valid because no nitrification occurred. 28 d (1x: $NH4^+$ +30.8 %, $NO3^-$ +42.9 %, total-N +36.4 %; 5 x: $NH4^+$ +27.5 %, $NO3^-$ +49.6 %, total-N +37.6 %	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451; BE-S-7-91-01-DEH-01; BMF1999-42; BMF96-00042; BASF DocID# 91/11908
C-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	Dehydrogenase activity; BBA 1-1 (C) 28 d loamy sand; clay silt	< 25 % 1.8 kg as/ ha and 9.0 kg as/ ha The study it is not considered valid anymore since platic bags are used.	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451; BE-S-7-91-01-DEH-01; BMF1999-42; BMF96-00042; BASF DocID# 91/11908 *(only the endpoint on C-mineralisation)
N-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 062 C; BASF RegDoc# 2008/1065116
C-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 062 N; BASF RegDoc# 2008/1065117
N-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 063 N; BASF RegDoc# 2008/1065119*
C-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 063 C; BASF RegDoc# 2008/1065118
N-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 064 N; BASF RegDoc# 2008/1065115
C-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 064 C; BASF RegDoc# 2008/1065109
N-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and **7.0 L prod./ha**	Krieg, W. 1999 49223; BMF1999-48; BASF RegDoc# 99/10134**[1)]

Endpoint	Substance	Exposure System	Results	Reference
			Equivalent to 0.99 **and 4.93 kg as/ha,** respectively	
C-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and **7.0 L prod./ha** equivalent to 0.99 and **4.93 kg as/ha**, respectively	Krieg, W. 1999 49222; BMF1999-49; BASF RegDoc# 99/10134 **1)

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
** Study evaluated in the initial monograph, 2000.
1) Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H from the EU review of dimethenamid-P).
2) 1.87 µL BAS 656 07 H per kg soil (corresponding to a field application rate of 1.4 L BAS 656 07 H per ha) and 9.33 µL BAS 656 07 H per kg soil corresponding to an field application rate of 7.0 L BAS 656 07 H per ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3).
Values in **bold** were chosen by RMS for risk assessment.

No valid study on N-transformation is available with the active substance dimethenamid-P. Studies submitted previously during the initial evaluation process of dimethenamid-P and dimethenamid (racemate) were considered not valid since no nitrification occurred.

The applicant used the study conducted with the formulation BAS 656 07 H (720 g as/L) as surrogate.

The uses have been grouped for the scenarios in BBCH 00-09 for maize (maize and sugar maize), soybean, sunflower, and sugar beet. The result is also covering the uses sugar beet BBCH 12-18 in terms of a risk envelope covering the uses sugar beet in BBCH 16-18, and sugar beet in BBCH 12-18 splitted in 2 or 3 applications.

Table B.9.10-2: Assessment of the risk for effects on soil micro-organisms due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	**1**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dimethenamid-P tested as formulation BAS 656 07 H	4.93 kg/ha	0.864 kg/ha	yes
M23	1.00 mg/kg	0.1533 mg/kg *	yes
M27	1.00 mg/kg	0.179 mg/kg	yes
M31	1.00 mg/kg	0.1276 mg/kg *	yes
BAS 656 07 H	7.0 L/ha	1.2 L/ha	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dimethenamid-P tested as formulation BAS 656 07 H	4.93 kg/ha	0.864 kg/ha	yes
M23	1.00 mg/kg	0.1533 mg/kg *	yes
M27	1.00 mg/kg	0.179 mg/kg	yes
M31	1.00 mg/kg	0.1276 mg/kg *	yes
BAS 656 07 H	7.0 L/ha	1.2 L/ha	yes

* PECsoil accu (pease refer to Section B.8 (Environmental Fate), Chapter 8.5.2.

B.9.10.1 Overall conclusions

Concentrations of dimethenamid-P metabolites M32, M27, M31, and the formulation BAS 656 07 H in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

B.9.11 Effects on terrestrial non-target higher plants

Two new studies on the effect of the representative formulation BAS 656 12 H to terrestrial non-target plants were submitted with the renewal dossier, one vegetative vigour study and one on seedling emergence.

To increase the transparency and comprehensibility of the overall assessment, summaries of the studies assessed with the initial evaluation of dimethenamid-P have been added by the RMS. No new evaluation of the previously submitted studies was performed.

B.9.11.1 Summary of screening data

KCP 10.6.1/1 Westphalen, 1999 (study evaluated in the initial monograph, 2000)

Author:	Westphalen, K.-O.
Title:	Herbicide tests of BAS 656 H (Dimethenamid) at plants in the greenhouse at post emergence application.
Date:	15.02.1999
Doc ID:	APRH 9903 (BASF 99/10374); PFL1999-16
Guidelines:	
GLP:	Yes
Validity:	Additional information

Material and Methods

Test substance: SAN 1289-Formulation (64 % S- dimethenamid).
Screening test: Post- emergence tests

Studies were submitted to determine efficacy of the herbicide BAS 656 H (Dimethenamid EC-Formulation) on higher plant species as applied under greenhouse conditions.

The herbicide BAS 656 H was applied post-emergence. For post-emergence tests, plants were cultivated in plastic pots of 8.6 cm diameter, containing loamy sand with about 1.2 % organic matter as the substrate. Test plants were sown and grown in the test pots up to heights of 2 to 18 cm, according to species, and then treated with the test compound in a spray chamber at a rate equivalent to 500, 250, 125, 62.5 and 31.3 g as/ha. The number of replicates was 1 and for comparison, four untreated control pots were included in each test. After the application, plants were kept at 18-27° C and their reaction to the individual treatments was assessed and recorded. The assessment of injury were expressed as a percentage relative to the untreated controls (Table B.9.11-1).

Results and Discussion

Table B.9.11-1: Phytotoxicity in [%] after application of different rates of BAS656 H

Species	500 [g as/ha]	250 [g as/ha]	125 [g as/ha]	62.5 [g as/ha]	31.3 [g as/ha]
Sommer wheat	-	0	0	0	0
Winter wheat	0	20	10	10	10
Zea mays	0	15	7	3	5
Glycine max	20	20	13	13	10
Chenopodium album	70	33	30	23	15
Sinapis alba	0	10	8	7	5

Results

6 species of 3 families were tested, most of them were Gramineae. Only the half (500 g as/ha) of the intended uses (1008 g as/ha) were tested. With that application rate only *Chenopodium album* showed high phytotoxic effects (70 %), calculated ER_{50} = 314 g as/ha.

Conclusion

The study is regarded as additional information. In a post-emergence screening test with 5 test rates effects > 50 % on phytotoxicity were observed for *Chenopodium album.* Only one replicate per treatment was evaluated.

KCP 10.6.1/2 Hoberg, 1997 (study evaluated in the initial monograph, 2000)

Author:	Hoberg, J. R.
Title:	SAN 1289H formulation - Determination of effects on seedling emergence and vegetative vigor of ten plant species.
Date:	30.01.1997
Doc ID:	96-12-6810; PFL1999-17; BASF RegDoc#97/5175
Guidelines:	EPA 122-1 and 123-1
GLP:	Yes
Validity:	Additional information

For the initial monograph, studies were submitted to determine effects of the herbicide SAN 1289H Formulation on seedling emergence and vegetative vigour of ten plant species (EPA 122-1 and 123-1).

Material and Methods

The plant species tested included four monocotyledons: corn (*Zea mays*), oat (*Avena sativa*), onion (*Allium cepa*) and perennial ryegrass (*Lolium perenne*); and six dicotyledons: cabbage (*Brassica oleracea*), cucumber (*Cucumis sativus*), lettuce (*Lactuca sativa*), soybean (*Glycine max*), tomato (*Lycopersicon esculentum*) and turnip (*Brassica rapa*). The seeds had not been pretreated with fungicides or insecticides. 5 test rates, 3 replicates for the control and each application rate per species.
The support medium consisted of washed, 20- to 40 mesh silica sand which was characterised as having a pH of 7.2 and an organic matter content of 0.23 %. The study was conducted within an environmental growth chamber designed to maintain the following conditions: an air temperature of 20 to 30° C, a relative humidity of ≥ 60 % and a photoperiod of 16 hours.

Results

Table B.9.11-2: Effects of SAN 1289H on seedling emergence of ten plant species

Species	NOEC [g as/ha]	EC_{25} [g as/ha]	EC_{50} [g as/ha]
Perennial Ryegrass	2.8	7.7	25
Lettuce	2.8	10.7	22
Turnip	5.3	12	50
Cucumber	11.1	12	44
Cabbage	22.4	31	109
Tomato	1.7	36	213
Soybean	22.4	64	190
Oat	43	69	160
Onion	91	157	430
Corn	202	520	1030

Table B.9.11-3: Effects of SAN 1289H on vegetative vigour of ten plant species

Species	NOEC [g as/ha]	EC_{25} [g as/ha]	EC_{50} [g as/ha]
Perennial Ryegrass	12.3	26	92
Cucumber	94	179	650
Lettuce	202	213	336
Onion	426	560	1120
Oat	415	680	1232
Turnsip	818	1064	1254
Cabbage	414	1064	> 1456
Tomato	818	1120	> 1456
Corn	1456	> 1456	> 1456
Soybean	1456	> 1456	> 1456

The seedling emergence parameter is more sensitive than the vegetative vigour one. In case of seedling emergence test the most sensitive species were perennial Rregrass EC_{50} 25 g as/ha (Gramineae), lettuce EC_{50} 22 g as/ha (Asteraceae), cucumber EC_{50} 44 g as/ha (Curcubitaceae) and turnip EC_{50} 50 g as/ha (Brassicaceae). Other species of Brassicaceae and Gramineae were less sensitive.
In case of vegetative vigour test the most sensitive species were perennial reygrass EC_{50} 92 g as/ha (Gramineae), lettuce EC_{50} 336 g as/ha (Asteraceae) and cucumber EC_{50} 650 g as/ha (Curcubitaceae).

Conclusion

The study is regarded as additional information. The formulation is not the representative formulation BAS 565 12 H. Seedling emergence: ER_{50} = 22 g as/ha; vegetative viguor: ER_{50} = 92 g as/ha.

KCP 10.6.1/3 N.N., (new study, to be submitted with renewal dossier)

Author: Unknown
Title: Unknown
Date: Unknown
Doc ID: Unknown; BASF RegDoc#2014/ 1101480
Guidelines: Unknown
GLP:
Validity: Additional information, subject to submission of the study; summary provided by the applicant in document N4 of the renewal dossier

Screening for biological activity

Material and Methods

BAS 656 12H, the active substance dimethenamid-P and different metabolites of dimethenamid-P were tested in a plant assay in the glasshouse using 4 monocot (*Bromus inermis; Echinochloa crus-galli, Setaria viridis, Lolium multiflorum*) and 2 dicot (*Geranium dissectum; Chenopodium album*) species. Test items were sprayed at rates corresponding to 43.2; 86.4; 172.8; 864 g as/ha). Each treatment was replicated 4-fold with several plants per treatment. After the spray application the plants were maintained inside a glasshouse.

Phytotoxicity was evaluated at 10 and 21 days after treatment.
For details please refer to Volume 3 CA B.9 of this RAR.

Results

Table B.9.11-4: Effects on phytotoxicity in [%] 21 d after application of different rates of BAS 656 12H

Test item application	g as/ha	*Bromus inermis*	*Echinochloa crus-galli*	*Setaria viridis*	*Lolium multiflorum*	*Geranium dissectum*	*Chenopodium album*
Pre-emergence	864	97	100	100	98	100	76
	172.8	97	98	100	98	96	48
	86.4	66	97	98	97	94	30
	43.2	15	88	95	80	83	20
	0 (control blank formulation)	0	0	0	0	0	0
Post-emergence	864	95	94	95	95	68	0
	172.8	50	93	90	86	55	0
	86.4	30	81	80	69	35	0
	43.2	5	70	61	28	18	0
	0 (control blank formulation)	0	0	0	0	0	0

Conclusion

The study has not been submitted yet and could therefore not have been evaluated in detail. Given the summary provided by the applicant in document N4 of the renewal dossier, BAS 656 12 H did show high effects in grasses as well as in broadleaf weeds, all indicating a rate-response relationship. Given the facts that 4 rates were tested with 4 replicates each, the test is deemed to give additional information which has to be considered in the risk assessment of the representative formulation BAS 656 12 H. Based on Probit analysis of phytotoxicity data, the calculated ER_{50} is 93.3 g as/ha following post emergence application and ER_{50} < 43.2 g as/ha following pre-emergence application, both for *Lolium multiflorum* treated with the active substance dimethenamid-P. For phytotoxicity of the formulation BAS 656 12 H in *Lolium multiflorum* the calculated ER_{50} = 63.3 g as/ha following post emergence application and ER_{50} < 43.2 g as/ha following pre-emergence application could be derived.

B.9.11.2 Testing on non-target plants

KCP 10.6.2/1 Marquardt, 2013a (new study, submitted with renewal dossier)

Author:	Marquardt, J.
Title:	BAS 656 12 H: A test to determine the effects on non-target plants
Date:	25.09.2013
Doc ID:	AS305; BASF RegDoc#2013/1134944
Guidelines:	OECD 208 (2006) - Seedling Emergence and Seedling Growth Test, EPA 850.4100
GLP:	Yes
Validity:	Not acceptable

Material and Methods

Test item: BAS 656 12 H, batch no. 0004701751; content of as: dimethenamid-P (BAS 656P H, Reg. no. 363 851): 707.8 g/L (nominal: 720.0 g/L); density: 1.119 g/cm³.

Test species: Oilseed rape *(Brassica napus)*, lettuce (*Lactuca sativa),* tomato (*Solanum lycopersicum*), green cabbage (*Brassica oleracea* var. *sabellica),* soya bean (*Glycine max*), carrot (*Daucus carota*), onion (*Allium cepa*), rye grass (*Lolium multiflorum*), wheat (*Triticum aestivum*) and corn (*Zea mays*).

Test design: Rate-response design; 6 treatments (5 test item rates, water treated control); 4 replicates per treatment, 1 or 2 pots per replicate depending on plant species, 5 or 10 seeds per replicate, depending on species; greenhouse cultivation; BAS 656 12 H was applied pre-emergence to the soil surface using a laboratory spray cabin in 200 L water/ha; assessments for seedling emergence, growth stage (BBCH code) and phytotoxicity were done 7, 14 and 21 days after application (DAA; ± 1 day), for lettuce 11, 18 and 25 DAA; at test termination, , plant height per plant and plant dry weight per replicate were determined for all species.

Endpoints: NOER, ER_{25}, ER_{50}.

Test rates:

Treatment	**Rate BAS 656 12 H [mL/ha]**	**Plant species**
0	0 (control)	all species
1	2.46	lettuce and rye grass
2	6.14	lettuce, tomato, green cabbage, carrot onion, rye grass and wheat
3	15.4	all species
4	38.4	all species
5	96	all species
6	240	oilseed rape, tomato, green cabbage, soya bean, carrot, onion, wheat and corn
7	600	oilseed rape, soya bean and corn

Test conditions: Temperatures between 24.3 °C and 27.5 °C, daily average; air humidity between 48 % - 61 %; photoperiod: 16 h light : 8 h dark, additional light when daylight was < 10 klx.

Statistics: Descriptive statistics, ANOVA followed by Dunnett's t-test, ER_x values were determined using a Probit-Model

Results and Discussion

The pre-emergence application of the test item BAS 656 12 H resulted in clearly treatment-related symptoms of phytotoxicity (average phytotoxicity score ≥ 5 % and/or symptoms in every replicate) for all tested plant species except of soya bean and corn. The most sensitive plant species in terms of phytotoxicity was lettuce with an NOER or 6.14 mL/ha. Adverse effects on seedling emergence were observed for carrot only. Adverse effects on plant height and plant dry weight were observed for all tested plant species with the exception of soya bean and corn. The lowest ER_{50} value in terms of plant height was determined for carrot with an ER_{50} value of 57.1 mL/ha. The most sensitive plant species in terms of plant dry weight was lettuce with an ER_{50} value of 28.6 mL/ha. The results are summarised in Table B.9.11-5 and Table B.9.11-6.

Table B.9.11-5: Effects of BAS 656 12 H on seedling emergence, phytotoxicity, plant height and plant dry weight 21 DAA (± 1 day; lettuce: 25 DAA)

Treatment [mL/ha]	Oilseed rape	Lettuce	Tomato	Green cabbage	Soya bean	Carrot	Onion	Rye grass	Wheat	Corn
Seedling emergence [% deviation from control]										
2.46	--	-9	--	--	--	--	--	--	--	--
6.14	--	-21	-3	-10	--	14	4	-6	5	--
15.4	-3	-21	19	-3	-17	18	18	6	8	-3
38.4	3	-12	16	-3	-8	14	-4	-6	-3	5
96	3	3	22	-8	-6	-4	18	-6	8	5
240	0	--	22	-10	3	-29	0	3	-8	5
600	-11	--	--	--	8	--	--	--	--	5
Phytotoxicity [% visual damages]										
Control	0	0	0	0	0	0	0	0	0	0
2.46	--	0	--	--	--	--	--	--	--	--
6.14	--	4	3	0	--	1	0	0	0	--
15.4	0	38	3	0	0	1	0	0	0	0
38.4	3	63	8	4	1	11	3	9	0	0
96	3	73	5	25	1	58	0	43	8	0
240	9	--	15	45	3	73	60	88	30	0
600	25	--	--	--	3	--	--	--	--	4
Plant height [% deviation from control]										
2.46	--	8	--	--	--	--	--	--	--	--
6.14	--	-4	-3	1	--	-14	8	-4	-3	--
15.4	-2	-14	-9	-7	-3	-16 *	0	-1	-5	2
38.4	-4	-26	-9	-14	-2	-38 *	-5	-15	-3	1
96	-8	-25	-13	-32 *	5	-64 *	-21	-49 *	-7 *	-1
240	-10	--	-16 *	-42 *	-2	-84 *	-41 *	-96 *	-23	0
600	-21 *	--	--	--	1	--	--	--	--	-4
Plant dry weight [% deviation from control]										
2.46	--	27	--	--	--	--	--	--	--	--
6.14	--	-21	-9	0	--	-22	43	-20	-8	--
15.4	-6	-38	-1	1	-9	-8	29	-16	-10	-2
38.4	-3	--61 *	-5	-7	-8	-34 *	31	-36 *	-12	-2
96	2	-69 *	-8	-24 *	-2	-73 *	0	-59 *	-10	-4
240	-8	--	-16	-40 *	-7	-93 *	-34	-97 *	-30 *	2
600	-34 *	--	--	--	-9	--	--	--	--	-8

* Statistically significant differences compared to the control (Dunnett`s t-test, α = 0.05).

Table B.9.11-6: NOER, ER_{25} and ER_{50} of BAS 656 12 H for phytotoxicity, seedling emergence, plant height and plant dry weight 21 DAA (± 1 day; lettuce: 25 DAA)

Endpoint [mL/ha]	Oilseed rape	Lettuce	Tomato	Green cabbage	Soya bean	Carrot	Onion	Rye grass	Wheat	Corn
Phytotoxicity										
NOER	96	6.14	15.4	38.4	≥ 600	15.4	96	15.4	38.4	≥ 600
Seedling emergence										
NOER	≥ 600	≥ 96	≥ 240	≥ 240	≥ 600	96	≥ 240	≥ 240	≥ 240	≥ 600
ER_{25}	> 600	> 96	> 240	> 240	> 600	311	> 240	> 240	> 240	> 600
ER_{50}	> 600	> 96	> 240	> 240	> 600	> 600	> 240	> 240	> 240	> 600
Plant height										
NOER	240	15.4	96	38.4	≥ 600	6.14	96	38.4	38.4	≥ 600
ER_{25}	> 600	67.4	> 240	78.1	> 600	20.5	127	57.3	268	> 600
ER_{50}	> 600	504	> 240	318	> 600	57.1	322	92.0	> 600	> 600
Plant dry weight (shoots above ground)										
NOER	240	6.14	≥ 240	38.4	≥ 600	15.4	96	15.4	96	≥ 600
ER_{25}	468	8.69	> 240	116	> 600	26.1	245	25.7	230	> 600
ER_{50}	> 600	28.6	> 240	341	> 600	54.2	> 600	61.4	> 600	> 600

Conclusion

The study is not acceptable for risk assessment.
The endpoint derived from the study is ER_{50} = 28.6 mL BAS 656 12 H/ha.
Although validity criteria are reached, the study is not acceptable due to the following shortcoming: For at least 12 days of the study, daytime temperature exceeds the limits, which is not in line with guideline specifications (temperature: 22 ± 10 °C). It is unclear whether the test substance is available. Therefore, the results of the study are questionable.

KCP 10.6.2/2 Marquardt, 2013b (new study, submitted with renewal dossier)

Author:	Marquardt, J.
Title:	BAS 656 12 H: A test to determine the effects on non-target plants
Date:	25.09.2013
Doc ID:	AS306; BASF RegDoc#2013/1134945
Guidelines:	OECD 227 July 2006, EPA 850.4150
GLP:	Yes
Validity:	Not acceptable

Material and Methods

Test item: BAS 656 12 H, batch no. 0004701751; content of as: dimethenamid-P (BAS 656P H, Reg. no. 363 851): 707.8 g/L (nominal: 720.0 g/L); density: 1.119 g/cm³.

Test species: Oilseed rape *(Brassica napus)*, lettuce (*Lactuca sativa),* tomato (*Solanum lycopersicum*), green cabbage (*Brassica oleracea* var. *sabellica),* soya bean (*Glycine max*), carrot (*Daucus carota*), onion (*Allium cepa*), rye grass (*Lolium multiflorum*), wheat (*Triticum aestivum*) and corn (*Zea mays*).

Test design: Dose response design; 6 treatment groups (5 treatment rates, water treated control); 5 replicates/treatment, 1 or 2 pots per replicate (plant species dependent); BAS 656 12 H was applied post-emergence at BBCH 12 - 14 using a laboratory spray cabin; applied water volume 200 L/ha. Following the application the plants were cultivated for 21 (± 1 day) days under greenhouse conditions. Assessments for phytotoxicity (e.g. chlorosis, necrosis) were done 7, 14 and 21 days after application (DAA, ± 1 day). Assessments of plant height were done 14 and 21 DAA (± 1 day). Plant dry weight was determined at study termination 21 DAA (± 1 day)

Endpoints: Plant dry weight, plant height, phytotoxicity, determination of NOEC, ER_{25} and ER_{50}.

Test rates:

Treatment	**Rate BAS 656 12 H [mL/ha]**	**Plant species**
0	0 (control)	all species
1	6.14	lettuce and rye grass
2	15.4	all species
3	38.4	all species
4	96.0	all species
5	240	all species
6	600	oilseed rape, tomato, green cabbage, soya bean, carrot, onion, wheat and corn

Test conditions: Greenhouse conditions, average temperature: 22.2 °C - 25.7 °C, daily average; average humidity: 53 % - 63 %; photoperiod: 16 h light: 8 h dark; additional light when outdoor illumination was less than 10 klx.

Statistics: Descriptive statistics, ANOVA followed by Dunnett's t-test, ER_x values were determined using a Probit-Model.

Results and Discussion

Treatment with BAS 656 12 H resulted in clearly treatment-related symptoms of phytotoxicity (average phytotoxicity score 5 % and/or symptoms in every replicate) for the tested plant species soya bean, carrot, rye grass, onion and wheat. The most sensitive plant species in case of phytotoxicity was soya bean with a NOER of 15.4 mL/ha. Adverse effects on plant height were assessed for the plant species green cabbage, carrot rye grass and wheat. The most sensitive species were carrot, rye grass and wheat with a NOER of 96 mL/ha. Furthermore, for carrot, rye grass and wheat adverse effects on plant dry weight were observed. The most sensitive plant species in case of plant dry weight was rye grass with an ER_{50} of 478 mL/ha.

The results are summarised in table B.9.11-7 and B.9.11-8.

Table B.9.11-7: Effect of BAS 656 12 H on phytotoxicity, plant height and plant dry weight 21 DAA (± 1 day)

Treatment [mL/ha]	Oilseed rape	Lettuce	Tomato	Green cabbage	Soya bean	Carrot	Onion	Rye grass	Wheat	Corn
Phytotoxicity [% visual damages]										
Control	0	0	0	0	0	0	0	0	0	0
6.14	--	0	--	--	--	--	--	0	--	--
15.4	0	0	0	0	1	2	2	0	0	0
38.4	0	0	0	0	5	4	1	0	0	0
96	0	0	0	0	11	18	2	5	0	1
240	0	1	0	0	18	34	0	12	16	0
600	0	--	0	2	36	50	5	--	17	1
Plant height [% deviation from control]										
6.14	--	-3	--	--	--	--	--	-3	--	--
15.4	1	4	-1	-2	4	-2	0	-7	-2	2
38.4	-2	0	-5	-3	3	3	7	-14 * 1)	0	1
96	-2	2	-6	-5	1	-5	3	-10	-5	-1
240	1	1	-9 *	-6	2	-16 *	0	-20 *	-16 *	-1
600	4	--	-4	-8 *	-14	-23 *	-2	--	-22 *	-5
Plant dry weight [% deviation from control]										
6.14	--	5	--	--	--	--	--	11	--	--
15.4	-2	4	-1	0	2	-4	-6	2	-4	4
38.4	2	-2	-13	-4	2	0	12	-11	-5	3
96	4	1	-14	-6	2	-16	-1	-19	-9	0
240	18	4	-18 *	-14	0	-18	-16	-35 *	-18 *	0
600	21 *	--	-13	-9	-9	-28 *	-18	--	-31 *	0

* Statistically significant differences compared to the control (Dunnett`s t-test, $\alpha = 0.05$).
1) The effect was considered to be not treatment-related.

Table B.9.11-8: NOER, ER_{25} and ER_{50} of BAS 656 12 H for phytotoxicity, plant height and plant dry weight 21 days after post-emergence application (± 1 day)

Endpoint [mL/ha]	Oilseed rape	Lettuce	Tomato	Green cabbage	Soya bean	Carrot	Onion	Rye grass	Wheat	Corn
Phytotoxicity										
NOER	≥ 600	≥ 240	≥ 600	≥ 600	15.4	38.4	240	38.4	96	≥ 600
Plant height										
NOER	≥ 600	≥ 240	≥ 600	240	≥ 600	96	≥ 600	96	96	≥ 600
ER_{25}	> 600	> 240	> 600	> 600	> 600	> 600	> 600	> 240	> 600	> 600
ER_{50}	> 600	> 240	> 600	> 600	> 600	> 600	> 600	> 240	> 600	> 600
Plant dry weight (shoots above ground)										
NOER	≥ 600	≥ 240	≥ 600	≥ 600	≥ 600	240	≥ 600	96	96	≥ 600
ER_{25}	> 600	> 240	> 600	> 600	> 600	435	> 600	138	402	> 600
ER_{50}	> 600	> 240	> 600	> 600	> 600	> 600	> 600	478	> 600	> 600

Conclusion

The study is not acceptable for risk assessment.
The endpoint derived from the study is ER_{50} > 240 mL BAS 656 12 H/ha.
Although validity criteria are reached, the study is not acceptable due to the following shortcoming: For all but 5 days of the study, temperature exceeds the limits, which is not in line with guideline specifications (temperature: 22 ± 10 °C). It is unclear whether the test substance is available. Therefore, the results of the study are questionable.

B.9.11.3 Extended laboratory studies on non-target plants

No studies submitted, not required.

B.9.11.4 Semi-field and field tests on non-target plants

No studies submitted, not required.

B.9.12 Risk assessment for terrestrial non-target higher plants

Table B.9.12-1: Endpoints and effect values relevant for the risk assessment for non-target plants

Species	Substance	Exposure System	Results	Reference
Avena fatua, m *Bromus tectorum, m* *Echinochloa crus-galli, m* *Setaria viridis, m* *Abutilon theophrasti, d* *Amaranthus retroflexus, d* *Sinapis alba, d* *Solanum nigrum, d*	M 23 and M 27	Pre- and post emergence 250 und 1000 g metabolite/ha Parent 0.16 g as/ha	no herbicidal effects (visual observation) ER_{50} >1000 g metabolite/ha ER_{50} >0.16 g as/ha	Kaethner, M. 30.01.1995 TDS-BS5094; PFL2002-227 and PFL2002-228*
Digitaria sanguinalis, m *Setaria viridis, m* *Lolium multiflorum, m* *Setaria faberi, m* *Echinocloa crus-galli, m* *Poa annua, m* *Capsella bursa-pastoris, d* *Chenopodium album, d* *Matricaria inodora, d* *Stellaria media, d*	M 31	21 d, pre-emergence screening, 684 and 1008 g as/ha	no herbicidal effects (visual observation) ER_{50} >1008 g metabolite/ha	Dutillie, H. and Sack, D. 26.09.2008 353446*
Bromus inermis, m *Echinochloa crus-galli, m* *Setaria viridis, m* *Lolium multiflorum, m* *Geranium dissectum, d* *Chenopodium album, d*	soil metabolites M656PH023, M656PH030, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH054, M656H055, the Na salt of M656PH027 and the ethylester derivate for M656PH062 parent dimethenamid-P BAS 656 12 H	21 d; Pre- and post emergence Blank formulation + 4 rates Blank formulation, 43.2; 86.4; 172.8, and 864 g ai / ha Blank formulation, 60, 120, 240, and 1200 mL prep. / ha	no herbicidal effects (visual observation) Effects on *Lolium multiflorum* based on phytotoxicity (at day 21): ER_{50} (SE) < 43.2 g as/ha (80 % effect) ER_{50} (VV) = 93.3 g as/ha (Probit analysis) ER_{50} (SE) < 43.2 g as/ha (96 % effect) ER_{50} (VV) = 62.3 g as/ha (Probit analysis)	N.N. (Document N4 of the dossier; Doc ID 2014/ 1101480) **(study can only be used subject to the submission of the document and to the evaluation by the RMS)**

Species	**Substance**	**Exposure System**	**Results**	**Reference**
Lactuca sativa; d *Zea mays; m* *Triticum aestivum; m* *Lolium multiflorum; m* *Allium cepa; m* *Daucus carota; d* *Glycine max; d* *Brassica oleracea; d* *Solanum sp.; d* *Brassica napus; d*	BAS 656 12 H	21 d Seedling emergence	ER_{50} = 28.6 mL BAS 656 12 H/ha Effects on *Lolium multiflorum* (at day 21) based on i) biomass: Probit analysis: ER_{50} (SE) = 61.4 mL prep./ha, corresponding to 44.2 g as/ha ii) phytotoxicity: 9 % at 38.4 mL prep./ha 43 % at 96 mL prep./ha 88 % at 240 mL prep./ha Probit analysis: ER_{50} (SE) = 264 mL prep./ha, corresponding to 190 g as/ha The results of the study are questionable due to increased temperature in the study. Other studies also indicate a lower endpoint.	Marquardt, J. 2013 2013/1134944*

Species	Substance	Exposure System	Results	Reference
Lactuca sativa; d *Zea mays; m* *Triticum aestivum; m* *Lolium multiflorum; m* *Allium cepa; m* *Daucus carota; d* *Glycine max; d* *Brassica oleracea; d* *Solanum sp.; d* *Brassica napus; d*	BAS 656 12 H	21 d Vegetative vigour	ER_{50} > 240 mL BAS 656 12 H/ha Effects on *Lolium multiflorum* (at day 21) based on i) biomass: Probit analysis: ER_{50} (SE) = 478 mL prep./ha, corresponding to 344 g as/ha ii) phytotoxicity: 5 % at 90 mL prep./ha, corresponding to 64.8 g as/ha 12 % at 240 mL prep./ha, corresponding to 173 g as/ha The results of the study are questionable due to increased temperature in the study. Also other studies indicate a lower endpoint.	Marquardt, J. 2013 2013/1134945*

m: monocotyledonous; d: dicotyledonous

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are there defined as non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for non-target terrestrial plants from all other intended uses in groups 2-10.

B.9.12.1 Tier-1 risk assessment (based on screening data)

Not relevant.

B.9.12.2 Tier-2 risk assessment (based on dose-response data)

Table B.9.12-2: Assessment of the risk for non-target plants due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	1-10			
Active substance/product	BAS 656 12 H			
Application rate (g/ha)	1 × 1.2 L prep./ha			
MAF	1			
Test species	**ER_{50} (mL prep./ha)**	**Drift rate**	**$PER_{off-field}$ (mL/ha)**	**TER criterion: TER ≥ 5**
Lactuca sativa	No adequate data available	2.77 %	33.24	

TER values shown in **bold** fall below the relevant trigger.
MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

B.9.12.3 Higher-tier risk assessment

Not relevant.

B.9.12.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table B.9-12-3: Risk assessment for non-target terrestrial plants due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		**1-9**			
Active substance/product		**BAS 656 12 H**			
Application rate		**1 × 1.2 L prep./ha**			
MAF		**1**			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (L prep./ha)**	**$PER_{off-field}$ 50 % drift red. (L prep./ha)**	**$PER_{off-field}$ 75 % drift red. (L prep./ha)**	**$PER_{off-field}$ 90 % drift red. (L prep./ha)**
1	2.77	33.24	16.62	8.31	3.33
5	0.57	6.84	3.42	1.71	0.684
10					
Toxicity value ER_{50} = No adequate data available		TER criterion: TER ≥ 5			
1					
5					
10					

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

B.9.12.5 Overall conclusions

TER values for non-target terrestrial plants could not be calculated due to lack of adequate toxicity data for BAS 656 12 H. The risk assessment for the representative formulation BAS 656 12 H could not be finalised.

B.9.13 Effects on other terrestrial organisms (flora and fauna)

No studies submitted.

B.9.14 Risk assessment for other terrestrial organisms (flora and fauna)

No studies submitted, not required.

B.9.15 References relied on

A search for open literature which included papers in peer-reviewed journals and reports from government and other agencies in the EU and several other countries was performed by the applicant. The literature search was done via databases such as PubMed, Agricola, and SciFinder using the key-word “Dimethenamid” or “Dimethenamid-P” and the CAS Numbers 87674-68-8 and 163515-14-8, respectively. The initial search was a net cast as wide as possible to ensure complete coverage of the literature. The references were then reviewed and, on the basis of the title and the abstract, a subset was retained for use in the characterisation. Priority was given to papers published since 2003 and, where possible, copies of these were obtained for more detailed review. No additional open-literature studies concerning ecotoxicology of dimethenamid-P were found helpful for risk assessment purposes.

For details please refer to the Appendix to Dimethenamid-P_RAR_11_Volume_3CA_B-9.

Data Point EU as of 2014	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N If yes, old data point
KCP 10.2	Brock T.C.M., Alix A., Brown C.D., Capri E., Gottesbue-ren B.F.F., Heimbach F., Lythgo C.M., Schulz R., Streloke M. eds.	2009	Linking Aquatic Exposure and Effects: Risk Assessment of Pesticides. SETAC Press\CRC Press, Boca Raton\Pensacola (FL), USA: 440 pp. Not GLP, published	N	N	New data for AIR3 renewal	LIT	N
KCP 10.2	Wang, W., Erzgräber, B. and Gottesbü-ren, B.	2010	EPAT – An Exposure Pattern Analysis Tool RIFCON GmbH Report No. R08270 Not GLP, published	N	N	New data for AIR3 renewal	LIT	N
KCP 10.2	Van Vlaardin-gen PLA, Traas TP, Wintersen AM, Aldenberg T.	2004	ETX 2.0. A program to calculate hazardous concentrations and fraction affected, based on normally distributed toxicity data. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 601501028/2004, 68 pp. GLP: No, published	N	N	New data for AIR3 renewal	LIT	N
KCP 10.2.1/1	[redacted]	1999 a	BAS 656 07 H. Acute toxicity study on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) in a static system (96 hours) 1999/10372 [redacted] GLP, unpublished	Y	N	Not applicable	BASF	KCP 10.2.1/1

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KCP 10.2.1/2	Jatzek, J.	1999	Determination of the acute effect of BAS 656 07 H on the swimming ability of the water flea *Daphnia magna* STRAUS according to GLP, EN 45001 and ISO 9002. 1999/10316 GLP, unpublished	N	Y	Not applicable	BASF	KCP 10.2.1/2
KCP 10.2.1/3	Reuschen-bach, P.	1999	Determination of the inhibitory effect of BAS 656 07 H on the cell multiplication of unicellular algae according to GLP, EN 45001 and ISO 9002. 1999/10315 GLP, unpublished	N	Y	Not applicable	BASF	KCP 10.2.1/3
KCP 10.2.1/4	Dohmen, G.P.	1999	Effects of BAS 656 07 H on the Aquatic Plant *Lemna gibba*. 1999/10314 GLP, unpublished	N	Y	Not applicable	BASF	KCP 10.2.1/4
KCP 10.3.2.1 /1	Fussell S.	2003	A rate-response laboratory test to determine the effects of BAS 656 08 H on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae) BASF-03-8; BASF RegDoc# 2003/1006351 Mambo-Tox Ltd., Southampton SO16 7PX, United Kingdom GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.5.1
KCP 10.3.2/1	Schuld M.	1999 a	BAS 656 07 H: Toxicity to the aphid parasitoid, Aphidius rhopalosiphi (Hymenoptera, Braconidae) 99010/01-NEAp, ANA1999-275 BASF RegDoc# 1999/10669 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1

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KCP 10.3.2/2	Kemmeter F.	1999 a	BAS 656 07 H: Toxicity to the staphylinid beetle, Aleochara bilineata GYLL. (Coleoptera, Staphylinidae) in the laboratory 99010/01-NLAb; ANA1999-277 BASF RegDoc# 1999/10856 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.3.2/3	Schmitzer S.	1999 a	Effects of BAS 656 07 H on the wolf spider Pardosa spec. (Araneae, Lycosidae) in the laboratory 5672065; ANA1999-276 BASF RegDoc# 1999/10751 Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.3.2.1/4	Kühner, C.	1998	BAS 656 07 H: Toxicity to the ground beetle, Poecilus cupreus L. (Coleoptera, Carabidae) in the laboratory. 98303/01-NLPc; ANA1999-147 BASF RegDoc# 98/11278 GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.3.2.1/1	Kühner, C.	1998	BAS 656 07 H: Toxicity to the aphid parasitoid, Aphidius rhopalosiphi (Hymenoptera, Braconidae) in the laboratory. 98303/01-NLAp; ANA1999-149 BASF RegDoc# 98/11333 GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1

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KCP 10.3.2.1 /3	Kühner, C.	1998	BAS 656 07 H: Toxicity to the green lacewing, Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) in the laboratory. 98303/02-NLCc; ANA1999-148 BASF RegDoc# 98/11334 GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.3.2.1 /2	Kühner, C.	1998	BAS 656 07 H: Toxicity to the predatory mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory. 98303/01-NLTp; ANA1999-146 BASF RegDoc# 98/11279 GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.4.1/3	Krieg, W.	1999	Effect of BAS 656 07 H on the mortality of the earthworm Eisenia foetida. 49224; ARW1999-47 BASF RegDoc# 1999/10267 GLP, unpublished	N	N	Not applicable	BASF	Y AIIIA-10.6.1.1
KCP 10.4.1.1 /1	Friedrich S.	2010	Sublethal toxicity of BAS 656 12 H to the earthworm Eisenia fetida in artificial soil with 5 % peat 10 10 48 085 S BASF RegDoc# 2010/1068962 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.1.2

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KCP 10.4.2.1/1	Friedrich S.	2010	Effects of BAS 656 12 H on the reproduction of the collembolans Folsomia candida 10 10 48 086 S BASF RegDoc# 2010/1068966 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.2
KCP 10.4.2.1/2	Friedrich S.	2013	Amendment No. 1 - Effects of BAS 656 12 H on the reproduction of the collembolans Folsomia candida 10 10 48 086 S BASF RegDoc# 2013/1335427 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.2
KCP 10.5/2	Krieg, W.	1999	Effects of BAS 656 07 H on the nitrogen turnover in soil. 49223; BMF1999-48 BASF RegDoc# 99/10134 GLP, unpublished BMF1999-48	N	N	Not applicable	BASF	Y AIIIA-10.5.1
KCP 10.6.1/4	Westpha-len, K.-O.	1999	Herbicide tests of BAS 656..H (dimethenamid) at plants in the greenhouse at post emergence application. APRH 9903 (BASF 99/10374) Not GLP, unpublished PFL1999-16	N	N	Not applicable	BASF	Y AIIIA-10.8
KCP 10.6.1/5	Hoberg, J. R.	1997	SAN 1289H formulation - Determination of effects on seedling emergence and vegetative vigor of ten plant species. Rep. No.: 96-12-6810 BASF RegDoc#97/5175 GLP, unpublished PFL1999-17	N	N	Not applicable	BASF	Y AIIIA-10.5.1

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KCP 10.6.2/1	Marquardt J.	2013	BAS 656 12 H: A test to determine the effects on non-target plants 2013/1134944 Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N
KCP 10.6.2/2	Marquardt J.	2013	BAS 656 12 H: A test to determine the effects on non-target plants 2013/1134945 Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N