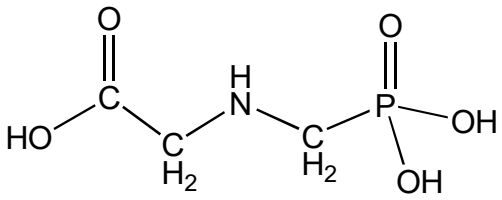
Miljø- og
Fødevareministeriet
Miljøstyrelsen

Fastsættelse af kvalitetskriterier for vandmiljøet

Glyphosat

CAS nr. 1071-83-6



Vandkvalitetskriterium	$VKK_{ferskvand}$	266 µg/l
Vandkvalitetskriterium	$VKK_{saltvand}$	26,2 µg/l
Korttidsvandkvalitetskriterium	$KVKK_{ferskvand}$	6.533 µg/l
Korttidsvandkvalitetskriterium	$KVKK_{saltvand}$	6.533 µg/l
Sedimentkvalitetskriterium	$SKK_{ferskvand}$	211,15 mg/kg tørvægt (ved 5% OC)
		4.223 mg/kg tørvægt x f_{oc}
Sedimentkvalitetskriterium	$SKK_{saltvand}$	21,115 mg/kg tørvægt (ved 5% OC)
		422,3 mg/kg tørvægt x f_{oc}

20. December 2019

Rev. September 2020

Opdateret: *Databladet er i juni 2024 opdateret i forhold til at tydeliggøre ved hvilket organisk kulstof (OC) indhold sedimentkvalitetskriterierne er bestemt ved.*

Indholdsfortegnelse

Forord

Et kvalitetskriterium i vandmiljøet er det højeste koncentrationsniveau, ved hvilket der skønnes, at der ikke vil forekomme uacceptable negative effekter på vandøkosystemer.

Miljøstyrelsen (MST) udarbejder kvalitetskriterier for kemikalier i vandsøjlen (vandkvalitetskriterium), i sediment og i dyr og planter (biota).

Miljøstyrelsen bruger kvalitetskriterierne som det faglige grundlag til at kunne fastsætte miljøkvalitetskrav, hvorved der forstås den endelige koncentration af et bestemt forurenende stof i vand, sediment eller biota, som ikke må overskrides af hensyn til beskyttelsen af miljøet og menneskers sundhed.

Metodikken, der anvendes til udarbejdelse af miljøkvalitetskrav er harmoniseret i EU og baserer sig på vandrammedirektivet (EU, 2000), EU's vejledning til fastsættelse af kvalitetskriterier i vandmiljøet (EU, 2011; 2018) og Miljøstyrelsens vejledning til fastsættelse af vandkvalitetskriterier (Miljøstyrelsen, 2004). Metodikken er endvidere i overensstemmelse med EU's vejledning til risikovurdering under REACH forordningen (EU, 2008).

Miljøstyrelsen har haft mulighed for at kommentere et udkast til databladet inden den endelige udgave.

Den sidste litteratursøgning er foretaget den 9.10.2019.

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English Summary and conclusions

This review is based on validated data from the EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate published in the EFSA Journal 13(11), 4302 in 2015. The data from the EFSA report was also checked against the ECHA (2016) report; CLH report. Proposal for Harmonised Classification and Labelling. Based on Regulation (EC) no 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance name: N-(phosphonomethyl)glycine; Glyphosate (ISO), published in May 2016. Another data source is the Canadian Council of Ministers of the Environment report: Canadian water quality guidelines for the protection of aquatic life: Glyphosate, published in 2012.

Based on these data sources we discerned the following conclusions in light of the EU technical guidance document (EU, 2011) for glyphosate:

$EQS_{freshwater}$ = 266 µg/L

$EQS_{saltwater}$ = 26.6 µg/L

$MAC_{salt- and freshwater}$ = 6,533 µg/L

$EQS_{sediment, freshwater}$ = 211.15 mg/kg dry weight (with 5% organic content (OC))

4,223 mg/kg dry weight x f_{oc}

$EQS_{sediment, marine}$ = 21.115 mg/kg dry weight (with 5% OC)

422.3 mg/kg dry weight x f_{oc}

EQS_{biota} = Not relevant

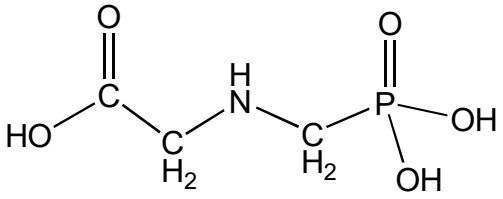
$EQS_{human helath}$ = Not relevant

Glyphosate has the following hazard notifications: H318; H411; H373; P273; P305 + P351 + P338 + P310; P391; P501; GHS09; GHS05.

1 Indledning

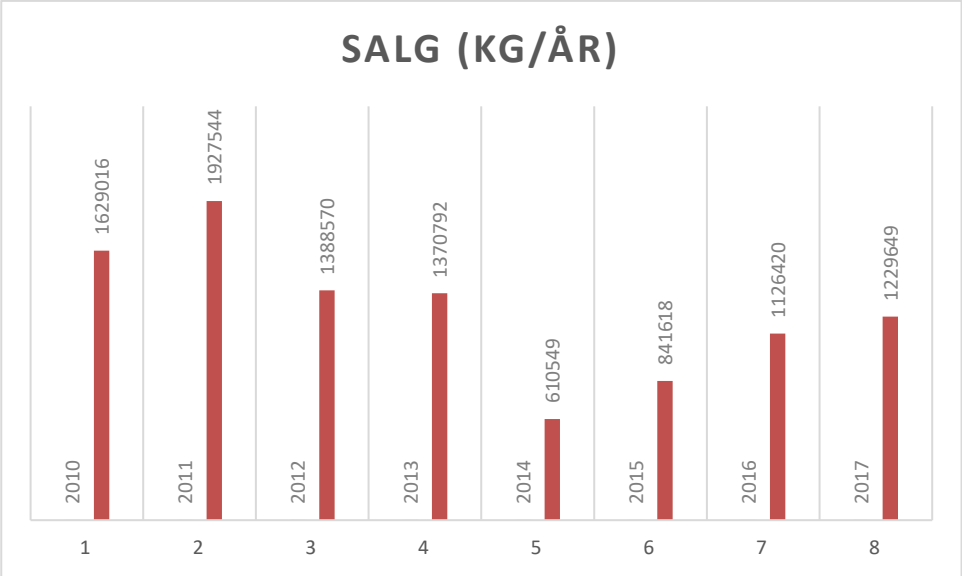
Identiteten af glyphosat fremgår af tabel 1.1.

Tabel 1.1. Identitet af glyphosat

IUPAC navn	2-(phosphonomethylamino)acetic acid
Strukturformel	
CAS nr.	1071-83-6
EINECS nr.	213-997-4
Kemisk formel	$C_3H_8NO_5P$
SMILES	C(C(=O)O)NCP(=O)(O)O

I dette dokument beskrives udelukkende stoffet glyphosat og ikke formuleringer eller nedbrydningsprodukter. Der anvendes heller ikke data på andre stoffer end glyphosat. Glyphosat er et bredspektret herbicid og hører under organofosfat-pesticiderne. Glyphosat blokerer syntesen af aromatiske aminosyrer ved at inhibere enzymet 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), og dræber derved planter. Nedenfor i figur 1.1 ses den solgte mængde i Danmark fra 2010 til 2017 ifølge Miljøstyrelsens bekæmpelsesmiddelstatistik[1]. Figur 1.1 viser et nogenlunde stabilt salg siden 2010 på omkring 1 million kg/år i Danmark.

[1] https://www2.mst.dk/Udgiv/publikationer/2019/03/978-87-7038-053-9.pdf



Figur 1.1: Salg af glyphosat i Danmark 2010-2017.

Glyphosats godkendelse til anvendelse i EU blev sidst fornyet i 2017, for en femårig periode[2]. I april 2019 blev der nedsat en arbejdsgruppe bestående af Frankrig, Holland, Sverige og Ungarn ("Assessment Group on Glyphosate, AGG"), der skal udarbejde en vurdering af glyphosat som grundlag for stillingtagen til fornyelse af glyphosats godkendelse i 2022.

I udarbejdelsen af miljøkvalitetskriterier for glyphosat benyttes primært data, der er godkendt af myndigheder i Europa (EFSA, 2015 og ECHA, 2016) suppleret med data, der er godkendt af det canadiske miljøministerium (Canada WQC, 2012). Desuden er der trukket samtlige data fra USEPA Ecotox database for perioden 2015-2019 angående glyphosat, som supplerende information (Bilag B).

[2] https://ec.europa.eu/food/plant/pesticides/glyphosate_en

2 Fysisk kemiske egenskaber

De fysisk kemiske egenskaber for glyphosat fremgår af tabel 2.1.

Tabel 2.1. Fysisk kemiske egenskaber for glyphosat.

Parameter	**Værdi**	**Reference**
Molekylevægt, M_w ($g \cdot mol^{-1}$)	169,1	EFSA (2015)
Smeltepunkt, T_m (ºC)	189	EFSA (2015)
Kogepunkt, T_b (ºC)	200	Ikke relevant; nedbrydes ved temperaturer over 200 grader (EFSA, 2015)
Damptryk, P_v (Pa) (20 ºC)	$1{,}31 \times 10^{-5}$	EFSA (2015)
Henry's konstant, H ($Pa \cdot m^3 \cdot mol^{-1}$)	$2{,}1 \times 10^{-7}$	EFSA (2015)
Vandopløselighed, S_w ($g \cdot L^{-1}$)	10,5	EFSA (2015)
Dissociationskonstant, pK_a	pKa_1= 2,34 pKa_2= 5,73	EFSA (2015)
Octanol/vand fordelingskoefficient, log K_{ow}	-3,2	EFSA (2015)
Log K_{oc} ($L \cdot kg^{-1}$)	4,20	EFSA (2015)

3 Skæbne i miljøet

3.1 Nedbrydelighed

Tolv eksperimenter med glyphosat-nedbrydning under aerobe forhold blev vurderet i EFSA's risikovurdering (EFSA, 2015). De viser, at glyphosat udviser en lav til meget høj persistens i jord. Nedbrydning af glyphosat i jord under anaerobe forhold blev undersøgt i tre jordarter, hvor glyphosat udviste høj til meget høj persistens ($DT_{50, anaerob}$ = 135 til > 1000 dage).

Fotolyse øger ikke signifikant nedbrydningen af glyphosat på jordoverfladen (EFSA, 2015). Halveringstiden af glyphosat i vand udsat for naturligt sollys var DT_{50} = 33 dage (pH 5), DT_{50} = 69 dage (pH 7) og DT_{50} = 77 dage (pH 9), mens der ikke skete nogen nedbrydning i mørke (ECHA, 2016).

Glyphosat er stabilt over for hydrolyse i intervallet for miljømæssigt relevante pH værdier, dvs. pH 5-9 (EFSA, 2015; ECHA, 2016).

Glyphosat er ikke let bionedbrydeligt i henhold til de tilgængelige studier (OECD 301 F og OECD 302B; OECD 1992a og OECD 1992b), som er benyttet i EFSA-rapporten (2015). Undersøgelser af glyphosatnedbrydning i vandmiljøet viste, at up til 61% af glyphosat (målt med radioaktivitet) blev bundet i sediment. Stabiliteten i disse systemer varierede meget, fra moderat til høj persistens (EFSA, 2015). Der blev identificeret to glyphosat-metabolitter: Den dominerende metabolit var aminomethyl phosphonic acid (AMPA), med op til ca. 16%, mens metabolitten hydoxymethyl phosphonic acid (HMPA) udgjorde max 10% (begge målt med radioaktivitet) (EFSA, 2015). Næsten halvdelen af glyphosat forblev bundet i sediment efter endt forsøg, i ikke-ekstraherbar form (EFSA, 2015).

3.2 Bioakkumulering

Stoffet har en lav log Kow værdi på -3.2 og forventes derfor ikke at bioakkumulere. BCF er målt til 1.1 (±0.61 SD) i ferskvandsfisk (*Lepomis macrochirus*) og det konkluderes derfor at bioakkumuleringspotentialet for glyphosat i akvatiske organismer er lavt (EFSA, 2015).

3.3 Naturlig forekomst

Glyphosat er ikke naturligt forekommende.

4 Giftighedsdata

4.1 Giftighed over for vandlevende organismer

Data benyttet i nærværende analyse er udelukkende data for glyphosat (CAS# 1071-83-6) og ikke fx nedbrydningsprodukterne AMPA, HMPA eller formuleringer som fx MON 52276. Der foreligger forbavsende få økotoksikologiske ferskvands- og saltvandsdata for glyphosat i de internationale databaser (USEPA OPP og USEPA ECOTOX), og de fleste af disse er af ældre dato og baseret på nominelle koncentrationer. Desuden foreligger der en hel del studier på forskellige formuleringer af Round-Up – men ganske få på selve stoffet. Fx i USEPA OPP (bilag B, tabel 2) findes et akut *Daphnia magna* studie; tre resultater for akut-toksikologiske fisketest og resultater for fem forskellige alger – alle af ældre dato.

I 2015 udgav EFSA *Conclusion on the peer-review of the pesticide risk assessment of the active substance glyphosate*[3], som indeholder giftighedsdata over for vandlevende organismer (EFSA, 2015). Dette dokument er den primære datakilde i nærværende analyse af stoffet. I 2012 udgav det canadiske miljøministerium deres analyse af stoffets giftighedsdata, som også indgår i nærværende SSD analyse (se afsnit 6.1) og kan findes i rapporten *Canadian Water Quality Guidelines for the Protection of Aquatic Life* (Canada WQC, 2012)[4]. Vi basere vores analyser på data som er valideret af EFSA og det canadiske miljøministerium i udledningen af kvalitetskriterier for glyphosat publiceret i 2012 og 2015. Vi har desuden opdateret litteratursøgningen fra 2019-2019 i bilag B, tabel 1, disse studier har en lav Klimisch og CRED score og indgår ikke i analyserne. Nedenfor i tabel 4.1.1 er samlet E(L)Cx og NOEC værdier for arter rapporteret i EFSA (2015). De samme studier indgår også i ECHA (2016).

[3] https://www.efsa.europa.eu/en/efsajournal/pub/4302
[4] https://www.ccme.ca/en/search.html?keywords=glyphosate&submit=&search=

Tabel 4.1.1. Akutte og kroniske giftighedsværdier for ferskvands- og saltvandsarter rapporteret i EFSA (2015). b: biomasse; r: vækstrate. Alle koncentrationer er nominelle koncentrationer.

Arter / Species	ECx	mg/L	Eksponeringstid	Endpoint
Alger				
Anabaena flos-aqua	$E_bC_{50;}$ $E_rC_{50;}$ NOErC	8,5; 22; 12	72 timer	Biomasse; vækst; NOErC
Skeletonema costatum[1]	E_bC_{50}; E_rC_{50}; NOErC	11; 18; 1,82	72 timer	Biomasse; vækst; NOErC
Pseudokirchneriella subcapitata	E_bC_{50}; E_rC_{50}; NOErC	18; 19; 10	72 timer	Biomasse; vækst; NOErC
Planter				
Lemna gibba	NOEC; EC_{50}	1.5; 12	14 dage	Vækst inhib.
Myriophyllum aquaticum	NOEC; EC_{50}	5; 12,3	14 dage	Vækst inhib.
Dafnier				
Daphnia magna	LC_{50}	40	48 timer	Akut dødelighed
Daphnia magna	$NOEC_{repro}$	12,5	21 dage	Reproduktion
Fisk				
Oncorhynchus mykiss[1]	LC_{50}	38	96 timer	Akut dødelighed
Lepomis macrochirus	LC_{50}	47	96 timer	Akut dødelighed

Danio rerio	LC_{50}	123	96 timer	Akut dødelighed
Cyprinus carpio	LC_{50}	> 100	96 timer	Akut dødelighed
Pimephales promelas	NOEC	25,7	255 dage	Vækst inhib.
Oncorhynchus mykiss[1]	NOEC	9,6	85 dage	Vækst inhib.
Brachydanio rerio (larvae)	NOEC	1	168 timer	Vækst inhib.

[1] Saltvandsarter

Nedenfor i tabel 4.1.2 fremgår de akutte toksicitetsdata fra Canada, som også indgår i SSD-analyserne (Canada WQC, 2012).

Tabel 4.1.2: Akutte toksicitetsværdier for ferskvands- og saltvandsarter (Canada WQC, 2012)

Art	Endpoint	Koncentration (mg/L)
Fisk		
Italurus punctatus	96 t LC_{50}	30*
Lepomis macrochirus	96 t LC_{50}	67,4*
Oncorhynchus gorbuscha[1]	96 t LC_{50}	56,7*
Oncorhynchus keta[1]	96 t LC_{50}	42,4*
Oncorhynchus kisutch[1]	96 t LC_{50}	73,2*
Oncorhynchus mykiss[1]	96 t LC_{50}	68,5*
Oncorhynchus tshawytscha[1]	96 t LC_{50}	66,7*
Pimephales promelas	96 t LC_{50}	56,6*
Invertebrater		
Ceriodaphnia dubia	48 t LC_{50}	147
Chironimus plumosus	48 t LC_{50}	23,4*
Daphnia magna	48 t LC_{50}	114,7*
Daphnia pulex	48 t LC_{50}	43,7*
Gammerus pseudolimnaeus	48 t LC_{50}	51,0*
Hyalla azteca	48 t LC_{50}	144,6*
Alger		
Pseudokirchneriella subcapitat	24 t EC_{50} vækst	270

*Geometrisk gennemsnit; 1: Saltvandsart

Tabel 4.1.3 indeholder de kroniske toksicitetsværdier fra den canadiske rapport som det canadiske miljøministerium benyttede til deres SSD-analyse.

Tabel 4.1.3: Kroniske toksicitetsværdier for ferskvands- og saltvandsarter (Canada WQC, 2012)

Art	Endpoint	Koncentration (mg/L)
Fisk		
Oncorhynchus kisutch[1]	21 d NOEC	130
Oncorhynchus mykiss[1]	7 d NOEC (klæk)	150
Pimephales promelas	255 d NOEC	27,5
Invertebrater		
Ceriodaphnia dubia	7 d NOEC	65
Daphnia magna	21 d MATC	10,5*
Hyalla azteca	14 d IC10 (dw)	20,5
Pseudosuccinea columella	12 d MATC	3,2*
Planter/alger		
Anabanea flosaqua	5 d NOEL	12
Chlorella pyreniodosa	96 t EC_{50} (vækst)	3,5
Chlorella vulgaris	96 t EC_{50} (vækst)	4,7
Lemna gibba	14 d NOEL	1,6*
Myriophyllum sibiricum	14 d IC10 (vækst)	1,5
Navicula pelliculosa	5 d NOEL	1,8
Potamogeton pectinatus	28 d MATC (vækst)	3,2*
Pseudokirchneriella subcapitat	5 d NOEL	10
Scenedesmus actus	96 d MATC (pop)	2,8*
Scenedesmus obliquus	96 t EC_{50} (vækst)	55,9
Scenedesmus quadricauda	96 d MATC (pop)	1,1*

*Geometrisk gennemsnit; 1: Saltvandsart

En gennemgang af litteraturen for perioden 2015-2019 resulterede i fem artikler i USEPA Ecotox databasen, som indeholder data på glyphosat, med henblik på at opdatere analyserne ovenfor med hensyn til akvatiske og sedimentlevende organismer. Disse data er naturligvis ikke indeholdt i EFSA-rapporten fra 2015 eller den canadiske WQC rapport fra 2012 og er derfor ikke kvalitetsvurderet af EFSA eller de canadiske myndigheder. De er derfor heller ikke indeholdt i SSD-analyserne i afsnit 6.1. Se bilag B, tabel 1, for disse data, som også indeholder en Klimisch og CRED score for hvert studie, som understreger hvorfor de ikke bør indgå i analysen.

Til beregning af VKK med en deterministisk tilgang vil den akutte toksicitetsværdi for glyphosat være *Oncorhynchus mykiss* LC_{50} = 38 mg/L og den kroniske toksicitetsværdi vil være *Brachydanio rerio* NOEC = 1 mg/L, baseret på EFSA-rapporten (2015).

4.2 Giftighed over for sedimentlevende organismer

Der er ikke sediment-toksicitetsværdier i EFSA-rapporten (2015) og heller ikke i rapporten fra ECHA (2016). Den canadiske rapport (2012) har følgende giftighedsværdier for sedimentlevende eller sediment-aktive (frøer) dyr (tabel 4.2).

Tabel 4.2: Toksicitetsværdier for sedimentlevende organismer i fersk- og saltvandsarter (Canada WQC, 2012)

Arter / Species	ECx	mg/L	Eksponeringstid	Endpoint

Amfibier				
Crinia insignifera	LC_{50}	78	96 timer	Akut dødelighed
*Litoria moorei**	LC_{50}	11,6	96 timer	Akut dødelighed
Rana clamitans	LC_{50}	38,9	96 timer	Akut dødelighed
Chaperina fusca	EC_{50}	377	24 timer	Reproduktion
Invertebrater				
Chironomus plumosus	EC_{50}	13	48 timer	Akut dødelighed
Gammarus pseudolimnaeus	EC_{50}	62	48 timer	Akut dødelighed
*Mysidopsis bahía**	EC_{50}	40	96 timer	Akut dødelighed
Hyalla azteca	IC_{50}	20,5	14 dage	Biomasse
Pseudosuccinea columella	NOEC	1	12 dage	Reproduktion

*Saltvandsart

4.3 Giftighed over for pattedyr og fugle

Tabel 4.3 viser glyphosats akutte og kroniske giftighed over for pattedyr og fugle, som følge af oral optagelse.

Tabel 4.3. Giftighedsværdier for pattedyr og fugle (EFSA, 2015).

Arter / Species	**ECx**	**mg/kg lgv./dag**	**Eksponeringstid**	**Endpoint**
Fugle				
Bobhvid vagtle	LD_{50}	4334	Akut	Dødelighed
Bobhvid vagtle	LD_{50}	>5200	Kortidstoksicitet	Dødelighed
Bobhvid vagtle	na	96,3	Langtidstoksicitet	na
Græsand	na	125,3	Langtidstoksicitet	na
Pattedyr				
Rotte	LD_{50}	>2000	Akut	Dødelighed
Rotte	na	197	Langtidstoksicitet	na
Kanin	na	50	Langtidstoksicitet	na

ECHA (2016) rapporterer følgende værdier, baseret på maternal toksicitet (kanin): NOAEL = 50 mg/kg lgv./d; LOAEL = 150 mg/kg lgv./d[5]. Effekter på næste generations udvikling blev kun fundet, hvor der også var maternal toksicitet. Den resulterende langtids NOAEL er ifølge ECHA (2016) for pattedyr ud fra data ovenfor bestemt til 100 mg/kg lgv./d.

4.4 Giftighed over for mennesker

Glyphosat har en lav human toksicitet med en generel ADI = 0,5 mg/kg lgv./d og en operatør-værdi udtrykt som AOEL = 0,1 mg/kg lgv./d (EFSA 2015). En vurdering af glyphosat (og dets metabolitter) i en gruppe under FN's verdenssundhedsorganisation (WHO) og Fødevare- og Landbrugsorganisation (FAO) resulterede i en ADI mellem 0-1 mg/kg lgv. i 2016, som blev bekræftet i 2019 (JMPR, 2016; 2019). Risikovurderingen for glyphosat i forbindelse med indtaget af planter og dyr omfatter glyphosat, N-acetylglyphosat, AMPA og N-acetyl-AMPA.

EFSA's vurdering viste ingen evidens for hormonforstyrrende virkninger af glyphosat (EFSA, 2015). Konklusionen var dog ikke sikker, da der manglede data. En efterfølgende specifik vurdering af glyphosats eventuelle hormonforstyrrende effekter bekræftede den tidligere konklusion og konkluderede derudover, at datamængden nu havde været tilstrækkelig til at tillade en vurdering (EFSA, 2017). Glyphosat har indgået i USEPA's Endocrine Disruptor Screening Program, hvor stoffet skal undersøges for forstyrrelser af østrogen-, androgen- og thyroidea-relaterede mekanismer (Tier 1). Pga. mangel på evidens for disse interaktioner blev der ikke anbefalet yderligere undersøgelser på Tier 2 (USEPA, 2015)[6,7].

Der er ikke fundet potentiale for neurotoksiske eller immunotoksiske effekter (EFSA, 2015).

WHO's internationale agentur for kræftforskning (International Agency for Research on Cancer, IARC) har publiceret, at glyphosat "sandsynligvis er kræftfremkaldende for mennesker" ("probably carcinogenic to humans"), gruppe 2A, baseret på en vurdering foretaget i 2015 (IARC, 2017). Denne vurdering blev inddraget i EFSA's evaluering af glyphosats godkendelse til anvendelse i EU. EFSA konkluderede, at det var usandsynligt, at glyphosat udgjorde en kræftfare for mennesker ("unlikely to pose a carcinogenic hazard to humans") (EFSA, 2015). EFSA's vurdering fokuserede på glyphosat alene, mens IARC's vurdering var baseret på glyphosat-formuleringer. Efterfølgende har en gruppe under WHO og FAO konkluderet, at det var usandsynligt, at glyphosat var genotoksisk eller kræftfremkaldende for mennesker, når eksponering sker gennem fødevarer (JMPR, 2016). For løbende opdatering henvises til EFSAs hjemmeside om glyphosat[8].

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[5] Rapporten indeholder også en LOAEL-værdi på 100 mg/kg lgv./d. Den stammer fra en supplerende undersøgelse af lavere kvalitet, men blev ikke udelukket i rapporten ("It should be emphasised that the studies […] are only supplementary due to inferior quality but for the endpoint under consideration (maternal toxicity and mortality) they may be taken into consideration" (ECHA, 2016)).

[6] https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and

[7] Tier 2 test omfatter: Avian Two-Generation Toxicity Test in the Japanese Quail; Medaka Extended One Generation Reproduction Test; Larval Amphibian Growth and Development Assay.
https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-890-endocrine-disruptor-screening-program

[8] https://www.efsa.europa.eu/en/topics/topic/glyphosate

5 Andre effekter

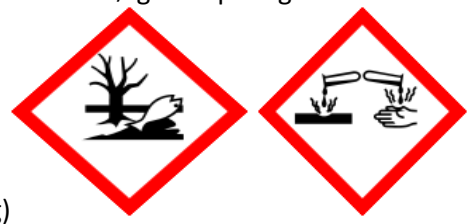
Ifølge EU's forordning for klassificering, mærkning og emballering af stoffer (CLP-forordning) er glyphosat klassificeret med følgende H (sundhed)-sætninger (ECHA, 2017):

- Eye Dam. 1; H318 (forårsager alvorlig øjenskade)
- Aquatic Chronic 2; H411 (giftig for vandlevende organismer, med langvarende virkninger).

Endelig har stoffet følgende P (håndtering)-sætninger:

- P273 (Undgå udledning til miljøet)
- P280 (Bær beskyttelseshandsker/beskyttelsestøj/øjenbeskyttelse/ansigtsbeskyttelse)
- P305 + P351 + P338 + P310 (Ved kontakt med øjnene: Skyl forsigtigt med vand i flere minutter, fjern evt. kontaktlinser, hvis det kan gøres let, ring omgående til en giftinformation eller læge)
- P391 (Udslip opsamles)
- P501 (Indholdet/Beholderen bortskaffes i overensstemmelse med nationale regler)

Glyphosat er mærket med følgende piktogrammer:



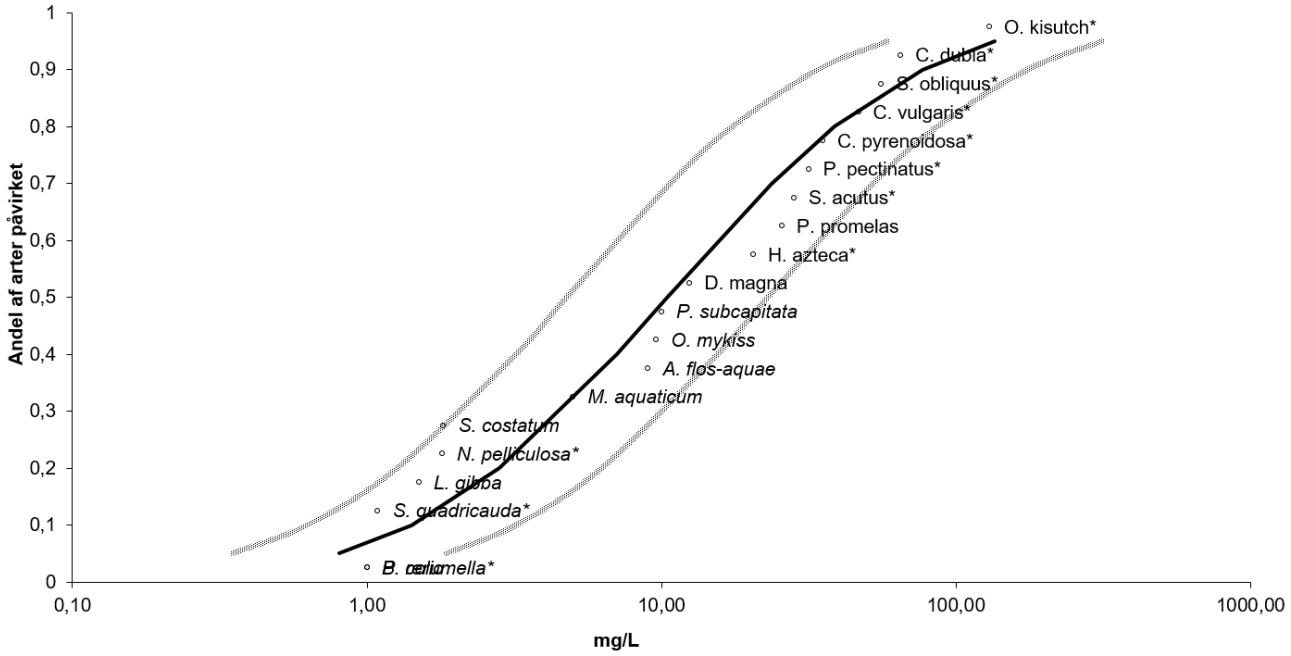
GHS09 (miljøfarlig)
GHS05 (ætsende)

6 Udledning af vandkvalitetskriterium

6.1 Vandkvalitetskriterium (VKK)

Beregningen af vandkvalitetskriteriet er baseret på SSD-metoden, og er foretaget på baggrund af data på kronisk toksicitet fra tyve forskellige arter, som repræsenterer seks forskellige taksonomiske grupper fra både EFSA (2015), ECHA (2016) og Canada WQC (2012). Kravene i det tekniske vejledningsdokument (EU, 2011) er dermed formelt ikke opfyldt for en SSD-tilgang, da dokumentet kræver minimum ti forskellige arter, som repræsenterer otte taksonomiske grupper, hvor der dog f.eks. må indgå to familier af fisk (EU, 2011). Pga. det høje antal arter er det dog vurderet, at den tilgængelige datamængde er tilstrækkelig til at udlede VKK ved anvendelse af SSD-metoden. Der benyttes data, som er kvalitetssikret og anvendt af henholdsvis de canadiske miljømyndigheder og EFSA i Europa.

Figur 6.1 viser SSD-fordelingen for de kroniske akvatiske økotoksikologiske data for hver art, som er medtaget i EFSA-rapporten fra 2015 (EFSA, 2015) samt i den canadiske reference: *Canadian Water Quality Guidelines for the Protection of Aquatic Life (Glyphosate, 2012)* (Canada WQC, 2012). De canadiske værdier er markeret med en stjerne i figur 6.1 og 95% konfidensintervallerne er indtegnet med gråt.



Figur 6.1: SSD-beregning baseret på kroniskedata fra EFSA (2015) og Canada WQC (2012).

Den resulterende kroniske HC5 for vandlevende organismer = 0,8 mg/L (R^2 = 0,929), Anderson-Darling test p = 0,00043, mean squared error (MSE) = 0,08.

Usikkerhedsfaktoren sættes til 3 pga. de mange studier, men også i lyset af, at de fleste studier er af ældre dato og baseret på nominelle koncentrationer. EU (2011) anbefaler en usikkerhedsfaktor mellem 1 og 5, med en case-by-case vurdering. Pga. ovenstående vurdering vælges derfor en usikkerhedsfaktor på 3, hvilket resulterer i følgende $VKK_{ferskvand}$:

$VKK_{ferskvand}$ = 0,8 mg/L/3 = 0,266 mg/L = <u>266 µg/L</u>

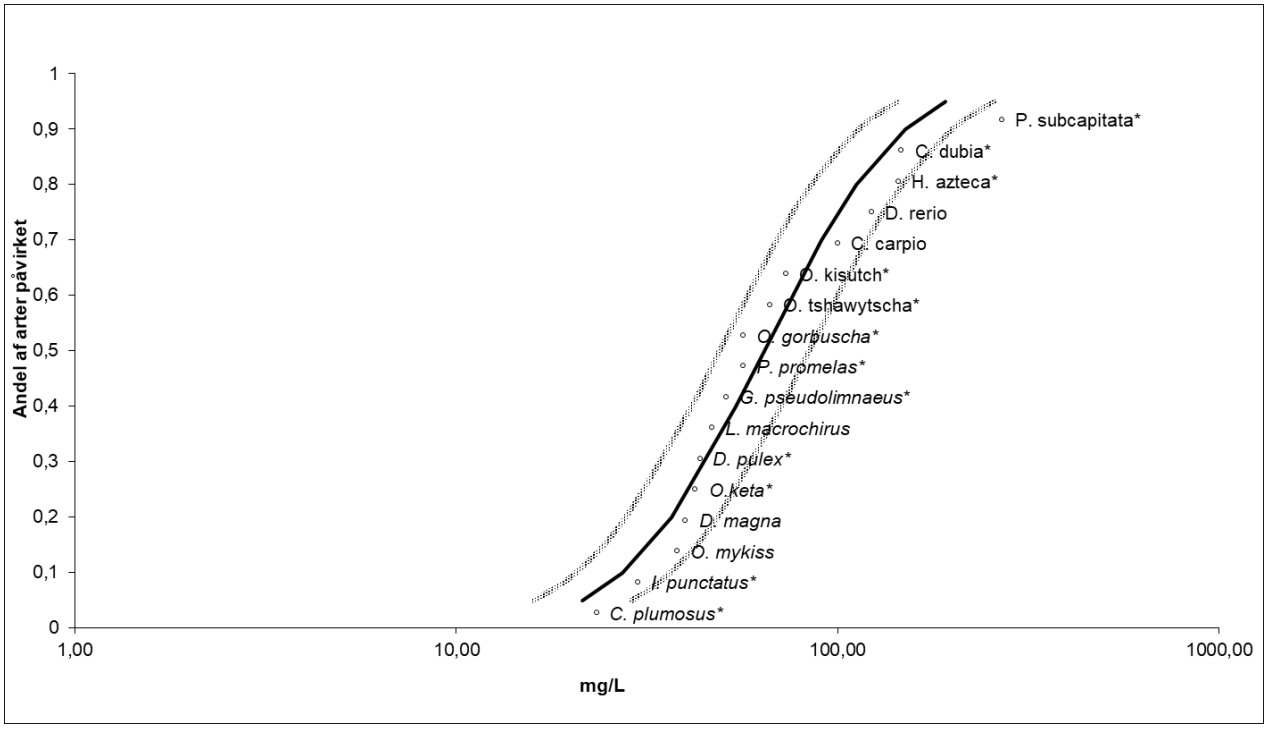
Da ferskvands- og saltvandsdata er slået sammen, beregnes $VKK_{saltvand}$ ud fra $VKK_{ferskvand}$ og der bruges en usikkerhedsfaktor på 10 til beregning af $VKK_{saltvand}$, da der indgår data for en saltvandsart (*O. mykiss*).

$VKK_{saltvand}$ = 266 µg/L/10 = <u>26,6 µg/L</u>

Hvis der vælges en deterministisk beregning af VKK, vil dataudgangspunkt være NOEC = 1 mg/L for *B. rerio* (EFSA, 2015) som det laveste datapunkt (EFSA, 2015). Ved brug af usikkerhedsfaktorer på 10 for ferskvand og yderligere 10 for saltvand, vil VKK-værdierne være $VKK_{ferskvand}$ = 0,1 mg/L = 100 µg/L. $VKK_{saltvand}$ = $VKK_{ferskvand}$/10 (usikkerhedsfaktor) = 10 µg/L. Disse værdier er sammenlignelige med de bedre dataunderbyggede SSD-værdier, hvorfor SSD-beregningen foretrækkes ud fra en faglig vurdering af validitet.

6.2 Korttidsvandkvalitetskriterium (KVKK)

Figur 6.2 viser tilsvarende en SSD for akut giftighed baseret på EC_{50}-værdier fra EFSA (2015) og Canada WQC (2012) med seks taxa og atten arter. De canadiske værdier er markeret med en stjerne i figuren og 95% konfidensintervallerne er indtegnet med gråt.



Figur 6.2: SSD-beregning baseret på akutte data fra EFSA (2015) og Canada WQC (2012).

Den resulterende akutte HC5 for vandlevende organismer = 19,6 mg/L (R^2 = 0,937), Anderson-Darling test p = 0,00035, mean squared error (MSE) = 0,06. Der benyttes en usikkerhedsfaktor på 3 ud fra samme overvejelser som ved beregningen af VKK. Det resulterende KVKK er

KVKK = 19,6 mg/L/3 = 6,53 mg/L = 6533 µg/L

En deterministisk beregning vil være baseret på den laveste akutte toksicitetsværdi for glyphosat på LC_{50} = 38 mg/L for *O. mykiss* EC50 (EFSA, 2015). Vi benytter denne værdi, da vi vurderer, at den er mere robust (pga. færre fejlkilder og mere præcis bestemmelse) end alge vækstrate værdien ikke mindst i betragtning af at studierne ikke er helt veldokumenteret, jf bilag A. Der er mere end tre akutte værdier hvorfor KVKK = 38/10 = 3,8 mg/L = 3800 µg/L. Denne værdi er sammenlignelig med den bedre dataunderbyggede SSD-værdi, hvorfor SSD-beregningen foretrækkes ud fra en faglig vurdering af validitet.

KVKK dækker både salt- og ferskvand.

6.3 Kvalitetskriterium for sediment (SKK)

Da den gennemsnitlige log Koc for glyphosat er 4,20 (EFSA, 2015), dvs. log K_{OC} > 3, skal der ifølge det tekniske guidance-dokument beregnes en SKK-værdi for glyphosat (EU, 2011).

De toksicitetsdata, der er sammendraget for sedimentlevende organismer (Tabel 4.2), angiver vandkoncentrationer og ikke sedimentkoncentrationer og er derfor ikke direkte egnede til en SKK-beregning. I stedet er SKK beregnet ud fra K_{OC}-værdien (K_{OC} = 15844 L/kg; EFSA, 2015) og en ligevægtsfordeling mellem sediment og vand.

Fremgangsmåden i beregningen følger beskrivelsen i den tekniske vejledning (EU, 2011) og bruger standardværdierne i dokumentets afsnit 5.2.1.2. Ovenstående $VKK_{ferskvand}$ og $VKK_{saltvand}$ indgår i beregningen for hhv. ferskvands- og marint sediment, dvs. de værdier, der er beregnet vha. SSD-modellen.

$$Kp_{sed} = F_{OC,sed} \cdot K_{OC} = 0{,}05\frac{kg}{kg} \cdot 15.844\ \frac{l}{kg} = 792{,}2\frac{l}{kg}$$

$$K_{sed-vand} = F_{luft,sed} \cdot\ K_{luft-vand} +\ F_{vand,sed} + F_{solid,sed} \cdot \frac{Kp_{sed}}{1000} \cdot RHO_{solid} =$$

$$0{,}8\frac{m^3}{m^3} + 0{,}2 \cdot \frac{792{,}2\frac{l}{kg}}{1000\frac{l}{m^3}} \cdot 2500\frac{kg}{m^3} = 396{,}9\frac{m^3}{m^3}$$

I det næste skridt i beregningen indgår $QS_{fw,eco}$, som er identisk med $VKK_{ferskvand}$ på 266 µg/l.

$$SKK_{ferskvand}\ (v\mathring{a}dv\ae gt) = QS_{sediment,EqP,ww} = \frac{K_{sed-vand}}{RHO_{sed}} \cdot QS_{fw,eco} \cdot 1000 =$$

$$\frac{396{,}9\frac{m^3}{m^3}}{1300\frac{kg}{m^3}} \cdot 266\frac{\mu g}{l} \cdot 1000\frac{l}{m^3} = 81.211\ \frac{\mu g}{kg\ v\mathring{a}dv\ae gt} = 81{,}2\ \frac{mg}{kg\ v\mathring{a}dv\ae gt}$$

Værdien omregnes til tørvægt vha. en konverteringsfaktor på 2,6 (EU, 2011). Det resulterer i følgende værdi på tørvægtsbasis:

$$SKK_{ferskvand}\ (tørstof) = \ QS_{sediment,EqP,dw} = 81.211\,\frac{\mu g}{kg\ vådvægt} \cdot 2{,}6 \approx 211.151\,\frac{\mu g}{kg\ tørstof}$$

$SKK_{ferskvand}$ = 81.211 µg/kg vådvægt ≈ 211.151 µg/kg tørvægt

Det beregnede kriterie er baseret på et indhold af organisk kulstof (OC) på 5%. $SKK_{ferskvand}$ kan tilpasses til sedimenttyper med anden organisk kulstof fraktion (f_{oc}) ved nedenstående formel:

$SKK_{ferskvand}$ = 211,15 mg/kg tørvægt (5% OC)

= 4.223 mg/kg tørvægt x f_{oc}

$SKK_{saltvand}$ er beregnet på samme vis, kun ved at bruge $VKK_{saltvand}$ i stedet for $VKK_{ferskvand}$. Da $VKK_{saltkvand}$ er ti gange lavere end $VKK_{ferskvand}$, bliver det resulterende $SKK_{saltvand}$ også ti gange lavere:

$SKK_{saltkvand}$ = 8.121 µg/kg vådvægt ≈ 21.115 µg/kg tørvægt

Denne er ligeledes beregnet ved 5% OC, men kan tilpasses sedimenttyper med anden f_{oc}:

$SKK_{saltvand}$ = 21,115 mg/kg tørvægt (5% OC)

= 422,3 mg/kg tørvægt x f_{oc}

6.4 Kvalitetskriterium for biota (BKK)

Der skal ifølge EU (2011) ikke laves en BKK-beregning for glyphosat, da BCF for glyphosat er 1,1 L/kg (EFSA, 2015).

6.5 Kvalitetskriterium for human konsum af vandlevende organismer (HKK)

Der skal ifølge EU (2011) ikke laves en HKK-beregning for glyphosat. Ingen kriterier eller fare-sætninger indikerer mistanke om giftighed over for mennesker som følge af konsumption af vandlevende organismer jf. afsnit 5 ovenfor.

7 Konklusion

Der er fundet følgende miljøkvalitetskriterier for glyphosat baseret på review data fra EFSA (2015) og Canada WQC (2012) og metoder beskrevet i det tekniske vejledningsdokument (EU 2011);

$VKK_{ferskvand}$ = 266 µg/L

$VKK_{saltvand}$ = 26,6 µg/L

KVKK = 6.533 µg/L

$SKK_{ferskvand}$ = 211,15 mg/kg tørvægt (5% OC)

4.223 mg/kg tørvægt x f_{oc}

$SKK_{saltkvand}$ = 21,115 mg/kg tørvægt (5% OC)

422,3 mg/kg tørvægt x f_{oc}

BKK = Ikke relevant

HKK = Ikke relevant

8 Referencer

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9 Bilag A. Kvalitetsevaluering af data

Evaluated study (full reference):	EFSA 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 13(11), 4302.
Test substance:	Glyphosate (CAS#107-83-6)
Evaluated test:	All tests have been reviewed by EFSA
Evaluated test species:	All species data have been reviewed by EFSA
Evaluated test endpoint(s):	All endpoints have been reviewed by EFSA
Evaluator (institution):	Hans Sanderson, Department of Environmental Science, Aarhus University

Relevance of the data *For each question, mark one appropriate answer with x.*

Remark: Relevance of a study mainly depends on the scope of the assessment / the regulatory framework, for which the study is evaluated. The following 12 questions should therefore be answered in the context of the overall assessment.

	Yes	No
Is the tested species relevant for the compartment under evaluation?	x	

Example: An aquatic species should be tested to evaluate risks for the aquatic environment.

	Yes	No
Are the tested organisms relevant for the tested compound?	x	

Example: In case of an ERA for an antibiotic, cyanobacteria should be used as test species instead of algae.

	Yes	No
Are the reported endpoints appropriate for the regulatory purpose?	x	

Example: Acute effects on aquatic organisms are not relevant for the environmental risk assessment of human pharmaceuticals.

	Yes	No
Are the reported endpoints appropriate for the investigated effects or the mode of action of the test substance?	x	

Explanation: When a risk assessment is performed for a substance, for which information is available on a specific mode of action that is considered relevant for environmental organisms, studies including endpoints assessing this particular mode of action are most appropriate. For instance, if an API is known to affect reproduction of vertebrates, the endpoints of the fish early life stage test may not be appropriate. Instead, fish tests should include endpoints such as vitellgenin levels, secondary sex characteristics, sex ratio and reproduction depending on the specific mode of action of the substance (OECD 2012).

	Yes	No

Is the effect relevant on a population level?	**x**	

Explanation: Endpoints of the guideline studies, on which the ERA of human pharmaceuticals is based, are generally population relevant. For non-standard tests, population relevance has to be evaluated on a case by case basis.

	Yes	**No**
Is the recorded effect statistically significant, biologically relevant and appropriate for the regulatory purpose?	**x**	

Explanation: In the context of environmental risk assessment, a biologically relevant effect is an effect that is important and meaningful for environmental health (EFSA 2011). In a test system with relatively little control variation, minor changes may be statistically significant without necessarily being biologically relevant. To evaluate risks caused by chronic exposure, NOEC or EC_{10} values are used, while EC_{50} values are not appropriate. For the EC_{10}, it has to be evaluated on a case by case basis, if the effect is within biological variation of the control response. To evaluate risks caused by acute exposure (note that this is only relevant for some terrestrial tests with human pharmaceuticals), EC_{50} values are preferred.

	Yes	**No**
Are appropriate life-stages studied?	**x**	

Explanation/example: The tested life stage should be (a) appropriate for the selected test and test design and (b) relevant for the expected effect of the API. For instance, fish early life stages are not appropriate for studying effects on reproduction.

	Yes	**No**
Are the test conditions appropriate for the tested species and relevant for the assessment?	**x**	

Explanation/example: Test organisms should be tested under appropriate conditions. For instance, freshwater species should be tested in freshwater, and saltwater species in saltwater. If a test with freshwater or saltwater species is required depends on the scope of the assessment.

	Yes	**No**
Is the timing and duration of exposure relevant and appropriate for the studied endpoints and species?	**x**	

Explanation: The required exposure time should be appropriate for the test organism and the studied endpoint. Chronic studies should include sensitive life stages or cover the whole life cycle.

	Yes	**No**
If recovery is studied, is this relevant for the framework for which the study is evaluated?		**x**

Explanation: In most regulatory frameworks (including the environmental risk assessment of human pharmaceuticals), recovery is not relevant (exception: authorisation of plant protection products).

	Yes	**No**
Is the substance tested representative and relevant for the substance being assessed?	**x**	

Explanation: Sufficient information should be provided to allow a clear identification of the test item. A substance may be tested as pure active substance or in a formulation. Tests performed with formulations are relevant for plant protection products, but less relevant within many other regulatory frameworks. Studies with mixtures of different substances are relevant for assessing toxicity of these mixtures, but not for assessing the individual substances contained in the mixture. For salts, the counter ion may influence toxicity. For pro-drugs, the active moiety and, if entering the environment in >10% of the administered does, the pro-drug need to be assessed (EMA/CHMP 2011). Depending on the regulatory framework, effects of transformation products may need to be considered. If the substance causing the effect is not the substance being assessed, expert judgement is needed to decide on how to deal with the results of the study and the resulting risk assessment.

	Yes	No
Is the tested exposure route relevant for the assessment?	**x**	

Explanation/example: The exposure route should be appropriate for the assessment. For instance, exposure by injection is generally not appropriate (Harris et al. 2014). For pharmaceuticals, exposure should be continuous. Intermittent exposure is generally not relevant. Exposure duration has to be sufficiently long. However, note that acute tests with some terrestrial organisms are also required in the environmental risk assessment of human pharmaceuticals.

Assigned relevance class	**Rx**

Reliability of the data

General information

Remark: Before evaluating the test, please check the physico-chemical characteristics of the test substance (what is the solubility, log K_{OW}, pK_a, is the compound volatile, does it hydrolyse, photolyse etc.?)

For each question, mark one appropriate answer with x.

Is a standard method (e.g. OECD, ISO, US EPA) or modified standard used? Please specify:

	Yes	No
A standard method is used.	**x**	
A slightly modified standard method is used.		**x**

	A substantially modified standard method is used.		
Is the test, including chemical analysis of the test substance where required, performed under GLP conditions?			**x**
Validity criteria:			
		Yes	**No**
a	**Are all validity criteria fulfilled if applicable?**		**x**
	Explanation: For standard tests, compliance with the validity criteria of the guideline is crucial for a study to be considered as reliable. Please check the corresponding test guideline where relevant. For non-guideline tests with standard species, validity criteria as described in a guideline for a similar test should be met if applicable.		
		Yes	**No**
b	**Are validity criteria clearly failed?**		**x**
	Explanation: If validity criteria are clearly failed, a test is classified as '3' (not reliable).		
Inclusion of appropriate controls:			
	Explanation: It depends on the test substance and test type which controls should be included; please check the corresponding test guideline where relevant. In addition to the negative control, a solvent control has to be included in all cases where a solvent is used. The concentration of solvent in the solvent control should correspond to the highest solvent concentration used in the test treatments. In some tests, a positive control with a reference substance is required. For standard tests, the corresponding guidelines provide information on how the controls should perform, e.g. with regard to survival, growth or reproduction. For non-standard tests and non-standard test organisms, expert judgement is needed to decide if performance of the controls is acceptable. Performance of the solvent control should preferably not differ significantly from performance of the negative control.		
		Yes	**No**
a	**Was a negative control included, and was its performance acceptable?**	**na**	**na**
b	**Was a positive control included, if required, and was its performance acceptable?**	**na**	**na**
c	**Was a solvent control included, if a solvent was used, and was its performance acceptable?**	**na**	**na**
Test substance			
		Yes	**No**
Is the test substance clearly identified with name, CAS-number or SMILES code and, where relevant, information on stereochemistry?		**x**	
	Explanation/example: If the salt of an API was tested, information on the type of salt should be provided. It should be specified if test concentrations relate to free acid / free base or salt. If the test substance is not clearly identified, a test is classified as '3' (not reliable).		
		Yes	**No**
a	**Is the purity of the test substance reported and in an acceptable range (>95%)?**		**x**

b	Is the source of the test substance reported and trustworthy?	na	na
	If a formulation is used or if impurities are present:		
		Yes	**No**
a	Can it be excluded that other ingredients in the formulation or impurities exert an effect?		x
b	Is the amount of test substance in the formulation indicated?		x
	Test organism		
	Description of the test organisms:		
		Yes	**No**
a	Is the test species clearly identified?	x	
	Explanation: If the test species is not clearly identified, a test is classified as '3' (not reliable).		
		Yes	**No**
b	For algae: is mean cell density at the test start within an appropriate range? For other test organisms: Is mean body weight/length of the test organism in an appropriate range?	x	
	Explanation for 8 b-e: For standard tests, the corresponding guidelines provide information on required range of mean cell densities, age / life stage of the test organisms etc. at the test start.		
		Yes	**No**
c	Is age/life stage of the organisms at test start reported and in the required range, where appropriate (e.g. not for algae)?	x	x
d	Is sex of the test organisms reported and is sex ratio appropriate, where relevant (e.g. when evaluating sexual-endocrine effects)?		x
e	Is the species strain reported where required?		x
a	Are the test organisms from a reliable source? For field collected organisms: is the site of origin well-described?	na	na
b	Have the organisms been acclimatized to test conditions (e.g. water type, temperature) before the start of exposure, where relevant? For tests with embryonic stages: have the parental organisms been held at appropriate conditions?	na	na
c	Are the test organisms exempt from previous exposure or any other kind of stressor?	na	na
	Test conditions and chemical analysis		
	Appropriateness of the experimental system for the test substance:		
		Yes	**No**
	Is the type of exposure (e.g. static, semi-static, flow-through) appropriate for the test substance, taking its physico-chemical characteristics into account?	x	

Explanation: Static systems are in most cases only appropriate for short-term tests (exception: water/sediment tests). Where appropriate, guideline requirements should be followed.

	Yes	No
In case that the test substance is a difficult substance as defined in OECD (2000): is the selected test system appropriate for testing of this substance?	x	

Explanation: Difficult test substances are substances which are e.g. poorly water soluble, volatile, photo-degradable, hydrolytically unstable, oxidizable, biodegradable, complexing or strongly adsorbing to surfaces of test vessels etc. In order to obtain reliable test results with such substances, test systems generally have to be adapted to take the difficult properties of the substance into account (e.g. by using a closed test system without headspace for volatile substances). For further details, please see OECD (2000). It has to be verified on a case-by-case basis, if the used test system is appropriate for the test substance.

	Yes	No
For ionisable substances: has the test been performed in an appropriate pH-range?	x	

Explanation: Relatively small changes in pH can significantly alter the balance between dissociated and non-dissociated forms of some substances. An altered dissociation equilibrium may significantly affect the water solubility and the partition coefficient of the substance and hence, its bioavailability and toxicity. Tests with such substances should therefore be performed at a pH, within the pH range required for maintaining the health of the test organisms, at which the more toxic form of the test substance prevails (as far as possible). For further guidance, see OECD (2000).

	Yes	No
Is the experimental system appropriate for the test organism (e.g. choice of medium / test water or soil, feeding, water or soil characteristics, temperature, light/dark conditions, pH, oxygen content)? Have conditions been stable during the test?	x	

Explanation: The general requirements of the test species should be considered with regard to the characteristics of the selected test medium etc. Temperature, pH and oxygen content should be stable and within the appropriate range for the organism (where applicable, check the corresponding guideline). If control performance is not good (e.g. high mortality), this may indicate that test conditions were not appropriate. Where applicable, feeding should follow the guideline requirements, and all excess should be removed after feeding to avoid decreased bioavailability of the test substance.

		Yes	No
a	**For aquatic tests: were exposure concentrations below the limit of water solubility?**		x
b	**For aquatic tests: if a solvent was used, was solvent concentration within the appropriate range (i.e. not higher than 0.01%)?**	x	
Is a correct spacing between exposure concentrations applied?		na	na

Explanation: For standard tests, the corresponding guidelines provide information on the spacing factor. A factor of 3.2 is often recommended. As rule of thumb, the spacing factor should not be >10.

	Yes	No
Is the exposure duration defined and appropriate?	x	

Chemical analysis		
	Yes	No
Are chemical analyses performed to verify test substance concentrations over the duration of the study where required?		x

Explanation: If required in the corresponding test guideline, nominal test substance concentrations should be verified by chemical analysis. Non-guideline test should be evaluated based on test guidelines for similar tests where appropriate.

	Yes	No
Is an appropriate analytical method used to measure test substance concentrations?		x
Are the measured test substance concentrations within the calibration range of the analytical method?		x
Are samples analysed from a sufficient number of treatments and controls, and from a sufficient number of time intervals?		x

Explanation: The frequency of chemical analyses should be evaluated based on the requirements of the corresponding test guideline or, for non-guideline studies, on a guideline for a similar test if appropriate.

	Yes	No
Are test substance concentrations sufficiently stable during the course of the exposure ?		x

Explanation: Please evaluate according to the requirements of the corresponding test guideline or, for non-guideline studies, a test guideline for a similar test where appropriate.

	Yes	No
Is the biomass loading of the organisms in the test system within an appropriate range?	x	

Explanation: For standard tests, the corresponding guidelines provide information on maximum biomass loading. For non-standard tests / non-standard test species, expert knowledge is required to decide if the loading rate is appropriate.

Statistical design			
		Yes	No
a	**Is a sufficient number of replicates used for all controls and treatments?**	na	na
b	**Is a sufficient number of organisms per replicate used for all controls and test concentrations?**	na	na

Explanation for 17 a and b: For standard tests, the guideline requirements should be followed. When a non-guideline study is evaluated, expert judgement is needed to assess if the study design is appropriate to obtain statistically reliable results.

	Yes	No
Are appropriate statistical methods used to derive the effect concentrations?	x	

Explanation: Generally, a description of the statistical methods is needed to assess the reliability of the test results. For standard tests, the corresponding guideline requirements should be followed. Further guidance is e.g. provided by OECD (2006). When a non-guideline study is evaluated, expert judgment may be needed. EC_x values should not be extrapolated considerably beyond the range of tested concentrations.

	Yes	No

a	**Is a concentration-response curve observed?**	**na**	**na**

Explanation: The requirement for a concentration-response relationship depends on the objective of the study. If a limit test is performed at one (or two) concentration(s) to verify the lack of toxicity and no toxicity is recorded, a concentration-response relationship is obviously not needed to conclude that the LC_{50} or NOEC is above the highest tested concentration. However, if the intention of the study is to demonstrate an effect, reliability of the test results is higher, if (1) a sufficient number of concentrations have been tested and (2) the observed effect is regularly increasing (or regularly decreasing) with increasing test concentration (i.e. the concentration-response relationship is monotonous). Expert knowledge is needed, if an effect is only observed at the highest tested concentration. Expert knowledge is also needed in the case of non-monotonous concentration-response curves (e.g. U-, J- or inverted U-shaped curves). In such cases, the underlying mechanisms of effects and the reproducibility of the results should be considered (Harris et al. 2014).

		Yes	**No**
b	**Is the observed effect statistically significant?**	**na**	**na**

Explanation: The significance level and the statistical method used to evaluate the specific effect should be indicated.

	Yes	**No**
Are sufficient data available to check the calculation of endpoints and (if applicable) fulfilment of the validity criteria (e.g. control data, concentration-response curves)?	**na**	**na**

Explanation: If enough data are presented, additional endpoints may be calculated by the assessor if not reported by the author of the study.

Assigned reliability class	**Rx1**

10 Bilag B. Ecotox og OPP data

Tabel 1: Glyphosat toksicitetsværdier fra USEPA Ecotox databasen 2015-2019 som ikke er kvalitetssikret af en offentlig myndighed.

Arter / Species	ECx	mg/L	Eksponeringstid	Endpoint	Reference	Klimish & CRED score
Algae (*N oculata*)	NOEC	1	40 dage	Lipid indhold	Deng et al. 2015	R3/C2. Følger ikke OECD guideline. Endpoint mindre relevant.
Algae (diatomer)	NOEC	0,5	48 timer	Vækst inhib. og sundhed	Wood et al. 2016a	R3/C2. Følger ikke OECD guideline. Endpoints er ikke direkte relevante.
Diatomer (8 forskellige bentiske diatomer)	EC_{10}	0,000001-0,277	48 timer	Vækst inhib. og sundhed.	Wood et al. 2016b	R3/C2. Følger ikke OECD guideline. Endpoints er ikke direkte relevante.
Haletudse (A. boreas)	LC_{50}	6392	48 timer	Akut dødelighed	Vincent & Davidson. 2015.	R2/C1: Følger næsten OECD guideline. Endpoint er relevant.
Haletudse (*A. terresris*)	NOEC	1,1	10 dage	Adfærd	Wood and Welch, 2015.	R3/C2. Følger ikke OECD guideline. Endpoint ikke direkte relevant.

Tabel 2: Glyphosat toksicitetsværdier fra USEPA OPP databasen.

OPP Pesticide Ecotoxicity Database						EC50 mg/L
Pesticide	**Type of Organism**	**Common Name**	**Category**	**Duration (d)**	**Scientific Name**	
Glyphosate	Aves	Mallard duck	c	17wk	*Anas platyrhynchos*	1000
Glyphosate	Aves	Bobwhite quail	c	17wk	*Colinus virginianus*	1000
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Freshwater green algae	c	3	*Pseudokirchneriella subcapitata*	12,54
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Freshwater diatom	c	7	*Navicula pelliculosa*	38,6
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Marine diatom	c	7	*Skeletonema costatum*	0,87
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Blue-green algae	c	4	*Anabaena flos-aquae*	11,7
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Duckweed	c	14	*Lemna gibba*	21,5
Glyphosate N-(phosphonomethyl) glycine	Aves	Bobwhite quail	c	14	*Colinus virginianus*	2000
Glyphosate N-(phosphonomethyl) glycine	Aves	Mallard duck	c	8	*Anas platyrhynchos*	5200
Glyphosate N-(phosphonomethyl) glycine	Aves	Bobwhite quail	c	8	*Anas platyrhynchos*	5200
Glyphosate N-(phosphonomethyl) glycine	Fishes	Rainbow trout	c	3	*Oncorhynchus mykiss*	134
Glyphosate N-(phosphonomethyl) glycine	Fishes	Bluegill sunfish	c	3	*Lepomis macrochirus*	45
Glyphosate N-(phosphonomethyl) glycine	Crustacea	Water flea	c	2	*Daphnia magna*	134
Glyphosate N-(phosphonomethyl) glycine	Fishes	Sheepshead minnow	c	3	*Cyprinodon variegatus*	240
Glyphosate N-(phosphonomethyl) glycine	Crustacea	Mysid	c	3	*Americamysis bahia*	79
Glyphosate N-(phosphonomethyl) glycine	Mollusca	Pacific oyster	c	3	*Crassostrea gigas*	40
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Freshwater green algae	c	5	*Pseudokirchneriella subcapitata*	14
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Duckweed	c	14	*Pseudokirchneriella subcapitata*	12,4
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Blue-green algae	c	5	*Pseudokirchneriella subcapitata*	15
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Marine diatom	c	5	*Pseudokirchneriella subcapitata*	12
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Freshwater diatom	c	5	*Pseudokirchneriella subcapitata*	22
Glyphosate N-(phosphonomethyl) glycine	Aquatic Plant	Duckweed	c	7	*Pseudokirchneriella subcapitata*	24
Glyphosate N-(phosphonomethyl) glycine	Aves	Mallard duck	s	21wk	*Anas platyrhynchos*	501
Glyphosate N-(phosphonomethyl) glycine	Insecta	Honey bee	c	2	*Apis mellifera*	103
Glyphosate N-(phosphonomethyl) glycine	Insecta	Honey bee	c	2	*Apis mellifera*	182
Glyphosate N-(phosphonomethyl) glycine	Aves	Canary	c	14	*Serinus canaria*	2000

Litteratur bilag B:

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Wood, L & AM Welch. 2015. Assessment of interactive effects of elevated salinity and three pesticides on life history and behavior of southern toad (*Anaxyrus terrestris*) tadpoles Environ. Toxicolo. Chem. 34 (3), 667-676

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