



Redegørelse for hvordan produkter med fosfonat må sælges og anvendes i planteproduktion

Dette notat beskriver de regler, der gælder for salg og anvendelse af produkter med fosfonat i planteproduktionen. Notatet redegør for hvilke regler der gælder for markedsføring og anvendelse af fosfonat i pesticidprodukter, i gødningsprodukter og i biostimulanter.

Definitioner og begreber

Fosfit er synonym med fosfonat. I dette notat anvendes betegnelsen fosfonat, da dette er den nyeste og internationalt mest anvendte betegnelse.

Betegnelsen erhvervsdrivende omfatter i dette notat producenter og forhandlere af gødnings- og pesticidprodukter.

Betegnelsen planteproducenter omfatter i dette notat landbrugere og gartnere (herunder producenter af grøntsager, potteplanter frugt og bær).

Kan fosfonat anvendes og sælges som fosforgødning?

Fosfonat bidrager ikke til planternes fosforernæring og bør ikke betragtes som en fosforkilde egnet til gødning af planter. Fosfonat-produkterne bliver optaget af planterne, men ikke metaboliseret. Fosfonat har ligefrem vist sig at have negative virkninger på væksten og stofskiftet hos planter, der lider af fosfor-mangel (bilag 1).

Fosfonater må ikke bevidst være tilsat i CE-mærkede gødningsprodukter, og der må maksimalt være 0,5 masseprocent utilsigtede fosfonater i CE-mærkede gødningsprodukter jf. gødningsforordningen (1009/2019)

Fosfonater kan heller ikke markedsføres som fosforgødning efter de nationale gødningsregler, fordi der heri står, at gødning skal have dokumenterbar virkning, og at gødning er defineret som produkter, hvis virkning helt eller overvejende beror på produktets indhold af planteneringsstoffer jf. gødningsloven.

EU-Kommissionen har berørt spørgsmålet om fosfonater i afsnit 13 i dokumentet: Questions and agreed answers concerning the implementation of regulation (EC) no 2003/2003

relation to fertilisers, version 8. Dokumentet fremgår af bilag 2. Heri har EU-Kommissionen fastslået at et hvilket som helst produkt, der består af eller indeholder fosfonat, og som er bestemt til anvendelse til et af de formål, der følger af pesticidforordningens art. 2, stk. 1, er et pesticidprodukt (bilag 2).

Kommissionen anfører endvidere, at i lyset af den tilgængelige viden om kalium fosfonats virkning (i særdeleshed dets fungicid egenskaber, samt svage evidens for dets virkning som plantenæringsstof) må det formodes, at dette er den tilsigtede anvendelse af produkter. Som konsekvens, skal alle produkter, der udelukkende indeholder fosfonat eller som indeholder bevidst tilsat fosfonat, derfor markedsføres under pesticid-reguleringen. Undtaget er situationer, hvor det kan påvises, at hensigten med brugen af produktet udelukkende er en anden end de formål der er anført i pesticidforordningens art. 2, stk. 1. I sådanne tilfælde er det den erhvervsdrivende, der skal demonstrere dette (bilag 2).

Godkendelse og autorisation af produktet i henhold til pesticidregulering skal også ske for produkter, der markedsføres som gødning efter gødningsforordningen (2003/2003) eller national regulering. Mærkning, inklusiv anpriste virkning og brugeranvisninger må i sådanne tilfælde ikke modsige de krav, der følger af pesticidreguleringen (bilag 2).

Fosfonat er ikke fosforgødning

- Fosfonat har ikke en fosfor-gødningseffekt for planter.
- Fosfonat kan ikke markedsføres som fosforgødning hverken ifølge den nye gødningsforordning eller i ifølge de nationale gødningsregler.

Vejledning i anvendelse og markedsføring af blandingsprodukter som f.eks. fosfonat-kalium produkter findes på side 3 til 5 i dette notat.

Fosfonat som aktivstof i pesticider

Fosfonat-forbindelser er effektive som fungicider til bekæmpelse af plantesygdomme forårsaget af oomyceter. Endvidere er de også effektive mod nematoder (bilag 1). Fosfonater er derfor virksomme mod nogle almindelige og alvorlige plantesygdomme.

Fosfonaterne dinatriumfosfonate, kaliumhydrogenfosfonat og dikaliumfosfonat er godkendte pesticid-aktivstoffer. Dinatriumfosfonat er virksom mod vinskimmel i vin (*Plasmopara viticola*) (bilag 3) og kaliumhydrogenfosfonat og dikaliumfosfonat er virksom mod *Oomycetes Peronosporales* og *Pythium* i vindruer (bilag 4).

Hvis du som erhvervsdrivende ønsker at markedsføre et pesticid med indhold af fosfonat, skal produktet være godkendt af Miljøstyrelsen som pesticid. Regler for salg og anvendelse af pesticider fremgår af pesticidforordningen (1107/2009).

Hvis du som planteproducent bruger fosfonat-produkter, skal brugen ske i overensstemmelse med anvisningerne på det godkendte produkt, og du skal for hver anvendelse opgøre brugen i sprøjtejournalen, og data skal årligt indberettes til Miljøstyrelsen jf.

sprøjtejournalbekendtgørelsen. Krav om årlig indberetning gælder for jordbrugsvirksomheder med et samlet dyrket areal på 10 ha eller derover og jordbrugsvirksomheder med en årlig momspligtig omsætning for det senest afsluttede regnskabsår på 50.000 kr. eller derover.

Regler for anvendelse af pesticider indgår endvidere i en række nationale bestemmelser, der ses i en publikation på Miljøstyrelsens hjemmeside.

[Klik her for at se Miljøstyrelsens publikation: Regler for erhvervmæssig anvendelse af bekæmpelsesmidler](#)

Produkter med fosfonat skal markedsføres som pesticider

- Lovlig markedsføring af fosfonatholdige pesticid-produkter til brug i planteproduktionen forudsætter, at produkterne markedsføres som pesticider og overholder pesticid-reguleringen.
- Det er ulovligt for planteproducenter at anvende fosfonat-holdige produkter, medmindre der anvendes godkendte pesticid-produkter, hvor mærkningens anvisninger overholdes.
- Brugen af fosfonatholdige pesticider skal fremgå af sprøjtejournalen og data skal indberettes til Miljøstyrelsen.

Kan pesticider med fosfonat også være gødninger?

Visse markedsførte fosfonatholdige produkter indeholder også gødningsstoffet kalium. Dette gælder fx Resistim, Lebosol Kalium-Plus og PhosFeed K. Som beskrevet ovenfor virker disse produkter ikke som fosfor-gødning til planterne. Dog kan kalium-indholdet godt betyde, at disse pesticidprodukter også virker som gødningsstoffer. Tilsvarende hvis et produkt indeholder både fosfat, fosfonat og kalium. Her kan kalium- og fosfat-indholdet godt betyde, at produktet både virker som kalium og fosfor-gødning samt pesticid.

Hvorvidt et sådant produkt - ud over pesticid-regulering - også skal overholde de nationale gødningsregler i forbindelse med markedsføring, vil blive afgjort ved individuel sagsbehandling af Landbrugsstyrelsen. Forhold, der bliver vægtet i sådanne sager, vedrører om pesticid-produktet har en betydende gødningseffekt, når anvendelsen sker i overensstemmelse med mærkningen. Hvis dette er tilfældet, skal produktet som hovedregel også markedsføres som gødning, og overholde alle relevante nationale krav for salg og anvendelse af gødning.

Hvis du som erhvervsdrivende skal markedsføre dit produkt som både fosfonat-pesticid og som gødning, fx kaliumgødning, er det relevant for dig at kende til de nationale regler for deklaration af næringsstofindholdet i dit produkt. Disse fremgår af gødningsbekendtgørelsen.

Landbrugsstyrelsen har overvejet om indholdet af fosfor fra fosfonat i gødningsprodukter, skal deklareres i overensstemmelse med bestemmelserne, der følger af bilagene i gødningsbekendtgørelsen. Landbrugsstyrelsen vurderer, at eftersom fosfonat ikke er et

fosfor-næringsstof, gælder kravene i bilaget ikke for angivelse af fosfonat-fosforindholdet i disse produkter.

Fosfonat-indholdet skal i stedet angives i overensstemmelse med pesticid-reguleringen. Det medfører, at der løbende skal føres sprøjtejournale over anvendelsen og disse data skal indberettes til Miljøstyrelsen jf. bekendtgørelse om sprøjtejournalinberetning.

Som erhvervsdrivende skal du på mærkningen af gødningsprodukter angive plantenæringsstofferne i produktet. Foruden deklaration af indholdet af næringsstoffer skal de ingredienser, der er tilsat gødningen i en mængde over 1 % af gødningens vægt, fremgå af mærkningen.

De nærmere krav til mærkningen afhænger af gødningstypen. Det er plantenæringsstofferne i gødningen, der er afgørende for, hvilken gødningstype dit produkt hører til. For gødninger, der består af fosfonat i blanding med et eller flere plantenæringsstoffer, vil disse næringsstoffer i gødningen være afgørende for typebetegnelsen. Fosfonat er ikke et gødningsstof egnet til planteernæring, og derfor ikke omfattet af anvendelsesområdet for gødningsloven. Der bør derfor ses bort fra indholdet af fosfonat, når der foretages vurdering af typebetegnelsen af gødningen.

Erhvervsdrivende bør være opmærksomme på, at oplysning om fosfonatindhold på gødningsprodukter, uden at produkterne har en fosforgødningseffekt, kan virke vildledende for brugerne af gødningen. For at imødegår dette problem bør erhvervsdrivende på mærkningen gøre opmærksom på, at produktet ikke er egnet som fosforgødning, da fosfonat ikke bidrager til planternes fosforernæring. Dette kan dog ikke påkræves af den erhvervsdrivende, eftersom et sådant krav til mærkningen ikke fremgår af gødningsbekendtgørelsen.

Fosfonater må ikke bevidst være tilsat i CE-mærkede gødningsprodukter, og der må maksimalt være 0,5 masseprocent utilsigtede fosfonater i CE-mærkede gødningsprodukter jf. gødningsforordningen (1009/2019). Derfor kan fosfonat-pesticider ikke også markedsføres som CE-mærkede gødningsprodukter. Dette er også beskrevet ovenfor i afsnittet: Kan fosfonat anvendes og sælges som fosforgødning?

Pesticider med fosfonat kan også samtidig være et gødningsprodukt

- Erhvervsdrivende, der ønsker at markedsføre produkter, der både indeholder fosfonater og gødningsstoffer, skal have produktet godkendt som pesticid hos Miljøstyrelsen.
- Produkter med fosfonat kan ikke markedsføres som CE-mærket gødningsprodukt.
- Om pesticid-produktet skal registreres til salg som gødningsprodukt efter nationale regler hos Landbrugsstyrelsen afgøres ved individuel sagsbehandling i Landbrugsstyrelsen.
- Fosfor-indholdet (fra fosfonat) skal oplyses på mærkningen i overensstemmelse med pesticid-reglerne.
- Hvis pesticid-produktet også skal registreres og mærkes i overensstemmelse med de nationale gødningsregler, er produktets indhold af plantenæringsstoffer afgørende for typebetegnelsen. Fosfonat-indholdet indgår ikke i vurderingen af typebetegnelsen ift. gødningsreglerne.

Kan fosfonat markedsføres som biostimulant?

I 2015 kommunikerede EU-Kommissionen, at produkter, der udelukkende indeholder fosfonat, eller som indeholder bevidst tilsat fosfonat, må formodes at være bestemt til anvendelse med pesticidformål og derfor skal markedsføres under pesticid-reguleringen. Undtaget er situationer, hvor den erhvervsdrivende kan demonstrere, at hensigten med brugen af produktet udelukkende er en anden end som pesticid (bilag 2).

Godkendelse og autorisation af produktet i henhold til pesticidregulering skal også ske for produkter, der markedsføres som gødning efter gødningsforordningen (2003/2003) eller national regulering. Mærkning, inklusiv anpriste virkning og brugeranvisninger må i sådanne tilfælde ikke modsige de krav, der følger af pesticidreguleringen (bilag 2).

Hvis et fosfonat-holdigt produkt ønskes markedsført som biostimulant i overensstemmelse med de nationale gødningsregler, skal produktet overholde gødningsreglerne.

Fra 16. juli 2022 er det muligt at markedsføre biostimulanter efter reglerne i gødningsbekendtgørelsen. Bekendtgørelsens regler for anmeldelse og salg af biostimulanter er dog først gældende for produkter, der sælges fra 1. januar 2024. Hvis erhvervsdrivende inden 1. januar 2024 markedsfører produkter som biostimulanter i overensstemmelse med gødningsreglerne, sker det på frivillig basis. Overgangbestemmelserne for biostimulanter er nærmere beskrevet i nyheden: [Nye regler for salg og markedsføring af gødningsprodukter, jordforbedringsmidler mv. fra 13. juli 2022.](#)

[Klik her for at se nyheden om nye regler for salg og markedsføring af gødningsprodukter](#)

I gødningsbekendtgørelsen fastsættes følgende definition af biostimulanter:

Et produkt som stimulerer planters næringsstofprocesser uafhængigt af produktets næringsstofindhold med det ene formål at forbedre et eller flere af følgende kendetegn ved planten eller dens rhizosfære:

- Næringsstofudnyttelse
- Tolerance over for abiotisk stress
- Kvalitetssegenskaber
- Tilgængelighed af afgrænsede næringsstoffer i jorden eller rhizosfæren

Endvidere gælder, at en biostimulant ikke kan være et plantebeskyttelsesmiddel omfattet af pesticidforordningen.

De nationale krav til biostimulanter omfatter, at produktet skal have en dokumenterbar biostimulerende virkning. På etiketten skal anføres den anpriste virkning for hver målplante. Endvidere er det udelukkende muligt at markedsføre en biostimulant med et indholdsstof med kendt pesticidvirkning, som tilfældet er med fosfonat-holdige produkter, hvis der i forbindelse med anmeldelse af produktet til Landbrugsstyrelsen vedlægges dokumentation, der viser, at produktet ikke er bestemt til et pesticid-formål. Ønsker en erhvervsdrivende at markedsføre et produkt med indhold af fosfonat som biostimulant, skal den erhvervsdrivende i forbindelse med anmeldelsen derfor vise dokumentation for, at produktet ved den dosering og anvendelse, der anpriseres på etiketten, ikke har virkning som pesticid.

Landbrugsstyrelsen er indtil videre ikke bekendt med fosfonat-holdige produkter, der lever op til ovennævnte nationale krav og regler for markedsføring af biostimulanter.

Produkter kan ikke markedsføres som CE-mærkede biostimulanter, hvis de indeholder bevidst tilsat fosfonat eller hvis de indeholder mere end 0,5 masseprocent utilsigtede fosfonater jf. gødningsforordningen (1009/2019).

Der er pt. stillet et forslag til EU-Kommissionen fra The European Biostimulant Industry Council (EBIC) om, at fosfonat skal kunne indgå i biostimulanter i lave koncentrationer i CE-mærkede biostimulant-produkter. Forslaget er under behandling af EU-kommissionen, der indledningsvis har vurderet, at forholdet omkring grænseværdier for pesticidrester i fødevarer bør overvejes sammen med evidens for en grænseværdi for indholdet af fosfonat i fødevarer.

Produkter med fosfonat kan som udgangspunkt ikke markedsføres som biostimulanter

- Biostimulanter med fosfonat skal registreres og markedsføres i henhold til gødningsbekendtgørelsen (forudsat at det ikke har pesticidvirkning).
- Den erhvervsdrivende skal ved anmeldelse af biostimulant-produktet til Landbrugsstyrelsen vise dokumentation for, at produktet ved den dosering og anvendelse, der anpriseres på etiketten, ikke har virkning som pesticid.
- Produkter med fosfonat kan ikke markedsføres som CE-mærket biostimulant.

Regler

Regler om, at nationalt markedsført gødning skal have en dokumenterbar virkning, fremgår af § 1, stk. 2, i gødningsloven og definitionen af gødning som produkter, hvis virkning helt eller overvejende beror på indholdet af plantenæringsstoffer, fremgår af lovens § 2, nr. 1. begge i gødningsloven (Lov om gødning og jordforbedringsmidler m.v., jf. lovbekendtgørelse nr. 16 af 4. januar 2017 med senere ændringer)

Regler om mærkning og emballering af gødning og jordforbedringsmidler m.v. står i §§ 7-11 samt § 13 i gødningsbekendtgørelsen (Bekendtgørelse om gødning og jordforbedringsmidler m.v. nr 1135 af 09/07/2022).

Krav til angivelse af gødningstype for produkttypen gødninger står i bekendtgørelsens bilag 1, pkt. A. nr. III, nr. 1, litra a, og gødningstyper fremgår af bekendtgørelsens bilag 1, tabel A-E.- og bilag 2, pkt. A. begge i gødningsbekendtgørelsen (Bekendtgørelse om gødning og jordforbedringsmidler m.v. nr. 1135 af 09/07/2022).

Definition af biostimulanter fremgår af § 2, nr. 3, i gødningsbekendtgørelsen og krav om dokumentation for at biostimulant med pesticid-aktivstof ikke virker som pesticid fremgår af § 6, stk. 4, nr. 2, i bekendtgørelsen. Krav om at der på mærkning af biostimulanter skal anføres virkning for hver målplante står i bekendtgørelsens bilag 6, nr. 9 (Bekendtgørelse om gødning og jordforbedringsmidler m.v. nr. 1135 af 09/07/2022).

Regler om fosfonater i CE-mærkede EU-gødningsprodukter står i bilag I, Del II, stk. 6 i EU-gødningsforordning (2019/1009).

Regler om hvilke plantebeskyttelsesmidler, der er omfattet af pesticidforordningen fremgår af pesticidforordningen (Forordning 1107/2009/EF om markedsføring af plantebeskyttelsesmidler)

Regler for salg og anvendelse af pesticider fremgår af pesticidforordningen (Forordning 1107/2009/EF om markedsføring af plantebeskyttelsesmidler).

Regler om pligt til at føre sprøjtejournal fremgår af § 3 og indberetningspligten fremgår af § 4-5 begge i bekendtgørelse om sprøjtejournalindberetning (bekendtgørelse nr. 1052 af 27/06/2022).

Regler for anvendelse af pesticider indgår endvidere i en række nationale bestemmelser, der ses i en publikation på Miljøstyrelsens hjemmeside.

[Klik her for at se Miljøstyrelsens publikation: Regler for erhvervmæssig anvendelse af bekæmpelsesmidler](#)

Vejledning til at finde love og regler

Nationale danske regler:

Du kan finde de danske regler på retsinfo.dk. Søg efter lovens eller bekendtgørelsens nummer og år for at finde den rette lov eller bekendtgørelse.

EU-regler:

Du kan finde den rette forordning på eur-lex.europa.eu. Brug feltet "Hurtigsøgning" og søg på forordningens nummer og årstal for at finde den rette forordning.

Bilag 1

DCA besvarelse: Redegørelse for den mulige anvendelse af fosfit (2015)



NaturErhvervstyrelsen

Redegørelse for den mulige anvendelse af fosfit/fosfonat som gødningsmiddel

NaturErhvervstyrelsen (NAER) har med bestilling af 16. september 2015 anmodet DCA - Nationalt Center for Fødevarer og Jordbrug (DCA) om at belyse om fosfit eller fosfonat kan betegnes som plantenæringsstof, der kan tilføre afgrøderne fosfor, og om stofferne falder ind under gødningsreglernes område.

Som besvarelse på bestillingen fremsendes hermed ”Redegørelse for den mulige anvendelse af fosfit/fosfonat som gødningsmiddel”, udarbejdet af lektor Bernd Wollenweber, Institut for Agroøkologi.

Besvarelsen er udarbejdet som led i ”Aftale mellem Aarhus Universitet og Fødevareministeriet om udførelse af forskningsbaseret myndighedsbetjening m.v. ved Aarhus Universitet, DCA – Nationalt Center for Fødevarer og Jordbrug, 2015-2018”.

Til orientering kan vi i øvrigt oplyse, at DCA tidligere har besvaret en lignende bestilling fra NAER (bestilling af 21. juli 2011 vedr. ”Optagelse af monokaliumfosfit som gødning i EU’s gødningsforsøg”). Emnet blev dengang behandlet af DCA i en rapport med titlen *Monopotassium phosphite, Part A: Review on the possible use of monopotassium phosphite as fertilizer; Part B: Review on the fungicidal effects and mode of action of monopotassium phosphite*, der satte fokus på dokumentation for fosfit både som gødningsmiddel og som fungicid. Rapporten blev udarbejdet af Bernd Wollenweber, René Gislum og Henrik Brinch-Pedersen, alle fra Institut for Agroøkologi, og blev fremsendt til NAER den 28. oktober 2011.

Med venlig hilsen

Rikke Flinterup
Specialkonsulent,
Koordinator for myndighedsrådgivning.

Kopi til: Innovation

DCA - Nationalt Center for
Fødevarer og Jordbrug

Rikke Flinterup

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Reference: rcf

Side 1/1

Redegørelse for den mulige anvendelse af fosfit / fosfonat som gødningsmiddel

Bernd Wollenweber, Aarhus Universitet, Institut for Agroøkologi

NaturErhvervstyrelsen (NAER) har med bestilling af den 16. september 2015 bedt DCA – Nationalt Center for Fødevarer og Jordbrug (DCA) om en redegørelse for den mulige anvendelse af fosfit / fosfonat som gødningsmiddel på grundlag af aktuel videnskabelig viden.

NAER har tidligere fremsendt en lignende anmodning (bestilling af 21. juli 2011 vedr. ”Optagelse af monokaliumfosfit som gødning i EU’s gødningsforsøg”), der blev behandlet af DCA i en rapport med titlen *Monopotassium phosphite, Part A: Review on the possible use of monopotassium phosphite as fertilizer; Part B: Review on the fungicidal effects and mode of action of monopotassium phosphite*, der satte fokus på dokumentation for fosfit både som gødningsmiddel og som fungicid. Rapporten blev udarbejdet af Bernd Wollenweber, René Gislum og Henrik Brinch-Pedersen, Institut for Agroøkologi, og blev fremsendt til NAER den 28. oktober 2011.

Sammendrag

Dokumentation i videnskabelig, fagfællebedømt litteratur viser entydigt, at fosfit / fosfonat ikke bidrager til planternes fosforemæring og ikke bør betragtes som en egnet fosforkilde. Fordelene ved praktisk anvendelse af fosfit i sammenligning med fosfat stammer sandsynligvis snarere fra dets virkemåde som fungicid end som gødningsmiddel (McDonald et al., 2001; Ratjen and Gerendas, 2009; Thao and Yamakawa, 2009).

Både den reviderede gødningsbekendtgørelse i Tyskland (fra 2008) og Europa-Kommissionens notat af 2015 foreslår, at kaliumfosfitter / -fosfonater ikke kan godkendes som gødningsmidler i henhold til vilkårene i Forordning 2003/2003 i betragtning af manglen på en påviselig gødningseffekt. Det bekræfter også, at for at kunne sælges i EU skal de godkendes som pesticider i henhold til Forordning 1107/2009.

Indledning: Fosfor – udnyttelse og funktion i planter

Fosfor (P) er et af væsentligste livsvigtige makronæringsstoffer. Efter kvælstof er uorganisk P (Pi) det næsthøjest begrænsende makronæringsstof for planternes vækst. Det forekommer i fuldt oxyderet form som fosfat anion (PO_4^{3-} ; Pi; valens +5) og som fosfit (PO_3^{3-} ; Phi; valens +3).

Fosfitalte er alkalialte af fosforsyrling og må ikke forveksles med fosfater, der er afledt fra fosforsyre. Fosfonat bruges ofte som et synonym for fosfit:

Fosfat (Pi)	Hovedkomponent i fosfatgødning; sædvanligvis i form af ammonium-, calcium-, magnesium- eller kaliumfosfat. Udnyttes i planternes stofskifte; ingen egenskaber som fungicid
Fosforsyre	H ₃ PO ₄ . Stærk syre anvendt i fremstillingen af fosfatgødning
Fosforsyrning	= fosforsyre H ₃ PO ₃ ⁻ . Basisingrediens i fosfonatprodukter
Fosfonat	Produkter lavet af salte af fosforsyrning
Fosfit (Phi)	Alkaliske (K ⁺ , Ca ⁺⁺ , Mg ⁺⁺) salte af fosforsyrning (H ₂ PO ₃ ⁻). De bliver optaget af planterne, men ikke metaboliseret. Fosfitprodukter har fungicide egenskaber

I gødningsmidler findes Pi normalt i form af fosforsyre (H₃PO₄) og salte heraf, såsom trippelsuperfosfat, ammoniumfosfat og kaliumfosfat. Alle disse former opløses let og danner hydrogenfosfat (HPO₄²⁻) og dihydrogenfosfat (H₂PO₄⁻). Hastighederne for Pi-optagelse er højest mellem pH 5,0 og 6,0 (hvor H₂PO₄⁻ dominerer). De kemiske syreopløsningskonstanter (pK'er) for opløsningen af H₃PO₄ til H₂PO₄⁻ og derpå til HPO₄²⁻ er henholdsvis 2,15 og 7,21. Dette betyder, at Pi er tilgængelig for planten som fosforsyre, med H₂PO₄⁻ som dominerende i forhold til H₃PO₄ og HPO₄²⁻. Ved meget lave pH-værdier i jord er optagelse af Pi som H₃PO₄ en teoretisk mulighed (Abel et al., 2002).

Pi lagres i forskellige celleområder og/eller indbygges hurtigt i organiske forbindelser, såsom nukleinsyrer og fosfolipider og har stor betydning for overførsel af energi i enzymatiske reaktioner via ATP. P-estere spiller en vigtig rolle som mellemlid i både anabolske og katabolske biokemiske reaktioner. I oplagringsvæv bliver Pi udskilt i korn- og frøvakuoler som fytat.

Fosfits mulige rolle som gødningsmiddel

Mens Phi-forbindelser er blevet anerkendt som fungicider til bekæmpelse af plantesygdomme forårsaget af oomyceter (Jackson et al., 2000; Jee et al., 2002; Smillie et al., 1989; Thao og Yamakawa, 2009) og som nematicider til bekæmpelse af nematoder (Habash og Al-Banna, 2011), har undersøgelser i begyndelsen af 1950'erne af fosfits rolle som P-gødning antydnet, at plantevækst kunne forbedres ved tilførsel af Phi (MacIntire et al., 1950). Interessen for fosfit som P-kilde blev fornyet, da det blev opdaget, at bladsprøjtning med kaliumfosfit på citrusplanter med P-mangel genoprettede normal plantevækst (Lovatt, 1990a), og at Phi kunne være et omkostningseffektivt alternativ til fosfat (Lovatt, 1990b). Der er antydninger af, at bladsprøjtning med Phi øgede udbyttet og forbedrede kvaliteten af adskillige afgrøder (Rickard, 2000). Der er imidlertid nyere bevis for det modsatte (Zambrosi et al., 2011), hvor det blev vist, at bladenes fotosyntese, effektiviteten af næringsstofudnyttelse og væksten af citrusplanter faldt med tilførsel af Phi.

Mange nye P-gødninger, der er baseret på Phi, bliver nu markedsført (se tabellen nedenfor) og godkendt i henhold til gødningslovene. Nogle bliver endog beskrevet som fungerende mere som "biostimulanter" end som gødningsmidler (Thao og Yamakawa, 2009). Fosfitholdige kemikalier bliver udbudt som gødningsmidler, der er egnede til anvendelse i økologisk jordbrug (Morton et al., 2005). Nyere rapporter viser imidlertid klart, at planter med P-mangel er meget følsomme over for tilførsel af fosfit (Fairbanks, et al., 2002; Lee et al., 2005; McDonald et al., 2001; Schroetter et al., 2006; Singh et al., 2003, Varadarajan et al., 2002). Som rapporteret af Ratjen og

Gerendas (2009), 'the issue gained additional impact from the revised German Fertilizer Ordinance, released on December 2008, which specifies phosphate as the only P-source in fertilizers, tolerating phosphite only as a naturally occurring contamination (Anonymous, 2008)'. Anvendelsen af Phi-holdige produkter som kilder til planteernæring er således blevet genstand for stadig igangværende diskussioner. Baseret på offentliggjort fagfællebedømt litteratur, er Phi's kontroversielle rolle som gødningsmiddel for nylig blevet underkastet en kritisk gennemgang (Ratjen og Gerendas, 2009; Thao og Yamakawa, 2009).

Table 1 From fungicides to fertilizers: the marketing of some products with phosphorous and phosphite as the active ingredient

Product	Company	Country	Active ingredient	Marketed as
Alicette	Bayer Cropscience	Germany	Aluminum phosphite	Fungicide
Nutri-phite	Biagro Westem Sales	USA	Phosphite and organic acids	Fertilizer
Elc-Max	Helena Chemical	USA	Phosphorous acid	Foliar fertilizer
ProPhyt	Luxembourg-pamol	USA	Monopotassium phosphite	Systemic fungicide
Nutrol	Lidochem	USA	Potassium phosphite	Fertilizer and fungicide
Phostrol	NuFarm America	USA	Phosphorous acid	Biochemical pesticide
Agrifos	Liquid Fert Pty (Agrichem)	USA	Monopotassium phosphite	Fungicide
Foli-r-fos 400	UiM Agrochemicals	Australia	Monopotassium phosphite	Fungicide
Fosphite	Jh Biotech	USA	Monopotassium phosphite	Fungicide
Lexx-a-phos	Foliar Nutrients Inc	USA	Monopotassium phosphite	Fungicide
Trafos line	Tradecorp	Spain	Potassium phosphite	Fertilizer and defense stimulator
Phytos'K	Valagro	Italy	Potassium phosphite	Biostimulant (registered as EC fertilizer)
Phosfik line	Biolchem	Italy	Phosphorous acid	EC fertilizer
Fosfisan, Vigorsan	Agrofill	Italy	Potassium phosphite	Defense stimulator (registered as fertilizer)
Geros-K	L-Gobbi	Italy	Potassium phosphite	EC fertilizer
Kalium Plus	Lebosol	Germany	Potassium phosphite	EC fertilizer
Frutoguard	Spieess Urania	Germany	Potassium phosphite	EC fertilizer
Foliaphos	Plantin	France	Potassium phosphite	EC fertilizer

Source: Leymonie 2007. EC, European Commission (for identifying chemicals).

Det er blevet påvist, at planter er i stand til at optage Phi, og denne proces er endog blevet målt i realtid ved *in vivo* ^{31}P NMR (Danova-Alt et al., 2008). Tilstedeværelsen af fosfit i skud efter bladsprøjtning (Ratjen og Gerendas, 2009) eller efter tilførsel af fosfit til roden (Thao et al., 2008) viser klart, at fosfit transporteres både i plantens si- og vedvæv. Selvom de fleste planter let absorberer og transporterer Phi, synes det imidlertid ikke at blive oxyderet eller metaboliseret i planterne og dermed heller ikke at bidrage til P-ernæringen (Carswell et al., 1997; Carswell et al., 1996). Derfor bør rapporter, der hævder, at Phi assimileres i planter, vurderes med størst mulig omhu.

På den anden side er oxydering af fosfit via mikroorganismer i jord veldokumenteret (Morton et al., 2005; Smith et al., 2011). Da omdannelseshastigheden for fosfit til fosfat er afhængig af de kemiske forhold i jorden, kan dette være en forklaring på fosfits positive ernæringsmæssige virkninger. Desuden kan fosfits større mobilitet i jord tilføre P til dybereliggende rødder (Morton et al., 2005). De mulige omsætnings-hastigheder af Phi til Pi i jord er imidlertid relativt langsomme (Morton et al., 2005).

Phi har vist sig at have negative virkninger på væksten og stofskiftet hos P-fattige planter ved at undertrykke de typiske molekylære og udviklingsmæssige reaktioner (Fairbanks et al., 2002) over for P-mangel (Carswell et al., 1997; Carswell et al.,

1996; Varadarajan et al., 2002). Phi intensiverer de skadelige virkninger af P-mangel ved at narre Pi-fattige planteceller til at føle, at de har tilstrækkeligt Pi, mens deres Pi-indhold i cellerne i virkeligheden er ekstremt lavt (McDonald et al., 2001).

Undersøgelser af afgrødereaktioner på kommercielle Phi-afledte P-gødninger er blevet opsummeret af Rickard (2000). De fleste af undersøgelserne i denne redegørelse blev udført under markforhold, og alle resultater viste, at jord- eller bladsprøjtning med Phi-gødning forbedrede udbyttet og kvaliteten af mange afgrøder. Der er imidlertid intet bevis for, at Phi anvendt i ”bladgødninger” eller ”biostimulanter” kan udnyttes direkte af planterne som en kilde til ernæring med P. Deres indflydelse på planterne synes mest sandsynligt at være ved at bekæmpe patogener. Dette fremgår nu af lærebøgerne: *“Unlike nitrate and sulphate, phosphate is not reduced in plants, but remains in its highest oxidized form. Therefore, even though the more reduced oxide of phosphorus (phosphite) is sometimes advertised as a fertilizer, it is harmful when given to plants that are already short of phosphate, because it is an analogue of phosphate and inhibits its uptake”* (Marschner, 2012). Forbedringerne af udbytte og kvalitet i nogle tilfælde kan således sagtens have været forårsaget af Phi’s virkning som fungicid (se nedenfor). Endvidere er data, der viser, at virkningen af Phi-afledt P-gødning er lig med eller bedre end virkningen af konventionelle Pi-gødninger, meget sjældne.

Mange andre undersøgelser har antydnet, at Phi-forbindelser ikke kan udnyttes af planter som P-gødning. Tomat- og peberplanter (Varadarajan et al., 2002) og majs (Avila et al., 2011; Schroetter et al., 2006) behandlet med Phi viste en signifikant vækstreduktion sammenlignet med Pi-gødede planter. For nylig er en række undersøgelser (Thao og Yamakawa, 2009; Thao og Yamakawa, 2010; Thao et al., 2008; Thao et al., 2009) af forskellige afgrøder med brug af forskellige metoder og doseringer af Phi-tilførsel blevet gennemført for intensivt at udforske virkningerne af Phi såvel som en kombination af Phi og Pi på vækst og P-ernæring i planter. Der blev fundet forgiftningssymptomer, og der blev ikke opdaget nogen gavnlig virkning af Phi på plantevæksten. Disse resultater antydede, at Phi ikke var en erstatning for Pi, og at der ikke var en stimulerende virkning af nogen kombination af Phi-Pi på plantevæksten. Bladsprøjtning med Phi øgede signifikant det totale indhold af henholdsvis P og Phi i plantevævet, men forbedrede ikke plantevæksten.

I begyndelsen af 2014 modtog Europa-Kommissionen data fra medlemsstaterne og aktører i fødevarerindustrien, der viste, at restkoncentrationer af fosforsyre var blevet opdaget i forbindelse med monitoring i et niveau over maksimalgrænseværdierne (*maximum residue level, MRL*) for visse handelsvarer. For at undgå afbrydelse i handlen hævdede Kommissionen derfor grænserne på kort sigt ved at fastsætte midlertidige MRL’er (*t-MRL*) for handelsvarer, der er mest sårbare over for overskridelser, for hvilke MRL tidligere er blevet sat til grænsen for kvantificering på 2 mg/kg (dokument *BayerCropScience position letter, March 2015* vedhæftet NAER’s bestilling af foreliggende udredning). Disse t-MRL’er gælder til udgangen af december 2015.

I januar 2015 offentliggjorde DG GROWTH resultatet af et tværgående samråd inden for Kommissionen: Deres notat (dokument *ares(2014)2846845.pdf* vedhæftet NAER’s bestilling af foreliggende udredning) foreslår, at kaliumfosfonater ikke godkendes som gødningsmidler i henhold til Forordning 2003/2003 i betragtning af

manglen på en påviselig gødningseffekt. Det bekræfter også, at fosfonat-/fosfitbaserede produkter først og fremmest har pesticidvirkemåde, hvilket betyder, at de for at blive solgt i EU bør registreres som pesticider i henhold til Forordning 1107/2009 (dokument *Phosphonate.pdf* vedhæftet NAER's bestilling af foreliggende udredning).

Fosfit som fungicid

Som angivet ovenfor er det velkendt, at Phi er effektivt inden for plantebeskyttelse over for patogener såsom oomyceter og svampe og mod planteskadegørende nematoder (Aleksic et al., 2014; Dalio et al., 2011; Lim et al., 2012; Lucero et al., 2014; Neves og Bassay Blum, 2014; Ogoshi et al., 2013). Der er dog stadig nogen uenighed om fosfitters / fosfonaters virkemåde. Mens de direkte virkninger på patogenerne er blevet diskuteret (Smillie et al., 1989), viser nye undersøgelser, at virkningen af fosfit / fosfonat tilsyneladende sker gennem stimulering af naturlige forsvarsmekanismer til forebyggelse af sygdomme eller nematodeinfektioner (Eshraghi et al., 2011; Jost et al., 2015). Til dato er det dog uklart, hvilke molekyllære mekanismer der ændres (Berkowitz et al., 2013; Eshraghi et al., 2011; Jost et al., 2015).

Konklusioner

Samlet set viser disse resultater konsekvent, at planterne ikke er i stand til direkte at udnytte Phi som en P-kilde, og Phi kan således ikke supplere eller erstatte Pi-gødning. Der er ingen grund til at antage, at stofskifteeffektiviteten af P afledt fra fosfit er bedre end af P afledt fra fosfat. Fosfit kan ikke betragtes som en egnet P-kilde og bør derfor ikke anvendes som P-gødning (Ratjen og Gerendas, 2009).

Antallet af produkter såsom kalium-, magnesium- og calciumfosfitter på markedet ville ikke være blevet så stort, hvis ikke der var fordele ved at tilføre Phi. Hvorfor nogle undersøgelser har vist en negativ virkning af Phi på plantevæksten og andre har fundet positive reaktioner står for tiden ikke klart. Fordelene i marken ved fosfit sammenlignet med fosfat stammer således sandsynligvis snarere fra dets virkemåde som fungicid end fra dets virkemåde som gødningsmiddel.

Under alle omstændigheder er der til dato intet, der klart beviser, at planter direkte udnytter Phi som et P-næringsstof. Desuden er der intet kendt planteenzym, der kan oxydere Phi til Pi (Thao og Yamakawa, 2009). Dette er i overensstemmelse med såvel den reviderede gødningsbekendtgørelse i Tyskland, der erklærer, at fosfat er den eneste lovlige form for P i P-gødninger, som notatet fra Europa-Kommissionen, DG GROWTH, af 2015. Phi i sig selv har ingen stimulerende virkninger på væksten hos sunde planter, og kombinationen af Phi og Pi giver ingen stimulerende virkninger sammenlignet med Pi alene.

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Bilag 2

EU-Kommissionen: Guidance document, Questions and agreed Answers concerning the implementation of regulation (EC) no 2003/2003 relation to fertilisers (2015)



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SME's

Resources Based, Manufacturing and Consumer Goods Industries

Chemicals Industry

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QUESTIONS AND AGREED ANSWERS

CONCERNING THE IMPLEMENTATION OF REGULATION (EC) No 2003/2003

RELATING TO FERTILISERS

Table of contents

1. INTRODUCTION	3
2. TESTING OF AMMONIUM NITRATE FERTILISERS UNDER ARTICLE 27.....	3
3. CLARIFICATION OF THE DEFINITION OF “MANUFACTURER”.....	4
4. ACCREDITATION OF LABORATORIES UNDER ANNEX V.....	4
5. DECLARATIONS OF THE SOLUBILITY OF THE P ₂ O ₅ CONTENT OF PHOSPHATE FERTILISERS	5
6. LABELLING REQUIREMENT FOR MIXTURES OF MICRO-NUTRIENTS	5
7. RULES ON MICRO-NUTRIENT CHELATE, MICRO-NUTRIENT SOLUTION AND MICRO-NUTRIENT COMPLEX	6
8. SOLUTIONS OF MICRO-NUTRIENT FERTILISER.....	7
9. EXAMPLE OF LABELLING FOR MIXTURES OF MICRO-NUTRIENTS	7
10. CLARIFICATION ON THE USE OF SEVERAL UREA CONDENSATES IN THE PRODUCTION OF COMPOUND FERTILISERS	8
11. NUMBERS INDICATING THE PHOSPHORUS CONTENT IN COMPOUND FERTILISERS	8
12. ORGANIC MATTER IN EC FERTILISERS	9
13. PHOSPHONATES IN FERTILISERS.....	10

1. INTRODUCTION

This document gathers some questions and agreed answers concerning the interpretation of Regulation (EC) No 003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers.

The answers were discussed and agreed between the Commission services and the representatives from the Member States in the Working Group on Fertilisers. It attempts to provide guidance to both Member States and economic operators.

These answers represent the opinion of the Commission services but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of Community legislation.

This guidance document will be regularly updated and published on the website of the European Commission.

2. TESTING OF AMMONIUM NITRATE FERTILISERS UNDER ARTICLE 27

Question: Article 27 requires the importer/manufacture to submit results of the test of resistance to detonation to the competent authority of the Member State five days before the fertiliser is imported or placed on the market. Thereafter the manufacturer shall continue to guarantee that all supplies of the fertiliser are capable of passing the detonation test. The question has arisen of how long such test results should be considered valid, and how can a manufacturer guarantee that his product is in compliance?

Answer: No period of validity for test results is foreseen in the Regulation. This is the result of a decision taken by the Council Working Party during the co-decision procedure where, after debate, it was decided that it would not be appropriate to specify one single period of validity for the test results.

Member States should therefore decide on a case-by-case basis how long test results should remain valid. They should take such a decision based on their confidence in the ability of the manufacturer/importer to continue supplying fertiliser to the specification of the sample that passed the test. The level of confidence should, however, be based on objective criteria, and excessive testing should be avoided.

For example, a manufacturer who produces fertiliser in a plant that is capable of delivering a reproducible product, and for which there is adequate quality control and record-keeping, might be considered by the Member States, after inspection of the plant, to provide the necessary guarantee through his plant records. On the other hand, an importer who receives supplies from a variety of manufacturing plants that are not accessible to inspection by the Member State might be required to provide test results for each shipment.

3. CLARIFICATION OF THE DEFINITION OF “MANUFACTURER”

Question: According to Article 2(x), the term “manufacturer” means the natural or legal person placing the fertiliser on the market. The definition goes on referring to producers, importers, packagers and distributors. The question has arisen whether this definition could apply to an operator changing the label of a national fertiliser into an “EC fertiliser” standard labelling.

Answer: The important act for the purpose of the Fertiliser Regulation is to place an “EC fertiliser” on the market, in other words, to supply it to the market. By changing the reference of the label into “EC-type” fertiliser, the operator becomes the person placing the EC fertiliser on the market, and therefore, the manufacturer.

Article 7(1) states that the manufacturer shall provide EC fertilisers with the identification markings listed in Article 9. As one of the markings listed in Article 9 is the words “EC fertilisers”, the operator becomes the manufacturer by changing the national label into an EC fertiliser labelling.

When a person is supplying an “EC fertiliser” to the market, his name or trade name and his address should appear on the label. If another person is marketing the same product to the national market, without the designation “EC fertiliser”, this person is not subject to the rights and obligations that derive from the Fertiliser Regulation and must comply instead with national legislation.

In Regulation (EC) No 2003/2003, manufacturers are directly responsible for the conformity of the EC fertilisers with the provisions of this Regulation. By making the claim that the EC fertiliser conforms to all the requirements of the Regulation, the person changing the national label may infringe some of its provisions (for example, the tolerances of Annex II, which a distributor is probably not in position to know). In that case, he may be subject to the penalties referred to in Article 36.

The European Court of First Instance has previously recognized, in other context, that a distinction must be made between the information content of the label and the language used to present that information (case C-33/97). According to this ruling, an accurate translation does not change the information content and such a translation is therefore not considered to be a change to the labelling. Within the meaning of the Fertiliser Regulation, a person who affixes an accurate translation to a package would therefore not be considered to be a manufacturer. An inaccurate translation which changes the information content of the label would however constitute a change to the labelling, and the person who does this assumes the responsibilities of a manufacturer.

4. ACCREDITATION OF LABORATORIES UNDER ANNEX V

Question: Annex V.B.1 lays down that laboratories authorized to provide services for checking the compliance of EC fertilisers shall be accredited in accordance with EN ISO/IEC 17025, for at least one of the methods of Annex IV. Does this mean that a laboratory accredited for just one method can be authorized to perform all methods of Annex IV?

Answer: No. The laboratory must be accredited for each of the analysis methods that are actually used in official controls.

From the requirements for laboratories given in Article 30 of the Regulation as well as in Annex V, it is clear that the laboratories must meet four conditions before a Member State can make valid use of the test results to check the compliance of EC fertilisers in order to enforce the legislation. Those conditions are: competence, accreditation, approval and notification.

According to Article 30, laboratories first have to be competent to carry out the necessary services for checking compliance of EC fertilisers, and they have to prove that competence through EN ISO/IEC 17025 accreditation. The Member State may then approve the laboratory and notify the Commission.

It would not seem plausible that a MS could make use in court of test results from an approved laboratory unless the analysis method that was used was included in the quality manual that is needed for accreditation, otherwise the laboratory could not demonstrate its competence.

The mention of “at least one of the techniques of Annex IV” in the Annex V text therefore does not absolve the MS or the laboratory concerned from being accredited for other test methods. Rather, the reverse is true: it means that it is a prerequisite for a test method to be included in the accreditation before the test results may be used in official controls.

EN ISO/IEC 17025 accreditation is a general standard for any testing laboratory and has no particular requirements for testing of fertilisers. Changes introduced in the 4th ATP of the Fertiliser Regulation (i.e. the words underlined in the question) ensure that there is a link to the testing of fertilisers. The new wording alerted manufacturers and Member States to the fact that the laboratories must be accredited for specific test methods, i.e. that in order to conform to the requirements of the Regulation the relevant test method must be included in the quality manual that is needed for accreditation of the laboratory.

5. DECLARATIONS OF THE SOLUBILITY OF THE P₂O₅ CONTENT OF PHOSPHATE FERTILISERS

Question: Regulation (EC) No 2003/2003 requires the P₂O₅ content in NP and NPK fertilisers to be declared in accordance with the solubility in various media, for example: (1) in water, (2) in neutral ammonium citrate, and (3) in neutral ammonium citrate and in water. Whereas there are methods specifically designated in Annex IV to determine solubility (1) and (2), namely Method 3.1.6 and Method 3.1.4 respectively, there is no method specifically designated to determine solubility (3). How should the solubility in neutral ammonium citrate and in water be determined?

Answer: Method 3.1.4 should be used to determine solubility (3). The water content of the neutral ammonium citrate solution is sufficient to extract the phosphate that is soluble in neutral ammonium citrate and in water. Solubilities (2) and (3) are therefore identical and differ only in name.

6. LABELLING REQUIREMENT FOR MIXTURES OF MICRO-NUTRIENTS

Question: Commission Regulation (EU) No 137/2011 introduced two mixed micro-nutrient fertiliser types with labelling provisions that go beyond the requirements of Articles 6(6) and 23(2) of the Regulation (EC) No 2003/2003. Which labelling rules should be applied?

Answer: Either set of rules may be used.

The existing rules contained in Article 6, 9 and 23 were not repealed when more detailed rules were introduced by Regulation 137/2011. The new rules in Table E.2.4 essentially reproduce the existing rules as set out in Articles 6, 9 and 23, but also require some additional labelling information on the mineral anions present and the micro-nutrient water-soluble content. Fertilisers that comply with the new rules therefore automatically comply with the pre-existing rules as well. However, the new rules have not replaced the old rules. Consequently, fertilisers that comply with the rules on labelling that are set out in the articles of the Fertiliser Regulation do not need relabeling, despite the entry into effect of the new rules on 9 March 2011.

The Commission will try to improve the coherence of the labelling rules for mixed micro-nutrient fertilisers as soon as possible in a future ATP while retaining the original objective of introducing a specific type 'mixture of micro-nutrients' in Annex I to make this fertiliser type fully compliant with the requirements of Article 3 of the Regulation. Once the new legislation is adopted, this entry in the FAQ document will be deleted.

7. RULES ON MICRO-NUTRIENT CHELATE, MICRO-NUTRIENT SOLUTION AND MICRO-NUTRIENT COMPLEX

Question: The rules on micro-nutrients have been amended in Commission Regulation (EC) No 137/2011 and Commission Regulation (EC) No 223/2012 in view of the harmonisation of their requirements. Could the Commission clarify the new rules by describing the labelling of such micro-nutrient fertiliser types?

Answer: To illustrate the different labelling provisions, copper is taken as an example:

a) Copper chelate (type 3d)

Mandatory labelling:

Copper chelate

Water-soluble Copper (Cu): 6%

Copper (Cu) chelated by (o,o) EDDHA: 3%

Copper (Cu) chelated by EDTA: 2%

If a product contains a chelating agent that does not chelate at least 1% of the water-soluble copper (e.g. 0.8% EDDHSA), the name of this chelating agent cannot appear in the label. However, the sum of the chelated form can optionally be declared.

Optional labelling:

Total copper (Cu) chelated by authorised chelating agents: 5.8% (i.e. in our example: 3%+2%+0.8%)

b) Copper fertiliser solution (type 3f)

The former product diluted in water would give:

Mandatory labelling:

Copper fertiliser solution

Mineral anions present: sulphate and chloride

Authorised chelating agents: (o,o) EDDHA, EDTA

Water-soluble copper (Cu): 3%

Copper (Cu) chelated by (o,o) EDDHA: 1.5%

Copper (Cu) chelated by EDTA: 1%

Optional labelling:

Total copper (Cu) chelated by authorised chelating agents: 2.9%

c) Copper complex (type 3i)

Mandatory labelling:

Copper complex

Lignosulphonate

Water-soluble copper (Cu): 5% (*at least*)

Copper (Cu) complexed: 4% (*at least*)

Authorised complexing agent: LS

8. SOLUTIONS OF MICRO-NUTRIENT FERTILISER

Question: Data on method of production of micro-nutrient solutions allow the use of micro-nutrient salts and/or micro-nutrient chelate or micro-nutrient complex. A clarification is needed to explain which combinations of such fertiliser types are allowed.

Answer: For copper fertiliser solution, the following combinations would be permitted:

Copper salts, or

Copper chelates, or

Copper complex, or

Copper salts and copper chelates, or

Copper salts and one copper complex.

The current analytical methods do not allow the combination of micro-nutrient salts, micro-nutrient chelates and micro-nutrient complex(es).

9. EXAMPLE OF LABELLING FOR MIXTURES OF MICRO-NUTRIENTS

Question: Commission Regulation (EC) No 223/2012 clarified the rules for mixtures of fertilisers in a revised Table E.2.4 by referring directly to the Articles of the Fertiliser Regulation. Could the Commission clarify the labelling requirements by giving an example of labelling for such micro-nutrient fertiliser?

Answer: The following table shows an example of labelling for mixtures of micro-nutrient fertiliser. A reference to the Articles of the Fertiliser Regulation is given in column 2 for information. As the current methods of analysis do not allow identifying which fraction of micro-nutrient is complexed by a specific complexing agent, the

labelling should bear the percentage of micro-nutrient complexed and the name of the complexing agent(s).

EC FERTILISER	Art 9(a), 1st bullet
Mixture of micronutrients Boron (B) (sodium), Cobalt (Co) (sulphate), Copper (Cu) (oxide, chloride), Iron (Fe) (sulphate)	Art 23(2) Each micronutrient present is followed by the name(s) of its counter-ion(s).
Water-soluble Boron (B) 1% Total Copper (Cu) 3% Water-soluble Copper (Cu) 1.6% Copper (Cu) chelated by EDTA 0.6% Water-soluble Cobalt (Co) 0.02% Water-soluble Iron (Fe) 2% Iron (Fe) chelated by [o,o] EDDHA 0.5% Iron (Fe) complexed 0.5% Complexing agent: LS	Art 6(6) i Art 6(6) ii Art 6(6) last para Art 9(1) (a), 6,7 bullet
« To be used only where there is a recognised need. Do not exceed the appropriate dose rate »	Art 23(5)

10. CLARIFICATION ON THE USE OF SEVERAL UREA CONDENSATES IN THE PRODUCTION OF COMPOUND FERTILISERS

Question: Tables B.1.2, B.2.2 and B.3.2 of Annex I to Regulation (EC) No 2003/2003 allow the use of crotonylidene diurea (CDU) **or** isobutylidene diurea (IBDU) **or** urea formaldehyde (UF) in the manufacture of NPK, NP and NK EC fertilisers. The wording ‘**or**’ has proven not to be without ambiguity. Two conflicting interpretations can be made: either that a cumulative presence of the 3 substances is allowed or that only an individual use of those substances is allowed.

Answer: The use of different combinations of CDU, IBDU and UF is acceptable. An inclusive interpretation of ‘or’ should be made to allow for the cumulative presence of the three substances in a given urea condensate. Those substances all have the same agronomic objective (slow release of nitrogen). Furthermore, EN 15705 (method B) allows the determination of the presence of IBDU, CDU and UF in compound fertilisers so that each substance can be individually detected in commercial products.

11. NUMBERS INDICATING THE PHOSPHORUS CONTENT IN COMPOUND FERTILISERS

Question: According to Article 19.2.ii of Regulation (EC) No 2003/2003, the type designation of compound fertilisers shall be followed by numbers indicating the primary

nutrient content. A question has been raised on how the phosphorus solubility has to be expressed in products free from Thomas slag, calcined phosphate, aluminium-calcium phosphate, partially solubilised rock phosphate and soft ground rock phosphate (Types B.1.1.1, B.2.1.1 and B.4.1 of Annex I). It appears that some producers have marketed such EC fertilisers by declaring the phosphorus content as the sum of the phosphorus soluble in neutral ammonium citrate and in water plus the phosphorus soluble in mineral acid only. Is that practice allowed under the rules of Regulation (EC) No 2003/2003?

Answer: Fertiliser producers can use different sources of phosphorus in the manufacture of NPK fertilisers. They can either use water soluble phosphates (monoammonium phosphate, diammonium phosphate, TSP, SSP) or choose to use sources that are hardly soluble in water (rock phosphate, partially solubilised rock phosphate...).

The first case corresponds to products complying with types B.1.1.1, B.2.1.1 and B.4.1 in which case the Fertilisers Regulation specifies that the quantity of phosphorus P soluble in mineral acids only must be less than 2% and cannot be declared.

It follows that under a correct application of Regulation (EC) No 2003/2003, the only forms of phosphorus that can be declared for products corresponding to entries B.1.1.1, B.2.1.1 and B.4.1 of Annex I are the following:

- (1) Water-soluble P₂O₅;
 - (2) P₂O₅ soluble in ammonium citrate;
 - (3) P₂O₅ soluble in neutral ammonium citrate and in water;
- depending on the actual content of water-soluble P₂O₅

Therefore, the number indicating the phosphorus content after the type designation for compound fertilisers free from Thomas slag, calcinated phosphate, aluminium-calcium phosphate, partially solubilised rock phosphate and soft ground phosphate has to be expressed as the solubility in neutral ammonium citrate and in water or as the solubility in neutral ammonium citrate.

12. ORGANIC MATTER IN EC FERTILISERS

Question: Can a product belong to one of the EC fertiliser types listed in Section B or C.2 (i.e., type B.1.1, B.1.2, B.2.1, B.2.2, B.3.1, B.3.2, B.4, C.2.1, C.2.2, C.2.3, C.2.4, C.2.5, C.2.6, C.2.7, or C.2.8; hereinafter the 'compound fertiliser types') ,of Annex I to Regulation (EC) No 2003/2003 (hereinafter 'the Fertilisers Regulation'), if organic matter of animal or vegetable origin is added to the product?

Answer: A product cannot belong to one of the compound fertiliser types, if organic nutrients of animal or vegetable origin have been added to the product. This follows from the "Data on method for production" specified for each of the compound fertiliser types.

In theory, if an organic matter would be entirely free of any plant nutrient, a product could belong to one of the compound fertiliser types even if that organic matter had been added to the product.¹ However, this scenario is highly unlikely, since organic matter will always contain traces of plant nutrients.

¹ The Spanish language version of the Fertilisers Regulation gives an indication to the contrary. However, most – if not all – the other language versions support the view taken in this document, and must therefore be seen as prevailing.

Therefore, the Commission services competent for fertilisers conclude, that a product *cannot* belong to one of the compound fertiliser types if organic matter of animal or vegetable origin has been added to the product.

13. PHOSPHONATES IN FERTILISERS

Question: Potassium phosphonates (potassium phosphonate and disodium phosphonate) are recognised as active substance according to Regulation (EC) No 1107/2009. Annex I to the Fertilisers Regulation does not contain any type designation for monopotassium phosphonate but phosphonate are often found as source of phosphorus in compound fertilisers. Several Member States have expressed concerns that phosphonates do not have fertiliser action but rather fungicidal properties and but can lead to residues that can have consequences as regards the compliance of plant commodities with food law. Can phosphonates be added to fertilisers and be labelled as EC fertilisers?

Answer: The Commission Units responsible for regulation of fertilisers and PPPs note, that any product, which consists of, or contains potassium phosphonates, and is intended for one of the uses listed in Article 2(1) of the PPPR (i.e., e.g., protecting plants from harmful organisms), is considered as a PPP and hence requires an authorisation. In view of current knowledge of the mode of action of potassium phosphonates (in particular its fungicidal properties, as well as the hitherto weak evidence of any significant nutritional effect for plants), this is presumed to be the intended use of any product consisting solely of, or intentionally incorporating, that substance.

In consequence, any product which consists of or intentionally incorporates potassium phosphonates can only be placed on the market and used if authorised for that specific use under the PPPR, unless it can be proven that the product is intended to be used solely for purposes *other* than those listed in Article 2(1) of the PPPR (i.e., e.g., other uses than that of protecting plants through the fungicidal properties of that active substance), which would be for the company placing the product on the market to demonstrate.

PPPR authorisation requirements would apply also in a case, where that product (be it a substance or a mixture) was marketed as a fertiliser, either based on compliance with any national rules, or as an EC fertiliser based on compliance with one of the type designations in Annex I to Regulation (EC) No 2003/2003. Label claims or user instructions related to the use of that mixture for the sake of its fertilising properties may not contradict the requirements contained in the PPPR authorisation.

As indicated in a letter of 1 September 2014, addressed to stakeholders by the Commission Unit responsible for regulation of PPPs, regardless of the legal status of products containing phosphonates, phosphonate residues fall within the scope of Regulation (EC) No 396/2005. It is therefore the responsibility of food business operators to find solutions to ensure compliance with the Maximum Residues Levels (MRLs) at 2 mg/kg, which will be applicable again from 1 January 2016. Producers of the concerned food products should thus consider discontinuing the use of such products and investigate the use of alternative fertilisers that do not lead to non-compliances with the EU MRLs.

Bilag 3

EU-Kommissionen: Final review report for the active substance disodium phosphonate (2018)



Disodium phosphonate
SANCO/10416/2013 rev. 0
16 July 2013
23 March 2018¹

Final Review report for the active substance **disodium phosphonate**
Finalised in the Standing Committee on the Food Chain and Animal Health
at its meeting on 16 July 2013
in view of the approval of disodium phosphonate as active substance
in accordance with Regulation (EC) No 1107/2009²

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance disodium phosphonate, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC³ concerning the placing of plant protection products on the market, to be read in conjunction with Regulation (EU) No 188/2011⁴, laying down detailed rules for the assessment of new active substances and the transitional provisions foreseen in Article 80(1)(a) of Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the authorities of France received on 11 February 2008 an application from ISK Biosciences Europe N.V., hereafter referred to as the applicant, for the inclusion of the active substance disodium phosphonate in Annex I to the Directive. The French authorities indicated to the Commission on 21 May 2008 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on disodium phosphonate was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health on 2 October 2008, during which the Member States confirmed the receipt of the dossier.

¹ On 23 March 2018 the Standing Committee on Plants, Animals, Food and Feed took note of the revision of the review report of the active substance disodium phosphonate after the assessment of the confirmatory data referred to in point 7 of this report (cfr. *infra*).

² Report initially established within the Standing Committee on the Food Chain and Animal Health and revised according to the principles of Article 13 of Regulation (EC) No 1107/2009 in March 2018; does not necessarily represent the views of the European Commission.

³ OJ L 230, 19.8.1991, p. 1.

⁴ OJ L 53, 26.2.2011, p. 51.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2008/953/EC⁵ of 8 December 2008 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to EFSA as soon as possible and at the latest within a period of one year.

Following an agreement between the Commission and the European Food Safety Authority (EFSA), the latter organises a peer review for those active substances for which the decision on completeness has been published after June 2002.

In analogy with the provisions of Article 8(1) of Regulation (EC) No 451/2000⁶ for existing active substances, France submitted on 27 August 2009 to EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of disodium phosphonate in Annex I to the Directive.

In analogy with the provisions of Article 8 of Regulation (EC) No 451/2000 for existing active substances and, where applicable, according to the provisions of Article 7 of Regulation (EU) No 188/2011, EFSA organised the consultation on the draft assessment report by all the Member States as well as by ISK Biosciences Europe N.V., being the sole data submitter, on 13 March 2012 by making it available.

EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

According to the provisions of Article 8(1) of Regulation (EU) No 188/2011, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion regarding the peer review of the pesticide risk assessment of the active substance disodium phosphonate (approved: 17 April 2013)⁷]. This conclusion refers to several background documents: the draft assessment report and the EFSA peer review report.

According to the provisions of Article 9 of that Regulation, the Commission produced a draft review report on disodium phosphonate. The Commission referred this draft to the applicant for commenting on 21 May 2013 and on 16 July 2013 to the Standing Committee on the Food Chain

⁵ OJ L 338, 17.12.2008, p. 62-63.

⁶ OJ L 55, 29.2.2000, p. 25.

⁷ EFSA Journal (2013) 11(5):3213, Conclusion on the peer review of the pesticide risk assessment of the active substance disodium phosphonate. doi:10.2903/j.efsa.2013.3213. Available online: www.efsa.europa.eu.

and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 16 July 2013.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA and its background documents, these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing **Regulation (EU) No 832/2013**⁸ concerning the approval of disodium phosphonate as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing disodium phosphonate they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing disodium phosphonate will fulfil the safety requirements laid down in Article 4(1) – (3)⁹ of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each disodium phosphonate containing plant protection product for which Member States will grant or review the authorisation.

⁸ OJ L 233, 31.8.2013, p. 3.

⁹ read in conjunction with articles 78(3) and 80(1).

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The following reference values have been finalised as part of this evaluation:

ADI: 2.25 mg/kg bw per day as phosphonic acid,
ArfD: Not relevant,
AOEL: 2.00 mg/kg bw per day.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) is 3% of the Acceptable Daily Intake (ADI), calculated according to WHO European diet and 7% calculated for the French diet.

Additional intake from water and products of animal origin is not expected to give rise to intake problems.

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity of disodium phosphonate is given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The active substance shall have a minimum purity of 917 g/kg.

The review has established that for the active substance notified by the applicant ISK Biosciences Europe S.A. there are no relevant impurities which are of toxicological, ecotoxicological and/or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing disodium phosphonate.

On the basis of the proposed and supported uses (as listed in Appendix II), the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to:

- the risk to aquatic organisms,
- the risk of eutrophication of surface water.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the approval of disodium phosphonate under the current approval conditions.

The concerned Member States shall request the submission of:

- information to further address the long term risk to earthworms and soil macro-organisms,
- information to address the chronic risk to fish from the active substance.

The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 31 January 2016.

On 23 March 2018 the Standing Committee on Plant, Animals, Food and Feed took note of the revision of this review report after the assessment of the confirmatory data as referred to above. This assessment has been carried out in line with the Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex to Regulation (EC) No 541/2011¹⁰.

It shows from the Technical Report by EFSA that the Authority and the involved Member States agree that a low chronic risk to fish was concluded. As regards soil macro-organisms, a low risk was concluded for soil macro-organisms other than earthworms.

¹⁰ Doc. SANCO/5634/2009 rev. 6.1, dated December 2013.

Furthermore, the risk to earthworms may need further consideration at national level when authorisations are sought.

The Committee considers from the above that the outstanding matters have well been addressed and that the conclusions of the original risk assessment are not modified by the evaluation of the submitted confirmatory information. As a consequence, there is no need to reconsider the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 14).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

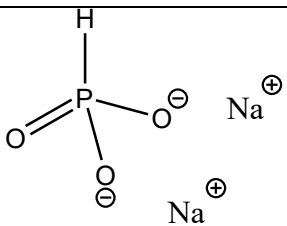
9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for disodium phosphonate.

APPENDIX I

Main identity

DISODIUM PHOSPHONATE

Common name (ISO)	Disodium phosphonate (Syn : sodium phosphite ; disodium salt of phosphonic acid) (No ISO name)
Chemical name (IUPAC)	disodium phosphonate
Chemical name (CA)	Not available
CIPAC No	808
CAS No	13708-85-5 (other registry numbers : 130184-07-5 ; 16926-95-7)
EC No (EINECS or ELINCS) ‡	EINECS : 237-249-1
FAO SPECIFICATION	None
Minimum purity	281-337 g/kg (TK) 917 g/kg (TC)
Molecular formula	Na ₂ HPO ₃
Molecular mass	125.96 g/mol
Structural formula	 <p>The structural formula shows a central phosphorus atom (P) bonded to a hydrogen atom (H) above it, a double-bonded oxygen atom (O) to its left, and two single-bonded oxygen atoms (O) below and to its right. Each of the single-bonded oxygen atoms has a negative charge (⊖). Two sodium ions (Na[⊕]) are shown to the right of the phosphorus atom, one above and one below the rightmost oxygen atom.</p>

APPENDIX II

List of uses supported by available data

DISODIUM PHOSPHONATE

Crop and/or situation (a)	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application	Application rate per treatment				PHI (days) (l)	Remarks (m)		
				Type (d-f)	Conc. of a.s. (i)		Method Kind (f-h)	Growth stage & season (j)	Number max (k)	Interval between apps. (min)			g a.s./hL min max	water (L/ha) min max
Vineyards	MILDICUT®	F	grape downy mildew (<i>Plasmopara viticola</i>)	25 g cyazofamid/L	SC	Foliar application	GS 13-89	8	12 days	7.5 – 37.5 (cyazofamid)	150-1500	0.112 5 (cyazofamid)	21	It is recommended to use the product in resistance management programs
				250 g disodium phosphonate /L						75-375 (disodium phosphonate)		1.125 (disodium phosphonate)		

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) G/CPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavicalarb-isopropyl).**

(j) Growth stage for the treatment window (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval

Bilag 4

EU-Kommissionen: Final review report for the active substance potassium phosphonates (2013)



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Potassium phosphonates
SANCO/10416/2013 rev 2
15 March 2013

Final

Review report for the active substance **potassium phosphonates**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
15 March 2013

in view of the approval of potassium phosphonates as active substance in accordance with
Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance potassium phosphonates, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC¹ concerning the placing of plant protection products on the market, to be read in conjunction with Regulation (EU) No 188/2011², laying down detailed rules for the assessment of new active substances and the transitional provisions foreseen in Article 80(1)(a) of Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the authorities of France received on 22 August 2002 an application from Luxembourg Industries (Pamol) Ltd (now: Luxembourg Industries Ltd), hereafter referred to as the applicant, for the inclusion of the active substance potassium phosphonates (initially referred to as 'potassium phosphite') in Annex I to the Directive. The French authorities indicated to the Commission on 20 February 2003 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on potassium phosphonates was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health on 4 July 2003, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information

¹ OJ L 230, 19.8.1991, p. 1.

² OJ L 53, 26.2.2011, p. 51

requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2003/636/EC³ of 2 September 2003 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to EFSA as soon as possible and at the latest within a period of one year.

Following an agreement between the Commission and the European Food Safety Authority (EFSA), the latter organises a peer review for those active substances for which the decision on completeness has been published after June 2002.

In analogy with the provisions of Article 8(1) of Regulation (EC) No 451/2000⁴ for existing active substances, France submitted on 1 February 2005 to EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of potassium phosphonates in Annex I to the Directive.

In analogy with the provisions of Article 8 of Regulation (EC) No 451/2000 for existing active substances and, where applicable, according to the provisions of Article 7 of Regulation (EU) No 188/2011, EFSA organised the consultation on the draft assessment report by all the Member States as well as by Luxembourg Industries (Pamol) Ltd (now: Luxembourg Industries Ltd), being the main data submitters, on 15 February 2005 by making it available.

EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

According to the provisions of Article 8(1) of Regulation (EU) No 188/2011, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion regarding the peer review of the pesticide risk assessment of the active substance potassium phosphonates (approved: 19 November 2012)⁵]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 9 of that Regulation, the Commission produced a draft review report on potassium phosphonates. The Commission referred this draft to the applicant for commenting on 31 January 2013 and on 14 March 2013 to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 15 March 2013.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications submitted after the conclusion of EFSA (background document C), these documents are also considered to be part of this review report.

³ OJ L 221, 4.9.2003, p. 42.

⁴ OJ L 55, 29.2.2000, p. 25.

⁵ EFSA Journal (2012) 10(12):2963, Conclusion on the peer review of the pesticide risk assessment of the active substance potassium phosphonates. doi:10.2903/j.efsa.2012.2963. Available online: www.efsa.europa.eu.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing **Regulation (EU) No 369/2013**⁶ concerning the approval of potassium phosphonates as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing potassium phosphonates they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing potassium phosphonates will fulfil the safety requirements laid down in Article 4(1) – (3)⁷ of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each potassium phosphonates containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the

⁶ OJ L 111, 23.4.2013, p. 39

⁷ read in conjunction with articles 78(3) and 80(1).

requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The following reference values have been finalised as part of this evaluation:

ADI: 3.90 mg/kg bw per day
ArfD: Not relevant
AOEL: 5.00 mg/kg bw per day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) is 12% of the Acceptable Daily Intake (ADI), calculated for the French diet using Primo 2. Additional intake from water and products of animal origin is not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity of potassium phosphonates is given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The active substance shall have a minimum purity of 990 g/kg on a dry weight basis.

The review has established that for the active substance notified by the applicant Luxembourg Industries (Pamol) Ltd (now: Luxembourg Industries Ltd) there are no relevant impurities which are of toxicological, ecotoxicological and/or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing potassium phosphonates.

On the basis of the proposed and supported uses (as listed in Appendix II), the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to:

- the risk to birds and mammals;
- the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the approval of potassium phosphonates under the current approval conditions. This is particularly the case for information to further address the long term risk to insectivorous birds.

The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 September 2015.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 14).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

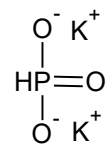
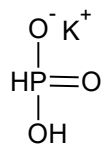
9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of

Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the approval conditions for potassium phosphonates.

APPENDIX I**Main identity****POTASSIUM PHOSPHONATES**

Common name (ISO)	Potassium phosphonates (No ISO name)
Chemical name (IUPAC)	potassium hydrogen phosphonate dipotassium phosphonate
Chemical name (CA)	potassium hydrogen phosphonate dipotassium phosphonate
CIPAC No	756 (for potassium phosphonates)
CAS No	13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none
EC No (EINECS or ELINCS) ‡	potassium hydrogen phosphonate: EC 604-162-9 dipotassium phosphonate: EC 236-809-2
FAO SPECIFICATION	None
Minimum purity	Specification for TK: 31.6 to 32.6 % phosphonate ions (sum of hydrogen phosphonate and phosphonate ions) 17.8 to 20.0 % potassium min. 990 g/kg on dry weight basis
Molecular formula	KH ₂ PO ₃ [HPO(OH)(O-K ⁺)] and K ₂ HPO ₃ [HPO(O-K ⁺) ₂]
Molecular mass	monopotassium phosphonate: 120.1 g/mol dipotassium phosphonate: 158.2 g/mol

Structural formula

APPENDIX II

List of uses supported by available data

POTASSIUM PHOSPHONATES

Crop and/or situation (a)	Member State or Country	Product name	F or I (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment				PHI (days)	Remarks (m)
					Type (d-f)	Conc. of as (PAI) (g/kg) (i)	method kind (f-h)	growth stage & season (j)	Number (k)	Interval between applications (min)	g as/hl	water L/ha	kg as/ha		
Grapes (VITVI)	EU	LBG-01F34	F	Oomycetes Peronosporales Pythium	SL	726 g/l	Spraying (motor-, knapsack- and hand sprayer)		6	9 ± 1 days	200- 1000	2.904	60 d		

Remarks

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions