

公表文献に関する報告書

有効成分名：プロパモカルブ塩酸塩

アリスタライフサイエンス株式会社 提出

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## プロパモカルブ塩酸塩に関する公表文献調査結果

アリスタライフサイエンス株式会社

### 1. 検索に用いたデータベース、検索日及び検索に用いたデータベースに関する情報

プロパモカルブ塩酸塩の公表文献検索は、システマティックレビューの目的である広範な文献検索を行うこと及び一定の質を確保した論文検索を行うことを考慮し、複数のデータベースを横断的に検索可能な電子ジャーナルプラットフォーム Web of Science (Core Collection) (英文検索) 及び J-STAGE (和文検索) を使用した。概要を表 1 に示す。

表 1 文献検索に用いたデータベースの概要

データベース名	データベースの特徴 収載分野等	収載範囲、 文献検索時の文献数	更新 頻度	検索 日	検索 対象 期間
Web of Science (Core Collection)	世界最大の出版社に中立な引用索引・研究情報プラットフォーム 科学技術分野、社会科学分野及び人文科学分野の主要な学術雑誌に掲載された文献の書誌・引用文献情報、1990 年以降の世界の重要会議、シンポジウム、セミナー等で発行された会議録の情報を収録	以下のようなデータベースに収載された文献の引用が可能。 Data Citation Index、Derwent Innovations Index、BIOSIS Previews、Biological Abstracts、BIOSIS Citation Index、Current Contents Connect、Zoological Record、Inspec、CABI:CAB Abstracts、CABI:Global Health、MEDLINE、FSTA – the food science resource、Russian Science Citation Index Chinese Science Citation Index、KCI - Korean Journal Database、SciELO Citation Index	毎週	2022/ 12/7	2007/ 04/01 ～ 2022/ 11/30
J-STAGE	科学技術振興機構が提供する、日本国内の科学技術情報の電子ジャーナルプラットフォーム	自然科学から人文・社会科学、さらに学際領域等の分野について、国内の 1,500 を超える発行機関が、3,000 誌以上のジャーナルや会議録等の刊行物を公開	不 定 期	2022/ 12/7	2007/ 01/01 ～ 2022/ 12/31

### 2. 検索に使用したキーワード、検索の条件

#### (1) 対象とする農薬

検索キーワードは、できるだけ広範な文献を収集するため、表 2 に示すとおり EU で提出済の「参考資料\_Summary of the literature data for Propamocarb」で用いられたキーワード及び日本における名称等様々な名称や主要な代謝物を検索対象とした。

表 2. 検索に用いたキーワード：有効成分プロパモカルブ塩酸塩

プロパモカルブ塩酸塩、Propamocarb hydrochloride	
一般名	プロパモカルブ塩酸塩 PROPAMOCARB HYDROCHLORIDE
IUPAC/CAS 名	(IUPAC 名) プロピル=3-(ジメチルアミノ)プロピルカルバマート塩酸塩 PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE HYDROCHLORIDE (CAS 名) プロピル=[3-(ジメチルアミノ)プロピル]カルバマート塩酸塩 PROPYL [3-(DIMETHYLAMINO)PROPYL]CARBAMATE HYDROCHLORIDE
その他名称等	N-(3-DIMETHYLAMINOPROPYL)CARBAMIC ACID PROPYL ESTER PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE SN 39744 AE B039744 PROPAMOCARB PLANTACUR SN 66752 AE B066752 CA701337 PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE MONOHYDROCHLORIDE
CAS 番号	24579-73-5, 1135443-13-8, 25606-41-1, 70323-53-4, 1135443-14-9
有効成分を含む 製剤名	プロプラント、ターフシャワー、PROPLANT、TURFSHOWER、INFINITO、VOLARE、 PROMESS
2-ヒドロキシ-プロパモカルブ	
一般名	2-ヒドロキシ-プロパモカルブ
IUPAC/CAS 名	(IUPAC 名) 2-ヒドロキシプロピル=3-(ジメチルアミノ)プロピルカルバマート 2-HYDROXYPROPYL 3-(DIMETHYLAMINO)-PROPYLCARBAMATE (CAS 名) 2-ヒドロキシプロピル=[3-(ジメチルアミノ)プロピル]カルバマート 2-HYDROXYPROPYL [3-(DIMETHYLAMINO)PROPYL]CARBAMATE
CAS 番号	142955-35-9
プロパモカルブ-N-オキシド	
一般名	プロパモカルブ-N-オキシド
IUPAC/CAS 名	(IUPAC 名) プロピル=3-(ジメチルアミノ)プロピルカルバマート=N-オキシド PROPYL 3-(DIMETHYL-AMINO)PROPYLCARBAMATE N-OXIDE (CAS 名) プロピル=[3-(ジメチルニトロリル)プロピル]カルバマート PROPYL [3-(DIMETHYLNITRORYL)PROPYL]CARBAMATE
CAS 番号	-

N-メチル-プロパモカルブ	
一般名	N-メチル-プロパモカルブ
IUPAC/CAS 名	(IUPAC 名) プロピル=3-メチルアミノ-プロピルカルバマート PROPYL 3-METHYLAMINO-PROPYLCARBAMATE (CAS 名) プロピル=[3-(メチルアミノ)プロピル]カルバマート PROPYL [3-(METHYLAMINO)PROPYL]CARBAMATE
CAS 番号	1392231-41-2

表 3. 検索キーワード (条件)

検索キーワード(条件)	
英文検索 Web of Science (Core Collection)	PROPAMOCARB HYDROCHLORIDE OR PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE HYDROCHLORIDE OR PROPYL [3-(DIMETHYLAMINO)PROPYL]CARBAMATE HYDROCHLORIDE OR N-(3-DIMETHYLAMINOPROPYL)CARBAMIC ACID PROPYL ESTER OR PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE OR SN 39744 OR AE B039744 OR PROPAMOCARB OR PLANTACUR OR SN 66752 OR AE B066752 OR CA701337 OR PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE MONOHYDROCHLORIDE OR 24579-73-5 OR 1135443-13-8 OR 25606-41-1 OR 70323-53-4 OR 1135443-14-9 OR PROPLANT OR TURFSOWER OR INFINITO OR VOLARE OR PROMESS OR 2-HYDROXYPROPYL 3-(DIMETHYLAMINO)-PROPYLCARBAMATE OR 2-HYDROXYPROPYL [3-(DIMETHYLAMINO)PROPYL]CARBAMATE OR 142955-35-9 OR PROPYL 3-(DIMETHYL-AMINO)PROPYLCARBAMATE N-OXIDE OR PROPYL [3-(DIMETHYLNITRORYL)PROPYL]CARBAMATE OR PROPYL 3-METHYLAMINO-PROPYLCARBAMATE OR PROPYL [3-(METHYLAMINO)PROPYL]CARBAMATE OR 1392231-41-2
和文検索 J-STAGE	プロパモカルブ塩酸塩、プロピル=3-(ジメチルアミノ)プロピルカルバマート塩酸塩、プロピル=[3-(ジメチルアミノ)プロピル]カルバマート塩酸塩、プロプラント、ターフシャワー

## (2) 評価対象となる影響

評価対象となる影響について、Web of Science を用いた検索では、(1)で抽出された全論文を表 4 に示した分類フィールドで選抜を行った。また、J-STAGE を用いて(1)で抽出された論文については、評価対象となる影響による抽出を行うことなく全論文を選抜した。

表 4. 評価対象となる影響に関する分類フィールド

ヒトに対する毒性	toxicology public environmental occupational health
農作物及び畜産物 への残留	plant sciences environmental sciences
生活環境動植物及び 家畜に対する毒性	toxicology environmental sciences entomology ecology
環境動態	environmental sciences

### (3) 評価対象の生物種等

評価対象の生物種等について、Web of Science を用いた検索では(2)で抽出された全論文から表 5 のキーワードのいずれかを含む論文を選抜した。なお、J-STAGE を用いて(1)で抽出された論文については、評価対象となる生物種等による抽出を行うことなく全論文を選抜した。

表 5. 評価対象となる生物種等に関するキーワード

ヒトに対する毒性	rat OR mouse OR dog OR rabbit OR monkey OR pig OR human OR hen OR S. typhimurium OR E. coli
農作物及び畜産物への残留	crop OR commodity OR feed OR livestock OR hen OR cattle OR goat OR pig OR ruminant OR cow OR poultry
生活環境動植物及び家畜に対する毒性	avian OR bird OR mallard duck OR quail OR bobwhite OR lemna OR algae OR fish OR crustacean OR aquatic OR chironomus OR bumble/honey/solitary bee OR pollinator OR apis
環境動態	soil OR water OR sediment

### 3. 評価目的との適合性評価（第1 段階、第 2 段階）及び信頼性評価で設定した判断基準

#### (1) 第 1 段階：文献の表題及び概要に基づく適合性評価（RA）

第 1 段階として、文献の表題及び要約に基づき、下記の①から⑮に該当するものは明らかに評価の目的と適合しない文献とみなした。

- ① 当該農薬と関係しない論文（当該農薬の代替剤等）
- ② 政策、社会、経済分析に関する論文
- ③ 農産物等の生産、流通に関する論文
- ④ 薬効、薬害、物理的・化学的性状に関する論文
- ⑤ 分析法やその開発に関する論文
- ⑥ 新規合成法や基礎化学の観点で記載された論文
- ⑦ 特許関連文献
- ⑧ リスク評価をする上で十分なデータや情報を含まない学会発表等の概要や総説、成書
- ⑨ リスク評価に使用できる新規のデータが提示されていない意見書
- ⑩ 科学論文や規制についての総説を含む二次情報において、当該文献が参照する一次資料（原著）の確認ができないもの
- ⑪ 一般的な農薬の暴露に関する論文（当該農薬に限定せず、広範囲の農薬について記載されたもの）
- ⑫ 異なる有効成分に由来する混合製剤の毒性に関する論文
- ⑬ IV. の 2. の②に掲げる4分野に関係しない論文
- ⑭ 日本で登録されている処方以外の製剤に関する論文
- ⑮ コンピュータシミュレーション等を用いたドライラボのみの論文

#### (2) 第 2 段階：文献の全文に基づく適合性評価と分類（DA）

第 1 段階で除外した以外の公表文献については、文献全文の内容に基づいて、以下の手順に従って評価目的との適合性を検証し、その結果により分類した。

(ア) 評価の目的と適合しない文献の除外

文献全文の内容に基づき、下記の①から⑰に該当するものは明らかに評価の目的と適合しない文献とみなした。

- ① 当該農薬と関係しない論文（当該農薬の代替剤等）
- ② 政策、社会、経済分析に関する論文
- ③ 農産物等の生産、流通に関する論文
- ④ 薬効、薬害、物理的・化学的性状に関する論文
- ⑤ 分析法やその開発に関する論文
- ⑥ 新規合成法や基礎化学の観点で記載された論文
- ⑦ 特許関連文献
- ⑧ リスク評価をする上で十分なデータや情報を含まない学会発表等の概要や総説、成書
- ⑨ リスク評価に使用できる新規のデータが提示されていない意見書
- ⑩ 科学論文や規制についての総説を含む二次情報において、当該文献が参照する一次資料（原著）の確認ができないもの
- ⑪ 一般的な農薬の暴露に関する論文（当該農薬に限定せず、広範囲の農薬について記載されたもの）
- ⑫ 異なる有効成分に由来する混合製剤の毒性に関する論文
- ⑬ 表3及び4に掲げる4分野に関係しない論文
- ⑭ 日本で登録されている処方以外の製剤に関する論文
- ⑮ コンピュータシミュレーション等を用いたドライラボのみの論文
- ⑯ 試験設計、試験系、試験種、被験物質、暴露経路等が評価に活用する観点で妥当でないもの
- a) 試験方法が記載されていないもの
- b) 適切に評価できる試験種で実施されていないもの
- c) 適切な経路で投与/処理されていないもの
- d) 投与又は処理した被験物質量が明記されていないもの
- e) 添加に用いた媒体が確認できないもの
- f) 分析法が記載されていないもの
- ⑰ 日本の代表的な使用方法/使用条件における評価に活用できない文献（ほ場条件、土性等）

(イ) 評価の目的と適合した文献の分類

(ア) で除外した以外の文献については、適合性があると判断した文献とし、下記の分類基準に従って、全文をレビューし3つの区分に分類した。

① 分類基準

1. 実施している試験環境がテストガイドライン（TG）で定める条件と合っていること
2. 投与又は処理した被験物質の純度が明記されていること
3. 統計解析が可能な動物数／例数が確保されていること
4. 複数の用量で実施されていること（最低3用量で実施）
5. 無処理区（コントロール区）が設定されており、TGに照らしその結果が適正であること

## 6. 解析方法及び結果が報告されていること

ヒトに対する毒性に関して、区分aに該当するかどうかについては、食品安全委員会ですされた「定量的データ」として分類される下記基準を参考とした。

- ・公表文献で用いられた用量が、研究内容と同等である安全性試験で用いられた最低用量よりも低いこと
- ・公表文献の研究結果が、他の試験結果と比較できる単位を用いて報告されていること
- ・研究の結論、エンドポイント及び用量が正確で、信頼でき、妥当であることを実証するための十分な情報が公表文献中に提供されており、研究結果が再現される可能性があることと判断できること

### ② 分類区分

区分	該当する文献
a	リスク評価パラメーター(ADI、ARfD、AOEL、残留基準、生活環境動植物の登録基準、水産PEC 等)を設定又は見直すために利用可能と判断される文献
b	リスク評価パラメーターを設定する際の補足データとして利用が可能と想定される文献
c	a又はbに分類されない文献

### (3) 結果の信頼性に基づく分類で設定した判断基準

#### 結果の信頼性に基づく分類

評価目的への適合性評価において「区分 a」に分類した文献については Klimisch 基準における分類を参考として、下記の分類基準に基づき、信頼性を評価した。

分類	信頼性	判断基準
1	信頼性あり (制限なし)	以下のいずれかの試験/データに該当する場合。 <ul style="list-style-type: none"> <li>・有効性が確認された方法又は国際的に認められたテストガイドラインに基づいて実施されている(GLP 適合が望ましい)。</li> <li>・試験項目(評価パラメーター)が特定(国レベル)のテストガイドラインに基づいている。</li> <li>・全ての試験項目がテストガイドラインに示された方法と関連性が強い/同等により報告されている。</li> </ul>
2	信頼性あり (制限あり)	以下のいずれかの試験/データに該当する場合(大抵は非GLP試験)。 <ul style="list-style-type: none"> <li>・試験項目は特定の試験ガイドラインに完全には準拠していないが、内容が受け入れ可能である。</li> <li>・試験方法がテストガイドラインから逸脱しているものの、詳細な報告に基づき科学的に受け入れ可能な結果が示されている。</li> </ul>
3	信頼性なし	試験系、被験物質又は暴露経路の妥当性、記載情報の不十分さ等の観点から、エキスパートジャッジのためには許容できないと考えられる試験/データ
4	評価不能	試験の詳細が不明であり、要約のみの記載又は二次情報(書籍、総論等)として記載された試験/データ

- 1) ヒトに対する毒性については、ToxRtool (Toxicological data Reliability assessment Tool) を分類基準として活用した。 (<https://ec.europa.eu/jrc/en/scientific-tool/toxrtool-toxicological-data-reliability-assessment-tool>)

- 2) それ以外の3分野については、6278号局長通知で定めるテストガイドラインへの適用状況を中心に以下のような分類基準を設定し、Klimisch 基準のどの分類に該当するかを判断した。

(ア) 農作物及び畜産物への残留

- ①試験した作物がTGで定める代表的な作物か
- ②試験系の条件が明記されているか（たとえば、作物の生育ステージ、ほ場の状況、処理量、処理方法、処理時期、PHI、サンプリング方法）
- ③サンプリング後の試料保管中の被験物質の安定性が検証されているか
- ④サンプリング後の試料の保管条件が明記されているか
- ⑤栽培条件（密度や仕立て）が適切であるか
- ⑥処理量が登録で定めるGAPの範囲内であるか

(イ) 生活環境動植物及び家畜に対する毒性

- ①水生生物試験では、被験物質が水に溶解していること
- ②供試した生物種の由来、飼育条件、系統、週齢、体重あるいは体長、等が明らかであること
- ③試験期間の環境（温度等）がTGに照らし適切であること
- ④試験期間を通じて計画した濃度で被験物質に暴露していること
- ⑤経時的な観察記録や結果の確認がなされていること

(ウ) 環境動態

- ①試験系の条件が明記されていること（たとえば、土壌の試験であれば、土質、pH、有機炭素含量、密度、水分含量、微生物活性等）
- ②試験に使用した土壌等がTGで定める条件を満たしていること
- ③サンプリング方法がTGで定めた条件をみたしていること
- ④サンプリング後の試料の保管中の被験物質の安定性が検証されていること
- ⑤サンプリング後の試料の保管条件が明記されている



#### 4. 検索結果のまとめ

##### (1) Web of Science (Core Collection)の検索結果まとめ

表 6. Web of Science (Core Collection)で検索した結果のまとめ

データベース名	Web of Science (Core Collection)		
検索日	2022/12/07		
検索に用いたキーワード	①AND②AND③		
	①	②	③
ヒトに対する毒性	表 3 英名検索参照	表 4 参照	表 5 参照
農作物及び畜産物への残留			
生活環境動植物及び家畜に対する毒性			
環境動態			
検索結果			
検索条件(キーワード)	①	①AND②	①AND②AND③
対象とする農薬名で検索抽出した総論文数	286	NA	NA
ヒトに対する毒性	NA	17	3
農作物及び畜産物への残留 <sup>1)</sup>	NA	84	14
生活環境動植物及び家畜に対する毒性	NA	50	5
環境動態 <sup>1)</sup>	NA	29	14

NA:該当するデータなし

1) 各分野にまたがって重複した論文数を除いた数

(分野にまたがって重複した論文は前出の分野にのみ論文数をカウント)

##### (2) J-STAGE の検索結果まとめ

表 7. J-STAGE で検索した結果まとめ

データベース名	J-STAGE
検索日	2022/12/07
検索に用いたキーワード	表 4 和文検索参照
検索結果	
対象とする農薬名で検索抽出した総論文数	7
ヒトに対する毒性	NA
農作物及び畜産物への残留	7
生活環境動植物及び家畜に対する毒性	NA
環境動態	NA

NA:該当するデータなし

(3) 評価目的との適合性評価（第1段階、第2段階）の結果のまとめ

表8. 評価目的との適合性評価（第1段階、第2段階）の結果のまとめ

分野	該当 する 論文数	第1段階		第2段階	
		適合性 なし	それ以外 (第2段階へ)	適合性 なし	適合性あり
ヒトに対する毒性	3	0	3	3	NA
農作物及び畜産物への残留	21	4	17	17	NA
生活環境動植物及び家畜 に対する毒性	5	0	5	5	NA
環境動態	14	0	14	14	NA
合計	43	4	39	39	NA

文献の全文の内容を確認して、再度4分野に分類しなおした結果は表8-2のとおり。

表8-2. 評価目的との適合性評価（第1段階、第2段階）の結果のまとめ

分野	該当 する 論文数	第1段階		第2段階	
		適合性 なし	それ以外 (第2段階へ)	適合性 なし	適合性あり
ヒトに対する毒性	7	0	7	7	NA
農作物及び畜産物への残留	11	4	7	7	NA
生活環境動植物及び家畜 に対する毒性	4	0	4	4	NA
環境動態	4	0	4	4	NA
その他	17	0	17	17	NA
合計	43	4	39	39	NA

5. 適合性評価の第2段階で「適合しない」と判断した論文リストとその理由

表9 適合性評価の第2段階で「適合しない」と判断した論文リストとその理由

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
ヒトに対する 毒性	5-1	IIIA 7.3.2	Lesmes- Fabian, C et al	2013	Pesticide Flow Analysis to Assess Human Exposure in Greenhouse Flower Production in Colombia	Int. J. Environ. Res. Public Health, <b>10(4)</b> , 1168-1185 DOI: 10.3390/ijerph10041168	数種農薬の農薬使用者への曝露量を推定するモデリング手法の開発に関する報告であり、⑤及び⑩に該当。
	5-2	—	Halwachs, S et al	2016	Assessment of ABCG2-mediated transport of pesticides across the rabbit placenta barrier using a novel MDCKII in vitro model	Toxicology and Applied Pharmacology, <b>305</b> , 66-74 DOI: 10.1016/j.taap.2016.06.007	ABCG2を介したウサギ胎盤における農薬の輸送の評価方法の開発に関する報告であり、⑤に該当。
	5-3	—	Jin, CY et al	2021	Propamocarb exposure has the potential to accelerate the formation of atherosclerosis in both WT and ApoE <sup>-/-</sup> mice accompanied by gut microbiota dysbiosis	Science of The Total Environment, <b>800</b> , Art. 149602 DOI: 10.1016/j.scitotenv.2021.149602	マウス 24 週間反復投与による動脈硬化への影響に関する報告であるが、投与条件がヒトにおける現実的な摂取とは異なり外挿性に乏しいため⑩cに該当。
	5-4	—	Zhang, Y et al	2019	Propamocarb exposure decreases the secretion of neurotransmitters and causes behavioral impairments in mice	ENVIRONMENTAL TOXICOLOGY, <b>34(1)</b> , 22-29 DOI: 10.1002/tox.22653	マウス急性または反復投与による神経毒性への影響に関する報告であるが、投与条件がヒトにおける現実的な摂取とは異なり外挿性に乏しいため⑩cに該当。
	5-5	—	Wu, SS et al	2018	Chronic exposure to fungicide propamocarb induces bile acid metabolic disorder and increases trimethylamine in C57BL/6J mice	Science of The Total Environment, <b>642</b> , 341-348 DOI: 10.1016/j.scitotenv.2018.06.084	マウス 10 週間反復投与による腸肝代謝への影響に関する報告であるが、投与条件がヒトにおける現実的な摂取とは異なり外挿性に乏しいため⑩cに該当。
	5-6	—	Wu, SS et al	2018	Exposure to the fungicide propamocarb causes gut microbiota dysbiosis and metabolic disorder in mice	Environmental Pollution, <b>237</b> , 775-783 DOI: 10.1016/j.envpol.2017.10.129	マウス 28 日間反復投与による腸内細菌叢及び代謝への影響に関する報告であるが、投与条件がヒトにおける現実的な摂取とは異なり外挿性に乏しいため⑩cに該当。
	5-7	—	Gencer, N et al	2012	IN VITRO EFFECTS OF SOME HERBICIDES AND FUNGICIDES ON HUMAN ERYTHROCYTE CARBONIC ANHYDRASE ACTIVITY	FRESENIUS ENVIRONMENTAL BULLETIN, <b>21(3)</b> , 549-552 DOI: 10.1007/s00216-008-2087-8	<i>in vitro</i> ヒト赤血球炭酸脱水酵素に対する影響を検討した報告であるが、生体反応を明確に反映していないことから、ヒトのリスク評価としての外挿性に乏しいため⑩cに該当。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
農作物及び畜産物への残留	5-8	IIA 4.3 IIA 6.3	Bempelou, E et al	2021	Temporal Variation in Pesticide Residues in Citrus Fruits from Chios, Greece, before and after the Development of an Integrated Pest Management Strategy (IPMS): A Five-Year Study (LIFE13 ENV GR/000414)	Toxics, <b>9(12)</b> , Art. 323 DOI: 10.3390/toxics9120323	柑橘中における数種農薬の分析法及び消長に関する報告であり、⑤及び⑩に該当。
	5-9	IIA 6.3	Sharma, KK et al	2016	Multilocation field trials for risk assessment of a combination fungicide Fluopicolide + Propamocarb in tomato	Environmental Monitoring and Assessment, <b>188</b> , Art. 604 DOI: 10.1007/s10661-016-5610-y	日本で登録されている処方以外の製剤によるインドでのトマトにおける残留分析に関する報告であり、⑭及び⑰に該当。
	5-10	IIA 4.3 IIA 4.4	Chen, KY et al	2017	Dissipation dynamics of fenamidone and propamocarb hydrochloride in pepper, soil and residue analysis in vegetables by ultra-performance liquid chromatography coupled with tandem mass spectrometry	International Journal of Environmental Analytical Chemistry, <b>97(2)</b> , 134-144 DOI: 10.1080/03067319.2017.1291807	野菜/土壌における残留濃度の分析法及び消長に関する報告であり、⑤に該当。
	5-11	IIA 4.3	Lopez- Ruiz, R et al	2019	Dissipation kinetic studies of fenamidone and propamocarb in vegetables under greenhouse conditions using liquid and gas chromatography coupled to high-resolution mass spectrometry	Chemosphere, <b>226</b> , 36-46 DOI: 10.1016/j.chemosphere.2019.03.118	日本で登録されている処方以外の製剤によるスペインでの野菜における残留濃度の分析方法及び消長の解析法の開発に関する報告であり、⑤、⑭及び⑰に該当。
	5-12	IIA 4.3 IIA 4.4	Manikrao, G et al	2016	Persistence and dissipation of fluopicolide and propamocarb on cabbage and soil under semi-arid climatic conditions	International Journal of Environmental Analytical Chemistry, <b>96(1)</b> , 68-86 DOI: 10.1080/03067319.2015.1128536	日本では登録がないキャベツ/土壌における残留濃度の分析方法及び消長の解析法の開発に関する報告であり、⑤及び⑰に該当。
	5-13	IIA 4.3 IIA 4.4	Wang, CW et al	2014	Dissipation and residues determination of propamocarb in ginseng and soil by high-performance liquid chromatography coupled with tandem mass spectrometry	Environmental Monitoring and Assessment, <b>186</b> , 5327-5336 DOI: 10.1007/s10661-014-3781-y	日本では登録がない高麗人参/土壌における残留濃度の分析方法及び消長の解析法の開発に関する報告であり、⑤及び⑰に該当。
	5-14	IIA 4.3 IIA 4.4	Manikrao, G et al	2018	EFFECT OF ENVIRONMENTAL PARAMETERS ON THE PERSISTENCE OF PROPAMOCARB, FLUOPICOLIDE AND 2,6-DICHLOROBENZAMIDE RESIDUES ON CAULIFLOWER AND SOIL	FRESENIUS ENVIRONMENTAL BULLETIN, <b>27</b> , 838-845	日本では登録がないカリフラワー/土壌における残留濃度の分析方法及び消長の解析法の開発に関する報告であり、⑤及び⑰に該当。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
生活環境 動植物及 び家畜に 対する毒 性	5-15	IIA 4.3 IIA 8.2.6	Polat, A et al	2018	Pesticide residues in muscles of some marine fish species and seaweeds of Iskenderun Bay (Northeastern Mediterranean), Turkey	Environmental Science and Pollution Research, <b>25(4)</b> , 3756-3764 DOI: 10.1007/s11356-017-0756-x	海産物における種々農薬の残留に関する報告であり、⑪に該当。
	5-16	IIIA 10.2.2.1	Liu, X et al	2020	Differential responses of larval zebrafish to the fungicide propamocarb: Endpoints at development, locomotor behavior and oxidative stress	Science of The Total Environment, <b>731</b> , Art. 139136 DOI: 10.1016/j.scitotenv.2020.139136	試験液中の被験物質濃度の確認がなされていないことから、⑩dに該当。
	5-17	IIA 8.2.1	Caioni, G et al	2021	An Experimental Approach to Study the Effects of Realistic Environmental Mixture of Linuron and Propamocarb on Zebrafish Synaptogenesis	INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH, <b>18(9)</b> , Art. 4664 DOI: 10.3390/ijerph18094664	当該農薬を含む2種の農薬のZebrafishへの複合影響に関する報告であり、⑫に該当。
	5-18	—	Falfushynska, HI et al	2013	In situ exposure history modulates the molecular responses to carbamate fungicide Tattoo in bivalve mollusk	Ecotoxicology, <b>22</b> , 433-445 DOI: 10.1007/s10646-012-1037-6	要求試験の試験種ではない淡水イガイを用いた影響に関する報告であり、⑪及び⑩bに該当。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
環境動態	5-19	IIA 4.5	Aliste, M et al	2020	Reclamation of agro-wastewater polluted with thirteen pesticides by solar photocatalysis to reuse in irrigation of greenhouse lettuce grown	Journal of Environmental Management, <b>266</b> , Art. 110565 DOI: 10.1016/j.jenvman.2020.110565	農業用排水の再生方法に関する報告であり、⑬に該当。
	5-20	IIA 4.4 IIA 4.5	Lopez-Ruiz, R et al	2020	Dissipation kinetics of fenamidone, propamocarb and their metabolites in ambient soil and water samples and unknown screening of metabolites	Journal of Environmental Management, <b>254</b> , Art. 109818 DOI: 10.1016/j.jenvman.2019.109818	日本で登録されている処方以外の製剤を用いた土壌/水中における消長及び土壌/水中生物への影響の解析法の開発に関する報告であり、⑤及び⑭に該当。
	5-21	IIA 4.5	Yurtkuran, Z et al	2013	Assessment of Pesticide Residues in Karabogaz Lake from Kizilirmak Delta, Turkey	Bulletin of Environmental Contamination and Toxicology, <b>91</b> , 165-170 DOI: 10.1007/s00128-013-1037-0	湖の水及び堆積物における種々農薬の残留に関する報告であり、⑪に該当。
	5-22	IIA 4.4 IIA 7.3.2	Fournier, B et al	2020	Impact of a synthetic fungicide (fosetyl-Al and propamocarb-hydrochloride) and a biopesticide ( <i>Clonostachys rosea</i> ) on soil bacterial, fungal, and protist communities	Science of The Total Environment, <b>738</b> , Art. 139635 DOI: 10.1016/j.scitotenv.2020.139635	非標的土壌微生物に対する影響の比較分析開発に関する報告であり、⑤に該当。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
その他	5-23	IIIA 6.1	Jones, JG et al	2021	Efficacy of Fungicides for Pseudoperonospora cubensis Determined Using Bioassays over Multiple Years in the Mid-Atlantic and Northeastern United States	PLANT HEALTH PROGRESS, <b>22(3)</b> , 355-361 DOI: 10.1094/PHP-10-20-0086-FI	きゅうりのべと病の病原菌への効果に関する報告であり、④に該当。
	5-24	IIIA 6.1	Homa, K et al	2014	Evaluation of Fungicides for the Control of Peronospora belbahrii on Sweet Basil in New Jersey	PLANT DISEASE, <b>98(11)</b> , 1561-1566 DOI: 10.1094/PDIS-02-14-0200-RE	バジルのべと病の病原菌への効果に関する報告であり、④に該当。
	5-25	IIIA 6.1	Qi, RD et al	2012	Activity of Ten Fungicides against Phytophthora capsici Isolates Resistant to Metalaxyl	Journal of Phytopathology, <b>166(11-12)</b> , 717-722 DOI: 10.1111/jph.12009	コショウのペッパー疫病への効果に関する報告であり、④に該当。
	5-26	IIIA 6.1	Jalal, A et al	2021	Hormesis in plants: Physiological and biochemical responses	Ecotoxicology and Environmental Safety, <b>207</b> , Art. 111225 DOI: 10.1016/j.ecoenv.2020.111225	数種除草剤による植物のホルミシス誘導に関する報告であり、①に該当。
	5-27	IIIA 6.1	You, MP et al	2020	Understanding Why Effective Fungicides Against Individual Soilborne Pathogens Are Ineffective with Soilborne Pathogen Complexes	PLANT DISEASE, <b>104(3)</b> , 904-920 DOI: 10.1094/PDIS-06-19-1252-RE	土壌伝染病原菌への効果の調査に関する報告であり、④に該当。
	5-28	IIIA 6.1	Salas, SE et al	2019	Disease Control Attributes of Oxathiapiprolin Fungicides for Management of Cucurbit Downy Mildew	PLANT DISEASE, <b>103(11)</b> , 2812-2820 DOI: 10.1094/PDIS-02-19-0396-RE	うりのべと病への効果に関する報告であり、④に該当。
	5-29	IIIA 6.1	Muchiri, FN et al	2009	Efficacy of fungicide mixtures for the management of Phytophthora infestans (US-1) on potato	PHYTOPROTECTION, <b>90(1)</b> , 19-29 DOI: 10.7202/038983ar	ばれいしょ疫病への効果に関する報告であり、④に該当。
	5-30	IIIA 6.1	Kikway, I et al	2022	Temporal Dynamics and Severity of Cucurbit Downy Mildew Epidemics as Affected by Chemical Control and Cucurbit Host Type	PLANT DISEASE, <b>106(3)</b> , 1009-1019 DOI: 10.1094/PDIS-09-21-1992-RE	うりのべと病への効果に関する報告であり、④に該当。
	5-31	IIIA 6.1	Taguian, JD et al	2020	Susceptibility of the three dragon fruit species to stem canker and growth inhibition of Neoscytalidium dimidiatum by chemicals	Journal of Plant Pathology, <b>102(4)</b> , 1077-1084 DOI: 10.1007/s42161-020-00551-0	ドラゴンフルーツの茎潰瘍への効果に関する報告であり、④に該当。
	5-32	IIIA 6.1	Zheng, L et al	2018	Selecting Bacterial Antagonists for Cucurbit Downy Mildew and Developing an Effective Application Method	PLANT DISEASE, <b>102(3)</b> , 628-639 DOI: 10.1094/PDIS-01-17-0058-RE	うりのべと病への効果に関する報告であり、④に該当。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	判断理由
その他	5-33	—	Skeltern, MP et al	2017	Meteorological and landscape influences on pollen beetle immigration into oilseed rape crops	Agriculture, Ecosystems & Environment, <b>241</b> , 150-159 DOI: 10.1016/j.agee.2017.03.008	アブラナ作物への花粉甲虫の移動に対する気象および景観の影響の調査に関する報告であり、当該農薬と関係しない論文であることから、①に該当。
	5-34	IIIA 6.1	Hu, JH et al	2010	Mefenoxam Sensitivity in Phytophthora cinnamomi Isolates	PLANT DISEASE, <b>94(1)</b> , 39-44 DOI: 10.1094/PDIS-94-1-0039	観葉植物の根の病原菌へのメフェノキサムの感受性に関する報告であり、①及び④に該当。
	5-35	IIIA 6.1	藤根統	2012	ジャガイモ疫病による塊茎腐敗に対する薬剤の効果試験条件の検討	北日本病虫研報, <b>63</b> , 37-41	ジャガイモ疫病による塊茎腐敗に対する効果に関する報告であり、④に該当。
	5-36	IIIA 6.1	寺見文宏ら	2010	ショウガ根茎腐敗病に有効な根茎消毒薬剤の室内試験による検討	関西病虫研報, <b>52</b> , 95-97	ショウガ根茎腐敗病に対する効果に関する報告であり、④に該当。
	5-37	IIIA 6.1	菅原優司ら	2015	小笠原諸島で発生した Globisporangium [Pythium] splendens によるキュウリ立枯病（新称）	関東東山病害虫研究会報, <b>62</b> , 21-23	Globisporangium (Pythium) splendens の初感染に関する報告であり、⑬に該当。
	5-38	IIIA 6.1	Stouvenakers, G et al	2022	First Study Case of Microbial Biocontrol Agents Isolated from Aquaponics Through the Mining of High-Throughput Sequencing Data to Control Pythium aphanidermatum on Lettuce	Microbial Ecology, in press DOI: 10.1007/s00248-022-02126-1	微生物生物防除剤の研究に関する報告であり、⑬に該当。
	5-39	—	Lpez, JE et al	2020	Aspergillus tubingensis and Talaromyces islandicus Solubilize Rock Phosphate Under Saline and Fungicide Stress and Improve Zea mays Growth and Phosphorus Nutrition	Journal of Soil Science and Plant Nutrition, <b>20</b> , 2490-2501 DOI: 10.1007/s42729-020-00315-w	Aspergillus tubingensis と Talaromyces islandicus の無機リン源の可溶性に関する報告であり、⑬に該当。



6. 適合性評価の第2段階で「区分 a」「区分 b」「区分 c」へ分類された論文リストとその理由分類の結果、区分 a、区分 b、区分 c に該当する公表文献はなかった。

7. 適合性評価の第2段階で「区分 a」と判断した論文リスト及び信頼性を評価した結果分類の結果、区分 a に該当する公表文献はなかった。

8. EFSA、USEPA、JMPR の評価において評価書に結果が引用されている場合は、引用した機関、引用された評価書名、発行年等の情報

プロパモカルブ塩酸塩は米国、欧州及び JMPR で評価が行われており、これらの評価書（Reregistration Eligibility Decision (RED) for Propamocarb Hydrochloride Case No. 3124, 1995 (Document ID; EPA-738-R-95-036)、EFSA Scientific Report (2006) 78, Conclusion regarding the peer review of the pesticide risk assessment of the active substance propamocarb (finalised 12 May 2006)及び Propamocarb JMPR 2005）を確認した結果、引用されている公表文献はなかった。

（Regulation (EC) No 1107/2009 Draft Renewal Assessment Report prepared according to the Commission Implementing Regulation (EC) No. 844/2012, Propamocarb Renewal assessment report, 2017）を確認したところ、14 文献が引用されていたが、日本の登録作物は「西洋芝（ベントグラス）」のみであること及び表 10 の理由から、これらの文献は日本の評価において用いる必要がないと判断した。

#### 参考資料

Sebastian Bott, 2015, Summary of the literature data for Propamocarb  
Arysta LifeScience Benelux and Bayer CropScience AG

表 10 参考資料において適合性評価の第 2 段階で「適合」と判断した論文で、EFSA の評価書に結果が引用されている論文

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	評価機関	評価書情報 (発行年等)	備考（理由）
ヒトに対する毒性	8-1	IIA5.4.4	Aydemir, Nilufer et al	2004	The investigation of the genotoxic effects of fenarimol and propamocarb in mouse bone marrow in vivo	Toxicology Letters 147(1), 73-78	EFSA	2017	ヒトでは摂取しえない投与条件及び投与量で検討。
	8-2	IIA8.1	Lian, Yong et al	2008	Experimental study on measurement of LD50 with the up-and-down procedure to take the place of Horns	Xiandai Yufang Yixue, 35(18), 3591-3593	EFSA	2017	11 種の農薬を使って up-and-down 法と Horns の比較。中国語
農作物及び畜産物への残留	8-3	IIA6.5	Bonnechere, Auror et al	2012	Effect of household and industrial processing on levels of five pesticide residues and two degradation products in spinach.	Food Control, Volume 25, Issue 1, Page 397-406	EFSA	2017	4 種の殺菌剤と 1 種の殺虫剤の家庭用及び工業用加工処理の影響調査。
生活環境動植物及び家畜に対する毒性	8-4	IIA8.2	Padilla, S.; Corum, D. et al	2012	Zebrafish developmental screening of the ToxCast Phase I chemical library	Reprod. Toxicol., Volume 33, Issue 2, Page 174-187	EFSA	2017	309 種の化学物質のゼブラフィッシュの発達毒性のスクリーニング。
	8-5	IIA8.6	Li, Jiao et al	2010	Acute toxicity of eight pesticides on the development of sea urchin embryos	Shengtai Duli Xuebao, 5(2), 255-261	EFSA	2017	8 種の農薬のウニ胚発生に対する毒性評価。中国語。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	評価機関	評価書情報 (発行年等)	備考（理由）
環境動態	8-6	IIA7.1	Boulard, Thierry et al	2011	Environmental impact of greenhouse tomato production in France	Agronomy for Sustainable Development, 31(4), 757- 777	EFSA	2017	ビニールハウス、ガラスハウス及びポリトンネルの環境負荷の比較。
	8-7	IIA7.1	Alikhanidi, Sokratis et al	2004	Pesticide persistence in the environment - collected data and structure-based analysis.	J. Comput. Chem., Jpn., Volume 3, Issue 2, Page 59-70,	EFSA	2017	420 種の農薬の圃場における半減期情報の収集と EKeeper モデルの開発。
	8-8	IIA7.1	Stenrod, Marianne et al	2008	Testing and comparison of three pesticide risk indicator models under Norwegian conditions - A case study in the Skuterud and Heiabekken catchments	Agric., Ecosyst. Environ., Volume 123, Issue 1-3, Page 15-29,	EFSA	2017	農薬リスク指標モデル NERI モデルと EIQ モデルの比較。
	8-9	IIA7.1 IIA8.15	Myresiotis, Charalampos K. et al	2012	Biodegradation of soil-applied pesticides by selected strains of plant growth-promoting rhizobacteria (PGPR) and their effects on bacterial growth.	Biodegradation, Volume 23, Issue 2, Page 297-310,	EFSA	2017	4 種の PGPR 株による農薬の分解能の調査。
	8-10	-	Licciardello, Feliciano et al	2011	Evaluation of groundwater contamination in a coastal area of south-eastern Sicily	Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, 46(6), 498-508	EFSA	2017	シチリア島南東部における地下水中農薬濃度モニタリング。
	8-11	-	Esteve-Turrillas, Francesc A. et al	2009	Use of semipermeable membrane devices for monitoring pesticides in indoor air.	J. AOAC Int., Volume 92, Issue 5, Page 1557-1565,	EFSA	2017	室内の空気中の農薬濃度分析法の開発とモニタリング。

分野	リスト No.	データ要求 (項目番号)	著者	出版 年	論文表題	掲載雑誌、号、ページ等	評価機関	評価書情報 (発行年等)	備考（理由）
環境動態	8-12	-	Moschet, Christoph et al	2014	How a Complete Pesticide Screening Changes the Assessment of Surface Water Quality	Environmental Science and Technology, 48(10), 5423-5432	EFSA	2017	結果のみ報告。
	8-13	-	Yurtkuran, Zeynep et al	2012	Determination of multiresidual pesticide bioaccumulation in aquatic food chain in the Karabogaz Lake (Samsun, Turkey).	Toxicology Letters Vol. 211, No. Suppl. S, pp. S50.	EFSA	2017	トルコの Karabogaz 湖における水、堆積物及び魚類中の残留農薬のモニタリング。
	8-14	IIA8.1 IIA8.2	Yurtkuran, Zeynep et al	2013	Assessment of Pesticide Residues in Karabogaz Lake from Kizilirmak Delta, Turkey	Bulletin of Environmental Contamination and Toxicology, 91(2), 165-170	EFSA	2017	トルコの Karabogaz 湖における水と堆積物中の残留農薬のモニタリング。

**Document Title**

**Summary of the Literature data for  
Propamocarb**

**Data Requirements**

**Regulation (EC) No. 1107/2009 & Regulation (EU) No. 283/2013  
Document MCA  
Section 9: Literature data**

**According to the Guidance Document SANCO/10181/2013 for applicants on  
preparing dossiers for the renewal of approval of a chemical active substance**

**Date**

**2015-11-20**

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### Version history

Date	Data Points containing amendments or additions <sup>1</sup>	Document identifier or version number

<sup>1</sup> Note how the amendments or additions are represented (italics/colour etc)

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## CA 9 LITERATURE DATA

### Summary

For Propamocarb and its metabolites, a total of 585 references were identified and evaluated for potential relevance. Besides references that were clearly out of the scope of the “Literature Review Report (LRR)” (e.g. publications dealing with efficacy), the area of analytical methods (153 references), residues (55 references) and ecotoxicology and fate and behaviour in the environment (combined 50 references) were most frequently represented in the search results.

479 identified studies have been considered irrelevant after rapid assessment according to the EFSA Guidance. For 106 references full-text documents have been obtained and assessed in detail according to the EFSA Guidance. Of these 106 references 92 publications have been considered irrelevant after detailed assessment (see Table 6).

The scientific full text of 14 literature references evaluated as relevant after detailed assessment have been inserted in the respective K-part of the dossier (as listed in Tables 4 and 5). The abstract of the non-relevant publications is not part of the LRR or the Annex I Renewal dossier.

For Propamocarb the publication of Bonnechere et al. (2012) was identified as a study relevant after detailed assessment and classified as case a) study according to EFSA Guidance Point 5.4.1. The study investigates effects of household and industrial processing on levels of residues of four fungicides (among them Propamocarb) and one insecticide and two degradation products in spinach. The study provides data for refining risk assessment parameters for residues in processed commodities. Thus, it is summarized and discussed in detail in section CA 6.5.3 “Magnitude of residues in processed commodities” of document MCA Section 6: “Summary of the residues in or on treated products, food and feed for the active substance Propamocarb”

Beside this, 13 other publications have been identified as studies relevant after detailed assessment and classified in accordance with the EFSA Guidance Point 5.4.1. However, none of these studies was considered to have an impact on an EU-agreed endpoint, or would require any adaptation of the risk assessments presented in the Propamocarb supplementary (Annex I Renewal) dossier.

### CA 9.1 Introduction

A literature review was carried out for Propamocarb and its metabolites by Bayer CropScience on behalf of the **Regulatory Task Force Propamocarb**, existing since 2005 and represented by Arysta LifeScience Benelux (formerly Agriphar S.A. or Chimac Agriphar respectively), and Bayer CropScience, according to the requirements of the Regulation (EU) No. 844/2012 (the AIR3 Renewal Regulation), which itself refers to Article 8(5) of Regulation (EC) No. 1107/2009.

The review has been done in accordance with the EFSA Guidance Document as published in the EFSA Journal 2011; 9 (2): 2092. For AIR 3 compounds, such as Propamocarb, a literature review is mandatory for the Annex I Renewal.

All steps in the LRR are based on the EFSA Guidance Document mentioned above. The key question is whether any scientific peer-reviewed open literature published within the last ten years before the date of submission of the dossier would be relevant for the risk assessment of Propamocarb and its relevant metabolites in the context of side-effects on health, the environment and non-target species. Wherever such relevance could not be excluded, the scientific findings need to be discussed in detail in the dossier for Annex I Renewal and, if necessary, the risk assessments would be updated accordingly.

## **CA 9.2 Search Strategy**

It has been the aim of Bayer CropScience on behalf of the Propamocarb Task Force to carry out the literature search for Propamocarb in a comprehensive and transparent way, to allow the concept to be widely accepted by evaluating Member States and the process to be used in subsequent analyses of other compounds (see Appendix I). The main parameters that allow the characterization of the literature search are listed below. Abstracts of all references have been downloaded and evaluated. Patents were not considered in the literature search, as they are not covered by the definition “scientific peer-reviewed open literature”.

### **CA 9.2.1 Time window of the literature search**

The first literature search was made in February 2014 recording publications over a ten years period back to January 2004; a second literature search followed in August 2015, roughly 6 months before the anticipated submission of the Annex I Renewal dossier in January 2016.

Therefore the time window of the literature search covers publications between January 2004 and August 2015.

### **CA 9.2.2 Databases used in the literature review**

Bayer CropScience on behalf of the Propamocarb Task Force has used a broad collection of relevant databases for the literature search (see Table 1 overleaf). STN, a scientific information platform hosted by CAS, itself a division of the American Chemical Society, was selected as the preferred provider (<http://www.cas.org/products/stnfamily/index.html>). It offers a reliable scientific search service that includes all databases considered relevant to cover the requirements established in the AIR3 Renewal Regulation and the EFSA Guidance Document. Moreover, hosted databases have a defined query language for different sources which facilitates duplicate removal. Bayer CropScience routinely works with STN for similar applications.

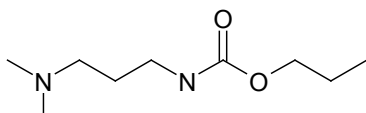
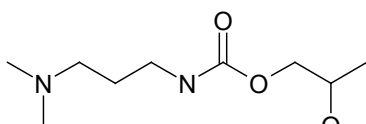
**Table 1: List of data bases used for the literature search**

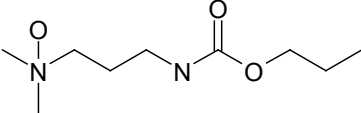
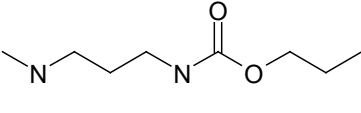
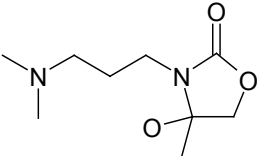
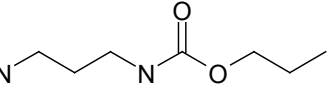
Database Name	Date of last Database Update
Agricola	2015-07-07
Biosis	2015-08-06
CABA	2015-08-05
Chemical Abstracts	2015-08-05
Derwent Drug File (DRUGU)	2015-07-31
EMBASE	2015-08-05
Esbiobase	2015-08-05
IPA	2015-08-05
Medline	2015-08-05
Pascal	2014-12-22
PQSciTech	2015-08-03
Registry	2015-08-04
Scisearch	2015-08-03
Toxcenter	2015-08-04
FSTA	2015-07-31

### CA 9.2.3 Input parameters for STN literature search

Table 2 presents the input parameters for the database search on Propamocarb and relevant metabolites. The information used for screening the selected databases to identify all relevant publications consists of IUPAC name, CAS name/number, common names, codes and abbreviations, molecular structure, molecular formula, molar mass and other names/codes, as far as available.

**Table 2: List of input parameters for the database search on Propamocarb and relevant Metabolites**

<b>Propamocarb (a.s.)</b>	
<b>IUPAC name:</b>	Propyl (3-(dimethylamino)propyl)carbamate
<b>CAS number:</b>	24579-73-5, 1135443-13-8, 25606-41-1, 70323-53-4, 1135443-14-9
<b>STN Query</b>	(24579-73-5 OR 1135443-13-8 OR "N-(3-DIMETHYLAMINOPROPYL)CARBAMIC ACID PROPYL ESTER" OR "PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE" OR SN 39744 OR AE B039744 OR PROPAMOCARB OR PLANTACUR OR (INFINITO OR VOLARE OR PROPLANT OR PROMESS)(W)(RTM OR TM OR R) OR 25606-41-1 OR 70323-53-4 OR 1135443-14-9 OR SN 66752 OR AE B066752 OR CA701337 OR PROPAMOCARB HYDROCHLORIDE OR "PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE MONOHYDROCHLORIDE" OR "PROPYL 3-(DIMETHYLAMINO)PROPYLCARBAMATE HYDROCHLORIDE") AND PY>2003 NOT P/DT
<b>Molecular structure:</b>	
<b>Metabolites (see also Document N – List of metabolites for more details)</b>	
<b>No.:</b>	IUPAC name Structure [CAS number] STN Query
<b>M01</b>	2-Hydroxypropyl (3-(dimethylamino)propyl)carbamate  CAS: 142955-35-9 Query: (142955-35-9 OR "2-HYDROXYPROPYL [3-(DIMETHYLAMINO)PROPYL]CARBAMATE") AND PY>2003 NOT P/DT

<p><b>M02</b></p>	<p>Propyl (3-(dimethylnitro)propyl)carbamate</p>  <p>CAS: - Query: ("PROPYL [3-(DIMETHYLNITRORYL)PROPYL]CARBAMATE") AND PY&gt;2003 NOT P/DT</p>
<p><b>M03</b></p>	<p>Propyl (3-(methylamino)propyl)carbamate</p>  <p>CAS: 1392231-41-2 Query: (1392231-41-2 OR "PROPYL [3-(METHYLAMINO)PROPYL]CARBAMATE") AND PY&gt;2003 NOT P/DT</p>
<p><b>M04</b></p>	<p>3-(3-(Dimethylamino)propyl)-4-hydroxy-4-methyl-1,3-oxazolidin-2-one</p>  <p>CAS: 743449-08-3 Query: (743449-08-3 OR "3-[3-(DIMETHYLAMINO)PROPYL]-4-HYDROXY-4-METHYL-1,3-OXAZOLIDIN-2-ONE") AND PY&gt;2003 NOT P/DT</p>
<p><b>M05</b></p>	<p>Propyl (3-(amino)propyl)carbamate</p>  <p>CAS: - Query: ("PROPYL [3-(AMINO)PROPYL]CARBAMATE") AND PY&gt;2003 NOT P/DT</p>

### **CA 9.3      Keyword Filter**

For the search of this substance, no keyword filter was used.

### **CA 9.4      Search results**

A total of 584 publications were found for Propamocarb and 1 for the metabolites.

### **CA 9.5      Evaluation**

The evaluation of the search results was performed according to the EFSA Guidance Document (details of the workflow are shown in Appendix I).

The criteria for the assessments are laid down below. The numbering of the Tables 3 – 6 corresponds to the numbering system of the EFSA Guidance Document.

#### **CA 9.5.1      Rapid assessment**

Based on the abstracts the following topics were used to classify publications as being obviously irrelevant:

- Efficacy
- Analytical method development
- New ways of synthesis
- Studies on a molecular level, which cannot be related to environmental risk assessment
- Non-EU monitoring studies
- Publications in non-EU language without English abstract
- Abstract refers to a conference contribution and does not contain data (full text not available)
- Not relevant due to missing information: Studies with target organisms

The number of obviously irrelevant publications appears in Table 3, documenting the study selection process.

#### **CA 9.5.2      Detailed Assessment**

Those publications, which have passed the rapid assessment, have been evaluated based on their full text versions. The criteria for the detailed assessment are shown below:

**MCA Section 9: Literature data for  
Propamocarb**

Not relevant, because

- Target substance is not a test item
- Conversion into units useful for risk assessment not possible
- Study design / test system not sufficiently described
- Study design / test system not adequate
- Study design / test system not relevant to EU data requirements
- Test system not relevant to representative uses/GAPs
- Test method does not cover the right targets
- Test material deviates from composition of BCS active ingredient / product
- Findings not related to a certain test system
- no endpoint can be derived
- observations are not attributable (i.e. ecotoxicology) to a specific substance
- effects are caused by a non-relevant route of exposure
- observations cannot be transferred into an endpoint

Table 3 gives a statistical overview of the rapid and detailed assessments.

**Table 3: Results of the study selection process, for each data requirement or group of data requirements searched**

<b>Propamocarb and its metabolites (abbreviations as indicated in Table 2 on Page 8-9):</b>	<b>a.s.</b>	<b>M01</b>	<b>M02</b>	<b>M03</b>	<b>M04</b>	<b>M05</b>
Total number of summary records retrieved after all* searches of peer-reviewed literature	584	1	0	0	0	0
Number of summary records excluded from the search results after rapid assessment for relevance	479	0	--	--	--	--
Total number of full-text documents assessed in detail*	105	1	--	--	--	--
Number of publications excluded from further consideration after detailed assessment for relevance	91	1	--	--	--	--
Number of publications not excluded for relevance after detailed assessment (i.e. relevant publications and publications of unclear relevance)	14	0	--	--	--	--



The results of the detailed assessment are shown in Tables 4 to 6.

While Table 6 contains the publications not meeting the relevance criteria for the detailed assessment, Tables 4 and 5 contain those publications meeting the criteria, respectively ordered by data requirement or author.



**MCA Section 9: Literature data for  
Propamocarb**

**Table 4: Report of all relevant studies/publications and literature of unclear relevance that are included in a dossier after detailed assessment of full-text documents for relevance: ordered by data requirement**

CA-SANCO Data Point	CP-SANCO Data Point	Author	Publication Year	Title	Source	Classification of study
KCA 5.4.2 In vivo studies in somatic cells		Aydemir, Nilufer; Bilaloglu, Rahmi	2004	The investigation of the genotoxic effects of fenarimol and propamocarb in mouse bone marrow in vivo	Toxicology Letters 147(1), 73-78	Case b) EFSA Guidance Point 5.4.1 Supportive paper showing negative results in mouse bone marrow in vivo test, thus confirming the risk assessment provided by the applicant
KCA 6.5.3 Magnitude of residues in processed commodities		Bonnechere, Aurore; Hanot, Vincent; Jolie, Ruben; Hendrickx, Marc; Bragard, Claude; Bedoret, Thomas; Van Loco, Joris.	2012	Effect of household and industrial processing on levels of five pesticide residues and two degradation products in spinach.	Food Control, Volume 25, Issue 1, Page 397-406	Case a) EFSA Guidance Point 5.4.1 The study provides data for refining risk assessment parameters for residues in processed commodities. It is summarized and discussed in detail in document MCA Section 6: Residues in or on treated products, food and feed
KCA 7.1 Fate and behaviour in soil		Boulard, Thierry; Raeppe, Caroline; Brun, Richard; Lecompte, Francois; Hayer, Frank; Carmassi, G.; Gaillard, Gerard	2011	Environmental impact of greenhouse tomato production in France	Agronomy for Sustainable Development, 31(4), 757-777	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment

**MCA Section 9: Literature data for  
Propamocarb**

CA-SANCO Data Point	CP-SANCO Data Point	Author	Publication Year	Title	Source	Classification of study
KCA 7.1 Fate and behaviour in soil		Alikhanidi, Sokratis; Takahashi, Yoshimasa.	2004	Pesticide persistence in the environment - collected data and structure-based analysis.	J. Comput. Chem., Jpn., Volume 3, Issue 2, Page 59-70,	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment. Moreover, the publication is a secondary source of information, e.g. review article that condenses information of primary nature which is evaluated elsewhere in this literature review.
KCA 7.1 Fate and behaviour in soil		Stenrod, Marianne; Heggen, Heidi E.; Bolli, Randi I.; Eklo, Ole Martin.	2008	Testing and comparison of three pesticide risk indicator models under Norwegian conditions - A case study in the Skuterud and Heiabekken catchments.	Agric., Ecosyst. Environ., Volume 123, Issue 1-3, Page 15-29,	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
KCA 7.1 Fate and behaviour in soil; KCA 8.7 Effects on other terrestrial organisms (flora and fauna)	KCP 9.1 Fate and behaviour in soil; KCP 10.7 Effects on other terrestrial organisms (flora and fauna)	Myresiotis, Charalampos K.; Vryzas, Zisis; Papadopoulou-Mourkidou, Euphemia.	2012	Biodegradation of soil-applied pesticides by selected strains of plant growth-promoting rhizobacteria (PGPR) and their effects on bacterial growth.	Biodegradation, Volume 23, Issue 2, Page 297-310,	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
KCA 7.5 Monitoring data		Licciardello, Feliciano; Antoci, Maria Lucia; Brugaletta, Luana; Cirelli, Giuseppe Luigi	2011	Evaluation of groundwater contamination in a coastal area of south-eastern Sicily	Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, 46(6), 498-508	Case b) EFSA Guidance Point 5.4.1 Supplemental information out of scope of EU data requirements

**MCA Section 9: Literature data for  
Propamocarb**

CA-SANCO Data Point	CP-SANCO Data Point	Author	Publication Year	Title	Source	Classification of study
KCA 7.5 Monitoring data		Esteve-Turrillas, Francesc A.; Pastor, Agustin; De La Guardia, Miguel.	2009	Use of semipermeable membrane devices for monitoring pesticides in indoor air.	J. AOAC Int., Volume 92, Issue 5, Page 1557-1565,	Case b) EFSA Guidance Point 5.4.1 Supplemental information out of scope of EU data requirements
KCA 7.5 Monitoring data		Moschet, Christoph; Wittmer, Irene; Simovic, Jelena; Junghans, Marion; Piazzoli, Alessandro; Singer, Heinz; Stamm, Christian; Leu, Christian; Hollender, Juliane	2014	How a Complete Pesticide Screening Changes the Assessment of Surface Water Quality	Environmental Science and Technology, 48(10), 5423- 5432	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
KCA 7.5 Monitoring data; KCA 8.2.2.3 Bioconcentra- tion in fish		Yurtkuran, Zeynep [Reprint Author]; Saygi, Yasemin; Kocak, Oner	2012	Determination of multiresidual pesticide bioaccumulation in aquatic food chain in the Karabogaz Lake (Samsun, Turkey).	Toxicology Letters Vol. 211, No. Suppl. S, pp. S50.	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
KCA 8.1 Effects on birds and other terrestrial vertebrates; KCA 8.2 Effects on aquatic organisms		Yurtkuran, Zeynep; Saygi, Yasemin	2013	Assessment of Pesticide Residues in Karabogaz Lake from Kizilirmak Delta, Turkey	Bulletin of Environmental Contamination and Toxicology, 91(2), 165-170	Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment

**MCA Section 9: Literature data for  
Propamocarb**

CA-SANCO Data Point	CP-SANCO Data Point	Author	Publication Year	Title	Source	Classification of study
KCA 8.1.2.1 Acute oral toxicity to mammals	KCP 10.1.2.1 Acute oral toxicity to mammals	Lian, Yong; Xu, Pei- Yu; Sun, Qiang	2008	Experimental study on measurement of LD50 with the up-and-down procedure to take the place of Horns	Xiandai Yufang Yixue, 35(18), 3591-3593	Case b) EFSA Guidance Point 5.4.1 Acute toxicity tests were done on rats according to two different methods and showed mild toxicity (with LD50>5000 mg/kg). These data give only supplementary information on the acute toxicity profile of propamocarb and do not alter the risk assessment.
KCA 8.2 Effects on aquatic organisms		Padilla, S.; Corum, D.; Padnos, B.; Hunter, D. L.; Beam, A.; Houck, K. A.; Sipes, N.; Kleinstreuer, N.; Knudsen, T.; Dix, D. J.; Reif, D. M.	2012	Zebrafish developmental screening of the ToxCast Phase I chemical library.	Reprod. Toxicol., Volume 33, Issue 2, Page 174-187	Case c) EFSA Guidance Point 5.4.1 Study does not include a dose response test and no LC50. Thus usability of data for risk assessment unclear.
KCA 8.2.8 Further testing on aquatic organisms		Li, Jiao; Wang, Heng; Han, Zhaocheng; Shi, Shengbao; Wang, Yonghua; Ding, Jun	2010	Acute toxicity of eight pesticides on the development of sea urchin embryos	Shengtai Duli Xuebao, 5(2), 255-261	Case c) EFSA Guidance Point 5.4.1 The taxonomic group not existing in freshwater.

**MCA Section 9: Literature data for  
Propamocarb**
**Table 5: Report of all relevant studies/publications and studies of unclear relevance that are included in a dossier after detailed assessment of full-text documents for relevance: ordered by author(s)**

Author	CA-SANCO Data Point	CP-SANCO Data Point	Publication Year	Title	Source	Classification of study
Alikhanidi, Sokratis; Takahashi, Yoshimasa.	KCA 7.1 Fate and behaviour in soil		2004	Pesticide persistence in the environment - collected data and structure-based analysis.	J. Comput. Chem., Jpn., Volume 3, Issue 2, Page 59-70	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment. Moreover, the publication is a secondary source of information, e.g. review article that condenses information of primary nature which is evaluated elsewhere in this literature review.
Aydemir, Nilufer; Bilaloglu, Rahmi	KCA 5.4.2 In vivo studies in somatic cells		2004	The investigation of the genotoxic effects of fenarimol and propamocarb in mouse bone marrow in vivo	Toxicology Letters, 147(1), 73-78	2 - Case b) EFSA Guidance Point 5.4.1 Supportive paper showing negative results in mouse bone marrow in vivo test, thus confirming the risk assessment provided by the applicant
Bonnechere, Aurore; Hanot, Vincent; Jolie, Ruben; Hendrickx, Marc; Bragard, Claude; Bedoret, Thomas; Van Loco, Joris.	KCA 6.5.3 Magnitude of residues in processed commodities		2012	Effect of household and industrial processing on levels of five pesticide residues and two degradation products in spinach.	Food Control, Volume 25, Issue 1, Page 397-406,	Case a) EFSA Guidance Point 5.4.1 The study provides data for refining risk assessment parameters for residues in processed commodities. It is summarized and discussed in detail in document MCA Section 6: Residues in or on treated products, food and feed and plant metabolism

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Author	CA-SANCO Data Point	CP-SANCO Data Point	Publication Year	Title	Source	Classification of study
Boulard, Thierry; Raeppl, Caroline; Brun, Richard; Lecompte, Francois; Hayer, Frank; Carmassi, G.; Gaillard, Gerard	KCA 7.1 Fate and behaviour in soil		2011	Environmental impact of greenhouse tomato production in France	Agronomy for Sustainable Development, 31(4), 757- 777	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
Esteve-Turrillas, Francesc A.; Pastor, Agustin; De La Guardia, Miguel.	KCA 7.5 Monitoring data		2009	Use of semipermeable membrane devices for monitoring pesticides in indoor air.	J. AOAC Int., Volume 92, Issue 5, Page 1557-1565	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information out of scope of EU data requirements
Li, Jiao; Wang, Heng; Han, Zhaoheng; Shi, Shengbao; Wang, Yonghua; Ding, Jun	KCA 8.2.8 Further testing on aquatic organisms		2010	Acute toxicity of eight pesticides on the development of sea urchin embryos	Shengtai Duli Xuebao, 5(2), 255-261	3 - Case c) EFSA Guidance Point 5.4.1 The taxonomic group not existing in freshwater.
Lian, Yong; Xu, Pei-Yu; Sun, Qiang	KCA 8.1.2.1 Acute oral toxicity to mammals	KCP 10.1.2.1 Acute oral toxicity to mammals	2008	Experimental study on measurement of LD50 with the up-and-down procedure to take the place of Horns	Xiandai Yufang Yixue, 35(18), 3591-3593	2 - Case b) EFSA Guidance Point 5.4.1 Acute toxicity tests were done on rats according to two different methods and showed mild toxicity (with LD50>5000 mg/kg). These data give only supplementary information on the acute toxicity profile of propamocarb and do not alter the risk assessment.

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Author	CA-SANCO Data Point	CP-SANCO Data Point	Publication Year	Title	Source	Classification of study
Licciardello, Feliciano; Antoci, Maria Lucia; Brugaletta, Luana; Cirelli, Giuseppe Luigi	KCA 7.5 Monitoring data		2011	Evaluation of groundwater contamination in a coastal area of south-eastern Sicily	Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, 46(6), 498-508	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information out of scope of EU data requirements
Moschet, Christoph; Wittmer, Irene; Simovic, Jelena; Junghans, Marion; Piazzoli, Alessandro; Singer, Heinz; Stamm, Christian; Leu, Christian; Hollender, Juliane	KCA 7.5 Monitoring data		2014	How a Complete Pesticide Screening Changes the Assessment of Surface Water Quality	Environmental Science and Technology, 48(10), 5423- 5432	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
Myresiotis, Charalampos K.; Vryzas, Zisis; Papadopoulou- Mourkidou, Euphemia.	KCA 7.1 Fate and behaviour in soil; KCA 8.7 Effects on other terrestrial organisms (flora and fauna)	KCP 9.1. Fate and behaviour in soil; KCP 10.7. Effects on other terrestrial organisms (flora and fauna)	2012	Biodegradation of soil-applied pesticides by selected strains of plant growth-promoting rhizobacteria (PGPR) and their effects on bacterial growth.	Biodegradation, Volume 23, Issue 2, Page 297-310	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment

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Author	CA-SANCO Data Point	CP-SANCO Data Point	Publication Year	Title	Source	Classification of study
Padilla, S.; Corum, D.; Padnos, B.; Hunter, D. L.; Beam, A.; Houck, K. A.; Sipes, N.; Kleinstreuer, N.; Knudsen, T.; Dix, D. J.; Reif, D. M.	KCA 8.2 Effects on aquatic organisms		2012	Zebrafish developmental screening of the ToxCast Phase I chemical library.	Reprod. Toxicol., Volume 33, Issue 2, Page 174-187	3 - Case c) EFSA Guidance Point 5.4.1 Study does not include a dose response test and no LC50. Thus usability of data for risk assessment unclear.
Stenrod, Marianne; Heggen, Heidi E.; Bolli, Randi I.; Eklo, Ole Martin.	KCA 7.1 Fate and behaviour in soil		2008	Testing and comparison of three pesticide risk indicator models under Norwegian conditions - A case study in the Skuterud and Heiabekken catchments.	Agric., Ecosyst. Environ., Volume 123, Issue 1-3, Page 15-29	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
Yurtkuran, Zeynep [Reprint Author]; Saygi, Yasemin; Kocak, Oner	KCA 7.5 Monitoring data; KCA 8.2.2.3 Bioconcentration in fish		2012	Determination of multiresidual pesticide bioaccumulation in aquatic food chain in the Karabogaz Lake (Samsun, Turkey).	Toxicology Letters, Vol. 211, No. Suppl. S, pp. S50.	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment
Yurtkuran, Zeynep; Saygi, Yasemin	KCA 8.1 Effects on birds and other terrestrial vertebrates; KCA 8.2 Effects on aquatic organisms		2013	Assessment of Pesticide Residues in Karabogaz Lake from Kizilirmak Delta, Turkey	Bulletin of Environmental Contamination and Toxicology, 91(2), 165-170	2 - Case b) EFSA Guidance Point 5.4.1 Supplemental information not useful for EU risk assessment



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**Table 6: Report of the studies excluded from the risk assessment after detailed assessment of full-text documents**

Author	Publication Year	Title	Source	Reason for not including in dossier
Abd Al-Rahman, Sherif Hussein; Almaz, Monir M; Ahmed, Nevin S	2012	Dissipation of Fungicides, Insecticides, and Acaricide in Tomato Using HPLC-DAD and QuEChERS Methodology	Food analytical methods, 5(3), 564-570	Study design / test system not relevant to EU data requirements
Abd-Alrahman, Sherif H.; Almaz, Monir M.	2012	Degradation of propamocarb - hydrochloride in tomatoes, potatoes, and cucumber using HPLC-DAD and QuEChERS methodology	Bulletin of Environmental Contamination and Toxicology, 89(2), 302-305	No information useful for influencing risk assessment
Aguilera-Luiz, M. M.; Plaza-Bolanos, P.; Romero-Gonzalez, R.; Martinez Vidal, J. L.; Frenich, A. Garrido.	2011	Comparison of the efficiency of different extraction methods for the simultaneous determination of mycotoxins and pesticides in milk samples by ultraHPLCaphy-tandem mass spectrometry.	Analytical and Bioanalytical Chemistry, 399(8), 2863-2875	Findings not related to a certain test system
Ahmed, Mohamed Ahmed Ibrahim; Khalil, Nasr Sobhy; Abd Elaliem Abd El Rahman, Tarek	2014	Carbamate pesticide residues analysis of potato tuber samples using high-performance liquid chromatography (HPLC)	Journal of Environmental Chemistry and Ecotoxicology, 6(1), 1-5,	No endpoint can be derived
Alder, Lutz; Luederitz, Sonja; Lindtner, Karen; Stan, Hans-Juergen.	2004	The ECHO technique - the more effective way of data evaluation in liquid chromatography-tandem mass spectrometry analysis.	Journal of Chromatography A, 1058(1-2), 67-79	No endpoint can be derived
Arienzo, M.; Cataldo, D.; Ferrara, L.	2013	Pesticide residues in fresh-cut vegetables from integrated pest management by ultra performance liquid chromatography coupled to tandem mass spectrometry.	Food Control, 31(1), 108-115	Findings not related to a certain test system
Bertrand, S.	2010	Pesticide consumption at farm level and residues in the environment and in milk.	Bulletin International Dairy Federation, 443(33-38)	No endpoint can be derived
Bruck, Denny J.	2009	Impact of fungicides on Metarhizium anisopliae in the rhizosphere, bulk soil and in vitro.	BioControl, 54(4), 597-606	The observations made relate to a formulation or product type of the substance of concern that is not considered representative for the intended uses applied for renewing its authorization

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Author	Publication Year	Title	Source	Reason for not including in dossier
Camino-Sanchez, F. J.; Zafra-Gomez, A.; Oliver-Rodriguez, B.; Ballesteros, O.; Navalon, A.; Crovetto, G.; Vilchez, J. L.	2010	UNE-EN ISO/IEC 17025:2005-accredited method for the determination of pesticide residues in fruit and vegetable samples by LC-MS/MS.	Food Additives & Contaminants, Part A, 27(11), 1532-1544	Findings not related to a certain test system
Carrillo, C; Diaz, G; Honrubia, M	2011	Testing the effect of routine fungicide application on ectomycorrhiza formation on Pinus halepensis seedlings in a nursery	Forest pathology Journal de pathologie forestiere equals Zeitschrift fur Forstpathologie, 41(1), 70-74	The investigation does not allow attributing the observations made to the substance of concern (e.g. mixture of substances, origin of exposure unclear)
Cheruiyot, C. [Reprint Author]; Kioko, J. I.; Berjak, P.; Wesley-Smith, J.	2007	In vitro regeneration of recalcitrant embryonic axes: Effects on the biomass characteristics of resulting plants.	South African Journal of Botany, 73(3), 483	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Claeys, W. L.; De Voghel, S.; Schmit, J.-F.; Vromman, V.; Pussemier, L.	2008	Exposure assessment of the Belgian population to pesticide residues through fruit and vegetable consumption	Food Additives and Contaminants, Part A: Chemistry, Analysis, Control, Exposure and Risk Assessment, 25(7), 851-863	The EU exposure has been evaluated for the representative uses supported in the dossier using the EFSA model: PRIMo. This model includes Belgium diets (adult and children) and therefore the chronic & acute risks have been assessed for the supported GAPs.
Dalessandro, C. P. [Reprint Author]; Padin, S.; Urrutia, M. I.; Lopez Lastra, C. C.	2011	Interaction of fungicides with the entomopathogenic fungus Isaria fumosoresea.	Biocontrol Science and Technology, Vol. 21, No. 2, pp. 189-197.	Germination of fungi do not represent an requirement for risk assessment. The topic is IPM related. However, growth and germination of I. fumosoresea was not affected.
Dawson, Andrew H.; Eddleston, Michael; Senarathna, Lalith; Mohamed, Fahim; Gawarammana, Indika; Bowe, Steven J.; Manuweera, Gamini; Buckley, Nicholas A.	2010	Acute human lethal toxicity of Agricultural pesticides: a prospective cohort study.	PLoS Med, 7(10), e1000357,	Poor data documentation : only one case of poisoning mentioned for propamocarb in a table without any information

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Author	Publication Year	Title	Source	Reason for not including in dossier
Deepak, SA; Chaluvaraju, G.; Basavaraju, P.; Amuthesh, Kn; Shekar Shetty, H.; Oros, G.	2005	Response of pearl millet downy mildew ( <i>Sclerospora graminicola</i> ) to diverse fungicides	International Journal of Pest Management, 51(1), 7-16	The observations made are based upon an application or exposure that does not allow transferring the results into a value that can be used for the purpose of the hazard assessment or risk characterization
Delcour, Ilse; Rademaker, Michael; Jacxsens, Liesbeth; De Win, Jessie; De Baets, Bernard; Spanoghe, Pieter.	2015	A risk-based pesticide residue monitoring tool to prioritize the sampling of fresh produce.	Food Control, 50, 690-698	No endpoint can be derived
Duran, J.; Carballo, M.; Hidalgo, E.	2004	Fungicide effect on <i>Beauveria bassiana</i> germination and growth. Efecto de fungicidas sobre la germinación y el crecimiento de <i>Beauveria bassiana</i> .	Manejo Integrado de Plagas y Agroecología, Number 71, pp. 73-78	Germination of fungi do not represent an requirement for risk assessment. The topic is IPM related. However, growth and spore formation was not affected.
Edison, S. E.; Lin, L. A.; Parrales, L.	2011	Practical considerations for the rapid screening for pesticides using ambient pressure desorption ionisation with high-resolution mass spectrometry.	Food Additives & Contaminants Part A, 28(10), 1393-1404	No endpoint can be derived
Escobar, C. [Reprint Author]; Hao, J.	2012	Assessing biological control agents and their fungicide sensitivities for potential integrated management of <i>Sclerotinia</i> stem rot in soybean.	Phytopathology, Vol. 102, No. 9, Suppl. 5, pp. 4.	Biocontrol of fungi for soybean do not represent a requirement for risk assessment. The topic is related to integrated pest management. Moreover, the evaluated biological control agent <i>Coniothyrium minitans</i> was not sensitive to Propamocarb hydrochloride based on growth on culture media amended with the fungicide.
Fantke, Peter; Gillespie, Brenda W.; Juraske, Ronnie; Jolliet, Olivier.	2014	Estimating Half-Lives for Pesticide Dissipation from Plants.	Environmental Science & Technology, 48(15), 8588-8602	Study design / test system not relevant to EU data requirements
Fantke, Peter; Juraske, Ronnie; Anton, Assumpcio; Friedrich, Rainer; Jolliet, Olivier.	2011	Dynamic Multicrop Model to Characterize Impacts of Pesticides in Food.	Environmental Science & Technology, 45(20), 8842-8849	Study design / test system not relevant to EU data requirements

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Author	Publication Year	Title	Source	Reason for not including in dossier
Farkas, Zsuzsa; Slate, Andrew; Whitaker, Thomas B.; Suszter, Gabriella; Ambrus, Arpad	2015	Use of Combined Uncertainty of Pesticide Residue Results for Testing Compliance with Maximum Residue Limits (MRLs)	Journal of Agricultural and Food Chemistry, 63(18), 4418-4428	No endpoint can be derived
Frenich, Antonia Garrido; Fernandez, Maria Del Mar Martin; Moreno, Laura Diaz; Vidal, Jose Luis Martinez; Lopez-Gutierrez, Noelia	2012	Multiresidue pesticide analysis of tuber and root commodities by QuEChERS extraction and ultra-performance liquid chromatography coupled to tandem mass spectrometry	Journal of AOAC International, 95(5), 1319-1330	Findings not related to a certain test system
Garrido Frenich, A.; Martinez Vidal, J. L.; Pastor-Montoro, E.; Romero-Gonzalez, R.	2008	High-throughput determination of pesticide residues in food commodities by use of ultra-performance liquid chromatography-tandem mass spectrometry.	Analytical and Bioanalytical Chemistry, 390(3), 947-959	Findings not related to a certain test system
Gomez, J.; Melero, J. M.	2011	Pathogenicity of Pythium aphanidermatum on cucumber adult plant in soilless crops: II. Influence of agricultural practices on the disease. Patogenia de Pythium aphanidermatum sobre plantas adultas de pepino en cultivo sin suelo: II. Influencia de algunos factores del cultivo en la enfermedad.	Boletin de Sanidad Vegetal, Plagas, 37(2), 225-249	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Gomez-Perez, Maria Luz; Plaza-Bolanos, Patricia; Romero-Gonzalez, Roberto; Martinez-Vidal, Jose Luis; Garrido-Frenich, Antonia.	2012	Comprehensive qualitative and quantitative determination of pesticides and veterinary drugs in honey using liquid chromatography-Orbitrap high resolution mass spectrometry.	Journal of Chromatography A, 1248, 130-138	Findings not related to a certain test system; The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Gomez-Ramos, Maria Del Mar; Rajski, Lukasz; Heinzen, Horacio; Fernandez-Alba, Amadeo R.	2015	Liquid chromatography Orbitrap mass spectrometry with simultaneous full scan and tandem MS/MS for highly selective pesticide residue analysis	Analytical and Bioanalytical Chemistry Ahead of Print	No endpoint can be derived
Greulich, Kerstin; Alder, Lutz.	2008	Fast multiresidue screening of 300 pesticides in water for human consumption by LC-MS/MS.	Analytical and Bioanalytical Chemistry, 391(1), 183-197	No endpoint can be derived
Haith, Douglas A.	2010	Ecological Risk Assessment of Pesticide Runoff from Grass Surfaces.	Environmental Science & Technology, 44(16), 6496-6502	The authors estimated the conc. of pesticides in run-off event by means of a model and US climatic scenarios. For the use of propamocarb in EU the models

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Author	Publication Year	Title	Source	Reason for not including in dossier
				as established under 1107/2009 need to be applied incl. the EU weather scenarios. Considered INAD
Haith, Douglas A.	2011	National Assessment of Pesticide Runoff Loads from Grass Surfaces.	Journal of Environmental Engineering, 137(9), 761-769	The authors estimated the conc. of pesticides in run-off event by means of a model and US climatic scenarios. For the use of propamocarb in EU the models as established under 1107/2009 need to be applied incl. the EU weather scenarios. Considered INAD
Hautier, L.; Jansen, J.-P.; Schiffers, B.; Deleu, R.; Moreira, C.	2004	Drawing-up of pesticide selectivity lists to beneficial arthropods for IPM programmes in potato.	Communications in agricultural and applied biological sciences, 69(3), 171-181	The observations made relate to a formulation or product type of the substance of concern that is not considered representative for the intended uses applied for renewing its authorization
Henning-De Jong, Irmgard; Van Zelm, Rosalie; Huijbregts, Mark A. J.; De Zwart, Dick; Van Der Linden, Ton M. A.; Wintersen, Arjen; Posthuma, Leo; Van De Meent, Dik.	2008	Ranking of agricultural pesticides in the Rhine-Meuse-Scheldt basin based on toxic pressure in marine ecosystems.	Environ. Toxicol. Chem., Volume 27, Issue 3, Page 737-745,	The publication is a secondary source of information, e.g. review article or study that condenses information of primary nature
Huang, Zhen; Ren, Shun-Xiang; Wu, Jian-Hui; Huang, Tao.	2008	Effect of pesticides on infectious activity of Paecilomyces fumosoroseus.	Huanan Nongye Daxue Xuebao, 29(3), 16-20,	The observations made relate to a formulation or product type of the substance of concern that is not considered representative for the intended uses applied for renewing its authorization
Ishibashi, Megumi; Izumi, Yoshihiro; Sakai, Miho; Ando, Takashi; Fukusaki, Eiichiro; Bamba, Takeshi	2014	High-throughput simultaneous analysis of pesticides by supercritical fluid chromatography coupled with high-resolution mass spectrometry	Journal of Agricultural and Food Chemistry Ahead of Print	No information useful for influencing risk assessment

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Author	Publication Year	Title	Source	Reason for not including in dossier
Jansson, Christer; Kreuger, Jenny.	2010	Multiresidue analysis of 95 pesticides at low nanogram/liter levels in surface waters using online preconcentration and high performance liquid chromatography/tandem mass spectrometry.	Journal of AOAC INTERNATIONAL, 93(6), 1732-1747	The article reports on chemical synthesis or development of methods for measurements of the chemical without its application to natural samples
Jian, Qiu; Zhu, Guang-Yan; Zheng, Zun-Tao	2015	Residue analysis and degradation dynamics of propamocarb in tobacco	Nongyao, 54(2), 112-114	No information useful for influencing risk assessment
Juraske, Ronnie; Mutel, Christopher L.; Stoessel, Franziska; Hellweg, Stefanie.	2009	Life cycle human toxicity assessment of pesticides: Comparing fruit and vegetable diets in Switzerland and the United States.	Chemosphere, 77(7), 939-945	Study design / test system not relevant to EU data requirements
Kakimoto, Yoshihisa; Naetoko, Yoshitaka; Iwasaki, Yoshinari; Nakamura, Shigeru; Tatsuguchi, Hisako.	2005	Multiresidue methods for determination of pesticides in fruits and vegetables by GC/MS (SCAN) and LC/MS (SIM).	Shokuhin Eiseigaku Zasshi, 46(4), 153-160	No endpoint can be derived
Kamata, Ryo; Itoh, Keisuke; Nakajima, Daisuke; Kageyama, Shiho; Sawabe, Akiyoshi; Terasaki, Masanori; Shiraishi, Fujio	2011	The feasibility of using mosquitofish (Gambusia affinis) for detecting endocrine-disrupting chemicals in the freshwater environment	Environmental Toxicology and Chemistry, 30(12), 2778-2785	The article does not contain information related to the substance of concern
Kennedy, T. F. [Reprint Author]; Connery, J.	2006	An evaluation of seed-pellet insecticides in a precision drilled crop of sugar beet.	Irish Journal of Agricultural and Food Research, 45(2), 211-222	The investigation does not allow attributing the observations made to the substance of concern (e.g. mixture of substances, origin of exposure unclear)
Kmellar, B.; Fodor, P.; Pareja, L.; Ferrer, C.; Martinez-Uroz, M. A.; Valverde, A.; Fernandez-Alba, A. R.	2008	Validation and uncertainty study of a comprehensive list of 160 pesticide residues in multi-class vegetables by liquid chromatography-tandem mass spectrometry.	Journal of Chromatography A, 1215(1-2), 37-50	No endpoint can be derived
Lacina, Ondrej; Urbanova, Jana; Poustka, Jan; Hajslova, Jana.	2010	Identification/quantification of multiple pesticide residues in food plants by ultra-high-performance liquid chromatography-time-of-flight mass spectrometry.	Journal of Chromatography A, 1217(5), 648-659	No endpoint can be derived



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Author	Publication Year	Title	Source	Reason for not including in dossier
Lacina, Ondrej; Zachariasova, Milena; Urbanova, Jana; Vacklavikova, Marta; Cajka, Tomas; Hajslova, Jana.	2012	Critical assessment of extraction methods for the simultaneous determination of pesticide residues and mycotoxins in fruits, cereals, spices and oil seeds employing ultra-high performance liquid chromatography-tandem mass spectrometry.	Journal of Chromatography A, 1262, 8-18	No endpoint can be derived
Landry, J. [Reprint Author]; Martinez, C.; Rochefort, L.	2011	The use of fungicide Nova to mitigate infection of Sphagnum by parasitic fungi in the greenhouse.	Botany-Botanique, 89(10), 655-661	The article reports on desired effects on organisms considered as such target organisms
Lesueur, C.; Gartner, M.	2005	Routine identification and quantification of pesticide multiresidues in fruit and vegetable samples with full scan, SIM and deconvolution reporting software.	Ernaehrung (Vienna, Austria), 29(11), 466-471	No endpoint can be derived
Lesueur, Celine; Gartner, Michael; Mentler, Axel; Fuerhacker, Maria.	2007	Qualitative and quantitative analysis of polar pesticide multiresidues in leaf samples with a liquid chromatography-ion-trap mass-selective detector.	International Journal of Environmental Analytical Chemistry, 87(13-14), 1013-1032	Findings not related to a certain test system
Liu, Fangfang; Qin, Zhiwei; Zhou, Xiuyan.	2010	Screening of germplasm resources of cucumber plant with low pesticide residue content.	Dongbei Nongye Daxue Xuebao, 41(7), 32-36	Poor data documentation
Liu, Yanan; Li, Minmin; Fan, Bei; Lu, Jia; He, Yan; Kong, Zhiqiang; Sun, Yufeng; Wang, Fengzhong	2015	Residues and dissipation of propamocarb in tomatoes and soil using UPLC-MS/MS	Huanjing Huaxue, 34(6), 1072-1077	Study design / test system not relevant to EU data requirements; NON-EU - The publication is a matter of observations for environmental responses in a region outside Europe
Liu, Yong.	2006	Injury by commonly used tobacco pesticides evaluated in a floating seedling assay.	Nongyao, 45(5), 353-356	The investigation does not report results in values reflecting agreed determinants for the hazard or exposure characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants

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Author	Publication Year	Title	Source	Reason for not including in dossier
Loos, Martin; Krauss, Martin; Fenner, Kathrin.	2012	Pesticide Nonextractable Residue Formation in Soil: Insights from Inverse Modeling of Degradation Time Series.	Environmental Science & Technology, 46(18), 9830-9837	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Mahugo Santana, C. Mahugo; Torres Padron, M. E.; Sosa Ferrera, Z.; Santana Rodriguez, J. J.	2007	Development of a solid-phase microextraction method with micellar desorption for the determination of chlorophenols in water samples	Journal of Chromatography, A, 1140(1-2), 13-20	The article does not contain information related to the substance of concern
Marucci, Alvaro; Campiglia, Enio; Colla, Giuseppe; Pagnello, Barbara.	2011	Environmental impact of fertilization and pesticide application in vegetable cropping systems under greenhouse and open field conditions.	J. Food, Agric. Environ., Volume 9, Issue 3 and 4, Pt. 2, Page 840-846,	The publication is a secondary source of information, e.g. review article or study that condenses information of primary nature
Masheva, S.; Velkov, N.; Valchev, N.; Yankova, V.	2013	Screening of plant protection products against downy mildew on cucumbers (Pseudoperonospora cubensis (Berkeley and M. A. Curtis) Rostovzev) in cultivation facilities.	Agricultural Science and Technology, 5(2), 194-199	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Mensin, Sumalee; Soyong, Kasem; McGovern, Robert J.; Toanun, Chaiwat	2013	Effect of agricultural pesticides on the growth and sporulation of nematophagous fungi	Agricultural Technology, 9(4), 953-961	The article does not present control data. No analysis of the data is possible. The article focus on efficacy of the product to its fungicidal use. Therefore, the article is not relevant for risk assessment.
Mezcua, Milagros; Malato, Octavio; Garcia-Reyes, Juan F.; Molina-Diaz, Antonio; Fernandez-Alba, Amadeo R.	2009	Accurate-Mass Databases for Comprehensive Screening of Pesticide Residues in Food by Fast Liquid Chromatography Time-of-Flight Mass Spectrometry.	Analytical Chemistry, 81(3), 913-929	No endpoint can be derived
Mondello, Luigi; Casilli, Alessandro; Tranchida, Peter Quinto; Lo Presti, Maria; Dugo, Paola; Dugo, Giovanni.	2007	Comprehensive gas chromatography coupled to mass spectrometry for the separation of pesticides in a very complex matrix.	Analytical and Bioanalytical Chemistry, 389(6), 1755-1763	No endpoint can be derived



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Author	Publication Year	Title	Source	Reason for not including in dossier
Muller, Erica; Van Der Schoor, Caroline; Brocca, Daniela; Medina-Pastor, Paula; Reich, Hermine; Triacchini, Giuseppe	2014	The 2011 European union report on pesticide residues in food	EFSA Journal, 12(5), 3694/1-3694/511, 511 pp.	The EU exposure has been evaluated for the representative uses supported in the dossier using the EFSA model (PRIMO). The chronic and acute risks have been assessed for the supported GAPs with GLP data.
Nermut, Jiri [Reprint Author]; Mracek, Zdenek	2010	The influence of pesticides on the viability and infectivity of entomopathogenic nematodes (Nematoda: Steinernematidae).	Russian Journal of Nematology, 18(2), 141-148	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Niculescu, S. P.; Lewis, M. A.; Tigner, J.	2008	Probabilistic neural networks modeling of the 48-h LC50 acute toxicity endpoint to Daphnia magna	SAR and QSAR in Environmental Research, 19(7-8), 735-750	The publication is a secondary source of information, e.g. review article or study that condenses information of primary nature
Nieto-Garcia, Antonio Jose; Romero-Gonzalez, Roberto; Garrido Frenich, Antonia	2014	Determination of multi-class pesticide residue in dietary supplements from grape seed extracts by ultra-high-performance liquid chromatography coupled to triple quadrupole mass spectrometry	Food Additives and Contaminants, Part A: Chemistry, Analysis, Control, Exposure and Risk Assessment, 31(9), 1550-1561	No information useful for influencing risk assessment
Nougadere, Alexandre; Reninger, Jean-Cedric; Volatier, Jean-Luc; Leblanc, Jean-Charles.	2011	Chronic dietary risk characterization for pesticide residues: A ranking and scoring method integrating agricultural uses and food contamination data.	Food Chem. Toxicol., Volume 49, Issue 7, Page 1484-1510,	The dietary risk assessments presented in the publication are not based on the methodology that has to be applied in a regulatory context and/or do not provide relevant information about the risks that result specifically from the representative use(s).

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Author	Publication Year	Title	Source	Reason for not including in dossier
Polgar, Laszlo; Garcia-Reyes, Juan F.; Fodor, Peter; Gyepes, Attila; Dernovics, Mihaly; Abranko, Laszlo; Gilbert-Lopez, Bienvenida; Molina-Diaz, Antonio.	2012	Retrospective screening of relevant pesticide metabolites in food using liquid chromatography high resolution mass spectrometry and accurate-mass databases of parent molecules and diagnostic fragment ions.	Journal of Chromatography A, 1249, 83-91	Study design / test system not adequate
Polgar, Laszlo; Garcia-Reyes, Juan F.; Fodor, Peter; Gyepes, Attila; Dernovics, Mihaly; Abranko, Laszlo; Gilbert-Lopez, Bienvenida; Molina-Diaz, Antonio.	2012	Retrospective screening of relevant pesticide metabolites in food using liquid chromatography high resolution mass spectrometry and accurate-mass databases of parent molecules and diagnostic fragment ions.	J. Chromatogr. A, Volume 1249, Page 83-91,	Study design / test system not adequate
Rajski, Lukasz; Gomez-Ramos, Maria Del Mar; Fernandez-Alba, Amadeo R.	2014	Large pesticide multiresidue screening method by liquid chromatography-Orbitrap mass spectrometry in full scan mode applied to fruit and vegetables	Journal of Chromatography A, Ahead of Print	No endpoint can be derived
Ricart, I. Sahuquillo; Anton-Fos, G. M.; Duarte, M. J.; Mateo, J. V. Garcia; Zamora, L. Lahuerta; Calatayud, J. Martinez.	2007	Theoretical prediction of the photoinduced chemiluminescence of pesticides.	Talanta, 72(2), 378-386	The article reports on chemical synthesis or development of methods for measurements of the chemical without its application to natural samples
Sahoo, Sanjay Kumar; Mandal, Kousik; Kumar, Rajinder; Singh, Balwinder	2014	Analysis of Fluopicolide and Propamocarb Residues on Tomato and Soil Using QuEChERS Sample Preparation Method in Combination with GLC and GCMS	Food analytical methods, 7(5), 1032-1042	Study design / test system not relevant to EU data requirements
Sandor, Zsolt.	2006	The effect of some herbicides on microbes and their activity in soil.	Cereal Research Communications, 34(1), 275-278	The article does not contain information related to the substance of concern
Song, Weiguo; Li, Baoju; Ye, Zhihua; Zhao, Zhihui; Shi, Yanxia.	2008	Concentration prediction of pesticides with different transformation fate in agricultural soil environment.	Nongye Huanjing Kexue Xuebao, 27(4), 1574-1581	The authors applied a model for prediction of environmental exposure concentrations. Exposure assessment under 1107/2009 needs to follow agreed principles, eg. FOCUS.

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Author	Publication Year	Title	Source	Reason for not including in dossier
Speck-Planche, Alejandro; Kleandrova, Valeria V.; Luan, Feng; Cordeiro, M. Natalia D. S.	2012	Predicting multiple ecotoxicological profiles in agrochemical fungicides: A multi-species chemoinformatic approach	Ecotoxicology and Environmental Safety, 80, 308-313	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Surviliene, E.; Raudonis, L.; Jankauskiene, J.	2009	Investigation of pesticides effect on pollination of bumblebees in greenhouse tomatoes.	Sodininkyste ir Darzininkyste, 28(3), 235-241	The investigation does not allow attributing the observations made to the substance of concern (e.g. mixture of substances, origin of exposure unclear)
Tan, He-Ping; Feng, De-Jian; Shi, Xie-Fei; Qian, Shan-Shan; Ye, Shan-Rong; Chen, Neng-Wu; Xu, Yang	2012	Environmental quality standard for ecological tea garden	Anhui Nongye Kexue, 40(28), 13963-13965	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Tomasevic, Anđelka V.; Gasic, Slavica M.	2012	Photoremediation of carbamate residues in water	Insecticides: Basic and Other Applications, 39-60	The investigation does not report results in values reflecting agreed determinants for the hazard characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Tsutsumi, Taizou; Sakamoto, Mitsushi; Kataoka, Hiroyuki; Pawliszyn, Janusz.	2006	Automated headspace solid-phase microextraction and gas chromatography-mass spectrometry for screening and determination of multiclass pesticides in water.	Methods in Biotechnology, 19(Pesticide Protocols), 343-364	No endpoint can be derived; The article reports on chemical synthesis or development of methods for measurements of the chemical without its application to natural samples
Uyanoez, Refik; Cetin, Uemmuehan; Karaarslan, Emel	2005	Effect of three fungicides on soil microbial activity and nitrogen dynamics	Pakistan Journal of Biological Sciences, 8(6), 805-809	Assessment in line with the results of the applicant and can be seen as supportive information. However the data set is insufficient to determine robust values (purity missing, temperature conditions missing a.s.o). Therefore the study is excluded from the risk assessment

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Author	Publication Year	Title	Source	Reason for not including in dossier
Van Den Boogert, P. H. J. F.; Luttikholt, A. J. G.	2004	Compatible Biological and Chemical Control Systems for Rhizoctonia solani in Potato	European Journal of Plant Pathology, 110(2), 111-118	Biocontrol fungi for potatoes do not represent an requirement for risk assessment. The topic is IPM related. However, no difference in reducing radial growth of tuber diseases was observed after contact with Propamocarb.
Wang, Chunwei; Wang, Yan; Gao, Jie; Xu, Yuncheng; Cui, Lili	2014	Dissipation and residues determination of propamocarb in ginseng and soil by high-performance liquid chromatography coupled with tandem mass spectrometry	Environmental Monitoring and Assessment, 186(9), 5327-5336	No essential use; NON-EU - The publication is a matter of observations for environmental responses in a region outside Europe
Wang, Xue-Mei; Cui, Jing-Ying; Yu, Rong; Xie, Hua; Feng, Zhi-Hong	2010	Effects of different chemical pesticides on marketability of melon	Beifang Yuanyi, (10), 57-59	The investigation does not report results in values reflecting agreed determinants for the hazard or exposure characterization or risk assessment under Reg. EC No 1107/2009 and information is insufficient to transfer values into such determinants
Wei, Li; Xiu-Fang, Wang; Cheng-Fa, Sheng [Reprint Author]	2004	Impact of sixteen chemical pesticides on conidial germination of two entomophthoralean fungi: Conidiobolus thromboides and Pandora nouryi.	Biocontrol Science and Technology, Vol. 14, No. 7, pp. 737-741.	Germination of an aphid fungus does not represent an requirement for risk assessment. The topic is IPM related. However, no difference in germination was observed after contact with Propamocarb.
Whiteside, Melanie; Mineau, Pierre; Morrison, Clare; Knopper, Loren D.	2008	Comparison of a score-based approach with risk-based ranking of in-use agricultural pesticides in Canada to aquatic receptors.	Integr. Environ. Assess. Manage., Volume 4, Issue 2, Page 215-236,	The publication is a secondary source of information, e.g. review article or study that condenses information of primary nature
Williams, E. Spencer; Berninger, Jason P.; Brooks, Bryan W.	2011	Application of chemical toxicity distributions to ecotoxicology data requirements under REACH	Environmental Toxicology and Chemistry, 30(8), 1943-1954	The publication is a secondary source of information, e.g. review article or study that condenses information of primary nature
Wittmer, Irene; Moschet, Christoph; Simovic, Jelena; Singer, Heinz; Stamm, Christian; Hollender, Juliane; Junghans, Marion; Leu, Christian	2014	Over 100 pesticides in water bodies. The NAWA SPE program shows the level of pesticides in Swiss waters	Aqua and Gas, 94(3), 32-43	Article contains the same information and from the same study as Doc ID 160_697916_-_Chemical_Abstracts

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Author	Publication Year	Title	Source	Reason for not including in dossier
Wojtkowiak-Gebarowska, E.; Pietr, S. J.	2006	Colonization of roots and growth stimulation of cucumber by iprodione-resistant isolates of <i>Trichoderma</i> spp. applied alone and combined with fungicides.	Phytopathologia Polonica, 41, 51-64	The article reports on desired effects on organisms considered as such target organisms
Wong, Jon; Hao, Chunyan; Zhang, Kai; Yang, Paul; Banerjee, Kaushik; Hayward, Douglas; Iftakhar, Imran; Schreiber, Andre; Tech, Katherine; Sack, Chris; Smoker, Michael; Chen, Xiangru; Utture, Sagar C.; Oulkar, Dasharath P.	2010	Development and Interlaboratory Validation of a QuEChERS-Based Liquid Chromatography-Tandem Mass Spectrometry Method for Multiresidue Pesticide Analysis.	Journal of Agricultural and Food Chemistry, 58(10), 5897-5903	Findings not related to a certain test system
Wu Peng; Qin Zhiwei; Zhou Xiuyan; Wu Tao; Xin Ming; Guo Qianqian; Wu, P.; Qin, Z. W.; Zhou, X. Y.; Wu, T.; Xin, M.; Guo, Q. Q.	2014	Study on relationship between cucumber germplasm and propamocarb residue using subjective rating technique.	Journal of Northeast Agricultural University (English Edition), Volume 21(1), 1-9	No essential use
Wu, Peng	2013	Studies on Physiological and Biochemical and Molecular Basis of Low Propamocarb Residue in Cucumber	Zhongguo Boshi Xuewei Lunwen Quanwen Shujuku 2013, 2013-1(D1231-1), No pp. given URL: <a href="http://acad.cnki.net/Kns55/brief/result.aspx?dbPrefix&gt;equals%20CDFD">http://acad.cnki.net/Kns55/brief/result.aspx?dbPrefix&gt;equals CDFD</a>	Study design / test system not relevant to EU data requirements
Yang, Angel; Park, Jong-Hyouk; Abd El-Aty, A. M.; Choi, Jeong-Heui; Oh, Jae-Ho; Do, Jung-Ah; Kwon, Kisung; Shim, Ki-Hoon; Choi, Ok-Ja; Shim, Jae-Han	2012	Synergistic effect of washing and cooking on the removal of multi-classes of pesticides from various food samples	Food Control, 28(1), 99-105	No endpoint can be derived

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Author	Publication Year	Title	Source	Reason for not including in dossier
Zhang Ruixia; Xu Weian; Li Zhaohui; Fu Zhesu; Zhang, R. X.; Xu, W. A.; Li, Z. H.; Fu, Z. S.	2004	Effect of 10 fungicides on conidial germination of <i>Conidiobolus thromboides</i> .	Plant Protection, Volume 30, Number 2, pp. 47-50,	Germination of an aphid fungus does not represent an requirement for risk assessment. The topic is IPM related. However, no difference in germination was observed after contact with Propamocarb.
Zhang, Kai; Wong, Jon W.; Yang, Paul; Tech, Katherine; Dibenedetto, Alex L.; Lee, Nathaniel S.; Hayward, Douglas G.; Makovi, Carolyn M.; Krynitsky, Alexander J.; Banerjee, Kaushik; Jao, Lillian; Dasgupta, Soma; Smoker, Michael S.; Simonds, Roger; Schreibe	2011	Multiresidue pesticide analysis of agricultural commodities using acetonitrile salt-out extraction, dispersive solid-phase sample clean-up, and high-performance liquid chromatography-tandem mass spectrometry.	Journal of Agricultural and Food Chemistry, 59(14), 7636-7646	Findings not related to a certain test system
Zhang, Ruixia; Fu, Zhenshu; Xu, Weian	2004	Fungicide Effect on Conidial Germination of <i>Pandora nouri</i> and <i>Conidiobolus thromboides</i>	Nongyao, 43(3), 135-139	Germination of an aphid fungus does not represent an requirement for risk assessment. The topic is IPM related. However, no difference in germination was observed after contact with Propamocarb.
Zhang, Xuejie; Fu, Meng; Guo, Ke; Ye, Zhihua; Wang, Jinyu; Li, Kun; Wang, Fudong.	2010	Residue dynamics of pesticides in head lettuce and impact of related factors.	Nongye Huanjing Kexue Xuebao, 29(1), 180-184	No essential use
Zhang, Yan-Jun; Wei, Wen-Bin; Ma, Quan-Wei; Zhang, Hong-Jie; Sun, Wei-Wei	2013	Potted trial on control effect of pepper blight by applying four kinds of chemical agents	Beifang Yuanyi, (2), 99-100	The article reports on desired effects on organisms considered as such target organisms
Zsolt, S.; Janos, K.; Peter, T. N.; Agnes, O. Z.	2007	The effect of different herbicides on some factors of carbon cycle in a chernozem.	Bulletin of University of Agricultural Sciences and Veterinary Medicine Cluj-Napoca. Agriculture, 63/64, 340 p.	The reference appears to be an information on studies conducted at the University of Cluj-Napoca. No detailed information is available, however, the summary does not indicate that tests included propamocarb.

## **CA 9.6 Conclusion**

For Propamocarb and its metabolites, a total of 585 references were identified and evaluated for potential relevance. 479 identified studies have been considered irrelevant after rapid assessment according to the EFSA Guidance. For 106 references full-text documents have been obtained and assessed in detail according to the EFSA Guidance. Of these 106 references 92 publications have been considered irrelevant after detailed assessment (see Table 6).

The scientific full text of 14 literature references evaluated as relevant after detailed assessment have been inserted in the respective K-part of the dossier (as listed in Tables 4 and 5).

One of these 14 publications, Bonnechere et al. (2012), was classified as case a) study according to the EFSA Guidance Point 5.4.1. The study investigates effects of household and industrial processing on levels of residues of four fungicides (among them Propamocarb) and one insecticide and two degradation products in spinach. The study provides data for refining risk assessment parameters for residues in processed commodities. Thus, it is summarized and discussed in detail in section CA 6.5.3 “Magnitude of residues in processed commodities” of document MCA Section 6: “Summary of the Residues in or on treated products, food and feed for the active substance Propamocarb”.

Beside this, 13 other publications have been identified as studies relevant after detailed assessment and classified in accordance with the EFSA Guidance Point 5.4.1. However, none of these studies was considered to have an impact on an EU-agreed endpoint, or would require any adaptation of the risk assessments presented in the Propamocarb supplementary (Annex I Renewal) dossier.



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**CA 9.7 Appendices**

**CA 9.7.1 Appendix I: Search and Evaluation Workflow**

