Pesticide Action Network Europe

Part 3:

TWISTING AND BENDING THE RULES: In 'Resubmission' all efforts are aimed to get pesticides approved

PAN Europe
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MEET (CHEMICAL) AGRICULTURE

The world of backdoors, derogations, sneaky pathways, and loopholes.

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SUMMARY

Rules demand pesticide companies to deliver dossiers with safety tests and to fulfil all data requirements in the application for their pesticide. However Member States and Health DG SANCO allow data gaps on a massive scale while assessing pesticides. Around 50 pesticides should be banned in 2008 because of the many data gaps present and the many risks shown, but these 50 and the companies behind them got a second chance in an invention called "Resubmission". The substance was "voluntarily withdrawn" but could stay on the market many years during a second assessment. More companies joined Resubmission applying in the end for a total of 87 substances. Data gaps however in many cases were not filled by data but whitewashed by a next invention of SANCO and Member States called "confirmatory data". This invention allows pesticide companies to deliver new tests or arguments in a later phase while the pesticide already gets the green light.

even pesticides with clear health risk can be approved in the Brussels voting system

In this way man and the environment are exposed to unknown risks.

Many years were wasted with this ‘Resubmission’ to ensure market access of pesticides (now around 350 active substances are approved, up from 250 in 2008), while necessary work on modernising data requirements and substitution was halted.

Worst of all, even pesticides with clear health risk can be approved in the Brussels voting system, while environment was never a reason at all for banning a pesticide. This is a clear violation of the pesticide regulation stating that pesticides shall not have any unacceptable effect on the environment. This failure to implement the rules will likely contribute to the current massive decline in biodiversity in Europe.

Behind the curtains of the closed meetings of the Standing Committee, national representatives and Commission twist, bend and redefine the rules. Democratic decisions taken by European Parliament and Council are disregarded. This is the conclusion of PAN Europe after evaluating the so-called “Resubmission” regime developed by DG SANCO in deciding on pesticides. PAN-Europe recommends a complete revision of decision-making on pesticides putting again citizens and the environment first and not aiming at getting as much as possible pesticides approved.

1. INTRODUCTION

Commission Regulation 33/2008 creates a second chance of getting pesticides approved if an application failed in first instance. This is remarkable because in the long process of EU-approval since 1991 many hundreds of pesticides were assessed and this resulted in either an approval (inclusion in the positive list Annex I) or non-inclusion. So why would 50 pesticides (Commission Decision 2008/934/EC) get a second chance after the decision of a non-inclusion or a withdrawal?

Pesticide producers can apply for an approval at any time, but Commission provided special services like a “mini-dossier” for these group of pesticides/applicants in Reg. 33/2008, and –most importantly- granted continued market access, called an ‘extended phase-out’, even till 31 December 2012 (Commission Decision 2010/455/EC). Companies in this way got 3-4 year market access while being non-included in Annex I. It is hard to understand why DG SANCO offers such enormous advantages to a special group of companies. And the question is what it is in it for DG SANCO and the Member States who decided to create this special regime? Why did they accept such unknown and potentially high risk for consumers and the environment? Why not simply decide to a non-inclusion?

It sounds very much like SANCO and Member States have been 'dealing and wheeling' behind the screens, offering "extended phase-out" in exchange for a 'voluntary' withdrawal. Should SANCO be negotiating about approvals of pesticides?

Still the question is why SANCO had this "conflicting and contradictory" behaviour for just one group of pesticide companies? One of the reason could be the threat of a massive number of court cases of industry which could completely paralyse DG SANCO's pesticide unit. DG SANCO couldn't approve these pesticides because of the (many) existing data gaps and because of high risks indicated. Industry claimed their information (not only tests but also assumptions and questionable calculations) was sufficient to decide for inclusion. They also claimed SANCO made many procedural mistakes, creating good chances for industry to win in court [1].

Below are the court case we are aware of. There is a peak in 2007/2008, indicating a fight between industry and SANCO, which seems resolved in later years.

In Case T-95/09 one of the producers, United Phosphorus (promoting a pesticide substance called Napropamide) sheds some light on what happened behind the screens. In this case the company objects to SANCO's "conflicting and contradictory behaviour denying to the applicant the right to withdraw the support of a substance in return for an extended phase-out period pending the resubmission of a dossier".

1. Note NGO's like PAN Europe up to now have no stance in court in spite of the fact European Commission signed the Arhus Treaty, ensuring access to court for NGO's. This –again- is a massive advantage for commercial interest over those defending the interests of citizens and the environment.

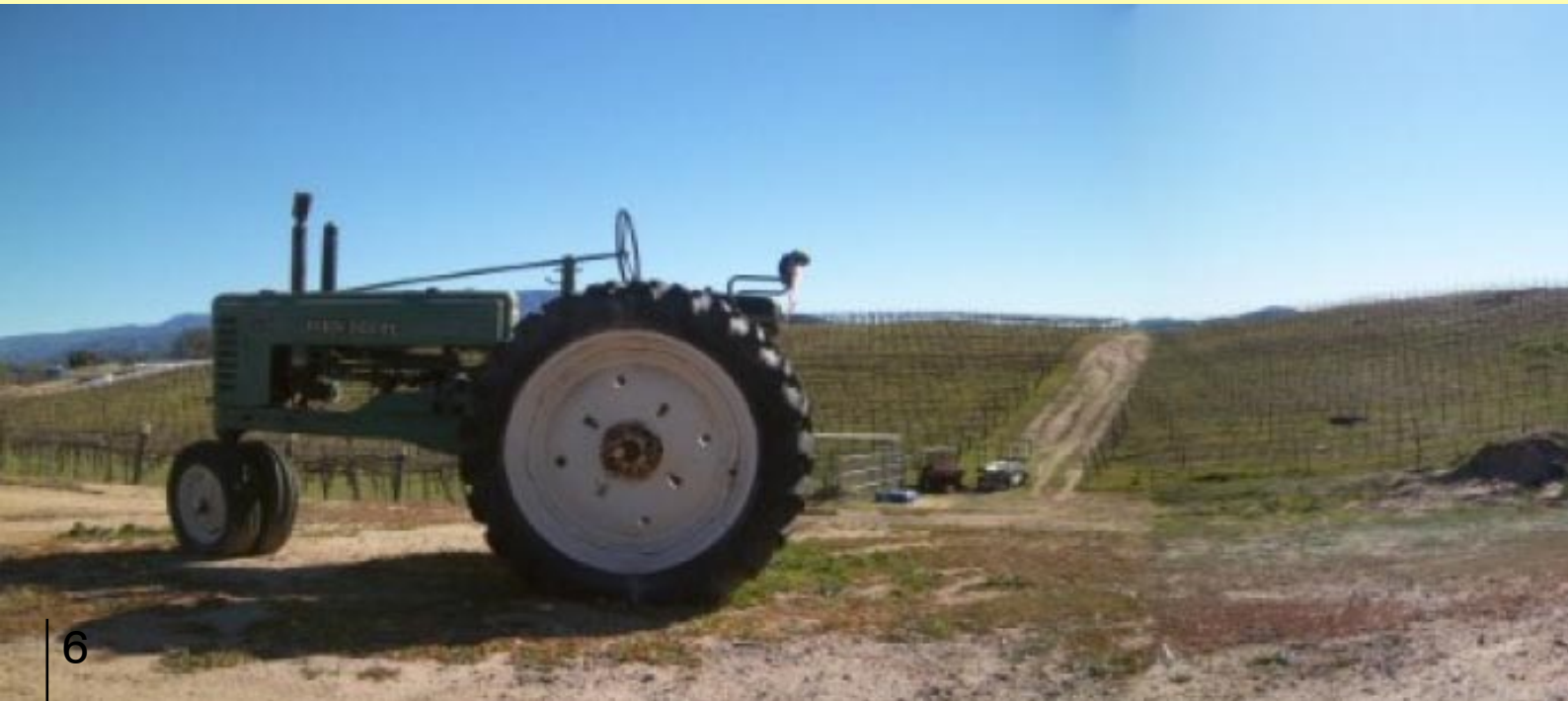
Because generally more cases are done for the same substance, over 60 industry court cases are currently running. This is already a heavy burden for DG SANCO; additionally it makes them nervous because for years the outcome is unsure.

Creating the Resubmission constructions to prevent further court cases seems to be one of the motives but creating a special regime only for a specific group of companies is not very justifiable. It also offers unwanted precedents for future loopholes and court cases.

Additionally SANCO was under internal pressure to finalise the much-delayed pesticide approval. It started long ago in 1991 and should have been finalised in 2003, but still wasn't in 2008. And the logic step to ban the pesticides with the data gaps would not be accepted by the Member States, represented generally by the Ministry of Agriculture. Given this situation SANCO had to find a way out. Legal services in Commission will have been involved and it is hard to understand why they approved the violations of the EU pesticide Directive.

The resubmission loophole unfortunately turned into a big 'hole' when industry applied for more than 80 substances (see Annex II, 87 substances), also applications for non-included substances who were regarded as being without chance of getting an approval. Many companies jumped on this train of the 'fast track' procedure with mini-dossiers. They hoped for a mild evaluation or hoped to put pressure on Commission through Member States who might be willing to support farmers being interested in getting back a banned substance. Nasty pesticides like 1,3-Dichlorpropene, Metam, Chlorpicrin and Methylbromide -all soil sterilising agents- are examples of pesticides where valuable time of civil servants was wasted.

The original 'deal' of DG SANCO was made with 50 applicants, 'voluntarily' withdrawing their chemicals in exchange for the advantages. Around 35 didn't get this offer (such as Napropamide), judged as having no chance of being approved. Despite being not part of the deal, these 35 could apply for the Resubmission regime and apparently with great success. Not only the 50 of the deal got the green light in recent



years but also at least an additional 12 (possibly up to 17) from the list of those judged for being ready for a ban. From the 87 pesticides in the Resubmission regime, 4 are withdrawn by applicants, 5 still pending, 14 not-included and 64 included.

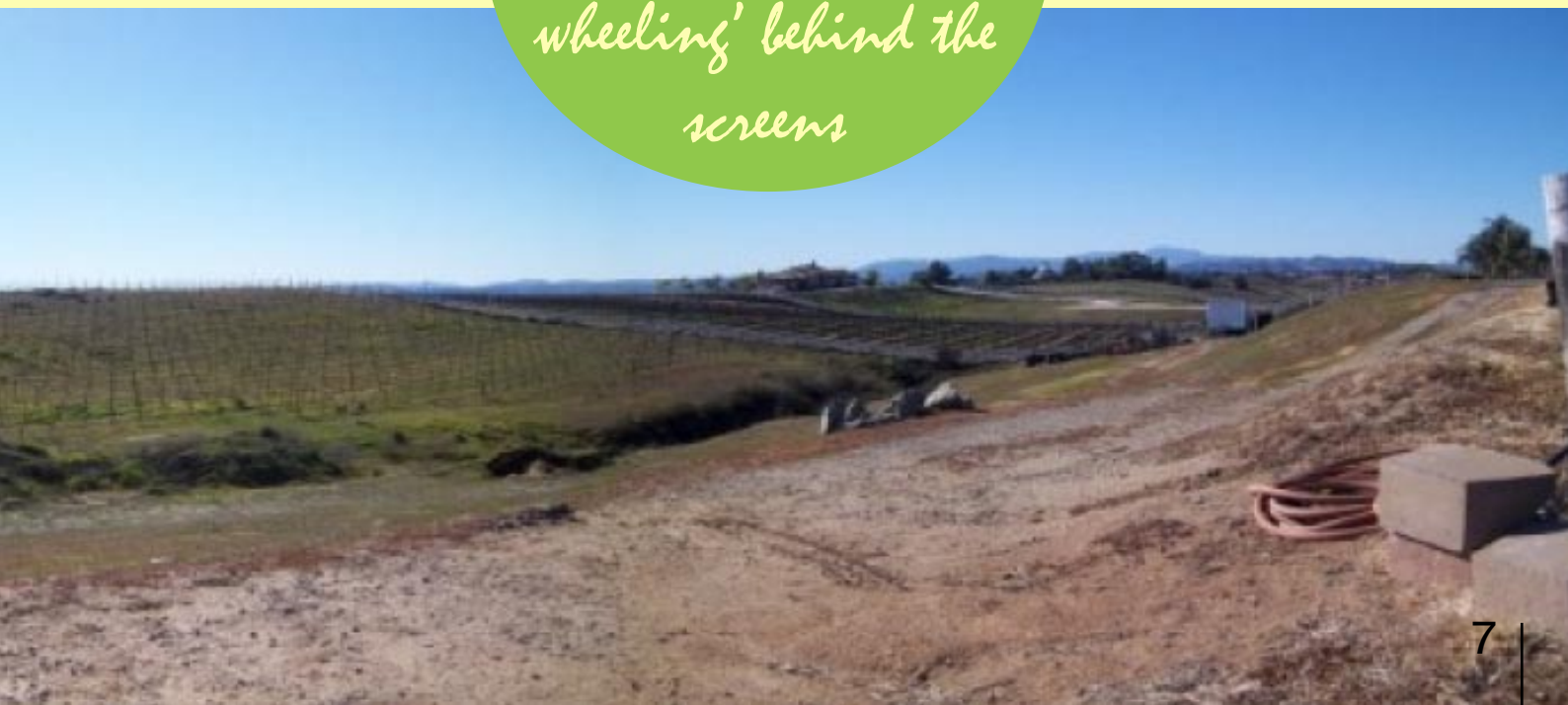
Another 'bad' innovation which adds to the Resubmission approach is the 'confirmatory data' regime. This regime allows market access of pesticides -while data gaps still exist- on the condition the company "confirms" in a later phase by studies or reasoning a risk is absent or acceptable. This confirmatory regime is used in a standard way, virtually for every approval. In effect it violates the provisions of Directive 91/414 but as long as nobody challenges this illegal practice it will remain in place. The confirmatory approach is a black-box. Risk could be acceptable, but also much higher and clearly unacceptable.

In the realm of agriculture loopholes and backdoors are major routes of allowing use of pesticides. A provision in Directive 91/414 allows use of illegal pesticides for 120 days (Art.8.2) in case of emergency. The use of this provision recently exploded when Member States massively started allowing all kinds of non-emergency pesticides to their farmers they claimed to be urgently needed. Once a few Member States started using this 'innovation', most Member States followed (PAN 2011 report on derogations).

Another invention of the agriculture loophole-world is "essential use", again allowing the use of illegal pesticides in case Member States -generally the Ministries of Agriculture- act as a service bureau for back-lagging farmers. An example is the essential use of the soil fumigant Metam sodium, effectively keeping old practices such as monocultures and weak, vulnerable crop varieties in place (PAN-report on essential use of Metam). This construction also was used in some member states allowing 'essential use" for minor crops when industry didn't want to pay for an authorisation for a minor crops.

In effect it will be hard to find a pesticide

SANCO and Member States have been 'dealing and wheeling' behind the screens



approved in Europe without having made use of some kind of loophole. It is strange to note that rules count for every citizens but Member State representatives are allowed to twist and bend the rules behind the screens in the obscure Brussels way of dealing called “comitology”. Democratic decisions are reversed and effective control on these practises is absent. European Parliament is also unable to interfere.

One of the further major drawbacks of the Resubmission construction is that DG SANCO, member states and EFSA need to spend most of their time and resources in 2009, 2010 , 2011, and even into 2012 on the evaluation of these substances. This means there was no time to work on the modernisation of pesticide approval which is required for the new Regulation 1107/2009. No time for modernising the data requirements (no inclusion immunotoxicity, nor endocrine disruption, combination toxicity, etc.), no time for modernising the uniform principles (which are very industry-biased), no time to work on the substitution principle, no time to work on guidelines for protection of residents to spraying, etc. No time in conclusion to protect citizens and all time dedicated to getting more pesticides on the market. In fact the opposite of the mission of DG SANCO.

As a result of this the number of approved pesticides in Europe is on the rise from around 250 in 2008 till around 350 on the moment. Resubmission resulted in an extra 64 pesticides approved. The -many times- repeated message of Commission that it was so extremely effective in banning large number of pesticides gets more and more questionable now many of the banned pesticides return via a loophole construction.

Regulation 33/2008 provides for a ‘fast track’ procedure with limited (‘mini’) dossiers. This made us wonder what the quality would be of the risk assessment done in Resubmission. We therefore selected 10 dossiers at random of ‘resubmission-pesticides’ which were non-included first and now included, and scrutinised the decisions taken by the Standing Committee.

Substance	Agenda Standing Committee	Court Case	Resubmission	Remarks
Malathion	Oct 2007	YES	YES	
Haloxyfop-R	Dec 2007	YES	YES	
Dichlorvos	Dec 2007	YES		Reply
Endosulfan	May 2008	YES		Appeal
1,3 - Dichloropropene	July 2008	YES	YES	
Carbosulfan	July 2008	YES	YES	
Fipronil	Sept 2008	YES		Confirmatory data/ Additional studies
Methomyl	Sept 2008	YES	YES	
Trifluralin	Sept 2008	YES	YES	
Azinphos-methyl	Oct 2008	YES		
Carbofuran	Oct 2008	YES	YES	
Chlorothalonil	Dec 2008	YES		
Flusilazole	Febr 2009	YES		
Napropamide	May 2009	YES	YES	
Diphenylamine	May 2010	YES	YES	
Procymidon	Jan 2011	YES		
Ethoxyqin	July 2011	YES	YES	
Flurprimidol	Nov 2011	YES	YES	
Napropamide	Nov 2011	YES	YES	

2. PAN Europe's evaluation of the Resubmission decisions

Pesticide evaluations are based solely on industry-sponsored studies. No-one knows how reliable these studies are and since they are not published and Member States are reluctant to grant 'access to documents', there is no way of finding out about reliability. What is more, we can't be sure European risk assessors do much effort to check reliability. The requirement of GLP (Good laboratory Practice) doesn't help much in assuring reliability because it is a simple administrative management system and no-one controls what is written down. For many chemicals it is known that industry-sponsored studies differ remarkably in outcome from independent academic studies (such as Glyphosate, Mancozeb, Atrazin, Bisphenol A, Aspartame). Therefore depending only on industry-sponsored studies is an unbalanced way of working.

In our analysis we however have no option but take these industry-sponsored studies as a starting point. Independent studies are not taken into account in the risk evaluation by SANCO and Member States. Most likely we have to deal with an underestimation of the risks.
The Rapporteur Member State is the (only) one (hopefully) reading the original documents of the industry-sponsored studies and preparing a summary -called Draft Assessment Report (DAR)- which also contains a first evaluation of the risks. At this point other Member States and EFSA start commenting. Since a few years EFSA puts a draft DAR on its website for consultation and this is also the moment other stakeholders learn about a new application and evaluation. The applicant/company itself is involved from the beginning, gets the chance to comment any document, also all (non-public) Member State opinions, is offered meetings with the Rapporteur Member State, many times having the semblance of negotiation.

We based our conclusion on what is available, the DAR, the peer-review of the DAR by EFSA, the review report (summary of SANCO before decision taking) and the final published decision. And -where available- independent literature. We checked human health toxicity tests as well as tests on the environment.

3. Results of the evaluation

Annex I. summarises the evaluation done for 10 pesticides where non-approval was turned into approval.

Based on the evaluations of the 10 examples chosen, we conclude:

1. The Resubmission regime approves pesticides while data are lacking which must show the absence of harmful effects. In 8 out of the 10 evaluations checked, Food Authority EFSA (doing the peer-review part) concludes consumer risk assessment is not finalised (see Annex I: bromuconazole/metabolites; myclobutanil/residues; hymexazole/not finalised; pyridaben/provisional; haloxyfop-P/groundwater pollution; quinmerac/groundwater; napropamide/drinking water; malathion/isomers & metabolites). This means in the majority of the cases Article 4.1.b.IV of Directive 91/414 (similar to Article 4.3 of new Regulation 1007/2009 [2]) is violated. The condition in this Article of having no harmful effects on human health is not met.

2. The Resubmission regime approves pesticides while data show clearly high risks for the environment; also many data are lacking to show the absence of unacceptable effects on the environment.

In 10 out of 10 evaluations checked Article 4.1.b.V of Directive 91/414 (similar to 4.3 of the new Regulation 1007/2009) is violated because the condition of having no unacceptable effects on the environment was not met. Very serious violations occurred in 7 out of 10 cases where high risks were shown and still the substance was approved (see Annex I: Bromuconazole: risk mammals; Hymexazole: high risk birds/mammals; Pyridaben: High risks waterorganisms/mammals/birds/non-target arthropods; Quinmerac: High earthworms; Metosulam: High risks waterorganisms/non-target plants; Oryzalin:

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:
(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;
(b) they shall not have any unacceptable effect on the environment.

High risks birds/mammals/bees; Malathion: high risks waterorganisms/bees). For Pyridaben almost all organisms tested ended in a high risk. It is hard to understand why this substance is approved.
In 10 out of 10 cases risk assessment for the environment was not possible due to lack of data (see Annex I ao. Bromuconazole: mammals; Myclobutanil: waterorganisms; etc.).

This means Art. 4.1.b.V of Directive 91/414 to protect the environment is completely disregarded in the decision making process. No single pesticide is banned because of the environment. This also means many pesticides are released in the environment with high and unacceptable risks. The massive decline of birds, bees and biodiversity in general will be a result of disregarding rules. Research shows[3] pesticides are very much linked to the decline of biodiversity. The authors of the study state: " Of the 13 components of intensification we measured, use of insecticides and fungicides had consistent negative effects on biodiversity". Current scientific knowledge is clearly not taken into account in the decision of the Standing Committee to disregard environmental effects of pesticides.

3. Commission decisions make no sense: Huge discrepancies between SANCO Review Report and EFSA peer-review. No matter how critical the EFSA peer-review is, the SANCO review report always ends with the same language stating no harmful effects for consumers and no unacceptable effects on the environment, all requirements met . The same artificial language having no relation to the EFSA peer-review is seen again in the final decision.

4. Data gaps are still there; what is the point of resubmission?

First of all we observe that the reason for non-inclusion of the 50 'resubmission pesticides' and the 'voluntary withdrawal' in 2008, the (many) data gaps, is not resolved in the 2010/2011 inclusion decisions. All 10 pesticides are approved while data gaps are still present.
In the case of Oryzalin 4 data gaps are accepted such as: lack of information on impurities, lack of information if the test materials in all tests was similar, lack of data on acceptable use for water organisms, lack of data showing absence of groundwater pollution of a metabolite. For Bromuconazole even 5 data gaps were considered acceptable.

Industry –most likely supported by some Member States- seems to play a game with SANCO since many data gaps are the same as years before, meaning industry is not investing in serious toxicity testing to fill the data gap with data and tries to convince SANCO with assumptions, reasoning and questionable calculations. Industry doesn't seem to be a reliable negotiating partner for SANCO.
It is hard to understand why these data gaps are now considered acceptable.

5. 'Confirmatory data' construction as a cover-up for the massive amount of data gaps.

The artificial regime of 'con-

3. Flavia Geiger, Jan Bengtsson, Frank Berendse, Wolfgang W. Weisser, Mark Emmerson, Manuel B. Morales, Piotr Ceryngier, Jaan Liira, Teja Tscharntke, Camilla Winqvist, Sönke Eggers, Riccardo Bommarco, Tomas Pärt, Vincent Bretagnolle, Manuel Plantegenest, Lars W.Clement, Christopher Dennis, Catherine Palmer, Juan J.Oñate, Irene Guerrero, Violetta Hawro, Tsipe Aavik, Carsten Thies,Andreas Flohre,Sebastian Hänke,Christina Fischer,Paul W.Goedhart, Pablo Inchausti, Persistent negative effects of pesticides on biodiversity and biological control potential on European farmland, Basic and Applied Ecology 11 (2010) 97–105

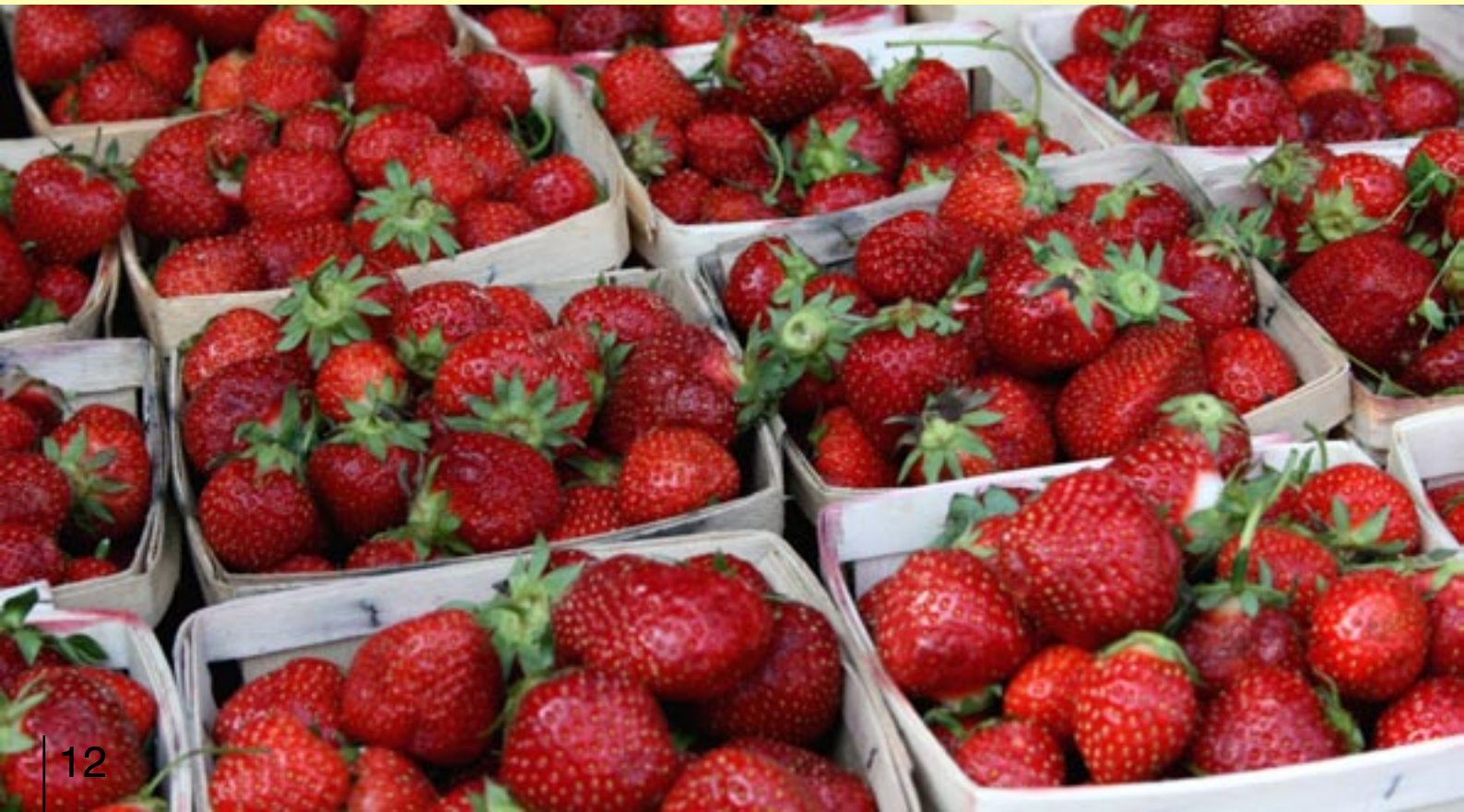
firmatory data' was used in all 10 cases. This construction seems to be used by DG SANCO as a routine instrument to make data gaps acceptable. But it will result in exposing EU citizens and the environment to unknown risks.

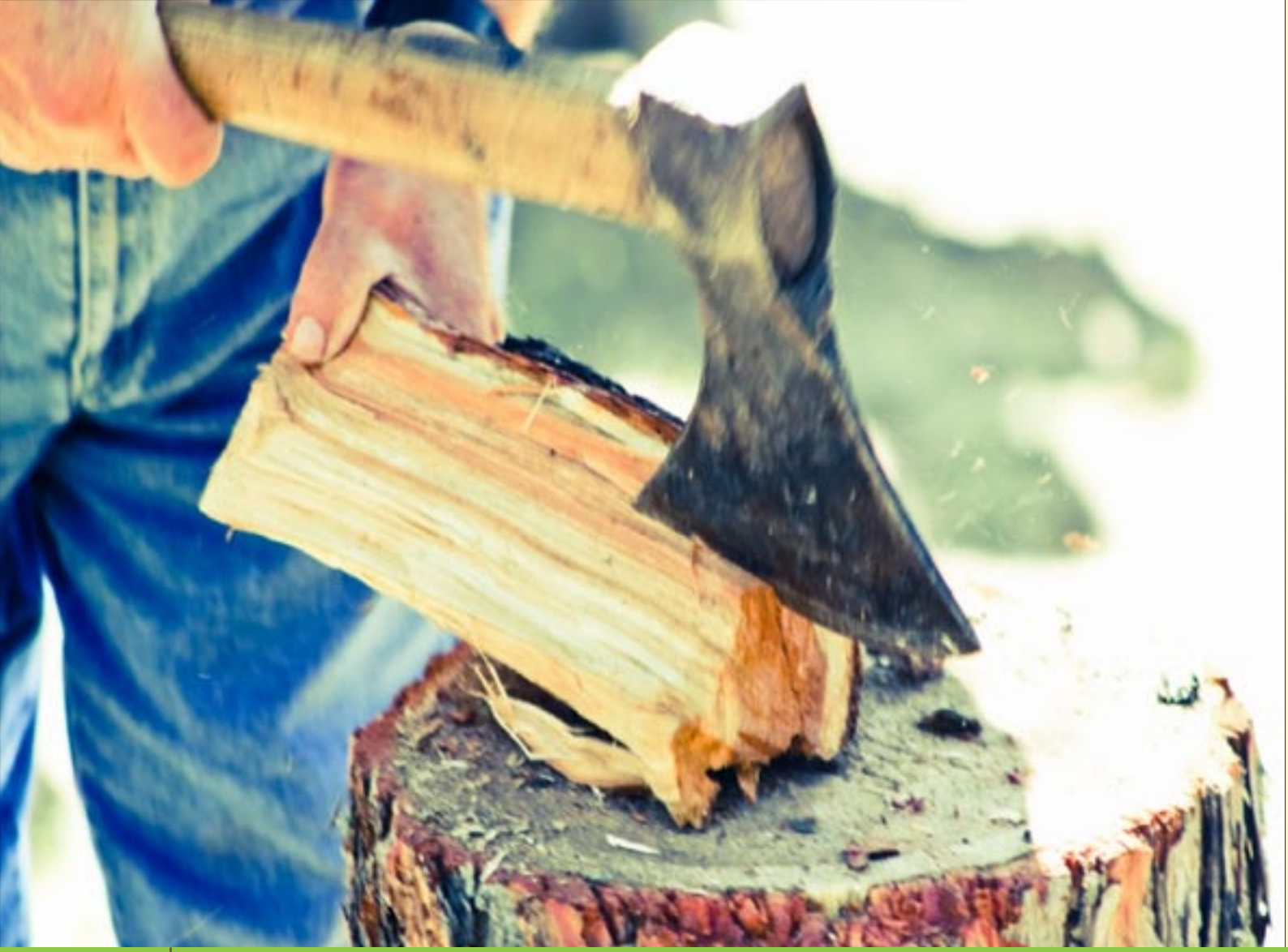
It is highly questionable if this construction is legal. Art. 6.2 of Directive 91/414 states the Rapporteur MS must ensure the data requirements are satisfied. The 'Rapporteur' Member States therefore started this misery by deciding the dossier is complete, and in the long run to a decision apparently there was no way back. The rules are clear: data gaps do not allow the assessment to be continued and certainly not make it to a final approval decision. But again in comitology rules can be bend.

6. Non-enforceable mitigation measures adopted.

In several of the cases investigated there was a high risk for water organisms. In these instances EFSA calculated a minimum buffer zone (non-spraying zone) necessary to prevent these high risks. For Bromuconazole >10 meter was necessary, for Haloxyfop-P > 5 meter, for Metosulam >20 meter, for Quinmerac >15 meter, and for Malathion even 30-40 meter (strawberries). Given the resistance of farmers against buffer zones and the low capacity on enforcement in Member States, it is highly questionable if these buffers can be realistically enforced.

7. Toxic impurities observed in peer-review largely ignored in the decision. In many dossiers and EFSA peer-reviews mentioning is made of unknown impurities, unknown metabolites of pesticides and the presence of isomers/enantiomers with possible different toxicity. Also questions were raised if batches of pesticides in the toxicity tests had the same (amount) of impurities, metabolites, isomers as the final product used in the field. An assessment of the risks of these substances emitted in the environment together with the active pesticide substance is generally not made but still the pesticide is approved.





4. Conclusion and recommendations

The evaluation shows that decision-making at lower level (comitology) is not in agreement with the 'higher' regulations, in this case Directive 91/414. This is illegal and puts the axe at the root of Brussels reliability. It also undermines consumer's confidence in European decisions. We urge Parliament and Council to put an end to all constructions and innovations bending and twisting the rules with the aim of easy access of pesticides to the market.

We feel it is not a single incident but part of a 'culture' of putting corporate interest at a higher level than citizen's health and the environment. Directive 91/414 on the contrary states that the interests of citizen's health and the environment should prevail over commercial interests.

Therefore a complete revision of pesticide decision making is necessary. Completely revise assessments, decision-making procedures, lower Commission regulations and guidelines, and bring them back in full agreement with the democratically established Directives and Regulations.

ANNEX I.

BROMUCONAZOLE

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(8):1704	DG SANCO Review Report	Approval decision (2010/92/EU)
Bromuconazole RMS: BE Appl.	* Impurities * Cancer in rats and mice considered non-relevant * Data gap on metabolism studies * Rotational crop metabolism studies * Data gap on 4 enantiomers * No information supplied on endocrine disruption * No calculation of cumulative effects azoles	* Very persistent * Metabolites unknown * Toxicity isomers unknown * Long-term risk for herbivorous mammals * 10 m non-spray zones not enough to prevent aquatoxicity	* Data gap on impurity * Data gap for consumer exposure to triazole metabolite * Data gaps of 4 isomers on the environment; * Data gap for endocrine disruption on fish and birds; * Risk for consumers cannot be excluded, in particular by metabolites * Data gap on RA herbivorous mammals	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to worker safety * Ms to pay attention to protection aquat. org & include mitigation measures * Appl. to present RMS information on metabolites (#) * Appl. to present RMS info on long-term risks of herbivorous mammals (#)

(#) This is called 'confirmatory data' by regulators. It is an invention to overcome the many data gaps in pesticide assessment. Applicant claims there is no risk problem in case of data gaps, and regulators allow industry extra time to 'confirm' the (by industry) expected lack of harmful effects (human) or unacceptable risks (environment).

MYCLOBUTANIL

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010;8(10):1682	DG SANCO Review Report	Approval decision (2011/2/EU)
Myclobutanil RMS: BE Appl. Dow Agro Sciences	* No toxicological info on impurities * Hepatocellular necrosis seen in high doses * Developmental effects observed in 2-gen. * Metabolites have higher toxicity; no further tests available (RMS agrees) * Residue trials incomplete * No toxicological info on isomers * No information supplied on endocrine disruption * No calculation of cumulative effects azoles	* Extremely persistent, DT50 up to 1216 days, soil accumulation of metabolites. * Exceeds groundwater standard in spec. cases * Metabolite exceeds standard in all cases, but classified "non-relevant" * No tox. info on isomers * No tox. info on bioconcentration/ fish * No tox. info on metabolites for aquat. org * No info on endocrine disruption fish/birds	* Information on test material and comparability is lacking; * Data gaps on isomers for human exposure, consumer safety and the environment; * Due to several data gaps on residues consumer risk assessment is not finalised	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to worker safety * Appl. to present RMS info on residues & residue definition (#)

HYMEXAZOL

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010 8(8):1653	DG SANCO Review Report	Approval decision (2011/5/EU)
Hymexazol (#) RMS: FI Appl.	* Genotoxic at high doses (chrom. aber.) * Reprotoxic effects at high doses * Developmental effects (foetus) * Insufficient data on residues & processing	* No information on aquatoxicity of metabolite * High risk for granivorous birds & mammals	* Data gaps on nature residues in plants and processing; * Consumer risk assessment could not be finalised * Data gap on aquatoxicity * Data gap on granivorous birds and mammals * Data gap on aquatox metabolite	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to worker safety * MS to pay attention to risks of granivorous birds and mammals * Appl. to present RMS confirmatory information as regards the nature of residues in root crops and the risk for granivorous birds and mammals (##)

(#) use in tomatoes was dropped at the last moment (many data gaps and groundwater contamination up to 1000x legal level). If the applicant asks for an authorisation for tomatoes in the future in MS's, it will be almost impossible to do a risk assessment. Approval based on one use allows entering Annex I based on the use with the least side-effects.
(##) So-called confirmatory data

PYRIDABEN

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(6):1632	DG SANCO Review Report	Approval decision (2010/90/EU)
Pyridaben RMS: NL Appl. Nissan Chemical Europe.	* Acute toxic (R23) * Potential risk for causing Parkinson disease * Data gaps on residues; provisional consumer risk assessment * Risks for oxidative damage and Parkinson's disease reported in literature	* High risk water organisms; 30 meter no-spraying zone even not enough * Aquatoxicity two metabolites unknown * High risk mammals on citrus * High risk for earthworm eating birds and mammals (#) * High risk for bees; 'safety phrases' need to be added * high risk for non-target arthropods; 10 meter buffer zones required to allow for recovery (##) * Negative effects on beneficial insects (###)	* Consumer risk assessment provisional * High risk for waterorganisms, mammals, birds, bees and non-target arthropods * Data gaps for long-term risk mammals and for bees; * Data gaps metabolites W1 and B3 for aquatic organisms; * 10 meter non-spray zone required for non-target arthr.	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to worker safety* MS to pay attention to risks of aquatic organisms and mammals, * Ms to pay attention to the risk to non target arthropods including honeybees. * Appl. to present RMS info on the risks for waterorg. of metabolites W-1 and B-3, * Appl. to present RMS info on the risk for mammals, * Appl. to present RMS info on fat sol. residues.

(#) after submitting a new study showing lower levels of Pyridaben in earthworms, the exposure of earthworm eating birds and mammals is considered acceptable
(##) regulators have a strange way of dealing with non-target arthropods. The Directive states no unacceptable effects are allowed; regulators interpret this as complete extinction is allowed if the organisms potentially return (from elsewhere) in the next year. One can have severe doubts if this is allowed legally.
(###) Integrated pest management (IPM) will be mandatory for all farmers from 2014 on. An essential part of IPM is biological control, the use of beneficial organisms. Pyridaben cannot be included in IPM crop growing schemes.

HALOXYFOP-P

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2009; 7(11):1348	DG SANCO Review Report	Approval decision (2010/86/EU)
Haloxyfop-P RMS: DK Appl. Dow Agro Sciences.	* Toxic (R22) * Irritating (R41) * cancer (hepatocellular adenomas) in mice * developmental toxicity critical effect * metabolites assumed non-relevant (no testing)	* Metabolites pyridinol and pyridine highly persistent and mobile * New metabolite dibenzofuran discovered in assessment (not considered) * groundwater legal level exceeded * groundwater exceedance that high that consumer risk assessment is needed (not happened) * data gap herbivorous mammals * data gap insectivorous mammals * very toxic for fish, minimum buffer zone needed of 5 meter to ditches	* High risk for groundwater pollution; RA for Haloxyfop and metabolites not finalised * Consumer risk assessment might be needed due to high level of groundwater pollution * Data gap on herbivorous mammals * Data gap on insectivorous mammals * 5 meter buffer zones are required to protect aquatic species	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to operator safety: * MS to pay attention to protection of aquatic organisms (buffer zones); * MS to pay attention to consumer safety as regards the occurrence in groundwater of metabolites DE-535 pyridinol and DE-535 pyridinone. * Appl. to present RMS information confirming the groundwater exposure assessment as regards the active substance and its soil metabolites DE-535 phenol, DE-535 pyridinol and DE-535 pyridinone. (#) *(no confirmatory data for mammals!).

(#) so-called confirmatory data.

QUINMERAC

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(3):1523	DG SANCO Review Report	Approval decision (2010/89/EU) Quinmerac
* Appl. BASF * RMS: UK	* Residu in crop has unknown compounds; * In rotational crops significant amounts of Quinmerac are taken up * Uncertainty on consumer risk; * Data gap on opening of quinoline ring and further metabolism; * Metabolite BH 518-2 'expected' to be of similar toxicity as Quinmerac	* It is not ensured all metabolites are identified * BH 518-2 and BH 518-5 highly persistent and mobile give high risk for groundwater pollution; consumer risk assessment needed * Quinmerac highly persistent and mobile and exceeds legal level in cases; * Quinmerac very toxic for aquatic organism; minimum buffer zone of 15 meter (!) required to ditches * BH 518-5 high risk for earthworms	* Consumer risk assessment not finalised * High risk for groundwater pollution * Data gap for RA birds and mammals * High risk for earthworms by metabolite * Non-spraying zone of 15 meter is requires to protect aquatic species	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to protection of groundwater; MS to pay attention to dietary exposure of consumers to residues; * MS to pay attention to the risks for aquatic organisms; * MS to pay attention to long-term risks for earthworms; * Appl. to present RMS information on opening of Quinoline ring in plant metabolism (#); * Appl. to present RMS information on residues in rotational crops and long-term risks for earthworms due to metabolite (#).

(#) so-called confirmatory data.

METOSULAM

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(5):1592	DG SANCO Review Report	Approval decision (2010/91/EU)
Metosulam	* uncertainty on specification of Metosulam: specification in tests differs from actual used pesticide: as a result uncertainty on mammalian toxicity * Data gap on genotoxic potential of impurity * Toxic for kidney (R48/22); * renal tumors found in rats: non-genotoxic carcinogen (R40);	* Annual average of metosolam already close to maximum legal level of groundwater pollution; * metabolites M01 and M02 highly mobile in soil * data gap on pH dependent leaching of M01 and M02; groundwater, surf. water and sediment risk ass. not possible; * long-term reproduction no-effect level relaxed from 5 to 30 mg/kg, accepting effects on body weight; * high risk aquatic organisms; 20 meter buffer zone still insufficient; *high risk non-target plants; 5 meter buffer zone needed.	* data gap specification * data gap genotoxicity impurity * data gap metabolites M01 and M02, pH dependency * data gap M01 and M02 groundwater leaching and surface water exposure; * high risk aquatic organisms (in some case 20 meter buffer is not enough); * high risk non-target plants	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to protection of groundwater; * MS to pay attention to risks of aquatic organisms; *MS to pay attention to risks of non-target plants * Appl. to present information to RMS on metabolites M01 and M02 on soil absorption, groundwater leaching and aquatoxicity (#); * Appl. to presentinformation to RMS on potential genotoxicity of impurity (#).

(#) so-called confirmatory data.

NAPROPAMIDE

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(4):1565	Review Report	Approval decision (2010/83/EU)
Napropamide RMS: DK Appl. United Phosphorus	* Unsure if tests are performed with comparable test substance * Napropamide genotoxic in some in-vitro tests; * Metabolite NOPA shows chromosome aberrations in some in-vitro test * Higher abortion rate shown in rabbit tests; * Metabolite NOPA is assumed not toxic relevant;	* Napropamide has a very high persistence; * Napropamide is very toxic for aquatic organisms; * Metabolite NOPA exceeds groundwater legal level in simulations (data gap); * Data gap for enantiomers for environmental risk assessment; * Data gaps metabolites in surface water; * Data gaps soil functioning, earthworms and soil microbes * Negative effects on microbes reported in open literature	* Data gap enantiomers * Data gap metabolite NOPA for groundwater * Consumer RA drinking water not finalised * Aquatic RA not finalised * Aquatic RA for metabolites not finalised * RA aquatic plants not finalised * Data gaps on soil exposure, earthworms and non-target microorganisms.	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to operator safety * MS to pay attention to the protection of aquatic organisms; * MS to pay attention to consumer safety as regard to groundwater pollution with metabolite NOPA * Appl. to present information to RMS concerning surface water exposure of metabolites (#); * Appl. to present information to RMS on risk aquatic plants of metabolites (#)

(#) so-called confirmatory data

ORYZALIN

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Journal 2010; 8(9):1707	Review Report	Approval decision (2011/27/EU)
Oryzalin RMS: FRAppl.: Dow Agrosciences.	* Thryoid and mammary tumors observed in rats; industry proposal to classify non-relevant for humans not followed (Carc. Cat.3); * Data gap on carcinogenicity metabolites; * Data gaps on 7 impurities in batches; * Batches in toxicity testing not representative of technical specification (!)	* Data gap metabolites OR-13 and OR-15 for groundwater pollution; * Industry proposed flawed calculation for groundwater pollution Oryzalin; EU models indicate cases of pollution for Oryzalin and OR-20; * High risk insectivorous birds and mammals (treated weeds); * Oryzalin very toxic for Daphnia and Mollusc; data gap in RA; * High risk for bees (in field); * Data gap for OR-13 for aquatic RA	* Data gap on toxicological relevance 7 impurities; * Data gap metabolites OR-13 and OR-15 for soil metabolism and groundwater pollution; * Same data gap for OR-14 and OR-16; * Data gap aquatic RA; * High risk non-target plants (5 m buffer needed); * high risk insect. birds, bees and mammals; * Batches not representative for specification proposed	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to operator safety; * MS to pay attention to protection of aquatic org.; * MS to pay attention to protection groundwater; * MS to pay attention to risks to herbivorous birds and mammals; * MS to pay att. to risks to bees; * MS to verify groundwater pollution by metabolites by monitoring; * Appl. to present info to MS/COM on specification including impurities (#); * Appl. to present info to MS/COM on relevance of test material in tests (#); * Appl. to present info to MS/COM on RA for aquatic org. (#); * Appl. to present info to MS/COM on relevance metab. for groundwater RA (#).

(#) so-called confirmatory data

MALATHION

Active substance	Health risk assessment	Environment risk assessment	EFSA conclusions EFSA Scientific Report (2009) 333, 1-118	Review Report	Approval decision (2010/17/EU)
Malathion (##) RMS: UK Appl.: Cheminova A/S.	* Malathion shows chromosome aberr. in-vitro * Since in-vivo no genotox, no classification by EFSA * Level isomalathion (max. 0,2%) unsure and many times not reported!; * Level isomalathion increased 2-10x on storage; * Malathion + 2% iso 10x more toxic; not assessed! * Nasal tumours in rats and liver tumours in mouse; not relevant acc. to EFSA; * In repro tox study iso content not reported; *metabolite malaoxon evidence of leukemia, rats; * Malaoxon much more toxic than Malathion * Metabolites MMCA/MDCA tox. relevant but no studies requested; * Human study used for safety level.	* Data gap on isomers; * Data gap on insectivorous birds; * High risk for aquatic organisms; * High risk for bees;	* Data gap on consumer risk assessment for isomers and metabolites; * Data gap on residues in rotational crops; * Data gap on insectivorous birds; * Risk for earthworms of isomer of MDCA * Data gap enantiomer MDCA on earthworms; * Buffer zones of 30-40 meter necessary in strawberries to protect aquat. org.; * Consumer risk assessment is provisional; * 'dangerous for bees" on the label.	* Will fulfil safety requirements of Dir. * Residues have no harmful effects on consumers * No unacceptable effects on the environment * Acceptable exposure for workers and bystanders	* MS to pay attention to operator safety * MS to pay attention to protection of aquatic org. * MS to pay attention to insectivorous birds and bees; * MS to ensure not excess isomalathion during storage and transport; * Appl. to present info to MS/COM on consumer RA (#); * Appl. to present info to MS/COM on RA insectivorous birds (#); * Appl. to present info to MS/COM on the quantification of the diff. potency of malaoxon and malathion (#).

(#) so-called confirmatory data

7. (##) Uses for apples and alfalfa dropped in resubmission.

ANNEX II.

Active substance (persuant Reg 33/2008, * Chapter III and ** Chapter II)	Date of Application	Name and adress of applicant	Rapporteur Member State	Decision in Standing Committee
8-Hydroxychinoline	14.03.2007	"PROBELTE S.A CTRA MADRID KM 389 APTDO. 4579 E - 30080 ESPAÑA"	Spain	Included 01/12
Haloxyfop-R	04.07.2007	"Dow Agrosciences European Development Centre 3 Milton Park Abington Oxfordshire OX14 4RN United Kingdom"	Denmark	Included 01/11
Methomyl*	11.02.2008	"DuPont de Nemours (Deutschland) GmBH DuPont Str 1, D 61352 Bad Homburg - Germany"	The United Kingdom	Included 06/09
Benfuracarb*	15.02.2008	"Otsuka Chemical Co., Ltd 615 Hanamen, Satoura, Naruto, Tokushima 772-8601 JAPAN Contact point: NOTOX B.V. Hambakenwetering 7 P.O. Box 3476 5203 DL S-Hertogenbosch The Netherlands"	Belgium	Withdrawn
Cadusafos*	8.04.2008	"FMC Chemical sprl Boulevard de la Plaine 9/3 1050 Brussels Belgium"	Greece	Withdrawn November 2009
Carbofuran*	06.05.2008	"FMC Chemical sprl Boulevard de la Plaine 9/3 1050 Brussels Belgium"	Belgium	Not included
1,3-Dichloropropene*	26.06.2008	"DOW AgrosciencesEuropean Development Centre 3 Milton Park Abington – Oxfordshire OX14 4RN United Kingdom and Kanesho Soil Treatment SPRL/BVBA Boulevard de la Woluwé 60 B-1200 Brussels"	Spain	Not included
Malathion*	30.06.2008	"Cheminova A/S P.O. Box 9 DK-7620 Lemvig Denmark"	The Uinited Kingdom	Included 05/10
Carbosulfan*	15.07.2008	"FMC Chemical sprl Boulevard de la Plaine 9/3 1050 Brussels Belgium"	Belgium	Withdrawn

Trifluralin*	15.07.2008	"European Union Trifluralin Task Force Contact point: Dow Agrosciences European Development Centre 3 Milton Park Abington – Oxfordshire OX14 4RN United Kingdom"	Greece	Not included
Triflumizole*	20.09.2008	"Certis Europe BV Safariweg 55, 3605 MA Maarssen The Netherlands"	The Netherlands	Included 07/10
Fenbuconazole*	11.12.2008	"Dow AgroScience Ltd Via Patroclo, 21 20151 Milan Italy"	The United king-dom	Included 05/11
Pyridaben*	11.12.2008	"Nissan Chemical Europe S.A.R.L., France and Nissan Chemical Indus-tries, Ltd., Japan Contact point: Huntingdon Life Sciences Woolley Road Alconbury, Huntingdon, Cambs PE28 4HS, England"	The Netherlands	Included 05/11
Diclofop*	11.12.2008	"BAYER CROPSCIENCE AG Alfred Nobel Strasse 50 D-40789 Monheim Allemagne"	France	Included 03/11
Metosulam*	11.12.2008	"BAYER CROPSCIENCE AG Alfred Nobel Strasse 50D-40789 Monheim Allemagne"	France	Included 05/11
Quinmerac*	11.12.2008	"BASF SE Agricultural center D-67117 Limburgerhof Germany"	United Kingdom	Included 05/11
Napropamide*	18.12.2008	"United Phosphorus Ltd. Chadwick House Birchwood park Warrington WA3 6AE UK"	Denmark	Included 01/11
Oryzalin*	29.01.2009	"DOW AGROSCIENCES European Development Centre, 3 Milton Park, Abingdon, Oxon, OX14 4RN, United Kingdom"	France	Included 06/11
Buprofezin*	27.02.2009	"Nihon Nohyaku Co., Ltd. 345, Oyamada-cho, Kawachi-Nagano, Osaka 586-0094, Japan"	United Kingdom	Included 02/11
Dodine*	04.03.2009	"Chimac-Agriphar S.A. Rue de Renory, 26 B-4102 Ougré Belgium"	Portugal	Included 06/11

Methyl Bromide*	16.03.2009	"DESCLEAN BELGIE N.V. OVERWINNINGSTRAAT 41 –B 2610 WILRIJK ANTWERPEN RPR. Antwerpen, Belgium"	United Kingdom	Not included
Dichlobenil*	16.03.2009	"Chemtura Netherlands B.V. Ankerweg 18 1041 Amsterdam The Netherlands"	Unikted kingdom	Not included
Cyanamide*	17.03.2009	"AlzChem Trostberg GmbH CHEMIEPARK TROSTBERGDr. Albert Frank Str., 32 83308 Trostberg, Germany"	Germany	Pending
Hymexazol*	19.03.2009	"TSGE Conyngham Hall Knaresborough North Yorkshire HG5 9AY United Kingdom"	Finland	Included 06/11
Dicloran*	19.03.2009	"Gowan Comércio Internacional e Serviços, Limitada (Margarita International) Avenida do Infante 50 9004 – 521 Funchal Madeira, Portugal"	Spain	Not included 06/11
Propanil*	31.03.2009	"Rice LLCc & Cequisa Contact address: Chem Service S.r.l. Via Fratelli Beltrani,15 20026 Novate Milanese (MI) Italy"	Italy	Not included
Tau-fluvalinate*	02.04.2009	"Makhteshim Agan ICC on behalf of IRVITA Plant Protection NV Pos Cabai Office Park Unit 13 PO Box 403 Curacao, Netherland Antilles"	Denmark	Included 06/11
Bromuconazole*	10.04.2009	"Sumitomo Chemical Agro Europe 2 rue Claude Chappe 69270 Saint Didier au Mont d'Or France"	Belgium	Included 02/11
Hexythiazox*	14.04.2009	"Nisso Chemical Europe GmbH Steinstrasse 27, 40210 Düsserldorf Germany"	Finland	Included 03/11
Myclobutanil*	24.04.2009	"Dow AgroSciences B.V. Sede secondaria in Italia Via Patroclo 21 Cap 20151 Milano Italy"	Belgium	Included 06/11

Bupimirate*	27.04.2009	"Makhteshim Chemical Works Ltd. PO Box 60 Beer-Sheva 84100 Israel Contact point: JSC International Limited Simpson HouseWindsor Court Clarence Drive, Harrogate North Yorkshire HG1 2PE United Kingdom"	The Netherlands	Included 06/11
Asulam*	01.05.2009	"United Phosphorus Limited Chadwick House Birchwood Park, Warrington Cheshire, WA3 6AE UK"	United Kingdom	Not included
Pencycuron*	04.05.2009	"Bayer CropScience AG Development RD-Global Regulatory Affairs Alfred-Nobel-Str. 50 D-40789 Monheim"	The Netherlands	Included 03/11
Cycloxydim*	04.05.2009	"BASF SE Agricultural Center Limburgerhof Crop Protection Division 67117 Limburgerhof, Germany"	Austria	Included 06/11
6-Benzyladenine*	05.05.2009	"Exponent International Limited (Consultant) on behalf of the ap- plicant ' EU 6-BA Taskforce II', Contact address: Exponent International Limited The Lenz Hornbeam Business Park Harrogate, HG2 8RE UK"	United Kingdom	Included 06/11
Flutriafol*	05.05.2009	"Cheminova A/S P.O. Box 9 DK-7620 Lemvig, Denmark."	United Kingdom	Included 03/11
Diethofencarb*	19.05.2009	"Sumitomo Chemical Agro Europe SAS Parc d'Affaires de Crécy 2 rue Claude Chappe 69771 Saint Didier au Mont d'Or Cedex, France"	France	Included 06/11
Tebufenozide*	20.05.2009	"Dow AgroSciences Prins Boudewijnlaan, 41 2650 EDEGEM, Belgium"	Germany	Included 03/11
Isoxaben*	22.05.2009	"Dow AgroSciences European Development Centre 3 Milton Park Abingdon, Oxon 0X14 4RN UK"	Sweden	Included 06/11
Zinc Phosphide*	22.05.2009	"Zinc Phosphide Pool (CFW, BASF, Detia Freyberg GmbH, frunol delicia GmbH) Chemische Fabrik Wülfel GmbH & Co KG Postfach 890109 30514 HANNOVER"	Germany	Included 05/11

Indolylbutyric acid*	25.05.2009	"Weterings Consultancy B.V. Iepenlaan 16 5248 AK Rosmalen, Netherlands"	France	Included 06/11
Oxyfluorfen*	26.05.2009	"Dow AgroSciences, 6 avenue de Charles de Gaulle 78151 Le Chesnay Cedex France and Makhteshim Agan International Coordination Center (MAICC) 283 Avenue Louise 1050 Brussels, Belgium"	Spain	Included 01/12
Carbetamide*	27.05.2009	"Feinchemie Schwebda GmbH Edmund-Rumpler-Str. 6 51149 Cologne, Germany"	France	Included 03/11
Acrinathrin*	28.05.2009	"Cheminova A/S P.O. Box 9 7620 Lemvig, Danemark"	France	Included 01/12
Propisochlor*	29.05.2009	"Arysta LifeScience S.A.S. (France) Route d'Artix BP 80 64150 Noguères,, France"	Hungary	Not included 04/11
Prochloraz*	29.05.2009	"BASF Global Registration Manager 21, chemin de la Sauvegarde, 69134 Ecully Cedex, France and Makhteshim Agan Global Product Manager, Regula- tory Affairs IRVITA Products, MAKHTESHIMAGAN France 2, Rue Troyon, 92316 SEVRES cedex, FRANCE"	Ireland	Included 01/12
Carboxin*	01.06.2009	"Chemtura Europe Ltd. Kenneth House, 4 Langley Quay- Slough, Berkshire, UK, SL3 6EH"	United Kingdom	Included 03/11
Bitertanol*	02.06.2009	"Bayer CropScience AG – Develop- ment Alfred-Nobel-Str.50 D-40789 Monheim Building 6100, D2.120 Germany"	United Kingdom	Included 01/12
Fenbutatin Oxide*	02.06.2009	"BASF Belgium S.A. Chaussée de la Hulpe, 178 B-1170 Brussels, Belgique"	Belgium	Included 06/11
Clethodim*	03.06.2009	"ARYSTA LIFESCIENCE S.A.S Route d'Artix BP80 64150 NOGUERES, FRANCE"	The Netherlands	Included 06/11

1-Naphthylacetamide*	03.06.2009	"1. Task Force : Nufarm S.A.S. 28, bd Camélinat - B.P.75 92233 Gennevilliers Cedex, France L. Gobbi s.r.l. Via Vallecalda, 33 16013 Campo Ligure (GE), ITALY 2. AMVAC : AMVAC Chemical UK Ltd Surrey Technology Centre 40 Occam Road The Surrey Research Park Guildford, Surrey GU2 7YG, UK"	France	Included 01/12
1-Naphthylacetic acid*	03.06.2009	"1. Task Force : Nufarm S.A.S. 28, bd Camélinat - B.P.75 92233 Gennevilliers Cedex, France L. Gobbi s.r.l. Via Vallecalda, 33 16013 Campo Ligure (GE), ITALY 2. AMVAC : AMVAC Chemical UK Ltd Surrey Technology Centre 40 Occam Road The Surrey Research Park Guildford, Surrey GU2 7YG UK"	France	Included 01/12
Sintofen*	03.06.2009	"JSC International Limited Simpson House Windsor Court Clarence Drive, Harrogate HG1 2PE North Yorkshire UK"	France	Included 03/11
Etridiazole*	04.06.2009	"Chemtura Europe Ltd. Kennet House 4 Langley Quay Slough, Berkshire SL3 6EH United Kingdom"	The Netherlands	Included 06/11
Flufenoxuron*	04.06.2009	"BASF Agro B.V., Arnhem (NL) – Wädenswil Branch Moosacherstrasse 2 CH – 8804 Wädenswil/Au Switzerland"	France	Pending
Bromadiolone	04.06.2009	"LiphaTech S.A.S Bonnel BP 3, 47480 Pont du Casse, France"	Sweden	Included 03/11
Propargite*	04.06.2009	"Crompton (Uniroyal Chemical) Registrations Ltd. Kennet House, 4 Langley Quay Slough, Berkshire SL3 6EH United Kingdom"	Italy	Pending
Guazatine*	05.06.2009	"Irvita Plant Protection N.V. Pos Cabai Office Park, Unit 13, P.O. Box 403 Coraçao, Netherlas Antilles"	United Kingdom	Pending
Fluazifop-P*	05.06.2009	"Syngenta Crop Protection AG Schwarzwaldallee 215 4058 Basel, Switzerland"	France	Included 01/12

Chloropicrin*	05.06.2009	"The European Chloropicrin Group c/o Edward W. Lyle, Chairman 1805, 45th Street NW WASHINGTON DC 20007-2070 USA Contact address: Rivendell Consulting Ltd., Rivendell House,Stamullen, County Meath,, Ireland"	Italy	Not included
Fenoxycarb*	09.06.2009	"Syngenta Crop Protection AG Schwarzwaldallee 215 CH-4058 Basel, Switzerland"	The Netherlands	Included 06/11
Tefluthrin*	10.06.2009	"Syngenta European regional Centre Priestley Road Surrey Research Park Guildford, SURREY GU2 7YH United Kingdom"	Germany	Included 01/12
1-Decanol*	10.06.2009	"Drexel Chemical Company Boodle Hatfield, 89 New Bond Street, London, DX 53 United Kingdom and Chemtura Europe Ltd. Kennet house, 4 Langley Quay, Slough SL3 6EH, United Kingdom and JSC International Limited Simpson House, Windsor Court, Clarence Drive, Harrogate, HG1 2PE, United Kingdom"	United Kingdom	Included 06/11
Flurochloridone*	10.06.2009	"Agan Chemical Manufacturers Ltd. Makhteshim Agan International Coordination Center 283 Avenue Louise, Box 7 1050 Brussels, Belgium"	Spain	Included 06/11
Metaldehyde*	10.06.2009	"Lonza GmbH Morianstrasse 32 DE-42103 Wuppertal"	Austria	Included 06/11
Terbuthylazine *	10.06.2009	"Oxon Italia SpA Via Sempione 95 20016 Pero (MI), Italy and Syngenta Crop Protection Ltd WRO-1007.8.17 P.O. Box, 4002 Basel, Switzerland"	United Kingdom	Included 01/12
Dithianon*	10.06.2009	"BASF SE Agricultural Center Limburgerhof Crop Protection Division 67117 Limburgerhof, Germany"	Greece	Included 03/11

Dazomet*	10.06.2009	"Kanesho Soil Treatment bvba-sprl Contact point: Werner Peeters Regulatory Affairs Manager Japan Agro Services S.A. Woluwedal, 60, Bd. de la woluwe B-1200 Brussels, Belgium"	Belgium	Included 03/11
Paclobutrazol*	10.06.2009	"Syngenta Crop Protection AG European Product Registration WRO 1007.8 Schwarzwaldallee 215 CH 4058 - Basel, Switzerland"	United Kingdom	Included 03/11
Fenazaquin*	11.06.2009	"Gowan Commercio International e Serviços Ltda Rua do Bom Jesus 18-3 Esq. P-9050-028, Funchal, Portugal"	Greece	Included 03/11
Fluometuron*	11.06.2009	"Makhtesim-Agan Agan Office Northern Industrial Zone P.O.B. 262 Ashod, 77102, ISRAEL and Nufarm GmbH &Co KG St.-Peter-strasse 25 A4021 Linz"	Greece	Included 03/11
Cyproconazole*	11.06.2009	"Syngenta Crop Protection AG Regualtory Manager European Product Registration WRO-1007.8.14, Schwarzwaldallee 215, PO Box CH-4002 Basel, Switzerland"	Ireland	Included 03/11
Fluquinconazole*	11.06.2009	"BASF Aktiengesellschaft, APD/RF - LI556, D-67117 Limburgerhof, Germany"	Ireland	Included 01/12
Ethoxyquin*	12.06.2009	"XEDA International S.A. 2 Zone Artisanale de la Crau 13670 ST.ANDIOL, France"	Germany	Not included 03/11
Azadirachtin*	12.06.2009	"Trifolio-M GmbH Dr.-Hans-Wilhelmi-Weg 1 D-35633 Lahnau Germany and SIPCAM S.p.A. Via Sempione 195 I-20016 Pero (Milan), Italy and MITSUI AgriScience International S.A./B.V. Boulevard de la Woluwe, 60 Woluwedal, 60 1200 Brussels, Belgium Contact: GAB Consulting GmbH Ms. Dunker Hinter den Hoefen 24 D-21769 Lamstedt, Germany"	Germany	Included 03/11

Aluminium sulphate*	12.06.2009	"Chrysal International BV Gooimeer 7 1411 DD Naarden The Netherlands"	The Netherlands	Included 03/11
Acetochlor*	12.06.2009	"Dow AgroSciences European Development Centre 2nd Floor, 3 Milton Park, Abingdon, Oxon, OX14 4 RN, United Kingdom and Monsanto Service International S.A., 270-272, Avenue de Tervuren, B – 1150 Brussels, Belgium"	Spain	Not included
Lime Sulphur*	12.06.2009	"Polisenio s.r.l. Via S. Andrea, 10 44022 Lugo (RA), Italy"	Spain	Included 03/11
Flurprimidol*	10.07.2009	"SePRO Europe Limited c/o DSC Chartered Accountants, 4 Princes Square, Harrogate, North Yorkshire HG1 1LX,UK"	Finland	Not included 06/11
2-Naphtyloxyacetic acid (□-NOA) *	24.07.2009	"L. Gobbi s.r.l. Via Vallecalda,33 Campo Ligure (GE) Italia"	Italy	Pending
Triflumuron*	08.09.2009	"Bayer Cropscience AG Strasse 50 40789 Monheim am Rhein Germany"	Italy	Included 04/11
Furfural**	29.09.2009	"ToXcel LLC (consultant) on behalf of Illovo Sugar Limited Market Development, 72 Ballantrae Road, Merebank, Durban 4052, Republic of South Africa"	United Kingdom	Withdrawn
Triazoxide*	12.01.2010	"Bayer CropScience AG Development Global Regulatory Affairs (BCS-D-GRA) D-40789 Monheim am Rhein"	United Kingdom	Included 01/12
Metam*	29.01.2010	"Taminco N.V. Pantserschipstraat 207, B-9000 Gent, Belgium"	Belgium	Included 04/12
Bifenthrin*	11.02.2010	"FMC Chemical S. P. R. L. Agricultural Products group Boulevard de la Plaine 9/3 B-1050- Brussels"	France	Included 04/12
Diphenylamine*	27.05.2010	"Mr Bruno Sornin (Cerexagri) On behalf of The Diphenylamine Data Develop- ment Consortium 1, rue des Frères Lumière 78370 Plaisir, France"	Ireland	Not included