Report of the ad-hoc expert group on pesticides in organic food production

on the following new substances:

- spinosad
- potassium bicarbonate
- copper octanoate

and on the following new uses of ethylene:

- degreening of citrus
- sprouting inhibition in potatoes and onions

Brussels, 22 – 23 January 2008

Report of the ad-hoc expert group on pesticides in organic food production, meeting on 22 – 23 January 2008

Upon invitation by the European Commission, the following experts attended a meeting in Brussels on 22 – 23 January, 2008:

- Rolf Forster, Germany
- Cristina Micheloni, Italy
- Eric Regouin, The Netherlands
- Bernhard Speiser, Switzerland
- Elisa Viñuela, Spain

The aim of the meeting was to elaborate recommendations to the Commission on the authorisation for use in organic farming of spinosad, potassium bicarbonate and copper octanoate and on the extension of the use of ethylene (for degreening of citrus, for sprouting inhibition in potatoes and onions). The recommendations are based on the objectives, principles and criteria for organic production as set out in Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/97. In the meeting, the experts discussed recommendations and considerations for each substance and use. The report given on the following pages represents a full consensus position reached among all experts. The glossary was added after the meeting as it was considered useful for a better understanding of the text.

Glossary with explanations

This section explains some of the specialist terms used in this document. The explanations are given to facilitate the understanding of the document and cannot be considered as comprehensive definitions.

Active substance	Substance which has an effect on crop pests or diseases, or acts as a growth regulator. Active substances are regulated at EU level by Directive 91/414/EEC and must be listed in Annex I of this directive, before they can be used in plant protection products in the Member States (MS) of the EU.
Annex I	Annex I of Directive 91/414/EEC. List of all active substances which are allowed to be used in plant protection products in the MS of the EU.
DAR	Draft Assessment Report. Report on an active substance, prepared by a RMS after evaluation of the application dossier submitted by a notifier. The DAR is subject to peer review by all Member States and EFSA (European Food Safety Authority), before a final decision on the substance is taken.
Field rate	Quantity of a single application of a plant protection product applied in the field, not including application frequency.
Label rate	Quantity of a single application of a plant protection product, for which efficacy has been declared sufficient during the authorization procedure. This rate is recommended on the product label.
Plant protection product (PPP)	Preparations or formulations of active substances, intended to be used for the control of a particular pest or disease, or as a growth regulator. Plant protection products usually contain one or several active substances (responsible for the effect) and one or several formulating agents (spreaders, stickers, UV protectants etc.). PPP and their uses (including label rates, maximum number of applications per year and crop, pre-harvest intervals together with risk management practices) are authorized at Member State level.
RMS	Rapporteur Member State. Member State to which an application for an active substance is submitted and which prepares a DAR.
3rd stage review / 4th stage review	Review of active substances which had been authorized in a Member State of the EU before Directive 91/414/EEC was in force. This review takes place in four stages. Among many other substances, the 3rd stage comprised all copper compounds and the 4th stage comprises many of the substances currently used in organic farming or discussed in this document. At the time of this meeting, the 3rd and 4th stage were not completed, and decisions on inclusion/ non-inclusion in Annex I were pending for some substances of the 3rd stage and for all substances of the 4th stage.

1. Request concerning the use of spinosad as an insecticide

1.1 Recommendations

The expert group recommends spinosad to be allowed as an insecticide in organic farming.

If spinosad would be envisaged for inclusion in Reg. 2092/91/EEC, the group recommends that it should be accompanied by the conditions for use "need recognized by the inspection body or inspection authority" for reasons of consistency with other substances.

If spinosad would be envisaged for inclusion in Reg. 834/2007, the expert group is of the opinion that, in addition to the specific provisions from product registration on the product label,

- risks to key parasitoids should be minimized, and
- risks of development of resistance should be minimized.

Appropriate restrictions can best be developed at national or regional level.

1.2 Considerations

Identification of substance

No issue.

Authorization in general agriculture

Authorization at Community level

Spinosad is registered in Annex I of Dir. 91/414/EEC as insecticide.

Authorizations at Member State level

Products based on spinosad are authorized in many EU Member States for many uses (glasshouses and field crops; vegetables, fruit, olives, citrus, grapes, arable crops, ornamentals).

Origin

Spinosad is of microbial origin (from the bacterium *Saccharopolyspora spinosa*). The organism presently used is not a GMO. It is a selected strain (chemical mutant). The technique of chemical induction of mutants is also widespread in plant breeding. Whether or not the growth medium contains GMO is not relevant (Art. 2(v)).

Necessity

Details of use

Main targets are Lepidoptera (caterpillars), Thysanoptera (thrips) and Diptera (mainly fruit flies and stable flies).

Two basic spray formulations are currently used in different crops: formulations without baits can be used in many crops, while formulations containing baits can be used for fruit fly control (currently in citrus and olives).

A different formulation is used for the control of stable flies.

Spinosad is compatible with biological control (e.g. release of predators and parasitoids), provided that direct exposure is avoided.

Alternative products and methods currently allowed
For many intended uses (crop-pest situations), there are no alternative products or viable methods available. Currently available alternatives: pyrethrum, rotenone, neem, *Bacillus thuringiensis*, granulosis viruses. Some of these may not be available in the future, e.g. rotenone will be withdrawn. Where there are alternative products, spinosad will contribute to decrease the risk of pest resistance to the few pesticides available.

Some of the available alternatives are less desirable than spinosad: for example, certain pyrethrum formulations, and rotenone show more undesired side-effects; pyrethroids in traps for control of some fruit flies are of synthetic origin.

Necessity of requested use
Spinosad is essential for the control of some key pests (e.g. thrips in leek, fruit flies in citrus, olive fly).

For some other crop-pest situations, spinosad contributes to the sustainability of production systems that are particularly vulnerable to pests or diseases, as it is often more efficient than the available alternatives and it may contribute to resistance management. For example, in the control of codling moth, alternation of spinosad and granulosis virus decreases the risk of resistance development.

Environmental issues

Environmental fate, hazards and risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. buffer zones). The expert group does not see the need to reassess these issues.

Environmental fate of substance
No concern during assessment in accordance with Dir. 91/414/EEC. For example rapid photodegradation, and also microbial breakdown. End-product CO_2.

Environmental hazards and risk management
Spinosad is hazardous to aquatic organisms and to some non-target insects (pollinators, beneficials):

- Aquatic organisms: spinosad is toxic for aquatic organisms. Authorization procedures already deal with this risk, requiring e.g. buffer zones or prohibiting air plane spraying.
- Non-target insects: spinosad is highly toxic for Hymenoptera (bees, bumble bees, parasitoid wasps, ants) and earwigs (dermaptera) when they are directly sprayed or exposed to fresh residues. Authorization procedures already deal with this risk, requiring e.g. buffer zones to protect terrestrial habitats or prohibiting spraying during flowering periods (to protect pollinators).

Human health
Human health risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. pre-harvest intervals). The expert group does not see the need to reassess these risks.

Objectives and principles of organic farming

Food quality
As long as registration requirements are fulfilled (e.g. maximum field rate, maximum number of applications, pre-harvest intervals), residues are no concern.

Effects on animal welfare
Control of stable flies is beneficial to animals in stables.

Harmonization

Historic use in EU organic farming
Spinosad is a new substance and has no historic use.

Use in organic farming outside the EU
Yes, e.g. USA, Switzerland.

Precedents in EU organic farming
No exactly matching precedents, the closest similar crop protection agent is *Bacillus thuringiensis* (B.t.). Preparations of B.t. contain spores together with a crystal toxin, while spinosad preparations contain only the substances spinosyn A and D, but not the micro-organism *Saccharopolyspora spinosa* which produces them.

Further remarks
The expert group recommends to clarify in the Regulation that micro-organisms are generally allowed, while specific microbial products are only allowed on a case-by-case basis and need to be listed individually.

2. Request concerning the use of potassium bicarbonate as a fungicide

2.1 Recommendations

The expert group recommends potassium bicarbonate to be allowed as a fungicide in organic farming and sees no need for further conditions.

2.2 Considerations

Identification of substance

No issue.

In the context of the 4th stage review, potassium bicarbonate is considered as the active substance. Infections only occur under moist conditions, under which potassium bicarbonate dissolves into its ions and only the bicarbonate ion is responsible for the fungicidal effect.

Authorization in general agriculture

Authorization at Community level

Under review during 4th stage. RMS Ireland proposes Annex I inclusion.

Authorizations at Member State level

Pending in several MS. Authorized as commodity in the UK.

Origin

Both potassium and bicarbonate are ubiquitous in nature. The commercial substance is manufactured from potassium chloride and carbon dioxide.

Necessity

Details of use

Effective against various diseases in a range of crops (some of which are high-value crops), e.g. scab in pome fruit, powdery mildew in various crops, grey mould. No systemic action.

Alternative products and methods currently allowed

For many intended uses (crop-pest situations), copper (not allowed by all MS), sulphur and a few other substances are available. Against grey mould in strawberries, there are no effective alternatives. Varietal resistance is often not sufficient, because fungi break resistance easily.

In general, substances which may complement copper and sulphur are highly desirable in organic farming.

Necessity of requested use

Potassium bicarbonate is a welcome management tool. Reduction of the use of currently available fungicides contributes to the sustainability of the production system.

Environmental issues

Environmental fate, hazards and risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. buffer zones). The expert group does not see the need to reassess these issues.

Environmental fate of substance

No concern during 4th stage review.

Environmental hazards and risk management
No critical concerns identified.

Human health
No concerns identified in DAR.

Objectives and principles of organic farming: Food quality
Residues are no concern. Potassium bicarbonate is also a food additive (E 501) listed in Annex VI A of Regulation 2092/91.

Harmonization

Use in organic farming outside the EU
Yes, e.g. USA.

Precedents in EU organic farming

- Sodium bicarbonate (with the same active agent bicarbonate) was included in the original version of Regulation (EEC) No. 2092/91.
- Listed plant strengtheners based on sodium and potassium bicarbonate are used in Germany and Austria.

3. Request concerning the use of copper octanoate as a fungicide

3.1 Recommendations

The expert group recommends copper octanoate to be allowed as a fungicide in organic farming for reasons of consistency with other copper compounds.

According to some field trials and currently registered label uses, copper octanoate may contribute to reduction of copper use.

The group recommends to apply the same conditions for use as for the other copper compounds.

3.2 Considerations

Identification of substance
No issue.

In the context of the 3rd stage review, copper octanoate is considered as the active substance. Infections only occur under moist conditions, under which copper octanoate dissolves into its ions, and the copper ion is the primary active agent.

Authorization in general agriculture

Authorization at Community level
Copper octanoate is subject to the 3rd stage of re-evaluation (3A); RMS is France. Annex I status is pending.

The same is the case for other copper compounds, for which the RMS proposes inclusion in Annex I.

Authorizations at Member State level
Currently, two products based on copper octanoate are authorized in Germany.

Origin
Copper is of mineral origin and undergoes saponification with fatty acids. Saponification is also used in manufacture of soft soap.

Necessity

Details of use
In principle, copper octanoate could be used for the same purposes as the other copper compounds and has a similar effectivity. In addition, it has an effect against powdery mildew.

Label rates for copper octanoate (in terms of pure copper ion) are lower than for other copper compounds, both per application and over a season.

Alternative products and methods currently allowed
Alternative products to copper compounds (e.g. sulphur) and methods are not sufficiently effective.

Necessity of requested use
Inclusion of copper octanoate would be consistent with the current listing of the other copper compounds in Annex II B of 2092/91.

Environmental issues
Environmental fate, hazards and risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. buffer zones). The expert group does not see the need to reassess these issues.

Environmental issues are the same as for other copper compounds: they are known to pose certain risks to the environment.

The total amount of copper applied per season is lower for copper octanoate than for other copper compounds, if both are used according to label rates.

Human health
Human health risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management practices (e.g. harvest intervals). The expert group does not see the need to reassess these risks.

Objectives and principles of organic farming: Food quality
The same as for other copper compounds.

Harmonization

Historic use in EU organic farming
Copper compounds have been traditionally used in organic farming. The octanoate form is new and has no historic use.

Use in organic farming outside the EU
Yes, USA. Copper octanoate is listed by OMRI (Organic Materials Review Institute).

Precedents in EU organic farming
Other copper compounds. These are inorganic salts, while copper octanoate is a salt of a natural fatty acid.

4. Request concerning the use of ethylene for degreening citrus fruit

4.1 Recommendations

The expert group recommends ethylene to be allowed for degreening of citrus fruit. However, it should be limited to situations where degreening is part of a strategy for the prevention of fruit fly damage in citrus.

4.2 Considerations

Identification of substance
No issue.

Authorization in general agriculture

Authorization at Community level
Ethylene for post-harvest treatment is subject to the 4th stage review. Annex I status is pending. RMS UK proposes Annex I inclusion.

Authorizations at Member State level
Has been considered a commodity, now registered for post-harvest treatment in various MS.

Origin
Ethylene is produced by all higher plants and therefore omnipresent in nature. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through chemical processes (see further remarks below).

Necessity

Details of use
By harvesting citrus when they are green, fruit fly infestation can be avoided. This practice necessitates the induction of colour change of the peel in the post-harvest stage. This can be achieved by post-harvest exposure to ethylene in closed chambers for 2 days.

The use of ethylene for degreening is a traditional practice in lemons. However, its use as part of a strategy for fruit fly prevention has been newly developed for organic citrus.

Alternative products and methods currently allowed
Bait spraying of spinosad would be an alternative, but is not currently allowed for organic farming. Pyrethrum, rotenone and pyrethroids (in traps) are alternatives with partial efficacy.

Necessity of requested use
Could contribute to solve problems with fruit flies and to avoid pesticide use in the field.

Any use for purposes other than in the context of fruit fly control is not considered essential by the expert group.

Environmental issues
Environmental fate, hazards and risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management. The expert group does not see the need to reassess these issues.

The DAR on ethylene does not raise any concerns.

Theoretically, after release from the storage rooms, ethylene could affect the vegetation, but

the quantities used are negligible in comparison to natural and industrial emissions.

Human health
No concern.

Objectives and principles of organic farming
Prevention of damage
The maintenance of plant health by preventative measures is one of the principles of organic farming (Art. 5(f)).

Food quality
No adverse effect on intrinsic food quality (internal ripening of citrus is completed before harvest). Effect on peel colour only, which facilitates marketing.

Harmonization

Historic use in EU organic farming
Yes, but not in citrus.

Use in organic farming outside the EU
Not known to the expert group.

Precedents in EU organic farming
Degreening of banana, khaki and kiwi.

Further remarks
This application should be seen in the context of crop protection.

According to Reg. 2173/2003, degreening of citrus is permitted only if the other natural organoleptic characteristics are not modified.

The expert group has only considered the use of ethylene on citrus (a non-climacteric fruit), where it has no influence on physiological ripening (taste, flavour, texture). The use on climacteric fruit (e.g. apples, tomatoes, kiwi, khaki), where ethylene does affect physiological ripening, was not discussed.

Ethylene can be applied in several ways. In airtight, closed chambers injection of compressed ethylene gas is proposed in the request for degreening citrus, while heating of ethanol on a catalyst is proposed in the request for sprouting inhibition in potatoes and onions.

There are ethylene field application methods which are not allowed in organic farming (calcium carbide, ethephon). The expert group recommends to clarify in the Regulation which ways of ethylene application are allowed.

5. Request concerning the use of ethylene for sprouting inhibition in potatoes and onions

5.1 Recommendations

The expert group recommends ethylene to be allowed for sprouting inhibition in potatoes and onions.

5.2 Considerations

Identification of substance
No issue.

Authorization in general agriculture

Authorization at Community level
Ethylene for post-harvest treatment is subject to the 4th stage review. Annex I status is pending. RMS UK proposes Annex I inclusion.

Authorizations at Member State level
Has been considered a commodity, now registered for post-harvest treatment in various MS.

Origin
Ethylene is produced by all higher plants and therefore omnipresent in nature. The ethylene (identical to the naturally occurring ethylene) used for agricultural purposes is obtained through chemical processes (see further remarks below).

Necessity

Details of use
Constant exposure of stored potatoes and onions to ethylene in low concentration inhibits sprouting.

Alternative products and methods currently allowed
Cold storage, use of varieties with high dormancy and/or caraway seed oil (for potatoes, where registered) may provide solutions in certain situations.

Necessity of requested use
A longer marketing period is important for the economic sustainability of farms.

This use of ethylene is not directly linked to the control of a pest or disease, but under Dir 91/414, this use of ethylene is considered to be plant protection. In Reg. 2092/91, products for similar uses (including sprout inhibition with caraway oil) are listed together with pesticides in Annex II B. Therefore, it is the opinion of the expert group that the criteria in Reg. 834/2007, Art. 16 are applicable in this case.

Environmental issues
Environmental fate, hazards and risks are assessed in detail during pesticide registration, and authorizations are accompanied by obligations for appropriate risk management. The expert group does not see the need to reassess these issues.

The DAR on ethylene does not raise any concerns.

Theoretically, after release from the storage rooms, ethylene could affect the vegetation, but

the quantities used are negligible in comparison to natural and industrial emissions.

Human health
No concern.

Objectives and principles of organic farming: Food quality
Under conditions of prolonged storage, a higher external and internal quality can be maintained (absence of sprouts and wrinkles, composition of tubers).

If it allows storage of potatoes at higher temperatures, it would contribute to reducing the risk of formation of acrylamide during processing, frying or baking of the potatoes.

Harmonization

Historic use in EU organic farming
Yes, but not in potatoes and onions.

Use in organic farming outside the EU
Not known to the expert group.

Precedents in EU organic farming
- Ethylene: Degreening of banana, khaki and kiwi, but no use for sprout inhibition.
- Sprout inhibition: caraway oil (listed in Annex II B under the generic term of “plant oils”)

Further remarks
This use can allow to store potatoes and onions for a longer period and, as a consequence, to supply the market with locally produced potatoes and onions for a longer period.

Ethylene can be applied in several ways. In airtight, closed chambers injection of compressed ethylene gas is proposed in the request for degreening citrus, while heating of ethanol on a catalyst is proposed in the request for sprouting inhibition in potatoes and onions.

There are ethylene field application methods which are not allowed in organic farming (calcium carbide, ethephon). The expert group recommends to clarify in the Regulation which ways of ethylene application are allowed.