COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

BEZOEKADRES:
A. VAN LEEUWENHOEKLAAN 9
3721 MA BILTHOVEN

POSTADRES:
POSTBUS 578
3720 AN BILTHOVEN

TEL.: 030 274 2777
FAX: 030 274 4476
INFO@COGEM.NET
WWW.COGEM.NET

Aan de staatssecretaris van
Infrastructuur en Milieu
Dhr J.J. Atsma
Postbus 30945
2500 GX Den Haag

DATUM 9 december 2011
KENMERK CGM/111209-01
ONDERWERP Additonieel advies m.b.t. de teelt van gg-maïslijn MON88017 n.a.v. verschijnen EFSA opinie

Geachte heer Atsma,

Naar aanleiding van het verschijnen van de EFSA opinie met betrekking tot de teelt van de genetisch gemodificeerde maïslijn MON88017, deelt de COGEM u het volgende mee.

Samenvatting
De COGEM heeft in 2008 geadviseerd over de vergunningaanvraag voor teelt, import en verwerking van de genetisch gemodificeerde maïslijn MON88017. Deze maïslijn brengt de *cp4 epsps* en *cry3Bb1*genen tot expressie en is hierdoor tolerant voor glyfosaat bevattende herbiciden en resistent tegen bepaalde kevers.
In haar eerdere advies concludeerde de COGEM dat door de vergunningaanvrager onvoldoende gegevens waren overlegd om eventuele effecten van de maïslijn op niet-doelwitorganismen te kunnen beoordelen. Het dossier bevatte weliswaar resultaten van veldproeven en laboratoriumstudies naar eventuele effecten op niet-doelwitorganismen, maar het merendeel van deze studies was uitgevoerd met een andere maïslijn of met varianten van het Cry3Bb1 eiwit dat in MON88017 aanwezig is.
Naar aanleiding van de recent verschenen EFSA opinie over deze vergunningaanvraag, is de COGEM gevraagd of haar eerdere opmerkingen voldoende zijn beantwoord.
Inmiddels zijn er een aantal wetenschappelijke publicaties verschenen die aantonen dat MON88017 geen negatief effect heeft op verschillende niet-doelwitorganismen (de grote wigwamspin, de bonespintmijt, een cicade, een blindwants, het goudoogje, het spintetende en het tweestippelige lieveheersbeestje).
De COGEM is echter van mening dat voor een aantal andere niet-doelwitorganismen onvoldoende is aangetoond dat zij geen nadelige effecten van de teelt van MON88017 zullen ondervinden. De COGEM wijst erop dat bij de laboratoriumstudies naar effecten op honingbijen de controle op de aanwezigheid van actief Cry3Bb1 eiwit ontbreekt. Ook vindt de COGEM de gegevens met betrekking tot niet-doelwit loopkevers niet voldoende om te kunnen concluderen dat zij geen nadelige effecten van de teelt van MON88017 maïs zullen ondervinden. Gezien het bovenstaande kan de COGEM niet positief adviseren over de teelt van MON88017 maïs.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c. Drs. H.P. de Wijs
Dr. I. van der Leij

Additional advice on cultivation of maize MON88017

COGEM advies CGM/111209-01

This advice concerns the application for cultivation, import and processing of genetically modified MON88017 maize. This maize line expresses the cp4 epsps *and* cry3Bb1 *genes conferring tolerance to glyphosate containing herbicides and resistance to coleopteran insects such as the Western corn rootworm and the Colorado potato beetle. These insects belong to the Chrysomelidae family.*

In its previous advice on this application, COGEM concluded that the provided data were insufficient to conclude that cultivation of MON88017 would not pose a risk to non-target organisms. The majority of the data in the original application was obtained using other maize lines or Cry3Bb1 protein variants that were not identical to the MON88017 Cry3Bb1 protein. COGEM was of the opinion that additional data from laboratory experiments and field trials had to be provided. These laboratory experiments should be carried out with the Cry3Bb1 protein that is present in maize line MON88017 or with the maize line itself.

Recently, EFSA published its opinion on cultivation of MON88017. The Dutch Ministry of Infrastructure and the Environment (IenM) asked COGEM whether the opinion of the EFSA GMO panel and the additional information that is provided by the applicant gives reason to reconsider its previous advice.

The applicant performed an additional laboratory experiment on the effect of MON88017 pollen on honeybee, but did not prove that active Cry3Bb1 protein was still present in the pollen.

In addition, the applicant provided new data on the LC50 values of the different Cry3Bb1 protein variants using the Colorado potato beetle (a target insect). The applicant did not compare the effect of the Cry3Bb1 protein variants on non-target organisms. As the different protein variants could affect a different range of organisms and data is lacking on the effect of the protein variants on non-target organisms, such as non-target coleopteran insects, COGEM is of the opinion that the functional equivalence of the two Cry3Bb1 protein variants was not sufficiently proven.

In addition, the applicant used a theoretical exposure analysis to assess whether non-target chrysomelid insects could be affected by MON88017 maize pollen and concluded that MON88017 does not pose a risk to these insects.

The applicant also reviewed the available scientific literature on the effect of Cry3Bb1 protein or Cry3Bb1 expressing maize on non-target organisms. In the opinion of COGEM the evidence is insufficient to proof the functional equivalence of the Cry3Bb1 protein variants that are present in other maize lines and the MON88017 Cry3Bb1 protein. Therefore, COGEM only took those studies into consideration that used MON88017 or the Cry3Bb1 protein that is present in MON88017. The available literature indicates that MON88017 does not adversely affect a range of non-target organisms (a predatory spider, spider mite, plant bug, leaf hopper, lacewing and two ladybird species). However, COGEM is of the opinion that sufficient data on the absence of an effect on ground beetles (Coleoptera: Carabidae) is lacking. Predatory ground beetles are present in agricultural fields and may be indirectly exposed to Cry3Bb1 protein via its prey. COGEM is of the opinion that in case of maize line MON88017 which is resistant to certain coleopteran insects, an assessment of the effect of this maize line on ground beetles is necessary.

In conclusion, sufficient data on the absence of an effect on ground beetles is lacking and the study on the effect of MON88017 pollen on honeybees did not contain the proper control experiments. Therefore, COGEM cannot advise positively on cultivation of MON88017 maize.

Introduction

Recently, EFSA published its opinion on cultivation of genetically modified maize line MON88017. This maize line expresses the *cp4 epsps* and *cry3Bb1* genes. As a consequence, it is tolerant to glyphosate containing herbicides and resistant to certain coleopteran insects such as the Western corn rootworm and the Colorado potato beetle.

EFSA considers it unlikely that MON88017 will have any adverse effect on the environment, except for the possible development of Cry3Bb1 resistant coleopteran target pests.[1]

In 2008, COGEM advised on cultivation of MON88017 maize.[2] COGEM was of the opinion that the molecular characterization of this maize line was adequate and complete. However, the provided data were insufficient to conclude that cultivation of MON88017 would not lead to adverse effects on non-target organisms. COGEM was of the opinion that additional data from laboratory experiments and field studies had to be provided.

Furthermore, in COGEM's view the general surveillance plan was at some points too informal and gave no guarantees that sufficient data would be collected. COGEM was of the opinion that the applicant should describe in more detail how the general surveillance is organized and which organizations are involved.

The Dutch Ministry of Infrastructure and the Environment (IenM) asked COGEM whether the opinion of the EFSA GMO panel and the additional information that is provided by the applicant gives COGEM reason to reconsider its previous advice.

Data evaluating effects on non-target organisms

Cry3Bb1 protein variants

In 2008, the applicant provided data from several laboratory studies and field trials on non-target organisms. Almost none of these studies were carried out with MON88017 itself or with the Cry3Bb1 protein that is produced by MON88017.

In the original application the majority of the laboratory studies were carried out with variants of Cry3Bb1 proteins. These variants were created to discover the optimal expression of the Cry3Bb1 protein against the target pest. The Cry3Bb1 proteins that are used in the laboratory studies are the Cry3Bb1 proteins that are produced by MON863 or MON853 maize. These proteins differ by one out of 653 amino acid from the MON88017 Cry3Bb1 protein. Unfortunately, no information was provided on the 3-dimensional structure of the MON88017 Cry3Bb1 protein itself, although the applicant did provide information on the structure of some of the other Cry3Bb1 protein variants. [3]

In response to questions of the Belgian Competent Authority, the applicant provided new data on the LC50 values of the *E. coli* produced Cry3Bb1 proteins from both MON88017 and MON863. These data were obtained in additional bio-assays using the Colorado potato beetle (*Leptinotarsa decemlineata*). The applicant compared the LC50 values of the two Cry3Bb1 proteins. According to the applicant the high degree of overlap between the LC50 values suggest that the two proteins are functionally equivalent.[4]

COGEM points out that an amino acid change could affect the range of organisms that is affected by the Cry3Bb1 protein. The applicant compared the LC50 values of the two Cry3Bb1 proteins using two susceptible species of insects, i.e. the Colorado potato beetle[4,5] and the Western corn rootworm[5]. COGEM is of the opinion that this is not sufficient to conclude that the two Cry3Bb1 proteins affect the same range of organisms. Hence, COGEM is of the opinion that the applicant has not sufficiently proven that the two proteins are functionally equivalent.

In COGEM's view, in order to prove that the two Cry3Bb1 proteins are functionally equivalent, the effect of the two Cry3Bb1 proteins should not only be tested on susceptible target-organisms, but also on non-target organisms including non-target coleopteran insects. Because this comparison is not made, COGEM is of the opinion that the laboratory studies that study the effect on non-target organisms of the Cry3Bb1 protein variants from MON863 or MON853, cannot be used to draw conclusions on the effect of the Cry3Bb1 protein that is present in maize MON88017 on non-target organisms.

Laboratory studies on effects of MON88017 on non-target organisms

The applicant provided additional laboratory studies on the effect of MON88017 pollen on honeybees (*Apis mellifera*).[6,7] In the study on honeybee larvae approximately 2 mg of MON88017 pollen was distributed to each cell. The honeybee adults were fed *ad libitum* with diet consisting of 4 g MON88017 pollen in 1 ml of honey. The applicant did not demonstrate that the MON88017 pollen contained active Cry3Bb1 protein nor in which concentration the Cry3Bb1 protein was present, but stated that MON88017 has been shown to be stable for storage periods that exceed the storage period of the pollen that was used in this experiment. No data was provided to substantiate this claim. As the specific conditions during storage could affect the stability and activity of the Cry3Bb1 protein, COGEM is of the opinion that the applicant should have demonstrated that the MON88017 pollen that was used in the laboratory experiments still contained active Cry3Bb1 protein. In addition, as the amount of Cry3Bb1 protein in pollen is influenced by environmental conditions, it would be preferable if the exact amount of Cry3Bb1 protein in the pollen that was used in the laboratory experiments would have been determined. As data on the presence of active Cry3Bb1 protein and its concentration were not provided, COGEM is of the opinion that the results from the honeybee studies cannot be used to draw conclusions on the effect of MON88017 pollen on honeybees.

Field trials with MON88017 maize

The majority of the field trials in the original application was carried out with MON863 instead of MON88017. COGEM is of the opinion that the results from these studies cannot be used to draw conclusions on the effect of MON88017 maize on non-target organisms, because it was not sufficiently proven that the Cry3Bb1 protein in MON863 is functionally equivalent to the Cry3Bb1 protein in MON88017.

In the original application, only one MON88017 field study is present. In this study (four locations in Germany and four locations in Spain) the susceptibility of maize MON88017 to insects (*Ostrinia nubilalis* and *Sesamia* spp.) was examined.[8] The qualitative data from this study was not subjected to statistical analysis. In its previous advice COGEM stated that quantitative data are necessary to draw conclusions on the occurrence of effects on non-target organisms. The applicant did not provide additional data from European field trials.

Theoretical exposure analysis concerning non-target chrysomelidae

In response to questions of the Belgian Competent Authority and EFSA the applicant also provided an assessment of the risk of MON88017 to non-target organisms that belong to the same family as the target organism of the Cry3Bb1 protein, i.e. the Chrysomelidae.[9] The applicant calculated the margin of safety for non-target chrysomelidae that do not feed on maize plants but are indirectly exposed to MON88017 when they consume maize pollen that is deposited on leaves of their host plants. The LC50 value of the Colorado potato beetle was used to calculate the margin of safety. COGEM strongly prefers the use of laboratory experiments over a theoretical exposure analysis as in the latter case flaws can be introduced by the use of assumptions, estimations and extrapolations.

Review of literature on non-target effects

COGEM notes that the assessment of the effect of MON88017 on non-target organisms is to a great extent based on studies that were carried out by other parties. The applicant did not provide the data that were requested by COGEM in its previous advice. However, in the meantime several other studies were published that assessed the effect of MON88017 maize on non-target organisms. In response to questions of the EFSA GMO panel, the applicant provided a review of the studies that assessed the effect of the Cry3Bb1 protein or Cry3Bb1 protein expressing Bt maize on non-target organisms. Some of these studies were carried out with MON88017. Because of reasons explained previously, COGEM is of the opinion that only the studies which are carried out with MON88017 maize or the Cry3Bb1 protein which is produced by MON88017 can be used to draw conclusions on the effect of MON88017 maize on non-target organisms. These studies are discussed below.

One of the studies that was carried out by another party assessed the effect of MON88017 on a predatory spider (*Theridion impressum*). The authors showed that this spider is exposed to the Cry3Bb1 protein as its prey contains the Cry3Bb1 protein. In laboratory studies in which juvenile and adult spiders were fed Cry3Bb1 containing food (MON88017 maize fed prey or MON88017 pollen) no adverse effects of MON88017 were observed, indicating that *T. impressum* is not affected by the Cry3Bb1 protein.[10] Another study examined the effect of MON88017 pollen and purified Cry3Bb1 protein from MON863 on lacewing adults (*Chrysoperla carnea* (Neuroptera; Chrysopidae)). The results from this study showed that lacewings are not affected by MON88017 pollen.[11]

A study was published on the effect of Cry3Bb protein on *Adalia bipunctata*. In this study the Cry3Bb protein resulted in a marginally, but significantly higher mortality than the control.[12] The degree of similarity of the Cry3Bb protein to the MON88017 Cry3Bb1 protein is not known. Moreover, the study has been criticised because of methodological flaws and inconsistencies.[13,14] Recently, another study assessed the effect of Cry3Bb1 protein on larvae of *A. bipunctata* (Coleoptera: Coccinellidae) using a tritrophic experiment in which *A. bipunctata* larvae were fed with spider mites (*Tetranychus urticae*) that had fed on MON88017 maize. In addition, *A. bipunctata* was fed a sucrose solution containing Cry3Bb1 protein from MON863. The authors concluded that there was no evidence that larvae of *A. bipunctata* would be adversely affected by MON88017 and concluded that the harmful effects of the Cry3Bb protein that were reported by Schmidt et al. (2009)[12] were probably artifacts of poor study design.[13]

In another study on the effect of MON88017 on the ladybird beetle *Stethorus punctillum* (Coleoptera: Coccinellidae) the ladybird beetles were fed spider mites (*T. urticae*) which were reared on MON88017 maize. These spider mites were not affected by the MON88017 maize and consumption of these mites did not affect mortality of *S. punctillum*. Interestingly, the MON88017 fed mites appeared to have a positive effect on female *S. punctillum* beetles as they had a shorter pre-oviposition period, increased fecundity and increased fertility. The authors postulate that these differences may be caused by unidentified differences in plant characteristics.[15]

Overall, there is no indication that MON88017 adversely affects the non-target organisms that were examined in the above described studies.

In other publications the results were described from field trials that studied the effect of MON88017 on the abundance of various arthropods. One of the studies examined the impact of MON88017 on the abundance of herbivorous plant bugs (Heteroptera: Miridae) in a German maize field. The field trial was performed in three successive years with 0.13 ha plots in eight replicates per corn line. The effect of MON88017 on the most abundant plant bug in the field trial, i.e. *Trigonotylus caelestialium* was determined. It was shown that this plant bug was not adversely affected by cultivation of MON88017 although the species is exposed to the Cry3Bb1 protein in all stages of its life. The abundance of other plant bug species was also determined. These plant bug species were present in much lower numbers. According to the authors analysis of the effect of MON88017 on these other plant bug species was not possible.[16]

The same field trial was used to examine the effect of MON88017 maize on plant hoppers and leaf hoppers (Auchenorrhyncha). *Zyginidia scutellaris* (Hemiptera: Cicadellidae) was the most abundant leaf hopper. Although other leaf hopper and plant hopper species were present in the maize field, their abundance was too low for robust statistical analysis. Therefore, only the abundance of *Z. scutellaris* was statistically analysed. No consistent differences were observed between the number of *Z. scutellaris* in MON88017 and its near-isogenic cultivar. These results indicate that *Z. scutellaris* is not adversely affected by MON88017.[17] In another study it was shown that *Z. scutellaris* accumulates the Cry3Bb1 protein in the field.[10]

The above described field trial was also used to study the effect of MON88017 on ground beetles (Coleoptera: Carabidae). These results were not published in a peer-reviewed journal. The author of the report states that no significant differences were found in the mean activity abundances of carabid species in the three years in which the field trial was performed and that the carabid beetle community did not differ significantly between the tested maize varieties.[18] However, the authors also mentioned that the natural heterogeneity of the site had a significant influence on the distribution of carabid species and therefore on the number of carabid species that were captured. The heterogeneity of activity abundances in the different plots is presumably due to different abiotic factors based on the heterogeneity of the study site. COGEM points out that possible differences between MON88017 and the near isogenic maize line could have been masked by the differences in the distribution of the carabid species on the study site. Therefore, COGEM is of the opinion that the study on the effect of MON88017 on carabid species is inconclusive.

The results from another field trial that was carried out in the Czech Republic were published in a non-peer-reviewed journal. This study determined the abundance of plant-dwelling arthropods (plant-sucking arthropods, predators and parasitoids) and epigeic arthropods (spiders, ground and rove beetles) in a one-year field trial with 0.5 ha plots in five replications per maize cultivar. COGEM has doubts on the statistical analysis of the data in this study. Amongst others because the insecticide treatment appears not to have affected arthropods apart from a small effect on ground beetles.[19]

In a research project that was commissioned by COGEM, Scholte and Dicke concluded that to assess the effect of Cry3 producing maize the following non-target organisms should be studied: a wolf spider, a predatory ground beetle, a predatory ladybird beetle, a lacewing and a honeybee or bumblebee.[20]

COGEM is of the opinion that it was sufficiently proven that MON88017 poses a neglible risk to the predatory spider (*Theridion impressum*), the spider mite *Tetranychus urticae*, the plant bug *Trigonotylus caelestialium,* (Heteroptera; Miridae), the leafhopper *Zyginidia scutellaris* (Hemiptera: Cicadellidae), the lacewing *Chrysoperla carnea* (Neuroptera; Chrysopidae) and the ladybird beetles *Adalia bipunctata* and *Stethorus punctillum* (Coleoptera: Coccinellidae).

However, COGEM noted that in the laboratory study on the effect of MON88017 on honeybees (*Apis mellifera*) the researchers did not prove that the Cry3Bb1 protein in the MON88017 pollen had not been degraded and remained active. Therefore, COGEM is of the opinion that this study is not sufficient to conclude that MON88017 will not affect honeybees.

Since the Cry3Bb1 protein is developed to control the Western corn rootworm *Diabrotica virgifera* (Coleoptera: Chrysomelidae) and is also active against the Colorado potato beetle *Leptinotarsa decemlineata* (Coleoptera: Chrysomelidae) studies on the effect of MON88017 on coleopteran non-target organisms are especially important. It was shown that MON88017 does not adversely affect the ladybird beetles *A. bipunctata* and *S. punctillum* (Coleoptera: Coccinellidae). In addition, using the LC50 values of the Colorado potato beetle the applicant estimated the margins of safety for non-target Chrysomelidae that are indirectly exposed to MON88017 by its pollen. Based on this estimation it is considered unlikely that non-target Chrysomelidae would be adversely affected by MON88017. However, COGEM is of the opinion that sufficient data on the absence of an effect on ground beetles (Coleoptera: Carabidae) is lacking. Predatory ground beetles are present in agricultural fields and may be indirectly exposed to the Cry3Bb1 protein via its prey. COGEM is of the opinion that in case a Cry3Bb1 protein expressing maize line like MON88017 an assessment of the effect of this maize line on ground beetles is necessary.

In conclusion, sufficient data on the absence of an effect on ground beetles is lacking and the study on the effect of MON88017 pollen on honeybees did not contain the proper control experiments. Therefore, COGEM cannot advise positively on cultivation of MON88017 maize.

References

1. EFSA (2011). Scientific opinion on application (EFSA-GMO-CZ-2008-54) for pllacing on the market of GM insect resistant and herbicide tolerant maize MON88017 for cultivation. EFSA Journal 9(11): 2428

2. COGEM (2008). Cultivation of genetically modified maize line MON88017. Advice CGM/081112-02

3. Astwood JD, Hileman RE *et al.* (2001). Safety assessment of Cry3Bb1 variants in corn rootworm protected corn. Report No. MSL-17225

4. Monsanto (2009). Responses to the BE CA questions (20 February 2009)

5. Duan JJ, Paradise MS & Jiang C (2003). Evaluation of the functional equivalence of two Cry3Bb1 protein variants against susceptible coleopteran insects. Report No. MSL-18799

6. Richards KB (2011). Evaluation of the potential for dietary effect(s) of pollen from corn product MON88017 on honey bee larvae (*Apis mellifera L.*) development. Monsanto study no. CA-2009-397

7. Richards KB (2011). Evaluation of the potential for dietary effect(s) of pollen from corn product MON88017 on honey bee adults. Monsanto study no. CA-2009-398

8. Martin C and de Billot M (2008). Phenotypic evaluation and ecological observations of coleopteran-protected and glyphosate-tolerant maize MON88017 in Germany and Spain field trials during 2006. Report number MSL0021086

9. Monsanto (2011). Responses to EFSA questions (1 April 2011)

10. Meissle M & Romeis J (2009) The web-building spider *Theridion impressum* (Araneae: Theridiidae) is not adversely affected by *Bt* maize resistant to corn rootworms. Plant Biotechnol J. 7: 645-656

11. Li Y, Meissle M & Romeis J (2008). Consumption of *Bt* maize pollen expressing Cry1Ab or Cry3Bb1 does not harm adult green lacewings, *Chrysoperla carnea* (Neuroptera: Chrysopidae) PloS One 3(8): e2909

12. Schmidt JEU, Braun CU, Whitehouse LP & Hilbeck A (2009). Effects of activated Bt transgene products (Cry1Ab, Cry3Bb) on immature stages of the ladybird *Adalia bipunctata* in laboratory ecotoxicity testing. Arch Environ Contam Toxicol. 56: 221-228

13. Álvarez-Alfageme F, Bigler F & Romeis J (2011). Laboratory toxicity studies demonstrate no adverse effects of Cry1Ab and Cry3Bb1 to larvae of *Adalia bipunctata* (Coleoptera: Coccinellidae): the importance of study design. Transgenic Res. 20:467-479

14. Rauschen S (2010). A case of 'pseudo science'? A study claiming effects of the Cry1Ab protein on larvae of the two-spotted ladybird is reminiscent of the case of the green lacewing. Transgenic Res. 19:13-16

15. Li Y & Romeis Y (2010). *Bt* maize expressing Cry3Bb1 does not harm the spider mite, *Tetranychus urticae*, or its ladybird beetle predator, *Stethorus punctillum*. Biological control 53: 337-344

16. Rauschen S, Schultheis E *et al.* (2008). Impact of *Bt*-corn MON88017 in comparison to three conventional lines on *Trigonotylus caelestialium* (Kirkaldy) (Heteroptera: Miridae) field densities. Transgenic Res. DOI 10.1007/s11248-008-9207-2

17. Rauschen S, Schutlheis E, *et al.* (2010). *Diabrotica*-resistant *Bt*-maize DKc5143 event MON88017 has no impact on the field densities of the leafhopper *Zyginidia scutellaris*. Environ Biosafety Res. 9: 87-99

18. Priesnitz KU (2010). Potential impact of *Diabrotica* resistant *Bt*-maize expressing Cry3Bb1 on ground beetles (Coleoptera: Carabidae). Dissertation RWTH Aachen University
19. Svobodová Z, Habuštová O *et al*. (2012). Impact of genetically modified maize expressing Cry3Bb1 on non-target arthropods: first year results of a field study. GMOs in integrated plant production, IOBC wprs Bulletin 73, 105-117 (in press)
20. Scholte E-J & Dicke M (2005). Effects of insect-resistant transgenic crops on non-target arthropods: first step in pre-market risk assessment studies. Research report CGM 2005-06