

GENETISCHE MODIFICATIE IN INTERNATIONAAL PERSPECTIEF COGEM EVALUATIERAPPORT 2011

NEDERLANDSE VERTALING

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COGEM EVALUATIECOMMISSIE 2011

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Dit deel is de Nederlandse vertaling van het Evaluation Report. De teksten en interviews zijn niet integraal overgenomen maar zijn na te lezen in het oorspronkelijke rapport. Gezien de samenstelling van de evaluatie commissie heeft de evaluatie in het Engels plaats gevonden en is het evaluatie rapport in het Engels opgesteld.

1. INLEIDING

Zoals voorgeschreven in de Wet Milieubeheer moet de Commissie Genetische Modificatie (COGEM) elke vier jaar worden geëvalueerd. De evaluatie is de verantwoordelijkheid van de COGEM. In de Wet milieubeheer (§ 2.3) staat dat de COGEM elke vier jaar een rapport uitbrengt waarin de rol, de structuur, de samenstelling en de procedures van de Commissie worden geëvalueerd en voorstellen ter verbetering worden gedaan. Het rapport wordt aangeboden aan de staatssecretaris van Infrastructuur en Milieu (IenM) die het vergezeld van een kabinetsreactie aan het parlement toestuurt.

Het Dagelijks Bestuur van de COGEM heeft een externe commissie gevraagd om de COGEM te evalueren in 2011. Deze evaluatiecommissie bestond uit de voorzitter prof. dr. ir. Rudy Rabbinge, en de leden dr. Christine Noiville en prof. dr. ir. Dirk Reheul. De opdracht van de evaluatiecommissie was om de COGEM te evalueren in het kader van de wettelijke eisen zoals vastgesteld in de Wet Milieubeheer.

RAPPORT

Het onderhavige rapport geeft de bevindingen van de evaluatiecommissie weer. Naast een beoordeling van de COGEM en de daaruit voortvloeiende diagnose en conclusies, biedt het rapport een aantal aanbevelingen ter verdere versterking van de kwaliteit van de COGEM en haar activiteiten.

De evaluatiecommissie heeft dit evaluatierapport aangeboden aan het Dagelijks Bestuur van de COGEM. Het Dagelijks Bestuur zal dit rapport naar de staatssecretaris sturen met een begeleidende brief, waarin ze haar visie geeft op de bevindingen van de evaluatiecommissie.

DE EVALUATIECOMMISSIE

Met het oog op maximale transparantie en objectiviteit, heeft de COGEM net als bij de voorgaande evaluaties in 2003 en 2007 besloten om de evaluatie door externe beoordelaars te laten uitvoeren. Een verschil met de vorige evaluaties is het internationale karakter van de evaluatiecommissie.

In 2003 is de evaluatie door een organisatieadviesbureau (Twynstra Gudde) uitgevoerd. Deze evaluatie stond in het teken van de destijds nieuw opgebouwde organisatie. In de evaluatie van 2007 lag de focus vooral op de relatie met de stakeholders in Nederland en de rol van de COGEM in het publieke debat. De internationale aanpak van de evaluatie van 2011 weerspiegelt het feit dat nationale adviesorganen, zoals de COGEM, in toenemende mate actief zijn in een internationaal speelveld. De EU en haar instellingen hebben een groeiende invloed op regelgeving, wetenschappelijke beoordelingsprocedures, beleid en besluitvormingsprocessen rond genetisch gemodificeerde organismen (ggo's).

Twee leden van de evaluatiecommissie zijn intensief betrokken bij buitenlandse zusterorganisaties van de COGEM en hebben praktijkervaring met de eisen waar de COGEM aan moet voldoen. Dr. Christine Noiville is de voorzitter van het 'Comité économique, éthique et social' van de Franse 'Haut Conseil des Biotechnologie' en hoofd van het 'Centre de Recherche Droit, Sciences et Techniques, CNRS-Université Paris I'. Professor Dirk Reheul is de voorzitter van de Belgische Bioveiligheidsraad en hoogleraar plantenveredeling en agronomie aan de Universiteit Gent.

De Nederlandse voorzitter van de evaluatiecommissie, professor Rudy Rabbinge, heeft onder meer ruime ervaring met verschillende soorten van nationale en internationale wetenschappelijke organisaties en heeft kennis van politiek en beleidsvorming in Nederland. Professor Rabbinge is onder andere hoogleraar Duurzame Ontwikkeling en Voedselzekerheid bij Wageningen-UR.

1. INLEIDING

FOCUS VAN DE EVALUATIE

Evenals in de vorige evaluaties waren de centrale vragen in 2011 "Heeft de COGEM de juiste dingen gedaan?" en "Heeft de COGEM deze dingen goed gedaan?".

In de evaluatie is ook gekeken of de organisatie, structuur en procedures van de COGEM opgewassen zijn tegen de veranderingen die zich mogelijk zullen voordoen binnen het speelveld waarin de commissie opereert. Daarom heeft de evaluatiecommissie zich voor de beantwoording van de bovengenoemde vragen gericht op een aantal aspecten die van direct belang zijn voor de activiteiten van de COGEM: de wetenschappelijke kwaliteit van de COGEM publicaties; communicatie en transparantie; de internationale positie van de COGEM en internationale samenwerking; de vervaging van de definitie van een ggo; een eventuele sociaal-economische beoordeling van ggo's; het onderscheid tussen rode, witte en groene biotechnologie; en regelgeving en deregulering.

EVALUATIEPROCES

Voor het uitvoeren van de evaluatie maakte de evaluatiecommissie hoofdzakelijk gebruik van drie informatiebronnen. Ten eerste het door de COGEM opgestelde statusrapport, dat een overzicht geeft van de organisatie en de structuur van de COGEM; de belangrijkste publicaties en activiteiten in de afgelopen drie en een half jaar; de hoogtepunten van de afgelopen jaren; de eventuele controverses rond COGEM, haar publicaties of activiteiten; en de relevante COGEM procedures. Ten tweede beoordeelde de evaluatiecommissie de wetenschappelijke kwaliteit van een representatieve selectie van COGEM adviezen en signaleringen uitgebracht in de laatste drie en een half jaar. Ten derde werden acht interviews gehouden met verschillende COGEM leden, met vertegenwoordigers van stakeholders en met het Ministerie van Infrastructuur en Milieu (IenM), welke de primaire opdrachtgever is van de COGEM.

De evaluatiecommissie is op 5 en 6 april 2011 in Den Haag bijeengekomen om de interviews af te nemen, haar bevindingen te bespreken en de belangrijkste conclusies en aanbevelingen vast te stellen. De verdere afhandeling en vaststelling van de definitieve tekst van het evaluatierapport heeft per e-mail plaatsgevonden.

2. STATUSRAPPORT EN INTERVIEW

Het eindoordeel van de evaluatiecommissie is gebaseerd op de beoordeling van de inhoud van het statusrapport 2008-2011, een aantal interviews met stakeholders, en van een review van een willekeurige selectie van COGEM adviezen en signaleringen. Dit hoofdstuk bevat de beoordeling van het statusrapport en geeft een overzicht van de geïnterviewden.

2.1 STATUSRAPPORT

De evaluatiecommissie is van mening dat het statusrapport 2008-2011 een goed overzicht geeft van de missie van de COGEM en hoe de commissie deze heeft vervuld in de periode sinds de vorige evaluatie. Terecht benadrukt het rapport de dubbele missie van de COGEM; (1) adviseren over de mogelijke risico's van handelingen met, of de productie van, ggo's; en (2) informeren over de ethische en maatschappelijke aspecten verbonden aan genetische modificatie.

Het rapport beschrijft de organisatie en de samenstelling van de COGEM in detail. Hieruit blijkt dat de organisatie van de COGEM in wetenschappelijke subcommissies onder toezicht van een Dagelijks Bestuur en ondersteund door een professioneel secretariaat een snelle en efficiënte uitvoering van de werkzaamheden mogelijk maakt. Een brede waaier van verschillende expertises is aanwezig binnen de COGEM. De COGEM leden zijn vooraanstaande wetenschappers en deskundigen in hun vakgebied.

De procedures en protocollen die de COGEM hanteert blijken de kwaliteit, integriteit en onafhankelijkheid van zijn leden, publicaties en de organisatie te kunnen waarborgen. In dit opzicht is met name de procedure voor het omgaan met minderheidsstandpunten van de leden van belang. Door deze procedure kunnen leden een afwijkende mening innemen waardoor een open discussie binnen de commissie wordt ondersteund en de geloofwaardigheid en onafhankelijkheid van de COGEM worden versterkt. De geloofwaardigheid en onafhankelijkheid van de COGEM worden verder versterkt door het feit dat de COGEM ongeraagd adviezen en signaleringen uit kan brengen over onderwerpen of thema's die de commissie relevant vindt.

Uit het statusrapport blijkt dat, hoewel de COGEM over een beperkte ondersteunende staf beschikt, er een grote hoeveelheid werk wordt geproduceerd in uiteenlopende gebieden. Noemenswaardig is dat de subcommissies zesmaal per jaar bijeenkomen en het meeste werk per e-mail behandelen. In het statusrapport wordt de output van de COGEM in detail gekwantificeerd. De commissie adviseert over alle types van vergunningaanvragen: ingeperkt gebruik, doelbewuste introducties en markttoelatingen. Daarnaast bestrijken de signaleringen ethische en maatschappelijke vraagstukken. De COGEM organiseert symposia, en vertegenwoordigers van de COGEM zijn aanwezig bij (inter)nationale bijeenkomsten om op de hoogte te blijven van de laatste ontwikkelingen, het (inter)nationale netwerk uit te breiden en de mogelijkheden van samenwerking te onderzoeken. Veel energie wordt gestoken in de communicatie met stakeholders, terwijl de COGEM vermijdt betrokken te raken bij het maatschappelijke debat over ggo's. Verder laat de COGEM onderzoeksprojecten uitvoeren ter ondersteuning van haar werkzaamheden. In de afgelopen periode zijn negentien onderzoeksrapporten uitgebracht. De evaluatiecommissie stelt met voldoening vast dat deze onderwerpen verder gaan dan alleen kwesties in de groene biotechnologie, en betrekking hebben op relevante vraagstukken in alle gebieden binnen het werkveld van de COGEM.

Het statusrapport eindigt met een lijst van controverses en belangwekkende zaken die de COGEM is tegengekomen in de laatste drie en een half jaar, en hoe de COGEM heeft gereageerd op deze problemen.

Hoewel het rapport het functioneren van de COGEM zeer goed beschrijft, zijn enkele kanttekeningen op zijn plaats. Het rapport geeft weinig informatie over de exacte inhoud van

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de dossiers die de COGEM behandelt en de mogelijke problemen die ontstaan bij de verwerking van de dossiers. Het is grotendeels onduidelijk welke dossiers het meest controversieel waren en hoe de discussie over deze kwesties verliep binnen de COGEM. Bovendien blijkt uit het statusrapport niet welke adviezen of signaleringen de meeste tijd en arbeid vergden, welke publicaties als zeer belangrijk werden aangemerkt door de COGEM leden, en welke publicaties tot conclusies of informatie hebben geleid die van belang zijn voor toekomstige COGEM publicaties.

2.2 INTERVIEWS

De evaluatiecommissie heeft acht interviews afgenomen met vertegenwoordigers van stakeholders, het ministerie van IenM, en COGEM leden. De volgende COGEM leden zijn geïnterviewd; dr. Raoul de Groot (subcommissie Medisch Veterinair), prof. dr. Rob Hoeben (subcommissie Medisch Veterinair), dr. Jan Kooter (subcommissie Landbouw), prof. dr. Sabine Roeser (subcommissie Ethiek en Maatschappelijke Aspecten), prof. dr. Nico van Straalen (subcommissie Landbouw), en ir. Huib de Vriend (subcommissie Ethiek en Maatschappelijke Aspecten). De interviews met de COGEM leden zijn uitgevoerd in twee groepssessies. Drs. ing. Peter Torbijn en dr. Dick Jung vertegenwoordigden het ministerie van IenM, afdeling Milieuveiligheid en Risicomanagement, in het interview met de evaluatiecommissie. Ir. Jan Wisse, secretaris van de Niaba, vertegenwoordigde de Nederlandse Biotechnologie sector. Vanuit Greenpeace werd ggo-campaigner drs. Herman van Bekkem geïnterviewd. Voor de Nederlandse Land- en Tuinbouworganisatie gaf Jaap van Wenum, beleidsadviseur gewasproductie en milieu, zijn visie op de COGEM. Vanuit het parlement nam mevrouw Janneke Snijder-Hazelhoff (VVD), Tweede Kamerlid en voorzitter van de vaste commissie voor Infrastructuur en Milieu, plaats tegenover de evaluatiecommissie. Tevens werd prof. dr. André Knottnerus, voorzitter van de Wetenschappelijke Raad voor de Regering (WRR) en voormalig voorzitter van de Gezondheidsraad, door de evaluatiecommissie geïnterviewd.

De evaluatiecommissie wil alle geïnterviewden bedanken voor hun bereidheid om deel te nemen aan het evaluatieproces. De Engelstalige verslagen van de interviews kunt u vinden in het Engelstalige deel van het evaluatierapport (§ 2.2, blz 8 – 20).

3. DIAGNOSE EN CONCLUSIES

3.1 DIAGNOSE

3.1.1 WETENSCHAPPELIJKE KWALITEIT EN OUTPUT

De wetenschappelijke kwaliteit van de adviezen en signaleringen van de COGEM is hoog en voldoet aan de eisen die hieraan gesteld worden. Dit blijkt ook uit het feit dat de adviezen en signaleringen van de COGEM internationaal zeer gewaardeerd worden en vaak gebruikt worden als een voorbeeld van hoge wetenschappelijke kwaliteit en pro-activiteit. De procedures (zoals in het statusrapport beschreven) die de COGEM hanteert om de kwaliteit van haar werk te waarborgen blijken effectief te zijn.

Ondanks het beperkte aantal secretariaatsmedewerkers, produceert de COGEM een grote hoeveelheid werk op uiteenlopende terreinen. Deze werkzaamheden worden verricht volgens regels en procedures die aangepast blijken te zijn aan de belangrijkste kwesties die spelen binnen een wetenschappelijke commissie die de overheid adviseert over een maatschappelijk controversieel onderwerp.

De evaluatiecommissie wijst erop dat een discussie gaande is over de mate waarin mogelijke indirecte 'effecten' als gevolg van landbouwpraktijken in de risicobeoordeling van genetisch gemodificeerde gewassen moeten worden meegenomen. Dit is grotendeels een politieke kwestie en een besluit over deze kwestie moet in de EU worden genomen. Echter, in haar overwegingen moet de COGEM de mogelijke indirecte gevolgen voor het milieu als gevolg van landbouwpraktijken of het teeltmanagementsysteem, en de wisselwerking met andere regelgeving, zoals die betreffende gewasbeschermingsmiddelen, niet uit het oog verliezen.

SCENARIOSTUDIES

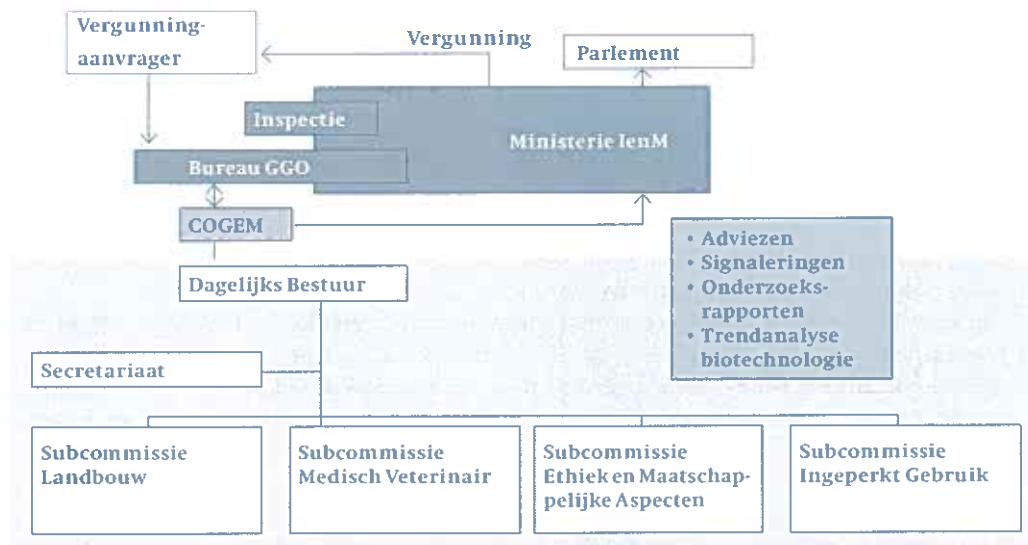
De evaluatiecommissie heeft twijfels over de recente gezamenlijke publicatie met het Rathenau Instituut "Mondiale Motivatie of Europese Eigenheid? Vier scenario's voor ggo's in de Europese landbouw". De scenariostudie is teveel gericht op beleidsmakers, waardoor het nut van de studie voor het vormgeven van de discussie over mogelijke toekomstige ontwikkelingen beperkt blijft. Bovendien is de studie meer een extrapolatie van bestaande trends dan een toekomstverkenning. Dit is deels inherent aan de gekozen aanpak en de 'drivers' die voor de ontwikkeling van de scenario's zijn geselecteerd. Hierdoor worden geen scenario's besproken die fundamenteel verschillen van de belangrijkste trends op dit moment. Scenario's die bijvoorbeeld ontbreken zijn een scenario waarbij ggo's geen rol in de voedselvoorziening spelen in Europa of andere delen van de wereld, of een scenario waarin het beleid ggo's actief stimuleert om de publieke aversie in Europa af te laten nemen en het ggo-areaal te laten toenemen.

3.1.2 ORGANISATIE EN SAMENSTELLING VAN DE COGEM

In het algemeen is de organisatie en samenstelling van de COGEM toegesneden op de taken en uitdagingen waarvoor een wetenschappelijk adviesorgaan zoals de COGEM staat. De COGEM herbergt een grote verscheidenheid aan verschillende expertises en heeft procedures opgesteld voor minderheidsstandpunten, wat garant staat voor een open debat binnen de commissie. Daarnaast wordt de onafhankelijkheid en geloofwaardigheid van de COGEM gewaarborgd door procedures om mogelijke belangenconflicten te voorkomen.

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Figuur 1: Rol en positie COGEM



INTERNE SAMENHANG

De organisatie van de COGEM in verschillende subcommissies onder toezicht van een Dagelijks Bestuur en ondersteunt door een professioneel secretariaat lijkt op de aard van de COGEM werkzaamheden toegesneden te zijn. Een nadeel van de noodzakelijke opsplitsing in verschillende subcommissies is dat het contact tussen leden van verschillende subcommissies beperkt is. De enige gelegenheid voor leden om elkaar in levende lijve te ontmoeten is de jaarlijkse plenaire vergadering. Zoals ook is gebleken uit de groepsinterviews met COGEM leden, kan meer interactie tussen de verschillende subcommissieleden tot nieuwe inzichten en een verdere verbetering van de activiteiten van de COGEM leiden. De interne samenhang kan worden versterkt door het opstellen van gezamenlijke publicaties en het organiseren van gezamenlijke activiteiten, zoals symposia.

SUBCOMMISSIE ETHIEK EN MAATSCHAPPELIJKE ASPECTEN

In tegenstelling tot de meeste andere wetenschappelijke adviesorganen in de verschillende EU-lidstaten heeft de COGEM, naast subcommissies die milieurisicoanalyses uitvoeren en technisch advies geven, ook een subcommissie die het kabinet informeert over de maatschappelijke en ethische aspecten van ggo's. Anders dan in bijvoorbeeld Frankrijk, is de subcommissie Ethiek en Maatschappelijke Aspecten niet samengesteld uit vertegenwoordigers van stakeholdergroepen, maar uit deskundigen die zijn aangesteld op basis van hun expertise en kennis van het publieke ggo-debat en haar deelnemers. Daarnaast werkt de subcommissie niet casusgewijs, maar informeert de overheid over algemene en transversale kwesties. De werkzaamheden en publicaties van deze subcommissie, zoals de signalering over criteria voor een sociaal-economische beoordeling van ggo's, zijn van hoge kwaliteit. De evaluatiecommissie merkt echter op dat de zichtbaarheid van deze subcommissie verbeterd moet worden. Sommige stakeholders zijn niet goed op de hoogte van de activiteiten van deze subcommissie of vinden de wettelijke rol en de taken van de subcommissie onduidelijk. Dit vraagt om een betere uitleg van de taken van de subcommissie Ethiek en Maatschappelijke Aspecten en hoe deze taken verschillen van die van de andere technische subcommissies.

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SAMENSTELLING VAN DE COGEM

De COGEM heeft een goede samenstelling wat betreft de expertise van de leden. De commissie herbergt een grote verscheidenheid aan verschillende wetenschappelijke expertise en disciplines. In het geval dat een benodigde specifieke expertise niet aanwezig is binnen de COGEM, worden externe deskundigen aangetrokken. De procedures waarmee in de COGEM mogelijke belangenconflicten voorkomen worden, lijken doeltreffend te zijn.

Met betrekking tot de subcommissie Landbouw wijst de Evaluatiecommissie erop dat kennis en expertise over agronomie en de landbouwpraktijk van zeer groot belang is. De betekenis van deze discipline zal in de toekomst verder toenemen door de verhoogde aandacht voor de mogelijke indirecte effecten van genetisch gemodificeerde gewassen en de discussie daaromheen. De evaluatiecommissie erkent dat door de aanwezigheid van twee of drie leden met kennis van dit onderwerp, agronomische expertise aanwezig is in de subcommissie Landbouw. Echter, deze discipline is niet formeel aanwezig in de line-up van de subcommissie. Veranderingen in het ledenbestand zouden kunnen leiden tot het verlies van voldoende expertise in deze belangrijke discipline. Daarom acht de Evaluatiecommissie het noodzakelijk om een theoretische productie-ecoloog of agronoom te benoemen in de COGEM.

De evaluatiecommissie benadrukt het belang van een evenwichtige verdeling tussen vrouwen en mannen binnen het ledenbestand van de COGEM. Met een verhouding van ongeveer 1:3 voldoet de COGEM hier niet aan. Zoals vermeld in het Statusrapport is de werving van vrouwelijke deskundigen moeilijk. Het aantal vrouwelijke wetenschappers die een tenure track volgen aan een Nederlandse universiteit is nog steeds erg laag en er is zeer veel vraag naar vrouwelijke hoogleraren door organisaties zoals de COGEM, die ernaar streven om hun 'gender-balance' te verbeteren. De evaluatiecommissie erkent deze feiten. Echter, een beter evenwicht tussen de seksen, zonder daarbij afbreuk te doen aan de kwaliteit van de leden, kan meer verscheidenheid toevoegen aan de COGEM rapporten en publicaties. Daarom is het van belang dat de COGEM initiatieven ontwikkelt om meer vrouwelijke wetenschappers en deskundigen aan te trekken.

De evaluatiecommissie merkt op dat de subcommissie Ingeperkt Gebruik in de afgelopen jaren niet bijeen is geroepen. Omdat deze subcommissie slapende lijkt te zijn, zou de COGEM moeten overwegen om deze op te heffen.

3.1.3 ROL EN POSITIE COGEM

De evaluatiecommissie merkt op dat de COGEM een aantal activiteiten samen met het Rathenau Instituut uitvoert. Ze wijst erop dat beide organisaties verschillende taken en rollen hebben. Het Rathenau Instituut organiseert debatten over vraagstukken en dilemma's in wetenschap en technologie om de meningsvorming van het publiek en de politiek over wetenschap en technologie te bevorderen. Het Rathenau Instituut heeft als taak om onderzoek te verrichten naar de maatschappelijke gevolgen van technische en wetenschappelijke ontwikkelingen, terwijl de taak van de COGEM is om de regering te informeren over ethische en maatschappelijke vraagstukken in verband met genetische modificatie.

Samenwerking tussen deze twee organisaties kan zeer waardevol zijn. Echter, de COGEM moet zich blijven richten op de risicobeoordeling en het verstrekken van informatie over sociaal-ethische aspecten van genetische modificatie aan de overheid, en moet oppassen haar activiteiten niet te mengen met de activiteiten van het Rathenau Instituut. In gezamenlijke projecten met organisaties zoals het Rathenau Instituut ligt de kracht van de COGEM in de bijdrage van gegevens en informatie voor onderzoek of het debat.

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SOCIAAL-ECONOMISCHE BEOORDELING VAN GGO'S

In de EU is een discussie gaande over de vraag of de beoordeling van sociaal-economische aspecten deel moet uitmaken van de toelatingsprocedure voor genetisch gemodificeerde gewassen. De huidige vergunningsprocedure is uitsluitend gebaseerd op een milieuveiligheidsbeoordeling. Op verzoek van de toenmalige minister van VROM heeft de COGEM criteria ontwikkeld voor de beoordeling van de duurzaamheid van gg-gewassen. Het politieke debat in Europa over een sociaal-economische beoordeling van genetisch gemodificeerde gewassen in de vergunningsprocedure is nog maar net begonnen en het is onduidelijk of en wanneer de EU tot een dergelijke beoordeling zal overgaan.

De evaluatiecommissie is van mening dat de COGEM signalering over sociaal-economische criteria een zeer waardevolle bijdrage levert aan het opzetten van een dergelijke beoordelingsprocedure. Echter, het uitvoeren van een dergelijke beoordeling strookt niet met de taken, rol en expertise van de COGEM. De COGEM zou wel kunnen bijdragen aan een sociaal-economische analyse door informatie te leveren, maar andere organisaties of consortia met ervaring op het gebied van economische en maatschappelijke evaluaties zijn meer geschikt voor het uitvoeren van een dergelijke beoordeling.

3.1.4 INTERNATIONALE ROL

De evaluatiecommissie merkt op dat de COGEM een voortrekkersrol heeft in Europa. Zoals eerder aangegeven, staan de adviezen en signaleringen internationaal hoog aangeschreven. De COGEM wordt gezien als een leidende internationale autoriteit en als een voorbeeld voor andere adviesorganen. Verschillende kwesties die de COGEM onder de aandacht heeft gebracht, staan nu op de agenda in Brussel.

SAMENWERKING

Echter, door de toenemende werkdruk kan de oplettendheid van de leden verminderen, wordt het secretariaat overvraagd en kan de wetenschappelijke kwaliteit van de productie van de COGEM in gevaar komen. Deze problematiek is niet uniek voor de COGEM; het overgrote deel van de Europese nationale adviesorganen wordt met hetzelfde probleem geconfronteerd. Naast hun andere taken beoordelen al deze nationale adviesorganen dezelfde vergunningsaanvragen voor toelating van genetisch gemodificeerde gewassen op de Europese markt. Een mogelijke oplossing voor de werkdruk zou daarom gevonden kunnen worden in het versterken van de internationale samenwerking tussen de nationale adviesorganen voor bioveiligheid. Het doel van deze samenwerking zou zijn om de onderlinge coördinatie te verbeteren en om de overlap van werkzaamheden en activiteiten van de verschillende adviesorganen zoveel mogelijk te beperken.

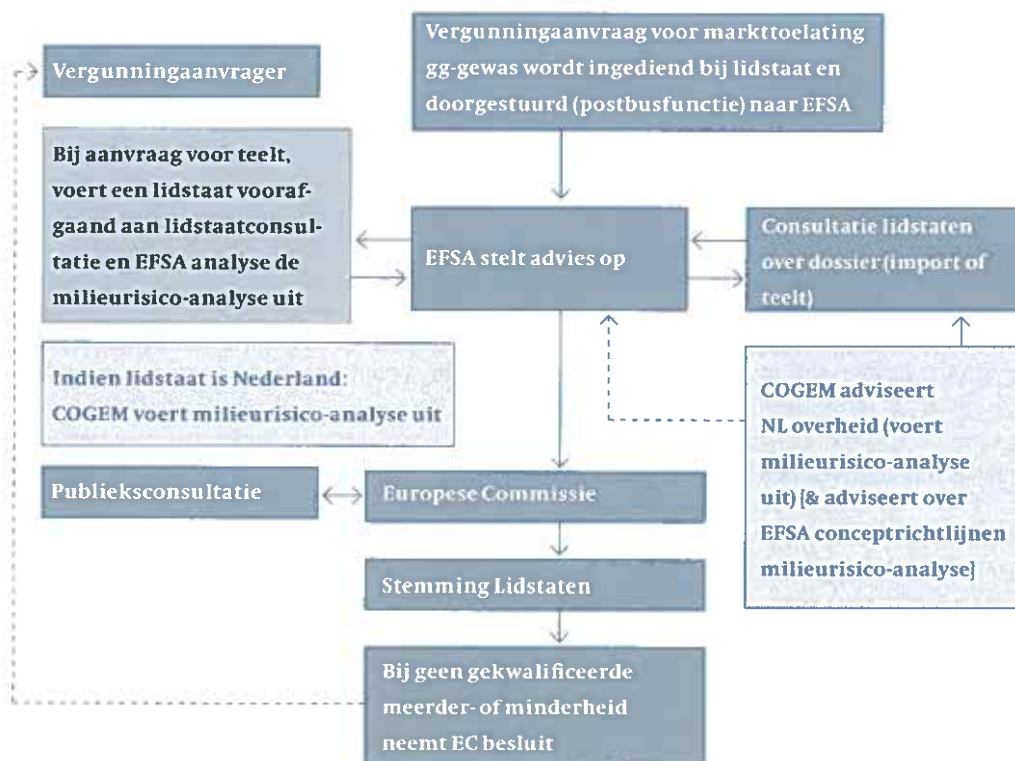
Verbetering van de internationale samenwerking heeft niet alleen betrekking op de nationale adviescommissies, maar ook op het 'GMO panel' van de Europese Autoriteit voor Voedselveiligheid (EFSA). Er kan grote winst geboekt worden door een verbetering van de communicatie en coördinatie tussen de EFSA en de nationale adviesorganen. Echter, de evaluatiecommissie merkt op dat de communicatie met de EFSA soms moeizaam gaat en dat inzichten van nationale adviesorganen niet altijd door de EFSA gewaardeerd lijken te worden. Anderzijds lijken de nationale adviesorganen soms de wetenschappelijke adviezen of risicobeoordelingsprocedures van de EFSA in twijfel te trekken.

OPTIES TER VERBETERING

Mogelijke opties om de internationale samenwerking te verbeteren zijn: 1) het zoeken naar mogelijkheden om de werklast voor routinedossiers te verdelen tussen de nationale commissies; en 2) het verenigen van de krachten van vergelijkbare nationale adviescommissies om de EFSA onder druk te zetten om a) meer transparant in haar acties te worden, b) de

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Figuur 2: Rol en taken COGEM met betrekking tot de Europese vergunningsprocedure markttoelating ggo's



communicatie aanzienlijk te verbeteren, c) het werk uitgevoerd door de nationale adviescommissies beter mee te nemen in haar werk en meer te waarderen, en d) dubbel werk te voorkomen. Deze actiepunten moeten door beleidsmakers in de EU-lidstaten ondersteund en opgepakt worden.

3.1.5 COMMUNICATIE

Het gezag en de geloofwaardigheid van de COGEM hangt af van de wetenschappelijke kwaliteit van haar publicaties, en het feit dat de COGEM niet door de stakeholders of het publiek ervaren wordt als een organisatie met een belang bij genetische modificatie. De communicatiestrategie van de COGEM is afgestemd op handhaving van het gezag en de geloofwaardigheid van de organisatie. De COGEM opereert niet vanuit een 'ivoren toren', maar is erin geslaagd om zichtbaar en transparant te zijn, zonder daarbij in de valkuil te stappen van een communicatiestrategie die de COGEM neerzet als een partijdige instantie waardoor haar geloofwaardigheid te gronde gericht zou worden. In haar communicatie beoogt de COGEM volledige transparantie. COGEM publicaties zijn toegankelijk via de website en de vergaderingen van de subcommissies zijn openbaar.

COMMUNICATIESTRATEGIE

Uit de evaluatie van 2007 kwam als aanbeveling dat de COGEM haar communicatie, profilering en zichtbaarheid in het publieke debat moest versterken. De huidige evaluatiecommissie is het op dit punt niet met haar voorganger eens. De evaluatiecommissie staat achter het

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standpunt van het Dagelijks Bestuur van de COGEM om terughoudend te zijn met betrekking tot het publieke debat over ggo's.

De taak van de COGEM is het geven van wetenschappelijk advies en het informeren van de Nederlandse regering over ethische en maatschappelijke vraagstukken rondom genetische modificatie. Om deze taak naar behoren uit te voeren is het van uiterst belang dat de COGEM door publiek, beleidsmakers en stakeholders gezien wordt als gezaghebbend en geloofwaardig. Haar gezag en geloofwaardigheid is gebaseerd op de kwaliteit van haar adviezen en signaleringen, en het feit dat de COGEM niet als een organisatie met een gevestigd belang wordt beschouwd. Het is niet de taak van de COGEM het publieke debat of de dialoog met stakeholders te initiëren, te faciliteren of om eraan deel te nemen. Een dergelijke rol zou kunnen leiden tot verwarring bij stakeholders en zou de geloofwaardigheid van de COGEM ernstig in gevaar kunnen brengen. Het is onvermijdelijk, dat het zou lijken alsof de COGEM een standpunt inneemt over ethische en maatschappelijke vraagstukken, of dat de COGEM gedwongen zou worden een standpunt in te nemen, waardoor zij een deelnemer wordt aan het debat. De COGEM moet daarom haar rol in het publieke debat beperken tot het geven van informatie. De focus van de communicatiestrategie van de COGEM moet liggen op het verschaffen van de grootst mogelijke transparantie over de COGEM, haar activiteiten en publicaties, met het oog op het verkrijgen en behouden van het vertrouwen van het publiek.

ROL VAN DE LEDEN

De terughoudende houding van de COGEM aangaande communicatie moet weerspiegeld worden door haar leden. Verschillende COGEM leden zijn actief op het gebied van genetische modificatie en kunnen daardoor belangen hebben. Om eventuele belangenverstrengelingen te voorkomen zijn effectieve protocollen en procedures in gebruik binnen de COGEM. Desondanks ligt de schijn van belangenverstrengeling op de loer. Een geïnterviewde stakeholder was verbaasd en in verwarring gebracht door de vele verschillende rollen die de voorzitter van de subcommissie Landbouw in het ggo-debat lijkt te hebben. De COGEM moet daarom leden kiezen met zo min mogelijk 'verdachte' affiliaties. Verder moeten de leden van de COGEM zich bewust zijn van hun bijzondere positie en voorkomen dat zij te gekleurd zijn in het publieke debat.

Het Dagelijks Bestuur heeft de centrale en cruciale rol om de neutraliteit en onafhankelijkheid van de COGEM te garanderen in alle omstandigheden, de transparantie te bevorderen, de consistentie van adviezen en signaleringen te bewaken en een uitstraling te bevorderen die zich niet richt op publieke perceptie maar op wetenschappelijke integriteit.

COGEM PUBLICATIES

De evaluatiecommissie wijst erop dat de COGEM publicaties kunnen worden onderverdeeld in drie categorieën: 1) Adviezen, waarin de COGEM op basis van technisch-wetenschappelijke overwegingen een advies geeft, en 2) Signaleringen, waarin de COGEM de minister en beleidsmakers informeert over nieuwe technologische ontwikkelingen en hun implicaties en over de ethische en maatschappelijke argumenten en aspecten die spelen rond toepassingen van genetische modificatie, om daarmee een evenwichtige besluitvorming te faciliteren en 3) Onderzoeksrapporten in opdracht van de COGEM. De inhoud van de onderzoeksrapporten is, in tegenstelling tot de eerste twee categorieën, niet de verantwoordelijkheid van de COGEM. Onderzoeksrapporten worden aan de minister aangeboden onder begeleiding van een signalerende of adviserende brief, die de mening van de COGEM beschrijft of die aangeeft welke informatie COGEM van belang acht voor de politiek en het beleid.

De verschillen in de drie categorieën COGEM publicaties lijken tot verwarring te leiden bij sommige stakeholders, wat wellicht ook te maken heeft met het feit dat niet alle stakeholders zich bewust zijn van de afwijkende rol van de subcommissie Ethiek en Maatschappe-

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lijke Aspecten ten opzichte van de technische subcommissies. Deze verwarring kan mogelijk worden opgelost door in de communicatie een duidelijker onderscheid te maken tussen de verschillende soorten publicaties.

ZICHTBAARHEID EN ONAFHANKELIJKHEID

Een ander belangrijk punt is de zichtbaarheid van de COGEM. De COGEM is primair het adviesorgaan van het ministerie van IenM. Alle publicaties worden aangeboden aan de staatssecretaris van IenM en het is aan dit ministerie om te beslissen of publicaties aan het parlement worden gestuurd. Dit besluit zal onvermijdelijk worden beïnvloed door beleidsdoelstellingen en andere politieke overwegingen. In de Wet milieubeheer staat dat de COGEM de minister van IenM en andere betrokken ministers adviseert en informeert. Daarmee is het onduidelijk of de COGEM haar adviezen en signaleringen gelijktijdig naar andere instellingen kan sturen, zoals het parlement.

De mogelijkheid om specifieke adviezen en signaleringen aan zowel het parlement als de minister te zenden zou niet alleen de zichtbaarheid van de COGEM, maar ook haar status als een onafhankelijk wetenschappelijk adviesorgaan, versterken.

3.1.6 DEFINITIE VAN GGO'S

De evaluatiecommissie wijst erop dat de huidige juridische definitie van een ggo in de EU achterhaald raakt door voortschrijdende wetenschappelijke inzichten en ontwikkelingen. Dit is waarschijnlijk inherent aan alle wettelijke definities die te maken hebben met wetenschappelijke kwesties. Wetenschap is dynamisch en het vinden van een duidelijke definitie die toepasbaar zal zijn over een langere periode is een illusie. Aan de andere kant kan een vage of vervagende juridische definitie tot aanzienlijke problemen in de toelatingsprocedure van ggo's leiden.

De huidige onduidelijke (wettelijke) definitie van een ggo lijkt de COGEM niet al te veel te hinderen bij haar werkzaamheden. De wetenschappelijke expertise en het gezonde verstand binnen de COGEM maakt het mogelijk om van geval tot geval tot een acceptabele interpretatie te komen. Blijkbaar is de COGEM in staat om haar expertise en gezag te gebruiken om de nodige flexibiliteit in de interpretatie van de ggo-regelgeving te bewerkstelligen.

Niettemin kan een pro-actieve houding van organisaties als de COGEM resulteren in een aanpassing van de wetenschappelijke ggo-definitie, mogelijk resulterend in de noodzakelijke wettelijke aanpassing. In de afgelopen jaren heeft de COGEM goed werk verricht bij de beoordeling van nieuwe technologieën in de biotechnologie, de gevolgen van deze nieuwe technologieën voor de ggo-regelgeving en het initiëren van de discussie over de interpretatie en eventuele aanpassing van de EU-wetgeving inzake ggo's. Deze initiatieven worden internationaal zeer gewaardeerd, en hebben geleid tot de instelling van een EU werkgroep over nieuwe technologieën in de plantenbiotechnologie in relatie tot de ggo-regelgeving. Deze pro-actieve houding van de COGEM moet worden voortgezet in de toekomst.

3.1.7 RODE, WITTE EN GROENE BIOTECHNOLOGIE

De evaluatiecommissie merkt op dat het publieke debat over ggo's wordt gedomineerd door kwesties in landbouw en voeding. Alles wat te maken heeft met 'groene' biotechnologie wordt onder de loep gelegd en betwist door de verschillende stakeholders. Echter, toepassingen van genetische modificatie en biotechnologie breiden zich uit naar alle gebieden van de samenleving. Deze technieken hebben hun weg gevonden naar de medische sector waar nieuwe geneesmiddelen en klinische behandelingen zoals gentherapie zijn ontwikkeld, en ook naar de industriële sector, om enzymen, antibiotica en chemicaliën te produceren. Veel

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van deze producten worden, grotendeels onopgemerkt en onbetwist, in het dagelijkse leven gebruikt, zoals enzymen in wasmiddelen geproduceerd door genetisch gemodificeerde micro-organismen. Andere producten zijn van vitaal belang voor de gezondheidszorg, zoals antibiotica, vaccins, immunosuppressieve of antitumor-geneesmiddelen. In dit opzicht is het weinig verrassend dat het merendeel van de ggo-vergunningaanvragen in Nederland laboratoriumexperimenten betreffen gericht op een beter begrip van ziekten, de ontwikkeling van medische en veterinaire toepassingen, fundamenteel onderzoek, of grootschalige productie van biomaterialen. Veldexperimenten of markttoelatingen van genetisch gemodificeerde gewassen vertegenwoordigen slechts een klein deel van het totale aantal vergunningaanvragen.

Desondanks is er een sterke bias in de media-aandacht en het publieke debat naar 'groene' biotechnologie, ten koste van de 'rode' en 'witte' biotechnologie. De COGEM is erin geslaagd om deze valkuil te vermijden. Haar adviezen, signaleringen en onderzoeksinspanningen zijn gelijkmatig verdeeld over de verschillende biotechnologievelden. In haar communicatie-activiteiten zou de COGEM dit punt moeten benadrukken, om de stakeholders bewust te maken van de eenzijdigheid in de discussie over genetische modificatie, en aan te tonen dat het werkveld en de activiteiten van de COGEM veel breder zijn dan de 'groene' biotechnologie alleen.

3.1.8 REGULERING EN DEREGULERING

In de ggo-regelgeving moet er een evenwicht zijn tussen het waarborgen van de veiligheid van mens en milieu, en het niet onnodig belemmeren van wetenschappelijk onderzoek en de ontwikkeling van potentiële nuttige toepassingen. Bovendien is een transparante regelgeving met zo min mogelijk administratieve rompslomp belangrijk voor het verwerven en behouden van het draagvlak voor de wetgeving en de opgelegde veiligheidsmaatregelen in de wetenschappelijke gemeenschap en de industrie. Adviesorganen, zoals de COGEM, hebben daarom mede als taak om kansen te identificeren, en de interesse van beleidsmakers te wekken, voor vermindering en vereenvoudiging van de regelgeving zonder dat daarbij de veiligheid in het geding komt.

In de afgelopen jaren heeft de COGEM verschillende adviezen uitgebracht over deregulering van de Nederlandse wetgeving op het gebied van ingeperkt gebruik van ggo's (regelgeving voor experimenten in laboratoria, kassen, diervverblijven etc.). Het ministerie van IenM is bezig met de vereenvoudiging van de Nederlandse ingeperkt gebruik regelgeving door aanpassing van het Besluit GGO. De doelstellingen van het ministerie zijn om de transparantie te vergroten en het vergunningsproces te vereenvoudigen, waardoor een verlaging van de administratieve lasten voor de aanvragers en de vergunningverlenende instanties bereikt moet worden. De eerdere adviezen van de COGEM over deze kwestie lijken een belangrijke rol te spelen bij de herziening van het Besluit. De initiatieven van de COGEM om aan te dringen op aanpassing van de regelgeving worden gewaardeerd door de evaluatiecommissie. De COGEM zou moeten proberen beleidsmakers te interesseren voor het versnellen van het proces van aanpassing van de regelgeving.

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3.2 CONCLUSIES

- De kwaliteit van het werk van de COGEM is uitstekend en voldoet aan de eisen die hieraan gesteld worden.
- De COGEM staat internationaal hoog aangeschreven. Haar adviezen en signaleringen worden op internationaal niveau zeer gewaardeerd en vaak gebruikt als voorbeelden van hoge wetenschappelijke kwaliteit en pro-activiteit.
- Ondanks haar beperkte middelen ontvouwt de COGEM veel verschillende activiteiten, waarbij ze kans ziet om een groot aantal publicaties te publiceren in verschillende aandachtsgebieden.
- De organisatie en de samenstelling van de COGEM is goed en opgewassen tegen de taken en uitdagingen van de COGEM.
- De interne samenhang en met name de communicatie tussen leden van de verschillende subcommissies, kan verbeterd worden.
- De evaluatiecommissie onderschrijft de huidige terughoudende communicatiestrategie van de COGEM.
- De verschillende types en aard van COGEM publicaties lijken soms te leiden tot verwarring bij stakeholders.
- Sommige stakeholders lijken onvoldoende op de hoogte te zijn van de wettelijke rol van de COGEM om de regering te informeren over ethische en maatschappelijke aspecten verbonden aan genetische modificatie en de activiteiten van de COGEM op dit gebied.
- Internationale samenwerking met adviesorganen voor bioveiligheid uit andere EU-lidstaten en de EFSA kan leiden tot het verlagen van de werkdruk en tot verhoging van de efficiëntie en de output van de COGEM.
- De COGEM moet vasthouden aan haar huidige rol, taken en activiteiten. Een eventuele toekomstige vraag om ggo's op hun sociale en economische aspecten te beoordelen of om de maatschappelijke gevolgen van technologieën te onderzoeken moet worden afgewezen. Dergelijke activiteiten maken geen deel uit van de kernactiviteiten van de COGEM, en kunnen haar geloofwaardigheid en wetenschappelijke autoriteit in gevaar brengen.
- De COGEM leden moeten zich bewust zijn van hun bijzondere positie en van de mogelijke schijn van belangenverstrengeling. Ze moeten hiermee rekening houden indien ze zich in de media of in de publieke discussie uit laten over vraagstukken op het werkterrein van de COGEM.
- Agronomische expertise is aanwezig binnen de COGEM subcommissie Landbouw. In weerwil van het toenemende belang van 'agronomie' of 'productie-ecologie' is het echter geen formeel onderdeel van de expertise binnen deze subcommissie.
- De man-vrouwverhouding in de COGEM moet worden verbeterd, zonder afbreuk te doen aan de hoge kwaliteit van het ledenbestand.
- De onafhankelijkheid en de zichtbaarheid van de COGEM kan worden versterkt door belangrijke adviezen en signaleringen rechtstreeks aan het parlement aan te bieden.

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De evaluatiecommissie beoordeelt de kwaliteit van de COGEM activiteiten en publicaties als hoog. Bovendien is de evaluatiecommissie van mening dat de COGEM de juiste taken uitvoert. Met andere woorden, het antwoord op de vragen "heeft de COGEM de juiste dingen gedaan?" en "heeft de COGEM deze dingen goed gedaan?" is ja. Bijgevolg ziet de evaluatiecommissie geen redenen voor radicale veranderingen in de taken, organisatie of procedures van de COGEM.

Echter, een organisatie als de COGEM moet er voortdurend naar streven om de kwaliteit van haar activiteiten te verbeteren. Naar aanleiding hiervan en in het licht van de voortgaande veranderingen in het werkveld van de COGEM, doet de evaluatiecommissie de volgende aanbevelingen ter verdere versterking van de activiteiten van de COGEM:

1. **Publicaties van breder belang aanbieden aan het parlement.** Op dit moment biedt de COGEM haar publicaties aan de staatssecretaris van IenM aan. Het is vervolgens aan het ministerie om te beslissen of COGEM publicaties naar het parlement worden doorgestuurd. Door haar publicaties gelijktijdig aan de staatssecretaris en aan het parlement aan te bieden, kan de COGEM haar onafhankelijke positie versterken en haar zichtbaarheid verhogen. Het parlement wordt immers in de gelegenheid gesteld om kennis te nemen van COGEM adviezen en signaleringen los van mogelijke politieke of beleidsmatige overwegingen van de regering.
2. **De huidige communicatiestrategie van de COGEM voortzetten.** In 2007 heeft de toenmalige visitatiecommissie gesteld dat de COGEM zich actiever in het publieke debat moest opstellen. De huidige evaluatiecommissie is het met haar voorgangers oneens. Ze onderschrijft de visie van het Dagelijks Bestuur van de COGEM dat om beschouwd te worden als een onafhankelijk gezaghebbend adviesorgaan, het noodzakelijk is dat de COGEM niet gezien wordt als een partij in het publieke debat met haar eigen standpunt of belangen. Daarom moet de COGEM een ingetogen communicatiestrategie volgen, waarbij de nadruk ligt op het verstrekken van wetenschappelijk verantwoorde informatie.
3. **Een beter onderscheid aanbrengen tussen de verschillende soorten COGEM publicaties.** De COGEM brengt verschillende types van publicaties uit. Dit betekent dat verschillende publicaties over hetzelfde onderwerp een andere boodschap kunnen bevatten. De evaluatiecommissie merkt op dat deze verschillen logisch zijn en een gevolg van de verschillende aard van de publicaties. De inhoud van een onderzoeksrapport is de verantwoordelijkheid van de auteurs en niet van de COGEM, en een signalering met een overzicht van de argumenten in het publieke debat is iets anders dan het geven van advies over mogelijke milieurisico's. De evaluatiecommissie is echter van mening dat deze verschillen beter uitgelicht moeten worden. Mogelijk kan dit bereikt worden door een andere lay-out van de diverse publicaties.
4. **Versterken van de samenwerking met andere internationale adviesorganen inzake bioveiligheid.** De zusterorganisaties van de COGEM in de andere lidstaten staan voor dezelfde problemen en uitdagingen, en adviseren over dezelfde EU vergunningaanvragen voor markttoelatingen van ggo's. De toenemende werkdruk zet de beperkte middelen waarover de verschillende adviesorganen beschikken steeds verder onder druk. Samenwerking op het gebied van de risicobeoordeling van markttoelatingen en het delen van middelen en informatie biedt de adviesorganen mogelijkheden om de efficiëntie te verhogen en de werkdruk te verlagen. Bovendien kan samenwerking de positie van de nationale adviesorganen ten opzichte van de EFSA versterken, zodat ze beter gehoord en als volwaardige en gerespecteerde partner geaccepteerd worden.
5. **Versterken van de samenwerking met de EFSA.** De EFSA heeft een centrale positie in het EU vergunningsproces. Zowel de EFSA als de COGEM (en de andere nationale adviesorganen) zouden veel kunnen winnen met een betere onderlinge coördinatie, en een verbeterde discussie en gedachte-uitwisseling over de risicobeoordeling van

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ggo's. Dit vereist zowel inspanningen van de COGEM als de EFSA. Echter, de evaluatiecommissie merkt op dat EFSA hier minder voor openstaat dan gewenst is. De COGEM moet dit onder de aandacht van de Nederlandse beleidsmakers brengen en aandringen op een initiatief van de Nederlandse overheid om een gedragsverandering van de EFSA te bewerkstelligen.

6. **Versterken van de samenwerking met nationale organisaties, zonder de specifieke rol of 'niche' van de COGEM uit het oog te verliezen.** Mede als gevolg van de bevindingen van de evaluatie in 2007 is de COGEM betrokken bij diverse samenwerkingsprojecten met het Rathenau Instituut. De evaluatiecommissie wijst erop dat de COGEM en het Rathenau Instituut verschillende rollen hebben en dat samenwerking voor de COGEM niet zonder risico's is. Terwijl het Rathenau Instituut het publieke debat wil organiseren en aanjagen, is de rol van de COGEM terughoudender en beperkt tot het verstrekken van informatie. De COGEM moet daarom haar positie en rol zorgvuldig bewaken. De evaluatiecommissie merkt verder op dat de COGEM haar samenwerkingsverbanden verder moet uitbreiden naar organisaties als de Planbureaus en de Gezondheidsraad.
7. **Een 'productie-ecoloog' of 'agronoom' benoemen in de COGEM subcommissie Landbouw.** Hoewel de evaluatiecommissie van mening is dat op dit moment genoeg praktijkervaring en agronomische expertise aanwezig is binnen de COGEM subcommissie Landbouw, merkt ze op dat dit soort expertise geen formeel onderdeel is van het kennispalet van deze subcommissie. Ze wijst erop dat dit soort expertise van vitaal belang is voor de kwaliteit van COGEM adviezen, met name op het gebied van teelttoelatingen, en dat in het licht van de toekomstige ontwikkelingen het belang van deze expertise steeds verder zal toenemen. Daarom is de evaluatiecommissie van mening dat een productie-ecoloog of agronoom in de subcommissie Landbouw moet worden benoemd.
8. **Streven naar een betere man-vrouwverhouding in het ledenbestand.** De evaluatiecommissie erkent de moeilijkheden bij het rekruteren van vrouwelijke leden. Echter, de evaluatiecommissie is van mening dat de huidige ratio van 1:3 te laag is en dat de COGEM al wat in haar mogelijkheden ligt moet doen om het aantal vrouwelijke leden te verhogen, zonder daarbij afbreuk te doen aan de hoge kwaliteit van haar deskundigen.
9. **Inschakelen van buitenlandse wetenschappers overwegen.** De evaluatiecommissie merkt op dat de beste deskundigen of wetenschappers voor bepaalde onderwerpen niet noodzakelijkerwijs nationale deskundigen zijn. Dit geldt voor alle landen. De COGEM (en andere nationale adviesorganen) zou moeten overwegen om wetenschappers uit het buitenland te werven of in te schakelen.
10. **Zich voortdurend bewust zijn van mogelijke belangenconflicten.** De evaluatiecommissie is tevreden over de procedures van de COGEM om belangenverstremming te voorkomen. Ze wijst erop dat de COGEM continu alert moet zijn op eventuele belangen van haar leden en mogelijke daaruit voortvloeiende belangenconflicten. De COGEM leden moeten zich scherp bewust zijn over hoe hun uitingen (in de verschillende rollen van lid, wetenschapper of werknemer) in de publieke discussie en de media door stakeholders en het publiek kunnen worden ervaren.
11. **Verbeteren van de communicatie binnen de COGEM tussen de leden van de verschillende subcommissies.** De interne communicatie binnen de COGEM lijkt vooral door de secretariaatsmedewerkers verzorgd te worden. Vanwege de drukke agenda's van de leden, de sterk uiteenlopende expertises en de soms geringe raakvlakken tussen de werkzaamheden van de leden, is het aantal contacten tussen de verschillende subcommissies beperkt. Alleen de jaarlijkse Plenaire vergadering biedt gelegenheid om elkaar te ontmoeten. De evaluatiecommissie wijst erop dat 'face to face' contact tussen leden van grote waarde is voor het verbeteren van de kwaliteit van de COGEM en haar activiteiten. Dergelijke contacten kunnen leiden tot nieuwe inzichten en ideeën.

4. AANBEVELINGEN

12. **Zich onthouden van een leidende rol in een mogelijke toekomstige sociaal-economische beoordeling van gg-gewassen.** In het geval dat een sociaal-economische beoordeling van ggo's een onderdeel wordt van de (EU) vergunningsprocedure voor markttoelating, is de evaluatiecommissie van mening dat deze beoordeling niet door de COGEM moet worden uitgevoerd. Andere organisaties of consortia van organisaties zijn beter geschikt voor het uitvoeren van dergelijke evaluaties. De COGEM heeft een specifieke rol en expertise en kan vanuit die rol een bijdrage leveren aan een sociaal-economische beoordeling. Echter, een leidende rol in dit beoordelingsproces moeten worden gereserveerd voor organisaties en instellingen met een uitgebreide kennis over economie, modellering, 'technology assessments', etc.

GENETIC MODIFICATION IN INTERNATIONAL PERSPECTIVE COGEM EVALUATION REPORT 2011

MAY 2011

THE COGEM EVALUATION COMMITTEE 2011

PROF. DR. IR. R. RABBINGE

DR. C. NOIVILLE

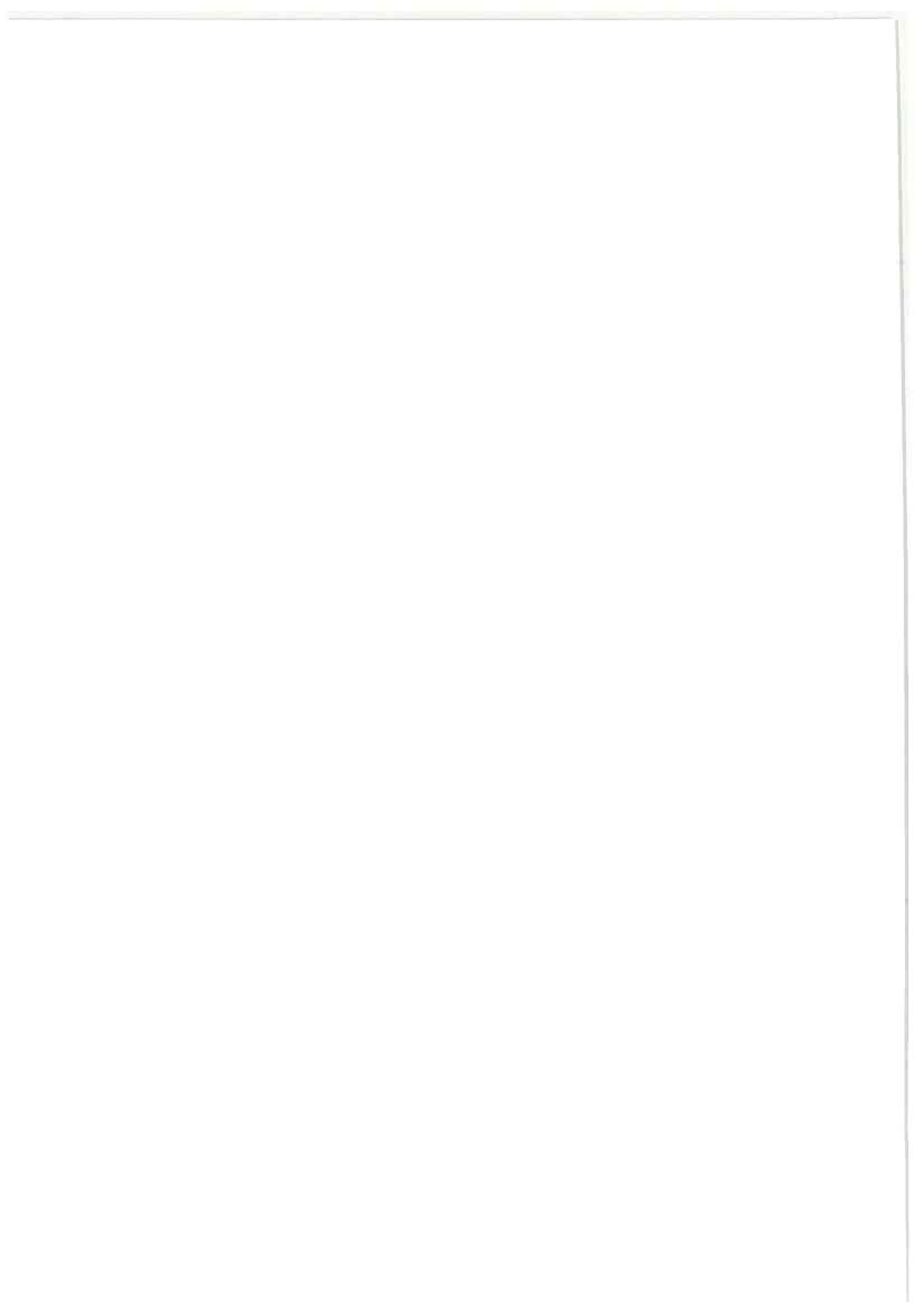
PROF. DR. IR. D. REHEUL

Colofon

Ontwerp: Avant la lettre

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1. INTRODUCTION

As stated in the Dutch Environmental Management Act, the Netherlands Commission on Genetic Modification (COGEM) has to be evaluated every four years. The evaluation is the responsibility of COGEM. The Act (§ 2.3) states that every four years COGEM will issue a report which evaluates the role, structure, constitution and procedures of the commission and makes proposals for improvement. The report is presented to the State Secretary of Infrastructure and the Environment (IandM) who forwards it, accompanied by the response of the cabinet, to parliament.

The Executive Board of COGEM asked an external committee to evaluate COGEM in 2011. This Evaluation Committee consisted of the chairman Professor Dr. Ir. Rudy Rabbinge, Dr. Christine Noiville and Professor Dr. Ir. Dirk Reheul. The remit of the Evaluation Committee was to evaluate COGEM in the context of the statutory requirements laid down in the Dutch Environmental Management Act.

REPORT

This report reflects the findings of the Evaluation Committee. Along with an assessment of COGEM, a resulting diagnosis and the conclusions, the report offers a number of recommendations to further enhance the quality of COGEM and its activities.

The Evaluation Committee presented the report to the Executive Board of COGEM. The Board will send the report to the State Secretary accompanied by a letter with its response to the findings of the Evaluation Committee.

THE EVALUATION COMMITTEE

As in the previous evaluations in 2003 and 2007, for reasons of transparency and objectivity, COGEM decided to involve external reviewers. A marked difference with the previous evaluations is the international flavour of the Evaluation Committee. In 2003 a consultancy carried out the evaluation in the context of a previous reorganisation. The 2007 evaluation focused mainly on the relationship with stakeholders in the Netherlands, and COGEM's role in the public debate. The international approach of the 2011 evaluation reflects the increasingly international context in which national advisory bodies like COGEM are operating. The influence of the EU and its institutions on regulations, scientific assessment procedures, policies and decision processes is growing.

Two members of the Evaluation Committee are closely involved with foreign counterpart organisations to COGEM and have hands-on experience of the requirements COGEM needs to meet. Dr. Christine Noiville chairs the 'Comité économique, éthique et social' of the French 'Haut Conseil des Biotechnologies' and is Head of the 'Centre de Recherche Droit, Sciences et Techniques, CNRS-Université Paris I'. Professor Dirk Reheul is chairman of the Belgian 'Bioveiligheidsraad' and professor in plant breeding and agronomy at Ghent University.

The Dutch chair, Professor Rudy Rabbinge, has extensive experience of different types of national and international scientific organisations and an in-depth understanding of the political and policymaking context in the Netherlands. Professor Rudy Rabbinge is among other things professor of Sustainable Development & Food Security at Wageningen UR.

FOCUS OF THE EVALUATION

As with the previous evaluations, the central questions in 2011 were "has COGEM done the right things?" and "has COGEM done these things right?".

The evaluation took into account whether the organisation, structure and procedures of COGEM can cope with the ever changing playing field in which the commission operates. Therefore, in answering the above questions the Evaluation Committee focused on a number of aspects of direct importance to the operations of COGEM: the scientific quality of COGEM's publications; communication and transparency; the international position of

1. INTRODUCTION

COGEM and international cooperation; the blurring definition of a GMO; the call for socio-economic assessment of GMOs; the distinctions between red, white and green biotechnology; and regulation and deregulation.

EVALUATION PROCESS

To carry out the evaluation, the Evaluation Committee primarily made use of three sources of information. Firstly, a status report was compiled by COGEM which gives an overview of the organisation and structure of COGEM, its main publications and activities over the past three and half years, the highlights of the last few years, possible controversies surrounding COGEM, its publications and activities, as well as the relevant COGEM procedures. Secondly, the Evaluation Committee assessed the scientific quality of a representative selection of COGEM advisory reports and topic reports issued in the last three and half years. Thirdly, eight interviews were held with COGEM members, representatives of stakeholders and the Ministry of Infrastructure and Environment (IandM), which is COGEM's primary principal. The minutes of these interviews are given in chapter 2 of this report.

The Evaluation Committee convened for two days in The Hague (5 and 6 April 2011) to hold interviews, discuss its findings and establish the main conclusions and recommendations. The finalisation and approval of the evaluation report was done by e-mail.

2. STATUS REPORT AND INTERVIEWS

The final verdict of the Evaluation Committee was based on an assessment of the Status Report 2008-2011 and its contents, a number of interviews with stakeholders held in The Hague, and a review of a fairly random selection of COGEM advisory reports, letters and topic reports. This chapter contains the appraisal of the Status Report, and provides a summary of the interviews.

2.1 STATUS REPORT

In the opinion of the Evaluation Committee the Status Report 2008-2011 gives an excellent overview of the mission of COGEM and how the commission has fulfilled its mission in the period 2008 - 2011. The report justly emphasizes the double mission of COGEM; (1) to advise on the potential risks of handling or production of GMOs, and (2) to provide information on the ethical and societal aspects linked to genetic modification.

The report goes into detail about the organisation and composition of COGEM. It shows that the organisation in scientific subcommittees supervised by an Executive Board and supported by a professional secretariat, allows for a fast and efficient performance. A wide variety of different expertise is present within COGEM. The COGEM members are prominent scientists and experts in their fields. The procedures and protocols COGEM has in place appear to be well matched to safeguard the quality, integrity and independence of its members, publications and the organisation. Importantly, a procedure is in place to deal with minority points of view among members allowing them to take a dissenting opinion, thus supporting an open-minded debate within the commission and consolidating the credibility and independence of COGEM. The credibility and independence of COGEM are confirmed by the fact that COGEM can issue unsolicited advice and topic reports on issues or themes that the commission finds relevant.

What is apparent from the Status Report is that although COGEM has a limited staff available, a large amount of work is produced in multiple fields. Noteworthy is that the subcommittees meet six times a year, and handle most of the workload by e-mail. The Status Report quantifies in detail the output of COGEM. The commission advises on all types of permit applications: contained use, deliberate releases and market authorisations.

Furthermore, the topic reports cover ethical and societal issues. Besides issuing advice and topic reports COGEM organises symposia, attends national and international meetings to keep up-to-date with the latest developments, expands its contacts and explores possible avenues for cooperation. Considerable effort is also put into communication with stakeholders while avoiding to become a party in the public debate in GMOs.

COGEM also commissions research. In the past period, 19 research reports were commissioned. The Evaluation Committee notes with satisfaction that these subjects go beyond the issues in green biotechnology alone, and cover relevant issues in all fields within the remit of COGEM.

The Status Report ends with a list of controversies and points of interest which COGEM has encountered in the past three years, and how COGEM has responded to these issues.

Although the report describes the functioning of COGEM very well, a few critical comments can be made. The report is sparse concerning the content of the dossiers COGEM handles and the problems which have arisen during the processing of the dossiers. It is largely unclear which dossiers were the most controversial and how the debate on these issues went within COGEM. Furthermore, data are not provided on which reports were the most time and labour consuming, which publications were deemed particularly important to COGEM members and which publications led to conclusions or information that can be used in future publications.

2. STATUS REPORT AND INTERVIEWS

2.2 INTERVIEWS

The Evaluation Committee held eight interviews with representatives of the Ministry of Land, Water and Forestry, stakeholders, and COGEM members. The interviews with the COGEM members were conducted in group sessions. The Evaluation Committee wishes to thank all the interviewees for their willingness to take part in the evaluation process. The summaries of the interviews are given below.

2.2.1 PROF. DR. SABINE ROESER¹, PROF. DR. ROB HOEBEN² & DR. RAOUL DE GROOT³

COGEM members; ¹subcommittee Ethics & Societal Aspects, ^{2,3}subcommittee Medical & Veterinary Aspects

¹ Professor of Political Philosophy and Ethics at Twente University and associate professor at TU Delft Philosophy Departments of Technical University Delft

² Leiden University Medical Centre

³ Utrecht University, Department of Veterinary Sciences

Ms. Roeser introduced herself. She is a professor in political philosophy and ethics at the University of Twente. She has been an associate member of subcommittee Ethics and Societal Aspects for 18 months now. She explained that the members of the subcommittee are a group with expertise on a broad range of subjects, representing different viewpoints. The issues are identified by the subcommittee itself, or come up further to advice. No recommendations are made in the topic reports, rather an evaluation of different points of view and the arguments involved is given to address all the ethical and societal aspects of a certain issue. Some publications are normative ethical analyses, like the topic report on socio-economic criteria.

Ms. Roeser mentioned that different viewpoints are covered in the subcommittee because several members are indirectly linked to stakeholders in e.g. organic agriculture, nature conservation and industry, or have expertise in ethics, philosophy or communication. No stakeholder consultations have been organised in the last 18 months. Although the subcommittee works closely with the Rathenau Institute on certain topics, stakeholders are not consulted during this process. However, once a topic report has been published, political considerations may demand that a stakeholder evaluation be carried out by an appropriate organisation, like the Rathenau Institute.

The Evaluation Committee asked if the demarcation of the roles of COGEM and the Rathenau Institute is a concern. Ms. Roeser was of the opinion that this is not the case. The demarcation lines are respected by both institutes and the cooperation is fruitful. Concerning the scenario study on GM agriculture, a joint publication by COGEM and the Rathenau Institute, Mr. Rabbinge pointed out that the scenarios seemed to have been developed without any reflection on the real issues at stake in society. He was of the opinion that scenarios should be explorative rather than a prediction of the future.

Ms. Roeser experienced no functional difference between associate and full members of COGEM; all members are treated as equals. Mr. Hoeben agreed and explained that full members are officially appointed by the minister, while associate members are appointed by the COGEM board.

Ms. Roeser explained to the Evaluation Committee that the members of her subcommittee usually do not provide comments on draft technical advice formulated by the other two

2. STATUS REPORT AND INTERVIEWS

technical subcommittees. The members rely on the COGEM board and staff to monitor technical advice for issues that might be relevant to the ethics subcommittee. One such topic recently was approval of the use of a GMO E.coli kit in school classes. The Ethics subcommittee, in cooperation with subcommittee Medical and Veterinary Aspects, sent a letter to the government covering both technical safety and ethical topics, like informed consent.

Mr. Hoeben was asked to introduce himself. Mr. Hoeben was a former chair of the subcommittee Medical and Veterinary Aspects for three years. He is a professor at Leiden University Medical Centre on molecular virology, focusing on gene therapy. He is also a member of the Society for Gene Therapy.

Gene therapy is a topic that continually needs explanation of its purpose and its risks to the general public. Mr. Hoeben stressed that scientists should be open to discussion with the public. It is very important to maintain public trust. In his laboratory, new employees who will work with GM organisms are examined. They should be able to explain in layman's terms what they do, why they do it, and why it's safe. His method of making science understandable has received acclaim, and subsequently he has been asked to organise such examinations for all LUMC employees.

Mr. Hoeben added that public confidence in COGEM is also influenced by the quality of the expertise of COGEM's members. The current high quality of expertise and commitment by COGEM members should be maintained. He noted that COGEM is considered to be of good standing within the scientific community.

Mr. Hoeben felt that it is important to strengthen the communication and cooperation between the different COGEM subcommittees. He mentioned that the chairs of the technical subcommittees are also members of the Ethics subcommittee. Coordinators and staff also work together closely. Ms. Roeser pointed out that members meet each other at the annual Plenary Meeting. In reply to a question by Mr. Reheul, Mr. Hoeben stated that unfortunately cooperation with other subcommittees on specific topics is not very frequent. There is too little time to involve ethical aspects in advice on permit applications. Mr. Hoeben is of the opinion that the short timelines however do not interfere with the quality of the advice. The pre-analysis of permit applications by the COGEM staff and the GMO Office focus COGEM members' attention on the most important issues of an application. The expertise of the members means that they can make their evaluation of these issues quickly. Mr. de Groot added that decisions on these issues are not made in haste. If a discussion arises, this is thoroughly addressed by COGEM staff with the members, by telephone or e-mail.

Mr. Hoeben mentioned that there is a discrepancy in the risk analysis of wild type viruses and GMO viruses. The product and the application should be considered in terms of risks. Several non-human wild type viruses are used for therapy in humans. Although these activities might involve risks, they are not as strictly regulated as work with GMO viruses. COGEM's role is to inform the ministry on this topic. In the meetings, the ministry is asked to provide feedback on what its follow-up actions are on COGEM's advice.

Mr. de Groot introduced himself. He is an assistant professor in fundamental molecular virology at the University of Utrecht, and lecturer for a university course on virology which also includes the topics of ethical considerations and the risks of working with GMOs. As a member of the subcommittee Medical and Veterinary Aspects, he lends his expertise to give advice on the risks of activities involving micro-organisms to the environment and humans. Certain applications raise more questions than others. Discussions among the subcommittee members on the issues concerning these applications may be fierce, but are also open and thorough. The subcommittee usually reaches balanced and unanimous conclusions.

2. STATUS REPORT AND INTERVIEWS

Ms. Noiville asked about Mr. de Groot's experience with minority opinions in COGEM. A minority opinion has been issued only once in the last four years. Mr. de Groot was one of the members with a minority opinion on the classification of a chimeric Human Metapneumovirus in 2009. The application in case entailed the exchange of homologous genes of unknown function among related paramyxoviruses and a debate about the expected fitness of the resulting GMOs and their ability to spread when inadvertently introduced into the human population. According to Mr. de Groot, the scientific information provided did not conclusively show these GMOs to be less fit, to spread less efficiently or to be less pathogenic than the parental viruses. Theoretically, such viruses could establish themselves in the human population. Mr. de Groot therefore deemed it advisable to perform the activities with the chimeric viruses on a higher containment level. His view was that colonization of the human population by genetically modified viruses that could only have arisen in the lab should be prevented at all times. He pointed out that if such an event would occur it would result in a difficult public discussion and a setback to the entire field. A discussion arose between Ms. Roeser and Mr. de Groot on the nature of these arguments, whether they are ethical or strategic. Mr. de Groot remembered that the discussion on this issue was balanced, and he was pleased with the outcome and the handling of the situation.

Ms. Noiville asked if COGEM could be considered a club or if different viewpoints are present among its members. Mr. Hoeben stated that COGEM members do not represent their organisations, but bring in their expertise. Discussion between them is not always easy. There is room for members to disagree, but they strive for consensus.

2.2.2 DR. JAN KOOTER¹, PROF. DR. NICO VAN STRAALEN², & IR. HUIB DE VRIEND³

COGEM members; ¹subcommittee Agriculture, ²subcommittee Ethics & Societal Aspects

¹ Department of Genetics VU University Amsterdam

² Department of Animal Ecology Amsterdam & Dean of the Amsterdam Graduate School of Science, VU University

³ LisConsult

Mr. van Straalen was asked to introduce himself. He is a professor in animal ecology at the VU University of Amsterdam. His research scope covers soil invertebrates, microbiology and entomology. He has been a member of COGEM since January 2010. His expertise is important for discussions on non-target organisms for the cultivation of GMO crops. Other topics, like the molecular characterisation of GM crops, he usually leaves to other COGEM members with more expertise on these subjects.

The members of the subcommittee Agriculture have differing backgrounds, making the subcommittee multidisciplinary. He noted that membership takes up considerable time and effort. The preparation of dossiers and other support provided by the COGEM staff is invaluable in helping to cope with the volume of work. Any issues arising are discussed during the subcommittee meetings or via e-mail. When viewpoints differ, which regularly occurs, the staff invite members to react to the issues in question. Mr. van Straalen complimented COGEM on its liveliness and high standards.

Mr. Reheul asked whether subcommittee Agriculture is in need of an agronomist, to handle discussions between ecology and agronomy. Mr. van Straalen remarked that agronomy expertise is not lacking in the discussions by the committee, but that there is no member specialising in agronomy at the moment. He pointed out that the subcommittee strives to

2. STATUS REPORT AND INTERVIEWS

arrive at advice which is unanimous, but does not necessarily take the most conservative view. Mr. Rabbinge felt that a theoretical production ecologist could bridge the gap between fundamental ecology and agronomy.

Mr. van Straalen mentioned that ecology may be the most critical point on which applications are evaluated. Specific guidelines have been established previously by the committee for aboveground environmental effects on non-target organisms. These include guidance on indicator species (pollinators, predators, etc.), but ecological functions are also considered. He regretted that basic science is not readily available for soil species and soil functioning. COGEM had identified this gap in the knowledge. In the 'ERGO' research programme concerning the ecology of GMOs, of which he is chairman, research is being carried out to fill this void.

Mr. Kooter introduced himself. He is a plant molecular biologist, working at the VU University of Amsterdam on the subject of epigenetics. He has a lot of experience in genetically modifying plants, and his family background is also in agriculture and horticulture. One of the biggest issues, in Mr. Kooter's opinion, is the lack of a definition of the baseline for GMO risk assessment. Insect populations vary naturally from year to year. Information on the baseline in regular agriculture, in his view, is not readily available.

Mr. Kooter felt that cisgenesis is one of the safest GM techniques. In that respect, the vandalisation of apple scab resistant GM apple trees by anti-GMO activists is a pity. It shows that activists often don't know the important details of a technique and the organisms involved. Mr. Reheul inquired whether the vagueness of the definition of GMOs, for example concerning cisgenesis, interfered with the work of COGEM. Mr. Kooter pointed out that as biotechnology and science continually develop, a scientific definition quickly becomes outdated. Therefore, for each application or advice, COGEM specifies the type of GMO under evaluation. Mr. van Straalen added that in a safety assessment, it is important to consider the product, not the process or technique used to make it.

Further to a question by Ms. Noiville, Mr. Kooter stated that having a representative of a biotechnical company (Avebe, a potato starch company) on the subcommittee is a useful addition. This member brings a practical perspective and is aware of interesting developments in the field. Mr. van Straalen added that this member does not advise on applications concerning potatoes, if he were to overemphasise the biotechnology company perspective, this would be counterbalanced by the opinions of the other members on the subcommittee.

Mr. de Vriend introduced himself. He studied Land and Water Management in Wageningen. In 1985 he became involved in the field of GM when he started an organisation aimed at providing information to NGOs on what GM could mean to society. He subsequently worked for consumer organisations, e.g. on product labelling. He has been an independent consultant in the area of life sciences for the past six years. He has been a member of the subcommittee Ethics and Societal Aspects for more than eight years.

In his opinion, his subcommittee has a good balance with a diversity of viewpoints. This leads to interesting discussions on values in the GM debate. He finds it difficult however to choose the right issues for topic reports proactively. The topic reports are usually an outlook on upcoming developments. The COGEM context is a highly political national and European arena. Though issues may be interesting scientifically, Mr. de Vriend pointed out that it is difficult to know what the impact on society or politics will be. He values the feedback of the ministry in the meetings, as they provide a more realistic view of the ongoing policy issues in the field.

Mr. Rabbinge inquired about the scenario study report recently published. Mr. de Vriend found this an interesting exercise but thought that the report was highly theoretical.

2. STATUS REPORT AND INTERVIEWS

Concerning the topic report on socio-economic criteria for cultivation of GM crops, Mr. de Vriend stated that, likewise, he would have preferred follow-up on this report to cover the extra step towards the application of the criteria for a number of concrete cases. Now, the report is so general that everyone can agree with it. Ms. Noiville mentioned that she considered it an excellent report, and asked how the report will be applied. Mr. de Vriend indicated that this depended on the developments in the political arena. It is now being discussed at the European level. Ms. Noiville asked if the Ethics subcommittee should be involved in making socio-economic assessments for each GMO in the future. Mr. de Vriend answered that in general, COGEM does not perform case-by-case ethical evaluations of GM crops. He thought it might be difficult to get useful background information for such an assessment of relevant cases for the Dutch situation.

Mr. de Vriend mentioned that the members of the Ethics subcommittee don't usually provide comments on the technical advice of the other subcommittees. A certain level of expertise is required for this sometimes highly technical advice, and often there is very limited time to respond. Since membership of COGEM is a job on the side, members generally don't have time to read all of the draft advice. They trust the technical experts on these topics. Mr. Kooter and Mr. van Straalen pointed out that important topic reports are discussed in the technical subcommittee meetings, e.g. the socio-economic criteria for GM cultivation.

Mr. Reheul inquired of Mr. de Vriend what the relationship is between politics, the perception of GMOs and the work of COGEM? How do these influence each other? Mr. de Vriend answered that political ideas do influence his work for COGEM and vice versa. The issues and ideas in society concerning GM and agriculture have changed over the years, e.g. concerning the world food supply or labelling. These changes influence the work and activities of COGEM and its members.

Those present agree that if one GM product creates a scandal, this will backfire on the entire biotechnology industry. Mr. van Straalen pointed out that in general, public belief in science is waning. Ms. Noiville noted that the French public do trust science as a countervailing power against politicians.

2.2.3 DRS. ING. PETER TORBIJN¹ & DR. DICK JUNG²

Ministry of Infrastructure and the Environment, ¹Director Environmental Safety and Risk Management; ²Member of management team of Environmental Safety and Risk Management

Mr. Jung explained that changes in the national regulation on GMOs will be presented in 2011. Under the new regulation, deregulation will be put in place for certain red and white biotechnology permits. This will mean that companies themselves will become responsible for relatively simple and straightforward GMO activities. Mr. Rabbinge mentioned that the Council of State (Raad van State) often comments on procedural aspects of a permit. Mr. Jung agreed and mentioned that the ministry took the opportunity to make the new Dutch GMO legislation more understandable and the application process more transparent and logical. The new legislation should be put in place in 2012.

In addition to the legislation being transparent, Mr. Torbijn and Mr. Jung stressed the importance of transparency in all aspects of the GMO permit process, including the roles of the bodies involved. The ministry is keen that COGEM be seen as an independent scientific organisation. COGEM should not become involved in the political process on GMOs. In the case of societal and ethical issues, COGEM should only provide information for the debate. The debate in the European Union on GMOs is partly driven by emotion. By becoming part of the political

2. STATUS REPORT AND INTERVIEWS

or public debate, the position and authority of COGEM as a scientific body will be weakened. The ministry finds COGEM as it is at the moment, nicely balanced between its scientific and technical advisory role and its task of informing the government on relevant developments and their ethical or societal aspects. The topic reports are not thought to be too political or advocative.

The topic reports by COGEM are used as input for the political processes on the subjects described. The ministry takes note of the reports and uses them at an appropriate time in the political process, which sometimes takes a while. The COGEM report on socio-economic criteria is being used in the European discussion on this issue.

Socio-economic aspects are not yet part of the European legislation on GMOs. The ministry pointed out that if the European Union wants the member states to decide on the cultivation of GMOs on their own territory, then a socio-economic assessment may come into play in the permit procedure. For now, the subcommittee Ethics and Societal Aspects should not include an opinion on socio-economic aspects or ethical aspects in the technical advice provided in the agricultural, medical and veterinary fields.

Mr. Torbijn and Mr. Jung are very pleased with how COGEM fulfils its tasks. Mr. Torbijn mentioned that since COGEM bases its judgment on science, the advice issued clearly states which aspects are certain or uncertain and what the outcome of the risk analysis is. Mr. Jung added that the viewpoints of the COGEM members are incorporated in the advice. This leads to transparency in the advisory process for the general public. It is a way of showing that all relevant information has been gathered and evaluated.

For a permit application to be granted, the risk of the activities has to be negligible according to the ministry. It was pointed out that it is very difficult to quantify the risks associated with GMOs. Since the analysis of GMO activities never takes the purpose of an application or permit into account, a permit cannot be denied on the basis of an assumption that a product will not be necessary or used in the Netherlands.

Monitoring of unexpected effects after a permit has been granted is necessary, but the ministry does not think COGEM should play a role in performing this. COGEM is very welcome, though, to give scientific advice on how to undertake such monitoring.

Mr. Jung and Mr. Torbijn were of the opinion that communication with the general public is an issue for all governmental organisations. COGEM has a nice balance between giving information but not participating in the discussions and debates. They were not in favour of COGEM issuing press releases to promote its publications. Press releases would be a waste of time as they could get lost in the enormous number of press releases editors receive every day. Moreover, this type of text could end up drawing COGEM more easily into the public debate.

2.2.4 IR. JAN WISSE

Managing director Niaba (Dutch Biotechnology Association)

Mr. Wisse was of the opinion that the quality of the scientific advice given by COGEM on applications for permits is good. He was not aware of many complaints about COGEM by the members of Niaba.

For red and white biotechnology, GMO permits mostly concern Contained Use. Niaba mostly has contact with COGEM about developments in green biotechnology. In this field, legislation is widely seen as 'overkill' and hindering developments. The system is getting too

2. STATUS REPORT AND INTERVIEWS

complex, while the risks are decreasing due to new knowledge. A hot topic is the discussion of whether novel breeding technologies should fall under GMO legislation or not. Mr. Wisse had noticed that COGEM is one of the players in the novel breeding discussion. For Niaba and the biotech companies it represents, it is important that the application process for a GMO permit becomes easier and quicker. Changing the GMO application process depends on both national and European regulations.

Mr. Wisse pointed out that three parties are involved in the GMO system in the Netherlands; the Ministry of Infrastructure and Environment, the GMO Office which handles the permits, and COGEM. Mr. Wisse thought that having three organisations to deal with GMO biosafety makes the situation needlessly complex for Niaba members.

The Evaluation Committee asked if COGEM ever has discussions with biotech companies directly. Mr. Wisse himself, as managing director of Niaba, is in direct contact with COGEM, the GMO Office and the ministry. He doesn't know if Niaba members discuss permits directly with COGEM. Since the Dutch biotech community is relatively small, Niaba members do however interact at times with COGEM, in e.g. stakeholder meetings or through membership of supervisory committees for COGEM research projects. The Evaluation Committee turned to Mr. van der Wilk to elucidate COGEM's role in the permit procedure. Mr. van der Wilk explained that the GMO Office is the interface between the applicant and COGEM. Mr. Wisse agreed that COGEM never contacts applicants directly about a certain application, but always through the GMO Office. Mr. Wisse was in favour of improving communication and limiting obstacles in the permit procedures (especially for field trials).

According to Mr. Wisse, biotech companies don't see a clear difference between the duties, tasks and responsibilities of each organisation, since they are all mainly perceived as governmental. The companies don't see the role of COGEM clearly, which might be due to the existence and tasks of the different ethical and technical subcommittees.

Mr. Wisse was of the opinion that confusion among stakeholders is mainly created by the non-technical scientific tasks, e.g. the involvement of COGEM in the Trend analysis biotechnology 2009. This could undermine COGEM's scientific position, because the Trend analysis gets a lot of political attention. The Trend analysis should not have been written by COGEM, because COGEM should not play a big role in the public debate. The Netherlands has other organisations, like the Rathenau Institute, who should perform these tasks. The main task of COGEM is to provide scientific advice on technical issues. The Evaluation Committee pointed out that if COGEM attracts top scientists for its risk analysis, these experts may also be very helpful in informing the government on upcoming technological trends.

Publications by COGEM are of interest to the biotech companies in Niaba. Mr. Wisse stated that these publications sometimes have multiple messages. A research report, for instance, has conclusions by the authors in the report itself and in the executive summary, by COGEM in the accompanying letter and in the press release drawing attention to the report. The message of these texts may differ, creating confusion among biotech companies. This is also perceived as mixing scientific and political tasks.

Further to a question by the Evaluation Committee, Mr. Wisse confirmed that COGEM member Peter Bruinenberg works for Avebe (a potato starch company), which is a Niaba member. He only recently discovered that Peter Bruinenberg has been a member of the agricultural subcommittee of COGEM since September 2010. To the Evaluation Committee, this shows that COGEM is not seen as an industrial lobby group.

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2.2.5 DRS. HERMAN VAN BEKKEM

GMO campaigner Greenpeace

Mr. van Bekkem began the interview with some positive feedback on COGEM. He was glad to see that COGEM will start a research project on honeybees and GMOs. GM crops in field trials produce GM pollen which may be spread to other plants by honeybees, or could contaminate honey. He was also glad that COGEM acknowledges the existence of farm potato breeders, who breed potatoes on a small scale in their fields. Farm breeders offer interesting potatoes from their fields to commercial companies. He pointed out that 40 metres isolation distance from field trials is too little, since bumblebees can fly further than that, spreading GM pollen.

Mr. van Bekkem continued by mentioning the points COGEM should improve upon or should be concerned about.

Mr. van Bekkem thought some COGEM publications were too politically motivated, for example, the topic report on freedom of choice for consumers. In this report, COGEM implicitly suggested starting a political debate on the feasibility of labelling of food. The report should also ring alarm bells on the current issue of the increase of contamination in supply chains during the import of GM crops. Research by Greenpeace has shown that a considerable amount of linseed, rice and corn in the supermarkets is contaminated with illegal GMOs. He felt that there is a lack of control by the Dutch Food and Consumer Products Safety Authority (VWA). Mr. van Bekkem would like COGEM to raise the problem that there is contamination but not enough control, and ask what should be done, instead of putting the issue of the feasibility of GM labelling on the political agenda.

Mr. van Bekkem suspected COGEM of having a hidden political agenda on new breeding technologies like cisgenesis. Cisgenesis has a Dutch lobby, but is not an issue outside the Netherlands. He noticed that COGEM always states that it is unclear how to assess new breeding technologies. Almost every COGEM topic report contains a chapter on this topic. In addition, the topic report on GM agriculture scenarios recently published by COGEM does not contain a scenario on a GMO-free Europe. Mr. van Bekkem read between the lines of this report that Europe should not want to be free of GM crops. He disagrees with this viewpoint and stated that Dutch plant breeding is a very innovative industry and other types of biotechnology may be used to develop new crop varieties e.g. with salt tolerance. In conclusion, COGEM should make more distinction in the choice of subjects and the points it highlights and discusses in its topic reports. Independent scientists give insight in facts and controversies, politicians make choices based on this info, instead of COGEM publishing political conclusions.

Mr. van Bekkem pointed out that the Board for the Authorisation of Plant Protection Products and Biocides (CtGB) handles pesticides and herbicides. This important topic also affects GM crops. He would like to see research on the use of pesticides on Bt-corn, since there may be a cumulative effect on insects. The effects (increase or cumulative effects) of pesticide use on specific GMOs are not assessed by any authority. Research should also be done to investigate whether herbicide use is increasing on herbicide resistant plants. In addition, COGEM's interpretation of the environmental effects of GMOs is too narrow, in his opinion. The effects go beyond the 'cutting and pasting' of genes. For example, weeds in the USA have become herbicide resistant, mostly to Roundup. COGEM should mention this in its advice on herbicide tolerant crops. He added that at the moment, for example, there are large quantities of Roundup in the river Maas, and this should not increase. Strikingly, in its advice on the EFSA draft guidance, COGEM stated that the environmental risk assess-

2. STATUS REPORT AND INTERVIEWS

ment of herbicide use should be carried out under the pesticide regulation system, apart from the GM authorisation procedures. In his opinion, it should be an integral part of a GM risk assessment.

Mr. van Bekkem mentioned that the problems Greenpeace has with COGEM's narrow or reductionist view of environmental effects also concerns field trials. Events in field trials are not yet authorised, so that outcrossing will have a major impact on neighbouring farms. He is of the opinion that a stacked crop variety is seen by COGEM as a sum of GMOs, not taking into account that these modifications could cross-react or have cumulative effects. In addition, he pointed out that COGEM advice fails to take indirect environmental impacts into account. Mr. van Bekkem stated that baseline measurements are needed before field trials can be started. Otherwise, measurements of adverse effects cannot be properly made. He questioned the objectivity of VROM inspection and the biotech companies in the assessment of adverse effects in the field.

Though Mr. van Bekkem does not doubt the integrity of the chairman of the subcommittee Agriculture, Mr. Schouten, he is surprised by the many different roles the chairman plays in the GM debate. Besides being chairman of the subcommittee, Mr. Schouten is a scientific researcher and a lobbyist for lifting safety regulations on cisgenic organisms. Mr. Schouten does not seem to be receptive to other views on cisgenesis. It worried Mr. van Bekkem that RIKILT and COGEM have different opinions on cisgenesis. Mr. van Bekkem stressed that COGEM should avoid having someone with a potential conflict of interest in an important position in COGEM.

Mr. van Bekkem mentioned that in his opinion there is no representative of the environmental movement in COGEM at the moment. Mr. Lucas Reijnders, a molecular and environmental biologist, used to be a member. In reply to a question by the Evaluation Committee he agreed that the multidisciplinary nature of the subcommittee Agriculture is good at the moment. However, he thought more diverse viewpoints should be covered in COGEM advice and the expertise should be broadened to cover the entire spectrum of environmental effects, including indirect effects.

The subcommittee on Ethics and Societal Aspects is very well balanced. Its members have viewpoints from both industry and NGOs, which is good.

Further to a question by the Evaluation Committee, Mr. van Bekkem responded that he is mostly an expert in the agricultural and environmental field, not in white and red biotechnology. Since white and red biotechnology are mostly concerned with contained use, there are more problems in green biotechnology.

According to Mr. van Bekkem, COGEM and, in particular, the subcommittee Ethics and Societal Aspects, theorises too much. The highly theoretical topic reports, like the one on sustainability perspectives for GM crops, are not necessary for policymaking. Instead, it's about practice and current issues. He offered an alternative report to the Committee on the socio-economic and ecological costs of GMOs.

Ms. Noiville asked what the value might be of including socio-economic effects in COGEM assessments. Mr. van Bekkem answered that indirect environmental aspects should be included in authorisations, as well as GMO-free alternatives. The starting point of the assessment should also be different. Mr. van Bekkem would be much more interested in an assessment of socio-economic issues like food security and food sustainability, and a subsequent evaluation of if and how technologies like GM can contribute to solving these issues. Perhaps there should be an institution assessing these socio-economic impacts of GMOs. Mr. van Bekkem added that he is positive about the Norwegian system of dealing with socio-economic aspects. He had also heard some good comments on the French approach.

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2.2.6 JAAP VAN WENUM

Policy advisor on crop production and the environment at LTO (Dutch Federation of Agriculture and Horticulture)

Mr. van Wenum was of the opinion that COGEM does its job properly. LTO does not doubt the scientific quality of the advice. In spite of this, LTO would like to see more focus on the benefits of GM crops. Positive aspects should be taken into account for an application, like reduction of pesticide use for pest resistant plants. More than 50% of Dutch fungicides are used on potato fields, so GM fungus resistant potatoes would mean a huge improvement.

Mr. van Wenum was displeased about the influential role that NGOs have in the public debate. When the topic of GMOs is discussed, they point to Monsanto and Roundup Ready and do not consider the advantages of GM crops. NGOs state that they don't want GMOs, not even to limit the use of pesticides. Mr. van Wenum pointed out that NGOs will have to accept that the cultivation of organic crops results in lower yields. He valued the input by COGEM, but it seemed to him that the usefulness of the advice issued by COGEM is limited in the current public debate.

Mr. van Wenum stressed that decisions concerning regulations and legislation should be made more quickly. At the moment, applications concerning developments like cisgenic apples with apple scab resistance are hindered. Cisgenic products should not be subject to GMO regulations. A report issued by RIKILT last year on the safety assessment of cisgenesis concluded that the safety assessment should be similar for cisgenic and transgenic (GM) products. Mr. van Wenum disagreed with this viewpoint and mentioned that the minimal potential risks of the cisgenic product are outweighed by the benefits of the technique and its products.

On certain conditions, LTO would be in favour of the cultivation of GM crops because of their benefits. LTO therefore wants to break through the cycle of anxiety which the public seems to have on GM crops, to be able to sell GM products in the future. Mr. van Wenum mentioned that GM starch potatoes would be a good first GM crop to grow in the Netherlands, as these are not intended for human consumption. In his opinion, the Dutch public is not ready for GM food products yet, but the cisgenic apple has potential. By cultivating GM starch potatoes, farmers can gain experience with the cultivation of GM crops. LTO does not want to avoid a public discussion of GM with this strategy, but thinks that it could demonstrate to consumers that cultivation of GM crops does not result in the supposed adverse environmental effects. Demonstrating beforehand that putative effects on human health do not occur will prove very difficult. In this way though, the public might gain more confidence in transgenic or cisgenic products.

Mr. van Wenum was of the opinion that COGEM should not promote cisgenesis. COGEM could, however, point out how small the risks of cisgenic products are and the advantages of an apple scab resistant cisgenic apple. Previous safe cultivation of GM crops in the USA also provides an important argument in the discussion. Using sound scientific arguments, COGEM could assist the debate.

Ms. Noiville asked if Mr. van Wenum was aware of the existence of the subcommittee Ethics and Societal Aspects of COGEM. Mr. van Wenum was not aware of it, but thought it might help the European public debate with its activities.

Ms. Noiville inquired about the co-existence system in the Netherlands. Mr. van Wenum explained that co-existence regulations were developed in consultation with various Dutch

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Product Boards and decided on by the Higher Commodity Board for Arable Products (Hoogproductieschap Akkerbouw). To avoid outcrossing from GMO fields to non-GMO crops, isolation distances have been defined. In addition, there is a compensation fund for financial claims if product batches are contaminated and the farmer is not to blame for this. Thus, Dutch farmers are prepared for the cultivation of GM crops. Mr. van Wenum added that the Netherlands is one of the few countries with such a co-existence system.

The Evaluation Committee asked if COGEM had been involved in the development of the co-existence system in the Netherlands. Mr. van der Wilk explained that COGEM gave scientific advice on co-existence rules and isolation distances. Agricultural experts from WUR were also requested to give advice on this topic.

In reply to another question, Mr. van Wenum responded that the labelling of GM products or cattle fed on GM feed is not required in the Netherlands. Organic products are labelled as such. Organic cattle is fed using batches of feed containing less than 0.9% of GMO products.

Further to a question by Mr. Reheul, Mr. van Wenum stated that LTO farmers see no future benefits in the use of herbicide tolerant plants. These GM plants promote the use of weed killers and force farmers to buy a specific type of weed killer. Moreover, resistance develops easily in weeds, so the plants lose their purpose and the farmer is left with an unsolvable weed problem.

Instead, LTO considers disease and pest resistance to be much more promising goals to pursue using GM techniques. By using GM pest-resistant plants, the use of pesticides can be avoided completely. Thus, these crops would have a clear benefit to society. He agreed with the Evaluation Committee that it will always be a race against resistance built-up in target organisms. Resistance development by target organisms is a certainty in all approaches to developing plants that are pest resistant.

2.2.7 JANNEKE SNIJDER-HAZELHOFF

Member of Parliament (VVD Dutch Liberal Party), chair of the Committee on Infrastructure and the Environment of the Dutch House of Representatives

In this interview, Ms. Snijder-Hazelhoff was not representing the views of the Committee on Infrastructure and the Environment.

Ms. Snijder-Hazelhoff was of the opinion that it is very important that COGEM maintains its independent position and therefore should not be involved in the political process. COGEM's credibility depends on the quality of its reports and its authority.

Ms. Snijder-Hazelhoff thought that COGEM should distribute its reports and information more widely among the government and the general public. COGEM should not promote itself, but make its advice and reports easier to understand and its advice better known to the government and the public. COGEM should be aware that it will not become part of the political debate by making itself more visible. Better presentation of the advice would be helpful in the ensuing policymaking by government.

Ms. Snijder-Hazelhoff was interested in the interaction between EFSA and COGEM. Research done in member states should be used more by EFSA. The activities of EFSA and the competent authorities in member states should not be duplicated. COGEM should strive for a coordinated agenda in terms of the activities and knowledge of the member states in EFSA.

Mr. Reheul informed her that communication between EFSA and the member states is dif-

2. STATUS REPORT AND INTERVIEWS

difficult at times. EFSA is not very responsive to member countries, and does not seem to want to strengthen the bonds between itself and the competent authorities of the member states. Even though biosafety advisory committees reach out and try to connect, EFSA does not appear to encourage or support this.

This surprised Ms. Snijder-Hazelhoff. In the current debates on GMOs in the parliament, referrals to EFSA for its independent scientific opinions were much more usual than referrals to COGEM. This tendency could gradually make COGEM obsolete, which should be prevented. A situation where EFSA sets the rules and member countries must follow these rules would be undesirable. She proposed informing the State Secretary of this difficulty.

Ms. Snijder-Hazelhoff mentioned that her party is in favour of the use of GMOs. She thought that the current government might give more elbow room to GMOs. Politically, and at the European level, however, GMOs are being held back. Since all European member states are operating in the same European market, she was in favour of a rapid decision-making process to allow the import and trade of GMOs across all European borders.

Ms. Noiville mentioned that if in the future member states would be able to choose whether GM crops may be cultivated within their borders or not, socio-economic arguments might be used to make this decision. Who should perform a socio-economic impact analysis in this case? Ms. Snijder-Hazelhoff thought that a socio-economic impact assessment would have to be done by an institute like the Rathenau Institute, not by COGEM.

2.2.8 PROF. DR. ANDRÉ KNOTTNERUS

Chairman of the Scientific Council for Government Policy

Mr. Knottnerus' views were mainly based on his experience as a former chairman of the Health Council of the Netherlands. However, for his current position as chairman of the Scientific Council for Government Policy (WRR) he expects COGEM information also to be useful.

Mr. Knottnerus remembered that, from 1995 to 2000, he had fruitful collaboration with COGEM in his position as chair of the national committee on ethical research. The predecessor to the CCMO committee (Central Committee on Research involving Human Subjects) was evaluating protocols for the use of GMOs in clinical gene therapy studies in humans. The chairman of COGEM was an advisor to this committee. The CCMO is now a statutory and independent committee. Mr. Knottnerus assumed that COGEM input is still important to CCMO.

The Health Council works most closely with COGEM on the Trend analysis biotechnology. Mr. Knottnerus explained to the Evaluation Committee that the first Trend analysis in 2004 was written by the Commission on Biotechnology in Animals (CBD), COGEM and the CCMO. In 2006, the Health Council was requested to take part instead of the CCMO, since the Health Council was thought to be better equipped to carry out a Trend analysis on medical biotechnology and health aspects. The most recent trend analysis, compiled in 2009, was presented to the Minister of the Environment at the beginning of 2010. The Trend analysis has been adopted as an important report by various other ministries. It has also been actively discussed in parliament. It was clear to Mr. Knottnerus that parliament is eager to keep track of developments in health, agricultural and industrial biotechnology.

COGEM coordinated the 2006 and 2009 Trend analyses and did this very well. The meeting organised by COGEM surrounding the launch of the Trend analysis 2009, with a speech by the Minister of the Environment, was successful, in Mr. Knottnerus' opinion. Mr. Knottnerus thought that the public debate around such an event could be more prominent, although it

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might be difficult for a small organisation like COGEM to organise this. He had television and the new media in mind for a public debate, as these have currently more public impact than printed media. The scientific audience can be reached via newspapers and professional journals.

In the field of medical sciences, Mr. Knottnerus mentioned that COGEM and Health Council staff are in touch on specific issues. They share expertise and advise each other when appropriate.

Politicians do not want the government and its advisory bodies to have too many employees. In spite of this, Mr. Knottnerus felt that COGEM's capacities should not be diminished. COGEM is both compact and very well organised. Its focus could be broader than GMOs or non-human organisms. COGEM can provide subject matter input for public discussions, and that role could become more important in the future, in collaboration with the Rathenau Institute which is a specialist in organising public and policy debates.

Mr. Knottnerus pointed out that COGEM's independence is important to its credibility. Moreover, COGEM should take the opportunity to 'sell' its expertise to parliament and the public. In this respect, COGEM could collaborate more closely with the Rathenau Institute. He agreed with the Evaluation Committee that it would be wise if COGEM could advise parliament directly. The Health Council has had a remit to advise parliament since 1997. Parliament sometimes even directly requests the Health Council for advice. If COGEM could get such a remit, in Mr. Knottnerus' opinion, it would provide better long term prospects for COGEM and would avoid the overly politicised discussion of health and environmental topics in parliament.

Mr. Knottnerus stated that an international orientation is important for COGEM. COGEM should take the opportunity to share experts and expertise internationally. Foreign experts could also be included in working parties of the committee as the Dutch experts are not necessarily always the best experts on a certain topic. The expertise COGEM needs is scarce. A more internationally oriented committee would stimulate scientific collaboration in the field.

The work done by COGEM also demands a lot of time and input from its staff. Using and adapting the reports of other trusted organisations internationally would save time and effort, such that staff can focus their efforts on other new and important issues. Mr. Knottnerus was in favour of increasing the international contact of COGEM staff with other organisations concerning GM and biosafety.

In Mr. Knottnerus' opinion, the implementation of a future socio-economic assessment should involve other organisations besides COGEM, since economic impact assessment is a field in itself. COGEM has expertise in risk analysis but other organisations, like the universities, the Netherlands Bureau for Economic Policy Analysis (CPB), the Netherlands Environmental Assessment Agency (PBL), and to a certain extent, the National Institute for Public Health and the Environment (RIVM), have expertise which might be more suited to a socio-economic assessment. COGEM would be able to point out which developments might have socio-economic impact and should then work with other organisations to evaluate them in detail. Maybe socio-economic effects should even be done by international experts on an occasional basis.

In reply to a question by Mr. Reheul, Mr. Knottnerus stressed that COGEM's technical advice on specific dossiers should not become part of the public or political debate. However, he thought it important that COGEM also brings its existence and its activities in this domain to the attention of the general public and politicians. Politicians should be aware that COGEM gives scientific and technical advice in the interest of public and societal safety, even if these duties and tasks are not the focus of public attention.

3. DIAGNOSIS AND CONCLUSIONS

3.1 DIAGNOSIS

3.1.1 SCIENTIFIC QUALITY AND OUTPUT

The scientific quality of COGEM's advisory and topic reports is high and meets the demand. This is also shown by the fact that the advisory and topic reports of COGEM are highly respected internationally and frequently used as examples of high scientific quality and proactivity. The procedures COGEM has in place to safeguard the quality of its work, as described in the Status Report, appear to be effective.

Despite a limited staff, COGEM produces a large volume of work in different fields in accordance with rules and procedures which seem appropriate to the main issues at stake, in the context of a scientific committee advising the government on a socially controversial subject.

The Evaluation Committee would like to point out that a discussion is in progress on the extent to which possible 'indirect effects' due to farming practices should be taken into account in the risk assessment of GM crops. This is not a risk assessment issue but a policy issue, and a decision on this matter has to be taken in the EU. However, in its considerations COGEM has to keep an eye open for potential indirect environmental effects due to farming practices or the crop management system, and the interplay with other regulations such as those on plant protection products.

SCENARIO STUDY

The Evaluation Committee has some criticisms regarding the recent joint publication with the Rathenau Institute "*Mondial motivation or European individuality? Four scenarios for GMOs in the European agriculture*". It is overly directed towards policymakers, thus limiting its usefulness for shaping the discussions on future developments. Moreover, this scenario study is not actually explorative but more an extrapolation of existing trends, due to the chosen approach and the selected drivers for the development of the scenarios. Consequently, scenarios fundamentally different from the prevailing trends at this moment are not discussed; such as a scenario in which GMOs do not play a role in Europe or other parts in the World, or a scenario in which GMOs are actively encouraged by policymakers resulting in a possibly diminished public aversion in Europe and a rapid growth of the GM acreage.

3.1.2 ORGANISATION AND COMPOSITION OF COGEM

In general, the organisation and composition of COGEM is well suited to the tasks and challenges a scientific advisory body like COGEM faces. COGEM harbours a wide variety of different expertise and has procedures in place for minority points of view thus guaranteeing open debate within the commission. Furthermore, the independence and credibility of COGEM is safeguarded by procedures to forestall potential conflicts of interest.

INTERNAL COHERENCE

The organisation of COGEM into four different subcommittees overseen by an Executive Board and supported by a professional secretariat seems to be well suited to the tasks COGEM faces. A disadvantage of the necessary division into different subcommittees is that the contact between members of the different subcommittees appears to be rather limited. The only occasion where members can meet face-to-face is at the annual Plenary Meeting. As evidenced by the discussions in the group interviews with the COGEM members, more interaction between the different subcommittee members could lead to new insights and improve the

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operations of COGEM even further. Internal coherence can be strengthened by formulating joint publications and organising activities, like symposia.

SUBCOMMITTEE ETHICS AND SOCIETAL ASPECTS

Contrary to the vast majority of other scientific committees in the various EU member states, besides technical advisory subcommittees carrying out environmental risk assessments, COGEM also has a subcommittee providing information on the societal and ethical aspects of GMOs. Unlike in France, for instance, this subcommittee is not made up of representatives of stakeholders but experts appointed on the basis of their expertise and knowledge of the public GMO debate and its participants. Furthermore, the subcommittee does not act on a case by case basis, but provides information on general issues to the government. The work and publications of this subcommittee, like the topic report on the criteria for socio-economic assessment of GMOs, is of high quality.

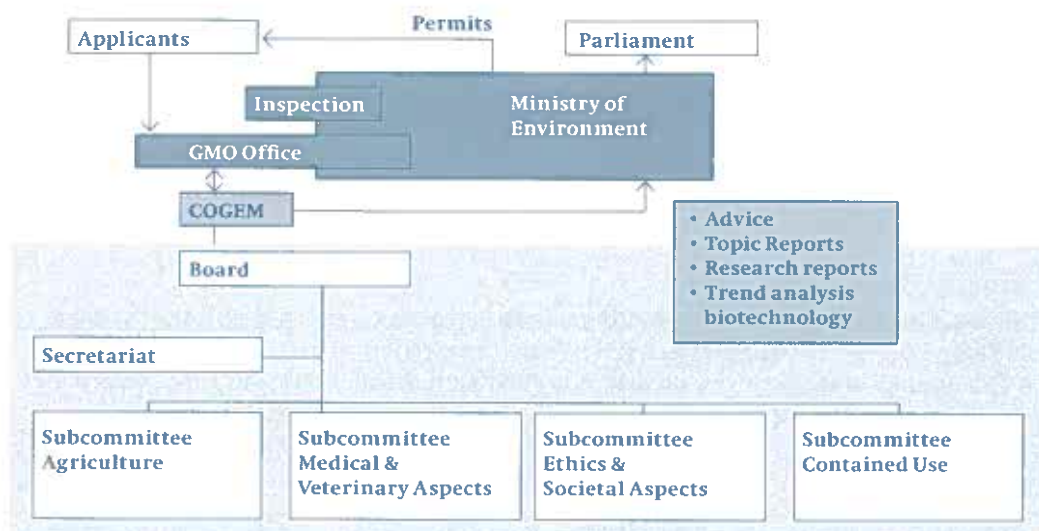
However, the Evaluation Committee noticed that the visibility of this subcommittee needs raising. Some stakeholders appear to be not entirely aware of the activities of this subcommittee or are uncertain about its statutory role and tasks. This calls for a better explanation of the tasks of this subcommittee and how they differ from those of the other subcommittees.

COMPOSITION OF COGEM

The composition or member line-up of COGEM is ample. The commission has a wide variety of scientific expertise and disciplines in the different subcommittees. Where a specific expertise is required that is not present within COGEM, external experts are recruited. Procedures to prevent possible conflicts of interest are in place and appear to be effective.

With respect to the subcommittee Agriculture, the Evaluation Committee would like to point out that knowledge and expertise on agronomy and farming practices, etc., is of the utmost importance. The significance of this discipline will only increase in the future as attention to and discussion of the potential indirect effects of GM crops growing. The Evaluation Committee acknowledges that this type of expertise is on-hand in the subcommittee, owing to the presence of two or three members with some knowledge of this subject. However, this discipline is not formally present within the line-up of the subcommittee. Altera-

Figure 1: Organisation and position COGEM



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tions in the membership could lead to loss of expertise in this important discipline. Therefore, the Evaluation Committee feels that there is need to appoint a 'theoretical production ecologist' or 'agronomist' to COGEM.

The Evaluation Committee would like to underline the importance of a gender balance in the members of COGEM. With a ratio of approximately 1:3, COGEM falls short on this. As indicated in the Status Report, it is difficult to recruit female experts. The number of female scientists in tenure track still lags behind in the Netherlands and female professors are widely in demand by organisations like COGEM that are striving to improve their representation. The Evaluation Committee acknowledges these facts. However, a better gender balance within the different subcommittees, without compromising on the quality of the membership may add extra differentiation into the reports and publications of COGEM. Therefore, it is important that COGEM develops initiatives to attract more female scientists and experts.

The Evaluation Committee notes that the subcommittee Contained Use has not convened in recent years. As this subcommittee appears to be dormant, COGEM should consider dismantling it.

3.1.3 ROLE AND POSITION COGEM

The Evaluation Committee notes that COGEM has several joint activities with the Rathenau Institute. It would like to point out that both organisations have different tasks and roles. The Rathenau Institute organises debates on issues and dilemmas in science and technology to promote the formation of political and public opinion on science and technology. The Rathenau Institute carries out technology assessments, while COGEM informs the government on ethical and societal issues linked to genetic modification.

Cooperation between these two organisations can be most valuable. However, COGEM has to maintain its focus on risk assessment and providing information to the government on the socio-ethical aspects of genetic modification, and has to be careful not to intermingle with the activities of the Rathenau Institute. In collaborative projects with organisations such as the Rathenau Institute, the strength of COGEM lies in the contribution of data and information.

SOCIO-ECONOMIC ASSESSMENT OF GMOS

In the EU a discussion is going-on on whether the assessment of socio-economic aspects should be part of the authorisation procedure. The current authorisation procedure is based on a safety assessment alone. At the request of the former Minister of VROM, COGEM has developed criteria for the assessment of the sustainability of GMO crops. The political debate in Europe on this issue has only just begun, and it is still unclear if and when the EU will decide to incorporate a socio-economic assessment of GM crops in its authorisation procedure.

The Evaluation Committee is of the opinion that the COGEM publication on socio-economic criteria is a very valuable contribution to the design of such an assessment. However, to actually carry out such an assessment would not be in keeping with the tasks and role of COGEM, or its expertise. COGEM could contribute to such an assessment as an input provider but other organisations or consortia of organisations with experience of economic and societal assessments would be better suited to carry out a socio-economic assessment.

3.1.4 INTERNATIONAL ROLE

The Evaluation Committee observes that COGEM has pioneering role in Europe. As mentioned earlier, its advisory reports and topic reports are highly respected internationally. COGEM is seen as a leading international authority and an example for many other advisory bodies. Several issues raised by COGEM are now on the agenda in Brussels.

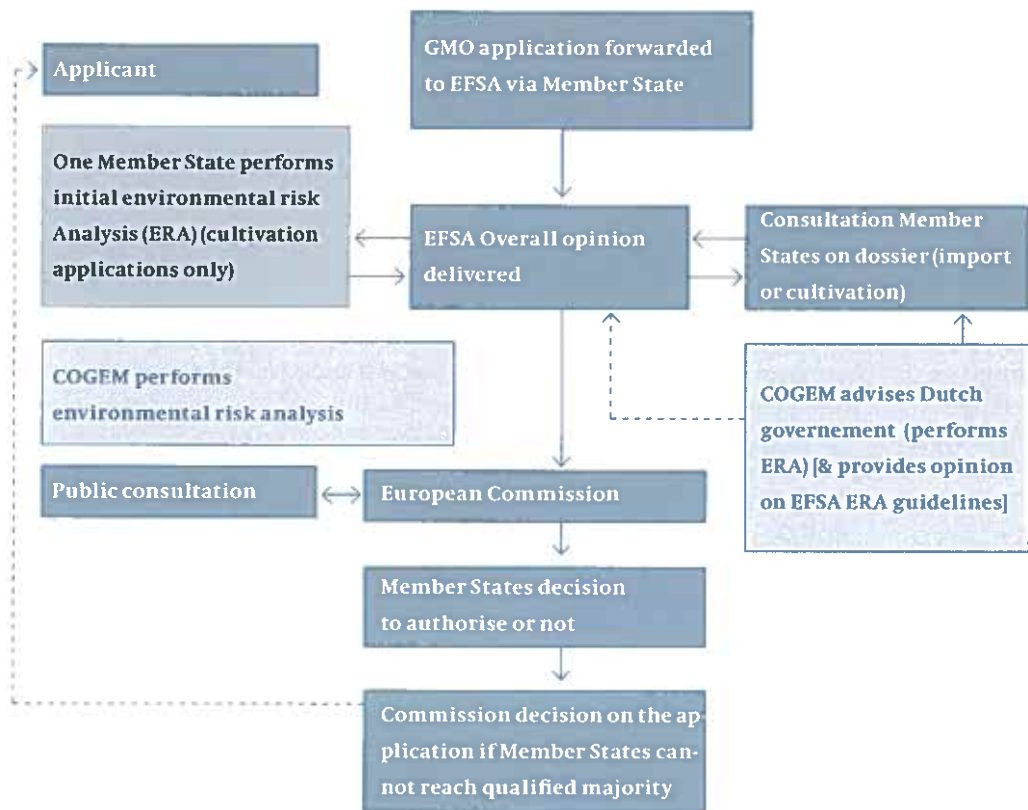
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COOPERATION

However, the growing workload may endanger the vigilance of the members, exhaust the capacities of the secretariat and endanger the scientific quality of COGEM's output. This is not unique to COGEM; most EU national advisory bodies on biosafety face similar problems. In addition to their other duties, all these national advisory bodies assess the same notifications for EU market authorisations of GM crops. Therefore, a solution may be found in strengthening the international cooperation between the national committees on biosafety. The aim of such cooperation would be to bring about better coordination and to minimise the duplication of work and other activities undertaken by the different advisory committees.

Improving international cooperation should not only involve the national advisory bodies but also the GMO unit of the European Food Safety Authority (EFSA). A great deal could also be achieved with better communication and coordination between EFSA and the national advisory bodies. However, the Evaluation Committee notes that communication with EFSA is sometimes difficult and that the insights of national advisory bodies do not always appear to be appreciated by EFSA. While the national advisory bodies sometimes appear to challenge the scientific opinions voiced or risk assessment procedures proposed by EFSA.

Figure 2: Role and tasks COGEM in relation to the European GMO notification procedure



3. DIAGNOSIS AND CONCLUSIONS

AVENUES FOR IMPROVEMENT

Potential avenues for improving international cooperation are: 1) looking for ways to divide the workload on routine dossiers between national committees; and 2) combining forces with comparable national advisory committees to put the EFSA under pressure to: a) be more transparent in its actions, b) to improve communication substantially, c) to take into account and to appreciate more than it currently does, the work done by national advisory committees, and d) to avoid the duplication of work. All of these actions need strong support and committed initiatives from policymakers in the EU member states.

3.1.5 COMMUNICATION

The authority and credibility of COGEM depends on its scientific quality and the fact that it is not perceived by stakeholders or the public as an organisation with vested interests. The communication strategy of COGEM is attuned to underlining the authority and credibility of the organisation. Far from working in 'clinical isolation', COGEM has managed to be visible and transparent, while avoiding becoming trapped by a communication strategy that would flag it as a dependent body and thus ruin its credibility. In its communication COGEM practices maximum transparency. All of its publications are published on the website and the meetings of the subcommittees are open to the public.

COMMUNICATION STRATEGY

In the evaluation of 2007 a recommendation was made that COGEM should strengthen its communication, profile and visibility in the public debate. The present Evaluation Committee disagrees with its predecessors on this matter and endorses the opinion and stance of the COGEM Executive Board that it should be reticent with regard to the public debate.

The role of COGEM is to issue scientific advice and to inform the Dutch government on ethical and societal issues linked to genetic modification. To carry out this role effectively, it is of paramount importance that COGEM is seen as authoritative and credible by the public, policymakers and stakeholders. Its authority and credibility is based upon the quality of its advice and reports and the fact that COGEM is not perceived as an organisation with a vested interest. It is not the task of COGEM to initiate, facilitate or participate in the public debate or stakeholder dialogue. Such a role could lead to confusion among the stakeholders and the credibility of COGEM could be severely jeopardised, since it is inevitable that COGEM would be perceived, or even forced, to take a stand on ethical and societal issues. Thus becoming a party in the debate. COGEM therefore has to limit its role in the public debate to the dissemination of information. The communication strategy of COGEM has to focus on providing maximum transparency over COGEM, its activities and publications, with the view of gaining public trust.

ROLE OF THE MEMBERS

COGEM's reticent position in its communication has to be reflected by its members. Several COGEM members are active in the field of genetic modification and may have vested interests, however, effective protocols and procedures are in place to avert possible conflicts of interest. Nevertheless, the pitfall of a perceived conflict of interests lurks. For instance, one of the stakeholders interviewed expressed surprise and confusion about the many different roles which the chairman of the COGEM subcommittee Agriculture seems to play in the GM debate. Therefore, COGEM should select members who are as free as possible of any suspicious liaisons, and members of COGEM have to be aware of their special position and should avoid being too opinionated in the public debate.

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The Executive Board plays a central and crucial 'filtering' role in guaranteeing neutrality and independence in all circumstances, promoting clarity and consistency in its advice and publications and sustaining a visibility which focuses not on perception but on scientific integrity.

COGEM PUBLICATIONS

The Evaluation Committee notes that COGEM's publications can be subdivided into three categories: 1) Advice in which COGEM issues an opinion on the basis of technical scientific considerations; 2) Topic reports, in which COGEM informs the State Secretary and policymakers of new technological developments and their implications, and of ethical and societal arguments or aspects which may come into play around applications of genetic modification, to facilitate a balanced decision-making process, and 3) Research reports commissioned by COGEM. In contrast with the first two categories, COGEM is not responsible for the content of the research reports. The research reports are presented to the minister accompanied by a topic or advisory letter, which states COGEM's opinion or which information COGEM feels is important for politicians or policymakers.

The differences in the types of COGEM publications appear to lead to confusion among some stakeholders; this may also be related to the fact that not all of them are aware of the different role of the COGEM subcommittee Ethical and Societal Aspects compared to the technical subcommittees. This confusion can possibly be averted by making a sharper distinction between the different types of publications in the communication activities.

VISIBILITY AND INDEPENDENCE

Another point that has to be raised is the visibility of COGEM. COGEM is primarily the advisory body of the Ministry of LandM. All publications are presented to the State Secretary of LandM and it is up to the ministry to decide whether or not publications will be passed on to parliament. Inevitably this decision will be influenced by policy goals and other policy considerations. The Environmental Management Act states that COGEM advises the Minister of Infrastructure and the Environment and other Ministers whom it may concern. Therefore, it is unclear whether COGEM can send its advice and topic reports simultaneously to other institutions, like parliament.

The possibility of presenting specific advisory and topic reports to parliament and the minister simultaneously would not only increase the visibility of COGEM but also strengthen its status as an independent scientific advisory body.

3.1.6 DEFINITION OF GMO

The Evaluation Committee notes that the legal definition of a GMO in the EU has been overtaken by scientific developments and insights. This is probably inherent to all legal definitions dealing with scientific issues. Science is dynamic and it is an illusion to strive for a clear-cut definition which will apply for a prolonged period. On the other hand, a vague or blurred legal definition could cause considerable problems in the authorisation process for GMOs.

The present vague (legal) definition of GMOs seems not to hinder COGEM substantially. Its scientific expertise and common sense allows an acceptable interpretation on a case-by-case basis. Apparently, COGEM is able to apply its expertise and authority to find the necessary flexibility in the interpretation of the GMO regulation.

Nevertheless, a pro-active stance by organisations such as COGEM may lead to a change in the scientific definition of GMOs, potentially resulting in a necessary legal amendment. Over the past few years COGEM has done a good job in the assessment of new technologies in biotechnology and their implications with regard to the GMO legislation, as well as in

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initiating the discussion on the interpretation of and possible changes to the EU legislation on GMOs. These initiatives were highly appreciated internationally, resulting in an EU workgroup on new technologies in plant biotechnology in relation to the GMO legislation. This pro-active attitude should continue in the future.

3.1.7 RED, WHITE AND GREEN BIOTECHNOLOGY

The Evaluation Committee notes that the public debate on GMOs is dominated by issues in agriculture and food. Anything to do with 'green' biotechnology is scrutinised and contested by the different stakeholders. However, genetic modification and biotechnology extend to all areas of society. These techniques have made their way into the medical sector where new medicines and clinical treatments, like gene therapy, have been developed, and into industrial production, to produce enzymes, antibiotics and chemicals. Many of these products are used in daily life largely unnoticed and uncontested, such as enzymes in detergents produced by GM micro-organisms. Other products are vital for health care like antibiotics, vaccines, immunosuppressive or anti tumour medicines. Not surprisingly, most of the GMO permit applications in the Netherlands are for laboratory experiments aimed at a better understanding of diseases, the development of medical and veterinary applications, or fundamental research purposes, or are for large scale production of biomaterials. And field experiments or market authorisations of GM crops represent only a small part of the total number of permit applications.

In spite of this, there is a strong bias in the public debate and media attention towards 'green' biotechnology, at the expense of 'red' and 'white' biotechnology. COGEM has managed to avoid this bias. Its advisory reports, topic reports and research efforts are evenly distributed over the different types of biotechnologies. In its communication activities COGEM could stress this point to make stakeholders aware of their bias towards green biotechnology issues and to show that the field of work and activities of COGEM extend beyond just green biotechnology.

3.1.8 REGULATION AND DEREGULATION

The GMO regulation has to strike a balance between safeguarding the safety of the environment and humans, on the one hand, and not needlessly hindering scientific research and the development of potentially useful applications, on the other. Moreover, a transparent regulation involving the least possible administrative hassle is important to secure support for the legislation and safety measures in the scientific community and industry.

Advisory bodies like COGEM therefore have the task of identifying opportunities, and getting policymakers' interest in reducing and simplifying the legislation without skimping on safety or the prevention of possible risks. In the past few years COGEM has issued several advisory reports and letters on deregulation of the Dutch legislation on contained use of GMOs. The Ministry of LandM is now in the process of simplifying the Dutch Contained Use regulations by adjusting the Dutch GMO Decree. The objectives of the ministry are to increase transparency and to simplify the process, thus reducing the administrative burden on applicants and the licensing authority. COGEM's advice on this issue has apparently played an important role in the revision of the Decree. COGEM's efforts to push for these amendments are appreciated by the Evaluation Committee. COGEM should try to interest policymakers in speeding up the process of amending the regulation.

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3.2 CONCLUSIONS

- The quality of the work of COGEM is excellent and meets the demand.
- COGEM is highly regarded internationally. Its advice and topic reports are highly respected at international level and frequently used as examples of high scientific quality and pro-activity.
- In spite of limited resources COGEM develops various activities and produces a large number of publications in different fields.
- The organisation and composition of COGEM is up to standard.
- The internal coherence of COGEM could be strengthened.
- The Evaluation Committee endorses the present restrained communication strategy.
- The different types of COGEM publications sometimes seem to lead to confusion among some stakeholders
- Some stakeholders appear to be insufficiently informed of the activities and statutory role of COGEM related to informing the government on ethical and societal aspects linked to genetic modification.
- International cooperation with other EU member state advisory bodies on biosafety and with the EFSA could help to reduce the pressure of work and increase the efficiency and output of COGEM.
- COGEM should stick to its present role and tasks, and current practices. A possible future request to carry out socio-economic assessments or technology assessments should be refused. These activities are not part of its core business, and could threaten its credibility and scientific authority.
- COGEM members have to be aware of their special position and of perceived conflicts of interest. Therefore, they have to avoid being too opinionated on issues in the fields covered by COGEM.
- Expertise on 'agronomy' is present indirectly within the COGEM subcommittee Agriculture. However, despite its growing importance 'agronomy' or 'production ecology' is not formally part of the make-up of this subcommittee.
- The gender balance in COGEM needs improvement, without compromising the high quality of its experts.
- The independence and visibility of COGEM could be strengthened by presenting important advisory reports and topic reports directly to parliament.

4. RECOMMENDATIONS

The Evaluation Committee's assessment of COGEM's activities and publications is that these are of high quality. The Evaluation Committee furthermore considers that COGEM carries out the appropriate tasks. In other words, the answer to the questions "has COGEM done the right things?" and "has COGEM done these things right?", is yes! Consequently, the Evaluation Committee sees no reason for radical changes in the tasks, organisation or procedures of COGEM. However, an organisation like COGEM has to strive continuously to improve its quality and the quality of its activities. In view of the ongoing changes in the fields covered by COGEM, the Evaluation Committee would also like to make the following recommendations to further strengthen COGEM's operations:

- 1. To present publications of broader interest to parliament.** Presently, publications are presented to the Minister of LandM. It is up to the ministry to decide whether COGEM publications are passed on to parliament. By presenting publications to the Minister and to parliament COGEM will both increase its visibility and augment its independent position. Parliament will have the opportunity to take cognizance of COGEM's advice and topic reports irrespective of possible political or policy considerations on the part of the government.
- 2. To continue COGEM's present communication strategy.** In 2007 the Evaluation Committee at that time was of the opinion that COGEM had to be more active in the public debate. The present Evaluation Committee strongly disagrees with the previous committee on this subject. It endorses the opinion of the COGEM Executive Board that in order to be seen as an independent authoritative advisory body, it is imperative that COGEM does not become party to the public debate, with its own standpoint or interests. Therefore, COGEM has to adopt a restrained communication strategy, with the focus on providing scientifically sound information.
- 3. To make a better distinction between the different kinds of COGEM publications.** Linked COGEM publications can contain different messages. The Evaluation Committee notes that these differences are logical and a consequence of the different nature of the publications. The content of a research report is the responsibility of the authors and not COGEM, and providing an overview of the arguments in the public debate is different from giving advice on possible environmental risks. However, the Evaluation Committee is of the opinion that these differences should be better spotlighted, and possibly reflected by a different layout for the various publications.
- 4. To strengthen the collaboration with other international advisory bodies on biosafety.** In all EU member states COGEM counterpart organisations deal with the same problems and challenges, and advise on the same notifications for market authorisations. Their limited resources are challenged by increasing workloads. By collaborating on European notifications and sharing resources and information, the advisory bodies will be able to deal with the increasing workload. Moreover, collaboration in this way will enable the national advisory bodies to be heard by and to act as a respected partner to the EFSA.
- 5. To strengthen the cooperation with EFSA. EFSA occupies a central position in the EU notification process.** Both EFSA and COGEM, like all national advisory bodies, could gain a great deal through better coordination, improving the discussion and exchanging views on risk assessment. This requires effort on the part of both COGEM and EFSA. However, the Evaluation Committee notes that EFSA has been less than forthcoming on this issue than had been hoped. To facilitate better cooperation the attitude on EFSA's side has to change on this. COGEM should bring this under the attention of Dutch policymakers and to urge for an initiative of the Dutch government to bring about a change in behaviour of EFSA.
- 6. To further strengthen the collaboration with national organisations without losing sight of COGEM's specific role or 'niche'.** As a result of the findings of the

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2007 evaluation, COGEM engaged in several projects with the Rathenau Institute. Firstly, the Evaluation Committee would like to point out that COGEM and the Rathenau Institute have different roles. While the Rathenau Institute seeks to organise and to stir up the public debate, COGEM's role is more restrained, i.e. to provide information. Therefore, COGEM has to guard its position and role carefully. Secondly, COGEM could widen the scope of its collaboration to include other organisations like government research and assessment agencies (planbureau's), or the Health Council etc.

7. **To include a 'production ecologist' or 'agronomist' on the COGEM subcommittee Agriculture.** Although the Evaluation Committee is satisfied with the practical experience present on this subcommittee at the moment, it was observed that this type of expertise is not a formal part of the make-up of COGEM. As this type of expertise is vital to the quality of COGEM advice, especially on market authorisations of GMOs, and the fact that in view of future developments this expertise will be of increasing importance, it is recommended that a production ecologist or agronomist be appointed as a COGEM member.
8. **To strive towards achieving a better gender balance in the line up of members.** The Evaluation Committee acknowledges the difficulties in recruiting female experts. However, the Evaluation Committee is of the opinion that the current 1:3 ratio is too low and that COGEM should do everything it can to improve the gender balance, without compromising the high quality of its experts.
9. **To consider recruiting foreign scientists.** The Evaluation Committee observes that the best experts or scientists available on certain topics are not necessarily always national experts. This is true for all countries. COGEM (and other national advisory bodies) should consider recruiting scientists from abroad.
10. **To be constantly aware of possible conflicts of interest.** The Evaluation Committee is satisfied with the procedures to preclude conflicts of interest among COGEM members. However, COGEM has to be constantly aware of the vested interests of its members and possible resulting conflicts of interest. COGEM members have to consider how their manifestations (in the different roles of members, scientists or employees) in public discussions and the media may be perceived by stakeholders and the public.
11. **To enhance the communication within COGEM between the members of the different subcommittees.** Internal communication is predominantly handled by the staff of COGEM. Not least, given the different fields of the subcommittees and the overfull schedules of the members, wider contact appears to be limited to the annual Plenary Meeting. The Evaluation Committee would like to point out that face-to-face contact between members would be of great value in enhancing the quality of COGEM and its activities. Such contact can lead to new insights and ideas.
12. **To refrain from taking a leading role in possible future socio-economic assessments.** If socio-economic assessment of GMOs becomes part of the procedure for market authorisations, the Evaluation Committee is of the opinion that this assessment should not be carried out by COGEM. Other organisations or consortia of organisations would be better suited to carry out such assessments. COGEM has a specific role and expertise and can contribute to the socio-economic assessment. However, a leading role in the assessment process should be reserved for organisations and institutes with extensive knowledge of economics, modelling, technology assessment, societal assessments, etc.

