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OECD Models for Biotechnology Regulation and Business Interests

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Introduction

1. In the process of international policy-making and policy-transfer, non-governmental actors (in addition to, or rather than, national governments) have shown their growing presence and role. International politics is not just a process of interactions (conflicts, negotiations, alliances, etc) among national governments, but also a process of involvements of diverse stakeholders: business communities [Clapp 2002; Levy and Newell 2002; Braithwaite and Drahos 2000], NGO/CSOs [Keck and Sikkink 1998; Colás 2002], epistemic communities [Haas 1992], etc. These stakeholders exercise their influence either on diverse settings of international institutions such as the UN organisations, the WTO, and the OECD, or on national governments which in turn exercise their legislative power on international institutions so as to formulate international rules in favour of stakeholders' interests.
2. In the issue area of biotechnology governance, increasing academic attentions have been paid on the role of UN organisations such as the FAO/WHO Codex Alimentarius Commission, or the CBD and its Biosafety Protocol, as well as the WTO and its SPS and TBT committees [Bail et al. 2002; Safrin 2002; Stewart and Johanson 2003; Isaac 2004]. The processes of negotiating, formulating and implementing their regulatory frameworks have also been analysed in detail [Gupta 1999; 2004]. Despite its significance and uniqueness, however, the role of the OECD and its detail activities in this issue area has drawn relatively little attention so far, whereas its name is often mentioned in relation to its controversial concepts of 'substantial equivalence' and 'familiarity'.
3. The OECD is sometimes referred as an intergovernmental think-tank, by which we are likely to assume that the role it plays and the measures it uses in the process of international policy-making and policy-transfer can be characterised as an authoritative source of reference based on its analytical capacity, professional impartiality and innovative capacity to play the role of policy model provider [Gass 2003]. Think-tank is generally defined as a group of people with experience or knowledge of a particular subject, who work to produce ideas and give advice. However, several political scientists define it in a different way: "Think tanks attempt to influence or inform policy through intellectual argument and analysis rather than direct lobbying" [Stone 2000a]; "Rather than organisations committed to objective analysis of policy problems, think tanks have become organisations that turn experts into advocates and policy information into ammunition" [Rich 2004]; etc. On the ground of these broadened, politicised definitions, the OECD is exactly an intergovernmental think-tank, regarded as an effective tool to legitimise its hegemonic ideology of 'sustainable development of capitalist economy' and transfer its policy models (norms) to member, non-member countries as well as other international fora, while masking this ideological motive by claiming its tasks as 'neutral legal-technical analyses' and 'collaborative dialogues'.
4. In this paper, I will elaborate on its historical activities and role in the international biotechnology regulation, where I'll also focus on the OECD's strong interactions with national and business interests. And by characterising its role in the international biotechnology politics, I will try to answer the question: why the OECD should not be overlooked in this political context. Finally, by examining the recent change in the OECD's approach to the issue, I will give some implications to understand

the dynamic, multifaceted and contradictory nature of the hegemonic power relations within which the OECD is functioning as a pivotal agent.

Overview of OECD

5. The OECD was established after World War II as the Organisation for European Economic Co-operation to co-ordinate the Marshall Plan, and transformed in 1961 into the international institution as it is with trans-Atlantic and global reach. It has now grown to be a group of like-minded 30 member countries sharing the values of market economy, especially focusing on its 'sustainable development' in the mid-long term. According to the OECD Convention Article 1, its aims "shall be to promote policies designed: (a) to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy; (b) to contribute to sound economic expansion in Member as well as non-Member countries in the process of economic development; and (c) to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations" [OECD 1960]. In fact, the OECD as a unique intergovernmental organisation has considerably contributed to harmonising congested national interests in the growing issue of international economic policy during the past four decades.
6. The OECD's activities to pursue the shared values mentioned above can be classified into the following key functions: i) policy-oriented research, ii) clearinghouse, iii) policy modelling (agenda, norms, or standard setting), and iv) policy transfer (harmonisation or co-ordination through peer review and/or dialogue). All of these functions are carried out based on its administrative, legal and scientific expertise. Indeed, the OECD defines itself as a provider of comparable data, analysis and forecasts to underpin multilateral co-operation for addressing the economic, social and environmental challenges; and a forum in which governments work together to help them shape policy that may be acted on in domestic or other international fora.
7. The OECD divides its structure into three distinct bodies. First pillar and the most powerful body is the Council, composed of representatives of all member countries and the EC. The Council, chaired by a Secretary-General and assisted by four Deputy Secretary-General, is in charge of oversight and steering strategic direction of the organisation, with the decision-making power. Second pillar is the Secretariat, directed by the Secretary-General. It is composed of about 2,300 staff working directly or indirectly to support the activities of committees. They are based in a dozen Directorates (Economics; Statistics; Environment; Development Co-operation; Public Governance and Territorial Development; Trade; Financial, Fiscal and Enterprise Affairs; Science, Technology and Industry; Employment, Labour and Social Affairs; Education; Food, Agriculture and Fisheries; and Public Affairs and Communications) as well as administrative sections. The Secretariat includes some 700 economists, lawyers, scientists and other professional staff providing research and analysis. Third pillar is specialised committees, working in more tightly defined areas of policy. There are about 200 committees, working groups and expert groups in all. Some 40,000 senior officials from national administrations come to OECD committee meetings each year. Other than these three bodies, there are several semi-autonomous bodies (Nuclear Energy Agency, Development Centre, Centre for Education Research and Innovation, International Energy Agency, European Conference of Ministers of Transport, Sahel and West Africa Club). Moreover, the OECD has been working with 'civil society' so to say, by consulting with business through the BIAC (The Business and Industry

Advisory Committee to the OECD), and with labour through the TUAC (The Trade Union Advisory Committee to the OECD) since the beginning of its history.

OECD's Activities on Biotechnology

8. Out of these Directorates, mainly the Directorate for Science, Technology and Industry (STI) and the Environment Directorate have been involved in biotechnology-related activities. The former is in charge of socio-economic issues related to science and technology policy in general. Supported by the STI, the Committee for Scientific and Technological Policy (CSTP) has been responsible for discussions over biotechnology policy since 1982. Mainly an Ad hoc Group of National Experts on Safety and Regulations in Biotechnology (GNE) created by the CSTP in 1983 and another Ad hoc Group renewed in 1988 have carried out the detail study on the safety in use of GMOs at the industrial, agricultural and environmental levels. The management and global networking of Biological Resource Centres is also directed by the STI. The Environment Directorate (ENV) has always collaborated with the STI, but not fully until when the ENV established the Working Group on Harmonisation of Regulatory Oversight in Biotechnology in 1995. The Task Force for the Safety of Novel Foods and Feeds is also working under the aegis of the ENV. Apart from the STI and the ENV, the Trade Directorate and the Directorate for Food, Agriculture and Fisheries are involved in biotechnology-related policies such as intellectual property rights issues, and issues related to the impact on agricultural market and trade (including international seed trade issues) and the Co-operative Research Programme respectively. In order to facilitate co-operation between these various OECD activities (i.e. science, technology and industry; agriculture; environment; and trade), the Internal Co-operation Group for Biotechnology (ICGB) was established in 1993.
9. Several semi-autonomous bodies of the OECD as well as other international organisations also collaborate in the issue areas of international co-ordination of Biosafety (BioTrak together with UNIDO's BINAS since 1996, and the Inter-Agency Network for Safety in Biotechnology or IANB since 1999), Development (Development Centre of the OECD), and Global Dialogue (Centre for Co-operation with Non-Members, or CCNM).
10. I'll divide the history of OECD's activities on biotechnology into several stages according to its milestones. The First Round (1982 - 86) can be summarised as a period for agenda setting and establishing general principles.

    1983) The Ad hoc Group of National Experts on Safety and Regulations in Biotechnology (GNE) was set up by the CSTP.

    1986) The GNE published the report, including the recommendation which was adopted by the Council, entitled "*Recombinant DNA Safety Considerations*" [OECD 1986]. This report is one of the first international scientific frameworks for the safe use of organisms derived from rDNA techniques. It also set out general principles (e.g. GILSP[1]) for the safe development of rDNA, precursors of the

[1] GILSP (Good Industrial Large Scale Practice): The hazards associated with GM micro-organisms can be assessed and managed in a similar way to those associated with other organisms. It should be recognised that, for organisms considered to be of low risk, only minimal controls and containment procedures are necessary. This will be the case for the vast majority of GMOs used in industrial large scale production. For these reasons, we endorse the concept of GILSP for organisms which may be handled at a minimal level of control. Later, the U.S. and Japan proposed the concept of GALSP (Good Agricultural Large Scale Practice). Although this concept was not adopted by the OECD due to negative opinion from the European side, it was institutionalised in the USDA's notification system.

concepts of 'substantial equivalence' and 'familiarity'.

However, due to a considerable lack of data and experiences concerning agricultural and environmental applications, most of work in the OECD (GNE) during this period focused on industrial use of GMOs, leaving the issue area of agriculture and food applications remained to be dealt with in the following round.

11. The Second Round (1988 - 93) is summarised as a period for scaling-up of general principles from industrial use to environmental release.

    1988) The Ad hoc Group was reorganised to a Group of National Experts on Safety in Biotechnology (GNE) to work on developing more defined principles adaptable to safe scale-up releases of GM micro-organisms and plants as well as food safety (since 1990).

    1993) The GNE Working Group on Large-scale Release of GMOs published two reports entitled "*Safety Considerations for Biotechnology: Scale-Up of Crop Plants*" [OECD 1993a] and "*Safety Considerations for Biotechnology: Scale-Up of Micro-organisms as Biofertilizers*" [OECD 1993b], in which the concept of 'familiarity[2]' was worked out.

    1993) The GNE Working Group on Food Safety published a report entitled "*Safety Evaluation of Foods Derived by Modern Biotechnology*" [OECD 1993c], in which the concept of 'substantial equivalence[3]' was worked out.

12. The Third Round (1993 - 98) is characterised by its activities for international harmonisation of regulatory frameworks.

    1993) The Internal Co-ordination Group on Biotechnology (ICGB) was established to facilitate internal co-ordination among related sectors.

    1994) The OECD held a Workshop on Food Safety Evaluation in Oxford to elaborate principles for the safety assessment of foods derived by modern biotechnology.

    1995) A Working Group on Harmonisation of Regulatory Oversight in Biotechnology was established to ensure that the information and methods used in safety assessment are harmonised as possible among countries. In the process of working out "Consensus Documents[4]", the UNIDO and the UNEP also participate [OECD 1999].

    1995) As a follow-up to the work of the GNE, an Ad hoc Expert Meeting on Safety Assessment of

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[2] Familiarity: The concept of familiarity is explained by the OECD member countries as: "... the knowledge and experience available for conducting a risk/safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment". Thus, general experience with the plant and the inserted construct is used to assess possible risks, and if the plant or the inserted construct is well known and unproblematic, the risk is assumed to be low. However, a high degree of familiarity does not necessarily imply safety. Instead, familiarity is desirable because familiarity with a specific cultivar or trait facilitates a risk evaluation. Thus, the concept of familiarity is, according to the OECD, not analogous to a risk assessment, but only a description of the amount of knowledge and experience available.

[3] Substantial Equivalence: Basically, food safety is assessed by comparison of the new final product (a novel food or food component) with an existing product that has an acceptable standard of safety. If a novel food or food component (i.e. GMO) is found to be substantially equivalent to an existing food it can be treated in the same manner with respect to safety. No additional safety concern would be expected. If a novel food or food ingredient has not been found to be substantially equivalent to its conventional counterpart, this does not imply that it is unsafe. It is then to be evaluated on the basis of its unique composition and properties.

[4] These consensus documents comprise technical information, mainly on the biology of organisms or introduced novel traits, for use during the regulatory assessment of GMOs and are intended to be mutually recognised among member countries. So far, 28 documents have been published, including those of oilseed rape (1997), rice (1999), sugar beet (2001) maize (2003), etc.

New Foods was held in Paris to identify tasks to be fulfilled [OECD 1998a].

1996) The FAO/WHO convened a consultation on "Biotechnology and Food Safety" to review national and international activities in the area, in which it was agreed that the comparative approach embodied in the OECD concept of 'substantial equivalence' is a basic tool in the assessment used to establish the safety of foods derived from genetically engineered plants [FAO/WHO 1997].

1997) A Workshop on the Toxicological and Nutritional Testing of Novel Foods was held in Aussois, France [OECD 1998b], according to the proposal of a Steering Group on the Safety Assessment of New Foods launched by the 1995 Ad hoc Expert Meeting.

OECD and Intergovernmental Politics

13. With this simplistic picture, it would be easy to assume a positivistic stance that sees policy as a reflection of the scientific facts, based on which the OECD claims its science-based, evidence-based impartiality. However, more detail insight into the OECD's way of framing issues and its process of working out several key concepts and publications as source of reference would allow us to conclude that OECD's activities have always been influenced and shaped by hegemonic national interests as well as business interests. Few can deny such influences in general, but little is known about how.
14. To understand the political nature of the OECD is quite important because of the following reasons. In general, guidelines or principles adopted by the OECD Council are not binding formally, but they assume a strong commitment of member countries to implement them in their own regulatory policies. They are also expected to serve as policy models for non-member countries. The OECD has always exercised its 'harmonising and co-ordinating power' in controversial but internationally pressing issues, and the results of the studies of its expert groups provide national authorities with a handle for working out their own regulations, and may also induce debates in other international fora [De Groot 1992], as seen in the FAO/WHO Consultation in 1996. This function to create non-binding 'soft-laws' based on legal-technical analyses by experts is often more effective than to establish legally binding agreements through tough political negotiations in the eyes of international community. Some observers describe such advantageous position of the OECD as 'agenda-setting power' [Ryan 2002].
15. By reference to the manuscript of a roundtable discussion given by four key Japanese figures[5] who have been involved in the OECD's activities on biotechnology, I'd like to show how OECD's activities as a think-tank have been embedded in the wider political economic power relations [JBA 1997].
16. The first round was launched based on, or following, the 'achievement' of NIH Guidelines, which had developed and deregulated during the period of 1976 and 1982. The revised NIH Guidelines eventually pioneered a concept that the process of genetically modification itself posed no unique or special risks, which were later followed by other agencies (e.g. USDA and FDA). However, as traced

[5] Dr. H. Uchida, an emeritus professor of University of Tokyo and a member of the Science Council of Japan, was working for the GNE as a vice chair from 1983 to 1994. Mr. M. Masuda, a manager of the Chemical Product Department of the Ministry of International Trade and Industry (MITI, now the Ministry of Economy, Trade and Industry), has been working for several working groups since 1980. Dr. S. Sumida, a director of JBA, was working for the Japan-U.S. Bioindustry Forum from 1988 to 1989, and for the GNE (an executive secretary) from 1991 to 1993. Mr. F. Ishikawa, an executive director of JBA (now retired), was working for the International Energy Agency of the OECD as a representative of the MITI and its external body, NEDO (New Energy Development Organization).

in detail by Susan Wright [1994], a large degree of scientific uncertainty persisted throughout the period, so no particular policy response could be derived from the state of science at the time. Instead, she reveals in her ethnographical analyses that the dominant interests, namely elite researchers and industry, influenced the process of, for example, organising the conferences, committees, or panels, framing the discussions there, disseminating their results, etc.

17. The launch of the OECD's involvement in biotechnology was also based on an assumption that the stage for discussion had already shifted from 'science and laboratory' (regulation of technology) to 'administration and industry' (regulation for business), without addressing 'uncertainty' or 'unknown risks' seriously. At that time public interest in genetically modification and life sciences in general was growing, and far-reaching social and economic consequences were recognised as policy challenges [De Groot 1992]. The U.S. government backed by elite scientists and industry strongly felt the necessity for international co-operation to bridge the gap between the U.S. and the rest of the world.
18. The second round was launched driven by necessity to 'regulate' impending commercialisation of agricultural biotechnology. As of the year of 1986, the U.S. government had been ready to approve the environmental release of GM crops without any regulatory framework specified to modern biotechnology. The policy was based on the assumption that the process of biotechnology itself posed no unique or special risks. Further, this policy stated that a commercial product, regardless of its manner of production, should be regulated based on the product's composition and its intended use. In other words, foods developed via biotechnology would be regulated in the same way as other foods developed through conventional processes. Likewise, microbial pesticides developed from biotechnology would be regulated in the same manner as other microbial pesticides. The U.S. policy on biotechnology has always prioritised the international competitiveness of the U.S. industry [Hisano 2002]. For example, the OTA (Office of Technology Assessment) released a report in 1984, entitled "*Commercial Biotechnology: An International Analysis*" that studied possible frameworks of biotechnology regulation from the standpoints of how to improve international competitiveness of the U.S. bioindustry. The NRC (National Research Council) Board on Agriculture also published a report entitled "*Agricultural Biotechnology: Strategies for National Competitiveness*" in 1987. And in 1990, the U.S. body responsible for co-ordinating biotechnology regulatory policies charged by different agencies was reorganised to be governed by the President's Council on Competitiveness along with the Office of Science and Technology Policy (OSTP). Its "*Report on National Biotechnology Policy*" in 1991 confirmed the already-working policy elements: technology transfer from the public sector to the private sector through 'industry - academic - government complex'; enforcement of knowledge infrastructure through intellectual property rights system (pro-patent policy); and deregulation to improve international competitiveness; and so on.
19. On the other hand, the situation in European countries has drastically changed since 1986. Even before that point, safety considerations of modern biotechnology have been led by the U.S. supported by Japan because European countries lagged behind the U.S. and Japan in terms of regulation 'for' technology development. In 1986, the European Commission submitted a communication "A Community Framework for the Regulation of Biotechnology" to the European Council. This communication was the Commission's response to, and compliance with, the OECD's 1986 report (recommendation on how to regulate biotechnology). At this point, there was not a big gap between the U.S. and Europe, but this was not to last. When the European Parliament released a report of its

Committee on Energy, Research and Technology, so called the Viehoff Report, in 1987, it brought strong concerns among the U.S. along with Canada, Japan and the OECD about the significant departure of the EU regulatory approach favouring the social rationality (rather than scientific and economic rationality) and the highest level of consumer and environmental protection in the face of possible risks [Isaac 2002].

20. During the second round, therefore, most part of discussions in the OECD (e.g. Working Groups) can be described as U.S.-Japan vs. Europe on the ground that the former pushed 'sound-science' (or product-based) approach while the latter pushed 'unscientific risk-conscious' (or process-based) approach. According to some contributors to the JBA's roundtable discussion, the European 'environmentalist' way of thinking was likely to draw back the scientific achievement into the level of 'before NIH Guidelines' (or the level of 'Asilomar Conference'). Such an 'irrational and emotional' discussion in the Europe was regarded to go along with the political trends, which lead to some EC regulations (1990) and the German Gene Law (1991), for instance. In the conflict between both sides, Japanese representatives and experts played a significant role to intermediate and reach a compromise in favour of the US. approach vis-à-vis the European approach as the basis for international harmonisation.

OECD and Business Interests

21. Japan and the U.S. have often delegated representatives from their bioindustry associations (Japan Bioindustry Association: JBA, and Industrial Biotechnology Association: IBA, a predecessor of Biotechnology Industry Organization: BIO). In 1988, the Japan-U.S. Businessmen's Conference established the Japan-U.S. Biotechnology Forum, and based on which the Trilateral Biotechnology Forum (including the European counterpart, the Senior Advisory Group on Biotechnology: SAGB, a predecessor of EuropaBio) was formed in 1990. In the following year, this Forum was reorganised into the International Bioindustry Forum (including Canadian counterpart), which is now renamed to the International Bioindustry Federation (IBF). Through these bioindustry associations, Japan and the U.S. have put pressure on the European Commission as well as the OECD to adopt the U.S.-Japan led framework and its international harmonisation. Indeed, some Japanese representatives (backed by JBA) were in charge of the chairmanship and secretariat of the GNE during the second round.
22. The BIAC (Business and Industry Advisory Committee to the OECD) was constituted in 1962 officially recognised by the OECD as being representative of business and industry, so to say a 'front organisation' of the international business community. Its role is to provide the OECD and its member governments with constructive comments based on the practical experience of the business community. Its policy recommendations are directly influenced by the needs expressed by its member organisations (i.e. the principal industrial and employers' organisations in member countries, such as VNO-NCW in the Netherlands and Nippon Keidanren in Japan) and associate expert groups (e.g. CropLife International, European Chemical Industry Council: CEFIC, International Bioindustry Federation: IBF, International Council Grocery Manufacturers' Associations: ICGMA, International Fertilizer Industry Association: IFA, etc.). Through its consultative status vis-à-vis the OECD, the BIAC offers the business community an excellent opportunity to participate in intergovernmental discussions on policy issues, thus giving a chance to shape the development of long-term policies in member countries. The BIAC's Committee on Biotechnology, now chaired by DuPont and assisted by Monsanto, Pfizer, Unilever, and BASF, is responsible for biotechnology-related policy issues. Its

representatives, apart from those delegated by member governments (as mentioned above), regularly attend the OECD's official meetings such as the Working Group on Harmonisation of Regulatory Oversight in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds.

23. Note, however, that despite its special (i.e. official) status in the OECD, the BIAC is one of several international/national business organisations that exercise their lobbying power on the OECD and its member governments, as well as other international institutions (e.g. the International Chamber of Commerce: ICC, the U.S. Council for International Business: USCIB, etc., each of which has its own committees, working groups or task forces specialised in biotechnology issues). Because of their superior access to scientific expertise and capital, bioindustry associations are able to nurture their own 'epistemic communities' who take a common view of the biotechnology risks and the forms of regulation [Newell and Glover 2003].

Harmonisation and Dialogue for Global Outreach

24. The development of GMOs raises questions in a variety of related policy areas other than risk/safety evaluation, such as international trade, intellectual property regimes and the adoption of new international protocols or treaty instruments. Whether international harmonisation of regulatory oversight of these policy areas is successfully carried out is a matter of vital importance for the development of biotechnology and related industries. "Business benefit from clear transparent regulations that help to make their activities more certain, stable and predictable, enabling them to make more informed, confident investment choices. Regulation can bring order to commercial interactions and lower transaction costs, as well as confer legitimacy upon business transactions. Internationally, harmonised regulation can reduce barriers to trade by creating common standards and rules of conduct, and prevent the growth of obstacles to investment" [Newell and Glover 2003: 9]. This explains why the OECD has prioritised the issue of international harmonisation since the mid 1990s, though its activities on harmonisation were initially focused on regulatory consensus among the member countries[6]. In November 1999, however, nine intergovernmental organisations – CGIAR, CBD, FAO, OIE, UNCTAD, UNIDO, WHO, WTO and OECD – agreed to form a network, an Inter-Agency Network for Safety in Biotechnology (IANB) to enhance the exchange of information and facilitate co-operation on biotechnology-related projects [IANB 2000][7].

25. Especially since 1998 when some incidents and 'scientific' evidences that allegedly proved the adverse effects of GMOs on human health and the environment as well as the institutional failure of risk management, we have seen a growing backlash against GMOs. Faced with exploding concerns with possible risks of GMOs among consumers from Europe to Asia, and spreading to developing countries, and also by necessity to address a growing trans-Atlantic gap in regulatory policies, the G8 summit in Köln asked the OECD to undertake a study of the implications of biotechnology and other

[6] The OECD explains the task of harmonisation of regulatory oversight as follows: "Recent commercialisation of a number of biotechnology products in several OECD member countries, particularly new crop varieties, has also moved into trade. In this context, international harmonisation of regulatory oversight in biotechnology will ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of the technology." [OECD website]

[7] As of 2000, the UNDP and the ICGEB had joined the network. But, after the IANB published its first newsletter in May 2000, there has been no substantial progress except an 'already-existed' joint activity between the OECD (BioTrack) and the UNIDO (BINAS) in their shared clearinghouse system: BIO-BIN, and some OECD conferences held in co-operation with FAO, WHO, UNEP, CBD, etc.

aspects of food safety in June 1999. As part of the response to the request, the OECD Council established an Ad hoc Group on Food Safety to overview national as well as international organisations' food safety systems and their activities. In July 2000, the following five reports were submitted as a package to the G8 summit in Okinawa: i) *Report of the OECD Task Force for the Safety of Novel Foods and Feeds*; ii) *Report of the OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology*; iii) *Report of the OECD Ad hoc Group on Food Safety*; iv) *Summary Report of the Consultation with Non-Governmental Organisations* (held in November 1999); and v) *Chairman's Report* and *Rapporteurs' Summary on the OECD Conference on "GM Food Safety: Facts, Uncertainties and Assessment"* (held in Edinburgh, February/March 2000). While the final communiqué issued by the G8 Okinawa summit reiterated the members' commitment to a science-based approach as a key principle in resolving the biotechnology safety question, it also acknowledged the need for open and transparent consultation with civil society and the particular attention to developing countries in assessing the 'potential value' of biotechnology. It is also important to note that the communiqué failed to demonstrate any advance on the stalemate between the U.S. and the EU on the use of their different concepts for the risk assessment of GMOs. This gap seems to have grown during a series of discussions as exemplified in the Edinburgh Conference, the rapporteurs' summary of which clearly mentioned that there were a lot of points of disagreement (e.g. whether or not wider issues like impact on the environment, trade and socio-economic factors and people's belief systems can be separable from human health aspects; the need for traceability of GM material; etc.) as well as lack of knowledge (e.g. long-term effects on human health and the environment; methods for testing toxicity and allergenicity; etc.) [OECD 2000][8].

26. In July 2001, the U.K./OECD Conference on "New Biotechnology Foods and Crops: Science, Safety and Society" was held in Bangkok in co-operation with the FAO, WHO, UNEP and CBD. This conference was meant to bring together 300 participants from more than 50 countries, including scientists, government regulators and representatives from industry, academia and civil society. Discussion covered topics ranging from the role of stakeholders, including consumer and environmental groups, in national and international decision-making, to the need for assistance for all countries in building relevant research, production and regulatory capacity in this area. In November of the same year, another OECD Conference on "Living Modified Organisms and the Environment" was held in Raleigh-Durham, the U.S., attended by around 250 participants from 20 member countries and 25 non-member countries, drawn from government, industry, academia and civil society. The objective of the conference was, again, to bring together a diverse group of participants for a constructive dialogue between science and society, as well as between member and non-member countries on biosafety issues.

27. These conferences are in line with two emerging trends of the OECD's policy: the Global Forum, which was launched by the Centre for Co-operation with Non-Members (CCNM) in 2001; and consultation and dialogue with civil society organisations (CSOs), an emphasis on which was clearly indicated at the OECD 2001 annual meeting and the OECD Forum on "Sustainable Development and the New Economy" held in that year [OECD 2001a; 2001b]. Biotechnology is one of eight Global

[8] Although these non-technical issues have been sidelined in such an international fora up until the present, I'd like to note here that even the OECD has got obliged to admit the relevance of those social factors as well as uncertainties or unknowns of biotechnology.

Forums, aiming to develop "stable, active networks of policymakers in both Member and non-Member economies … through informal meetings of policymakers" [OECD 2001c][9]. In the light of a new situation, I'd like to characterise the period from 1999 as a Fourth Round for dialogue with non-member countries and civil societies for global outreach. Although it is not clearly mentioned, it is supposed that this focusing on dialogue with and participation of non-member countries as well as civil societies (multi-stakeholders) takes a lesson from failure in the Multilateral Agreement on Investment (MAI) in 1998.

28. In 1995, the OECD called for a strong, comprehensive investment agreement that would remove restrictions on the global movement of capital. The OECD argued that the MAI would complement existing international bodies on trade (WTO) and finance (IMF), thereby further developing a global infrastructure for capital. The narrow membership base of the OECD provided considerable opportunities for these countries, not least the U.S., to define the nature of internationalisation with regard to investment. However, the process did not work as smoothly as member countries might have anticipated: negotiations began in September 1995 and were scheduled to be completed by May 1997. This deadline had been subsequently postponed, and at the OECD 1998 ministerial meeting negotiations were suspended indefinitely. According to Daniel Egan [2003], conflicts over the MAI emerged at the very beginning in choosing the appropriate forum for an agreement. EU countries, many of which have seen the rise of social-democratic power in both national parliaments and the European Parliament, initially argued for the MAI to be negotiated in the WTO, which has a much broader membership than the OECD. On the other hand, the U.S., who has no political constraint to institutionalise the neo-liberal agenda, argued forcefully and successfully for using the OECD as the proper forum for the MAI. Thus, the OECD, composed of relatively small number of like-minded countries negotiating behind the doors with 'agenda-setting' power, was regarded by the U.S. as an effective arena for its political purpose, though its hegemonic project finally resulted in failure. Conflicts between nation-states were also brought about when some core countries (e.g. Australia, Canada, France, and even the U.S.) attempted to protect their national interests and sovereignty by reason that an agreement was supposed to remove national barriers to the global movement of capital. Other than the conflict between OECD member countries, two other conflicts between the OECD and subordinate social forces (NGO/CSOs), and ultimately between the OECD and important elements of multinational capital, which began to question whether the compromised MAI agreement could deliver what they sought, were examined by Egan [ibid.]. This fact reveals the contradictory nature of the international 'hegemonic bloc', within which the OECD is tactically functioning as a pivotal agent.

Conclusion

29. Explicitly or implicitly, the OECD has consistently made a tactical commitment to the process of international policy-making and policy transfer concerning biotechnology. Partly due to its intellectual authority, and partly due to its consensus-based policy modelling, the OECD has exerted

[9] "An increasingly important aspect of the Working Group [on the Harmonisation of Regulatory Oversight in Biotechnology …*added by the author*] activities concerns outreach activities to non-member countries which are designed to integrate input from non-member countries into Consensus Documents and to disseminate as widely as possible, the results of the work. This will ensure that OECD's work on harmonisation will develop within the context of other related international activities." [Buckingham and Phillips 2001: 8]

effectively its significant influence over the harmonisation and transfer processes of its policy models. This explains why its concepts of 'substantial equivalence' and 'familiarity' among others have been successfully adopted by other international and national regulatory frameworks. Its narrow base of membership, composed of like-minded countries sharing the value of 'sustainable development of capitalist market', has attracted hegemonic national interests as well as business interests to use such OECD's functions as an effective tool to legitimise their hegemonic project. There is no reason to disregard the role of the OECD vis-à-vis hegemonic national and business interests in the context of international biotechnology politics.

30. Hegemonic power is, however, not imposed on society overwhelmingly, but instead is a negotiated process. As Gramsci argued, both within the dominant coalition of capital, state managers, and 'organic intellectuals', and in its relations with subordinate forces, dominant groups must negotiate (within historically specific conditions) with subordinate groups in order to secure the latter's consent to their rule [Gramsci 1971]. Although hegemony seeks to incorporate subordinate groups within the existing social order, the negotiated nature of hegemony means that this incorporation is never complete or absolute as happened in the negotiation process of MAI. Also, a recent trend toward increased attention, if only at a relatively superficial level, to the relevance of transparency, inclusiveness, participation and the like implies that once a political process is made open to broader social groups (e.g. developing countries, civil society groups, previously-excluded expertise, etc.), any hegemonic project would be undermined, or at least readjusted and reshaped in the face of alternative policy models possibly counterposed by those social groups.

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