



The Voice of OECD Business

Transparency and the Protection of Regulatory Data

OECD Joint Meeting, June 2009

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PART 1: OVERARCHING CONCERNS

In November 2008, BIAC presented a first discussion paper to the OECD Joint Meeting on the need for balancing between transparency and the protection of regulatory data. The Joint Meeting requested additional information on industry's concerns and what specific role the OECD could play in this area. This paper has been developed as follow-up to the November meeting and has benefitted from the input of the range of sectors represented within the BIAC Chemicals Committee.

When addressing the concerns of the pesticides industry, the OECD Working Group on Pesticides raised the point that the solutions they were proposing may have implications for other industry sectors. The various sectors which are represented in the BIAC Chemicals Committee confirmed that the issue of balancing between the protection of regulatory data and transparency is a key concern for them. In BIAC's view, this is an important area where the OECD can not only provide guidance to its members, but can also establish standards that accession countries should meet and establish a benchmark for the international community.

The detailed sector reports providing further information on the specific concerns of the sectors represented in the BIAC Chemicals Committee are attached as Annex 1. We have extracted and highlighted below some of the common elements and overarching concerns. BIAC stands ready to provide additional information and examples during the presentation and discussion at the Joint Meeting in June.

Protection of Regulatory Data

The protection of regulatory data (PRD) is a unique proprietary right that consists of two elements:

1. A period of time during which the owner of the data has exclusive control of the use of the information which he has generated.
2. The recognition that a limited amount of information, commonly called trade secret or confidential business information, should only be made available to third parties by a regulatory authority in exceptional circumstances.

PRD is recognised by the WTO TRIPS Agreement Article 39 (see Annex 2), but the text restricts the applicability to those industries of concern in 1995. It also allows discretion and is open to broad interpretation.

PRD has gained additional importance because of increased regulation requiring ownership or access to data and the fact that emerging technologies are subject to extensive testing before products can be placed on the market. PRD is a vulnerable right as there is no equivalent of a patent or trademark office to police the owners' rights. It is sometimes

impossible to establish if the owners' rights have been violated. PRD can be subverted by using summaries made publicly available or by concluding that a requirement has been met by a previous applicant, thus allowing unfair competition by enabling a second applicant to avoid contributing to the costs of the studies.

Transparency

The sectors represented in the BIAC Chemicals Committee agree that there is a need for transparency in order to build and maintain confidence in regulatory decisions. However, unless common principles for the release of regulatory data are agreed, the current divergent rules amongst OECD Member countries will erode industry's proprietary rights.

Industry's concerns in this area include the following:

- Clarification on what is CBI or a trade secret: Business would benefit from a common understanding across the OECD. Currently there is no common definition and the principles for establishing CBI vary from a strict interpretation of what can be claimed to a list of items which cannot be claimed as CBI.
- Rules on transparency generally allow the release of CBI if there is an overriding public concern. However, we need a harmonised view of what is meant by the term "overriding concern".

For example: A German court has given an opinion in a case regarding plant biotechnology that, as an item had appeared in the press, it was an overriding public concern and the information was released. Subsequently a Swedish Court ruled that, as the information had been released in Germany, it was available and should be released by the Swedish officials.

- We equally need to establish a list of the principles applicable to strike the balance between the various interests such as the proportionality principle (see part 3 below).
- Should data be released before or after a regulatory body has proposed a decision?

There is increasing pressure for public involvement in decision making. Industry would suggest that this should be limited until after the initial assessment has been made, as otherwise experts may be subject to external pressures and not come to an independent decision.

- How do you prevent commercial misuse?

The majority of applications for access to, for example, pesticide information in the EU are from Brussels-based lawyers.

For example, a Canadian company can get information directly from the EU under conditions which would not allow its release by the Canadian Government. In Canada and the US, released information cannot be used for commercial purposes. However, there is no such restriction in the EU. In fact, in the case of environment-related data, EU officials are not allowed to ask why the information is being requested.

The unprotected release of complete studies is considered by countries, such as Brazil, as making the information available to the public, and hence removes the owners'

proprietary rights. We would therefore benefit from a harmonised guideline on the principles/systems to be used when releasing information.

- The question of financial compensation for the studies should be addressed.

Societal factors

- *Unnecessary use of laboratory animals:*

Industry accepts that it is appropriate to avoid the unnecessary testing of products on vertebrate animals. Among OECD countries, there is inconsistency regarding governments requiring duplicative testing involving vertebrate animals. Guidelines are needed to create consistency. Without such guidelines, industry is faced with the decision to rerun a study if any one authority requires the work to be done.

In those cases where data-sharing is desired, fair cost compensation guidance should be available.

To appropriately minimise vertebrate testing, various authorities have introduced arbitration/sharing systems and it may be appropriate that the factors taken into account in any such system should be listed.

- *Worker safety:*

Industry is concerned that the release of information that can help to identify individual workers who are engaged in legitimate research can lead to criminal attacks and property damage.

PART 2: POSSIBLE ACTIONS FOR THE OECD

Industry would like to put forward the following proposals for consideration by the OECD Joint Meeting:

1. Official recognition that PRD is a unique and legitimate intellectual property right for all highly regulated industry sectors

We encourage the OECD to explore how the status of protection of regulatory data can be integrated into discussions with non-OECD members, in particular accession and enhanced engagement countries. This would include conducting awareness campaigns on PRD, in particular directed to national administrations and agencies.

2. A review of the 1983 OECD Recommendations 83/96-98

Are the 1983 OECD Council Recommendations on the protection of proprietary rights to data submitted in notifications of new chemicals still adequate for chemicals and pesticides? In particular, the following issues need to be addressed:

- i) Confirmation that the term “chemicals” should have the widest definition and include emerging sectors, such as nanotechnology and plant biotechnology. A broad definition may require some adaptation of the principles for “chemicals”.

There is uncertainty as to whether the 1983 *OECD Council Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals* applies to other products (e.g., nanomaterials, biotech). The Act recommends that regulatory authorities that receive “notifications of new chemicals” not accept health, safety, and environmental data if the notifier cannot provide a certification of the right of use. This is a good instrument and limits the mis-use of proprietary data. As the nanotechnology and biotechnology industries are in earlier stages and considerable proprietary research is underway, protection of such information is vital. Yet, it is unclear whether the Act applies to such information.

- ii) While this Council Act does address the problem of a company “submitting” health and safety data which it does not own, the Act does not address the “use” of such data by that company for commercial purposes. For example, Company A may conduct a series of preliminary tests to determine the appropriate dosing level to use in a test study. While Company B, which does not own such data, cannot submit the same studies to a regulatory authority, it can still use Company A’s proprietary results for commercial and development purposes, by identifying how issues have been addressed or by removing the need for initial assessments.

Some governments have been able to address this concern by striking a balance which ensures transparency and the protection of proprietary data. For instance,

some, but only a few OECD governments, provide access to proprietary data provided the second party signs a binding agreement that they will not use the data for commercial purposes.

- iii) The Council Act does not address the use of proprietary data in non-OECD countries. This is a concern given the growing propensity of OECD governments to post full studies or comprehensive summaries on the Internet, which can be downloaded in any country in the world. Again, the submission of such studies by a second company is covered by the Council Act, but only applies to OECD countries. Obviously, OECD initiatives can only be directly addressed to its members; however, OECD can influence non-members.

For example, the OECD Pesticides Programme has addressed this issue by including suggested text in its Guidance Document for Monographs that all regulatory authorities should include in their actual monographs. This text specifies that regulatory authorities should not use the contents of a monograph from another country as a basis for their regulatory decisions unless the owner of the supporting data has consented or been fairly compensated.

- iv) The CBI section of the Act could be revised to include the names of individuals who conducted legitimate research in sensitive areas, such as vertebrate animal or GM testing, as there is currently no reference to them. If they are not specifically included as items of CBI, it will put those individuals at risk of physical harm. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has proposed a scheme to implement this protection. However, any possible solutions may only apply to tests conducted in support of pesticide applications.
- v) The Act could establish rules concerning the repetition of animal studies so that they are co-ordinated and avoid repetitive testing due to differences in Member States' requirements.

3. Develop best practices regarding enforcement of PRD

Develop best practices for striking the balance between PRD and transparency rules across sectors. These need to cover:

1. Common definitions
2. At what point PRD should be made available
3. Conditions for release and for what purposes
4. What should be released
5. Periods of exclusive use (recognising sector differences)

4. Clarify the concept and develop a common understanding of CBI

Different CBI requirements across OECD countries affect companies that submit the same data to different countries. If a data element cannot be claimed as CBI in one country and is placed in the public domain, the element cannot be claimed as CBI in a second country – even if such information would normally be afforded CBI protection in that country – because the information is in the public domain. This means that the country which allows the least amount of CBI claims on data, sets the bar internationally. This impacts on companies that

submit the same data to multiple countries and is becoming increasingly a concern as more governments are now working together on the review of chemicals.

5. Develop guidance on what factors should be considered in any adjudication on due compensation

PART 3: SUPPORTING BACKGROUND

I. LEGAL SOURCES

The principles of protection of regulatory data can be traced back to the fundamental human right of owning property, as declared by the United Nations in 1948. The international covenant expressing the right to benefit from scientific works combined with the convention which outlaws unfair competition was first included in the 1967 Paris Convention for the Protection of Industrial Property, and ultimately resulted in the agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS), which laid the foundations for the rules on protection of regulatory data. Broadly, TRIPS splits such protection into two sections:

- i) Members must respect confidentiality;
- ii) Members must protect information submitted for regulatory approval from unfair commercial use.

Although the section on the protection of information specifically mentions pharmaceuticals and agricultural chemicals, it should be applicable to all situations where regulatory data are required to gain authorisation. The same international conventions and covenants used to develop the rules for pharmaceutical and agricultural chemicals equally apply to those sectors which either did not exist, or whose regulatory rules have been expanded, since the TRIPS agreement came into existence.

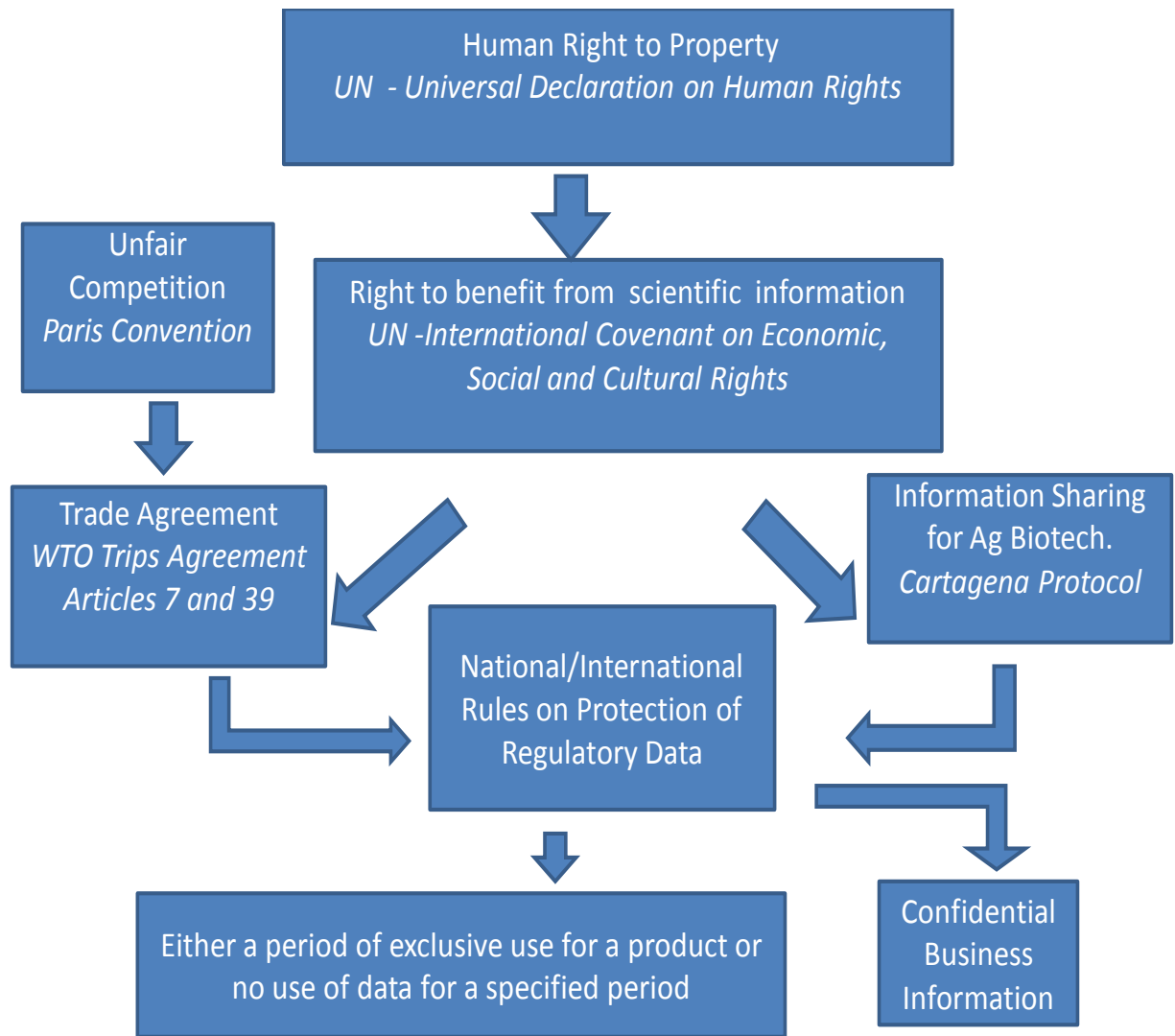
Like many international agreements the sections of TRIPS that deal with protection of regulatory data contain a degree of flexibility to allow for implementation by national governments, but they clearly oblige members to respect confidentiality and to protect the information from unfair commercial use.

National authorities have frequently implemented their rules on confidential data by defining what cannot be kept as confidential. The lack of a definition of what *is* confidential, leads to case-by-case decisions, but also, from an industry perspective, leaves uncertainty and a potential conflict in the final decisions of individual national authorities. Similarly, by not defining a period for the protection of regulatory data, there is a divergence of protection periods at national level, and some protection periods are inadequate.

Some governments have adopted either national or regionally harmonised rules for individual sectors. For example, for products of plant biotechnology, the Convention on Biological Diversity developed the “Cartagena Protocol on Biosafety”, which includes an

article on the handling of confidential information and defines what cannot be claimed as confidential.

The diagram below demonstrates the principles behind the protection of regulatory data and the corresponding international agreements.



See annex 2 for detailed information on the key principles behind the protection of regulatory data and the corresponding international agreements.

II. STRIKING THE BALANCE BETWEEN IPR AND OTHER INTERESTS, IN PARTICULAR TRANSPARENCY

A. Transparency

Transparency, in a regulatory capacity, implies openness in decision making and is a key element in obtaining the stakeholder consent required by industry to operate in an increasingly complex regulatory environment. Participative democracy builds on open procedures, the first stage of which is access to the information, followed by an opportunity to provide inputs into the final decision.

Transparency is not a new concept. Rules on the subject were first formally introduced in Sweden in 1766, and governments together with international organisations have continued to develop and legislate in this area, normally through “freedom of information” laws coupled with granting rights of participation.

Selective sectors and types of information are covered by international conventions. The UNECE Convention on Access to Information, Public Participation and Decision-Making and Access to Justice (the Aarhus Convention) covers (1) the right of access to environmental information, (2) public participation, and (3) access to justice.

A second example is the Cartagena Protocol which, as already mentioned, details the rules for agricultural biotechnology on confidentiality and establishes rules for transparency (see Annex II, pages 21-22).

In discussions on greater openness and transparency, it is often forgotten that a large amount of information is already in the public domain. Therefore, key elements in achieving transparency are building awareness of and improving access to this information.

It should also be recognised that access to all information is not a feasible option. There are commercial interests, as well as issues of public and state security and privacy, which have to be taken into account. For the common good, there have to be restrictions on transparency.

B. Intellectual Property Rights

While transparency is a crucial component of regulatory decision-making, so is the protection of legitimate intellectual property rights. Two important issues in this regard are confidential business information and exclusive use of regulatory data.

1. Confidential Business Information (CBI): While there is no agreed definition of CBI, business generally understands that CBI is information, which is not generally known, that is critical to the functioning of the business and its operations. It has to be kept confidential unless there is a critical health or environmental need for its release. The extent of any

release of this type of information should be limited to that necessary to address the critical need.

2. Exclusive Use of Regulatory Data refers to the obligation of regulatory authorities to ensure that proprietary information made available to it by an applicant is not used for commercial purposes by a third party for a specified period of time. If the information is released either to the public or to specific individuals or companies, measures should be taken to prevent misuse.

This protection of commercial interests, coupled with the rapid availability of information through modern electronic communication tools, is of concern to industry.

C. Striking the Balance

When striking the balance between the various interests, it is important that authorities apply the proportionality principle. In general terms, the proportionality principle requires that any exception must be appropriate and necessary to realise the objectives defined, must not constitute an excessive restraint on companies' rights and not affect the very substance of those rights. It is therefore imperative that any transparency regime allows companies to benefit from legitimate protection of their data and confidential information.

The European Court of Justice has summarised this principle very well:

“The right of property... forms part of general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property may be restricted, provided restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed.”

III. 1983 OECD RECOMMENDATIONS

The OECD has introduced a number of “principles” of confidentiality and availability of data. In July 1983, the OECD Council adopted three recommendations concerning confidential business information and intellectual property rights to data.¹

- Recommendation of the Council concerning the protection of proprietary rights to data submitted in notifications of new chemicals, C(83)96/Final,
- Recommendation of the Council concerning the exchange of confidential data on chemicals, C(83)97/Final,
- Recommendation of the Council concerning the OECD list of non-confidential data on chemicals, C(83)98/Final.

In 1998, the results of a survey of OECD Member countries’ approaches to the protection of proprietary rights and CBI in the registration and re-registration of pesticides were published². The purpose of the survey was to identify procedures that would facilitate the exchange of pesticide data review reports among countries while ensuring appropriate protection of proprietary rights and CBI.

A summary of the major findings, extracted from the report (shown by bullet points) follows, together with a description of the current status (shown in ***bold italics***).

Proprietary rights

- Most of the countries have national laws or regulations to protect proprietary rights with regard to pesticide data. In most countries these are specific to pesticides. Almost all countries apply the same laws or regulations for first registration and for re-registration data.

Differences have emerged on the length of time data is protected between an original novel registration and a re-registration.

- In most of the countries, there is an “exclusive use period” during which only the owner can use the data. The duration of this period differs among countries. It varies from one year to permanently. However, the first or current registrant can often give permission for this data to be used for the benefit of another registrant,

¹ For legal reasons pertaining at the time, Australia abstained on all three recommendations.

² ENV/MC/CHEM(98)20, OECD Governments’ Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration, OECD Environmental Health and Safety Publications Series on Pesticides No. 6, OECD Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998. Twenty-one OECD countries, the European Commission and the Food and Agriculture Organisation (FAO) participated.

although permission of the owner is not always necessary for the use of data involving animal testing (e.g. in some EU countries).

The periods of exclusive use are now, generally, a minimum of 10 years, with some members using an extension of this period to act as an incentive for the development of minor crop uses.

- In most of the countries, compensation for the use of another company's data is not legally set. Arrangements (e.g. financial) are left to the interested parties.

There is an increasing reference to arbitration in members' legislation, especially when studies involve vertebrate animals.

- OECD Recommendation C(83)96, concerning the protection of proprietary rights to data submitted in notification of new chemicals, is applied to pesticides in almost all the countries.

This is now questionable as a number of OECD member countries have introduced their own independent rules on access to information.

Confidential business information (CBI)

- No country responding to the survey provided a definition of CBI. However, other similar terms were defined, such as "confidential information", "confidential commercial information", and "confidential supporting information".

There is still a lack of definition of CBI as Member countries have listed those items which cannot be kept confidential rather than defining CBI.

- Most of the countries have laws and regulations to protect CBI on pesticides. In general, these regulations are specific to pesticides.

This reflects an appropriate implementation of the TRIPS agreement.

- More than half of the countries require pesticide registrants to identify confidential information in their data submissions, e.g. by putting it in a separate volume. However, most of the countries do not automatically accept what the registrant wishes to be treated as confidential, since national authorities often need to establish that registrants' requests are warranted.

Still true and in general information which is confidential is treated as such.

- The amount and type of data treated as confidential vary among countries. The only common finding is that information on hazard categories, the nature of the risks, relevant warnings, and precautions to be taken, as well as ways to render the substance harmless, are never treated as confidential. For many countries, it seems generally easier to indicate what is non-confidential than to indicate what is confidential.

This is still the case. Only the United States and Canada had entered into a bilateral agreement regarding the protection of CBI during exchange of reports. A similar agreement seems to be in effect among Scandinavian countries.

When required, the EU countries are able to exchange confidential information through their Circa server.

- OECD Recommendation C(83)98, concerning non-confidential data on chemicals, is applied to pesticides in almost all the countries.

Far more information can now be made available to the public than is listed in the 1983 Guidelines. By exceeding what is listed in the Guidelines, it can be said that Member countries do comply, but the individual rules adopted by Members lead to different levels of accessibility, which for industry enhances the potential for commercial misuse.

There are significant differences in implementation identified across OECD countries. It is also reasonable to point out that the initial survey was carried out before the widespread availability of the Internet and the implementation of the Aarhus Convention on Public Access to Information.

ANNEX 1: SECTORIAL ISSUES

I. Ag Chem Industry

Background to the ag chem industry raising the issue of protection of regulatory data in the OECD context

In order to prevent any misunderstanding, the Ag Chem industry is in favour of openness and transparency when considering the regulatory data which support the safety assessments of its products. However, openness and transparency need to be balanced with the legitimate right of intellectual property protection and be implemented in a manner which protects the industry's proprietary rights.

The cost of producing a regulatory package for a new agchem product is now greater than US\$ 200 million (established in dollars of the year 2000, Philipps/McDougall, 2003). This is obviously a considerable investment. However, this investment does not stop with the initial approval. On renewal or review of registrations, significant investments in new or upgraded studies are required. Currently the norm for such regular reviews is a review every 10 years. As can be seen from the EU Biocides and Pesticides reviews, the economic implications of these periodic reviews are significant, as a large number of active ingredients have not been submitted for re-registration solely based on cost.

Our issues:

1. Because of the lower requirements for information to support an approval in non-OECD countries, it has been found that published summaries are being used to meet regulatory requirements. These may, or may not be appropriate for the product under consideration, which is a concern, but it also circumvents the intellectual property rights of the study owner, because the summaries are based on his or her data.
2. Because of the open transparency rules, it has been found that applications for access to complete studies are often coming from third parties seeking commercial advantage by examining the results in the full study reports.
3. The OECD Working Group Pesticides has actively promoted the concept of regulatory work-sharing which has the effect of both minimising the number of submissions that companies have to make and the reviews which the regulators have to complete. While welcoming the initiative, industry has raised a number of points regarding the potential misuse for commercial purposes of submissions or evaluations. These areas of concern arose from 4 main points:
 - i. The original OECD rules on information exchange on chemicals were put in place in 1983. They have not been updated and may not be dealing with the present situation.

- ii. The “electronic age” now means that information can be swiftly circulated around the world with little or no control, thus great care needs to be taken when handling CBI.
- iii. There may be conflicts between proprietary rights as detailed in WTO TRIPS Agreement and emerging regulations on transparency and the right of public access to information. If information is placed in the public domain, then some authorities question if any proprietary rights have been waived.
- iv. Industry is concerned that the names and locations involved in vertebrate animal testing could be released to the general public, thus subjecting them to terrorist threats and activities.

The current situation

The OECD Working Group on Pesticides has accepted that the property rights issues have to be resolved, if sharing of regulatory reviews between government authorities is to become a regular feature. In the absence of a wider approach within OECD to deal with the problem, the WGP’s Registration Steering Group proceeded with finding a solution for the sector while highlighting that there may be implications for other sectors.

The major concern of all parties was to devise solutions which protect industry’s information, but do not oblige OECD member countries to amend their existing legislation – FIFRA, TSCA, Directive 91/414/EC etc.

Recommended improvements

Issue 1:

The “Guidelines for the Preparation of Monographs” were amended to include the instruction that a statement should be added to the cover page of each monograph or summary indicating that the document should not be used for regulatory purposes without having received the consent of the owner of the original data which supports the monograph.

Issue 2 and 3:

The WGP considered these as valid issues and recommended that authorities should use means of information release which minimise potential misuse, such as reading rooms and agreed to monitor the situation.

Issue 4

There was no agreement but a general understanding of the concern. In fact, a number of Member countries, as well as the EU, have now agreed to treat names and addresses of individuals as confidential. That said, it would be better if all OECD countries could agree to this, as the release by one member circumvents the good intentions of all other members.

II. Plant Biotechnology Industry

Currently, the protection of regulatory data for this sector is under discussion in at least Canada, Australia and Japan, and as a general item in the EU.

The situation of the plant biotechnology sector in terms of protection of regulatory data is characterised by a fundamental lack of consistency among countries. This results in significant vulnerability for a sector which is under constant public pressure for increased transparency. In recent years, the desire for greater transparency has progressively limited the amount of information that the plant biotechnology industry can protect as CBI in applications submitted to public authorities to obtain the multiple approvals required to place products on the market. As a consequence, while the public benefits from increased transparency, the plant biotechnology sector experiences significant challenges to protect its proprietary rights.

The protection of regulatory data and IPR is especially sensitive in the area of plant biotechnology because the product is biological in nature, making it susceptible to potentially illicit competitive behaviours. In other sectors, 'generic' producers must create their own chemical processes or formulation facilities through the application of their own specialised forms of expertise. In contrast, 'generic' competitors can take possession of plant biological material (e.g., biotech seed) and multiply it without a comparable input of added expertise. Thus, the protection of the information contained in product applications is a critical business asset.

In most OECD countries, CBI provisions are in place, and the plant biotechnology industry protects the information deemed sensitive in product applications primarily by confidentiality. Industry must clearly identify CBI and, if necessary due to a third party's request for access, provide governments a justification indicating the reason why the information must remain confidential. If governments deem this justification adequate, CBI will not be divulged to the public without permission from industry. While in the past CBI provisions granted some level of protection to regulatory data, in recent years, governments have come under increasing pressure to release more and more information to the public and to challenge CBI claims provided by industry. Hence, the importance of exclusive use of regulatory data has increased dramatically.

Many OECD countries do not have specific provisions for data protection in the legislation for plant biotechnology products, but government officials are generally required by law not to release any CBI they acquire during their working activities. In the EU, the situation is slightly different since the legislation on genetically modified organisms (GMOs) contains specific provisions for CBI and data exclusivity for the information submitted by the plant biotechnology industry to EU institutions and Member States authorities to obtain product authorisations. EU institutions are also required to comply with the principles governing the right of public access to documents received from industry. These principles were recently revisited due to the EU implementation of the Aarhus Convention. Compared to the past, the provisions for public access have been broadened and the amount of information currently protected by CBI is drastically limited. Public access is now allowed at the beginning of the regulatory review to *"any natural or legal person"*, *"without discrimination as to citizenship,*

nationality or domicile”, either by CD-ROM or by Internet connection to a password-protected website, where most, if not all the information provided in product applications can be downloaded and printed. In such a context, provisions for data exclusivity envisaged by the EU legislation are fundamental to ensure that the information made publicly available by electronic tools cannot be used for the benefit of another applicant in the EU. Nonetheless, this information can still be used for the benefit of other applicants in countries where rules for data exclusivity are not in place, *de facto* jeopardising industry IPRs and investments.

At the international level, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 21, foresees the protection of data submitted by the Parties under the procedures of the Protocol. Furthermore, the rules on protection of regulatory data from unfair commercial use and disclosure are captured in the WTO TRIPS Agreement, Article 39.3. However, this article refers to pharmaceutical and agricultural chemical products and its extension to plant biotechnology products has not been established.

Our concerns

- Unrestrained transparency can lead to a claim that our data are in the public domain. Due to the increased amount of information released to the public by electronic tools and the lack of harmonisation of provisions for data exclusivity, the regulatory studies supporting a product application released in one country can effectively support the registration of the same product in other geographies by generic applicants, giving “free riders” an unfair competitive advantage.
- The release of names of scientists involved in animal testing to the public by electronic means subjects them to threats, as evidenced by activist attacks.
- The premature release of product information in some countries has seriously undermined the conclusions of the scientific review and/or delayed the approval of the product in the country itself or in other geographies.
- In some OECD countries, the obligation to provide information on the locations of R&D trials for plant biotechnology products often results in the destruction of field trials used to generate research and regulatory data, thereby delaying the beginning of any regulatory process and product commercialisation.
- The global regulatory community has not yet achieved the maturity of considering work sharing agreements in the area of plant biotechnology. However, there is a growing interest in sharing regulatory conclusions with the potential for ratification of determinations made elsewhere and mutual recognition of decisions. In light of this, it is important to ensure the ownership of the various regulatory authorisations remains linked to the original registrant and cannot be shifted to third parties without express written permission from the developer.

III. Chemical Industry

The International Council of Chemical Associations (ICCA) has endorsed a set of principles for effective chemical management with the goal of fostering greater consistency and transparency in chemical regulatory programs to promote regulatory convergence (where appropriate) and provide enough flexibility to accommodate existing and anticipated national or regional laws and regulations. The following principles are relevant in the context of this paper:

- A chemical regulatory system must be based on risk, not hazard.
- Chemicals should be screened to determine further information needs, applying a tiered, risk-based approach.
- The system should leverage existing, available information.
- The system should promote data quality and transparency and allow access to useful information to interested parties including the general public; it should guarantee a fair balance between public access to data and legitimate protection of business information.

The appropriate protection of proprietary data, including CBI, is essential for realising any of the above principles in a chemical regulatory framework. As chemical regulatory programmes around the world develop and mature, it is increasingly important to ensure that information submitted to regulatory agencies for the purposes of gaining market access and regulatory compliance is not at risk of misuse and IPR protected as included in Article 39 of the TRIPs Agreement (see Annex 2), is not eroded.

Like any other IP right, protection of regulatory data plays an important role in driving innovation in the chemical industry. In the past however, when governments considered the relationship between IP and innovation, much attention was given to patents, but protection of CBI and regulatory data, which are valuable assets, received less formal legal protection. The effective management of and right of chemical companies to exploit these assets is equally important to patents. This is particularly true for small and medium-sized enterprises, which may not have the resources to create and maintain a portfolio of patents and similar forms of registered IPR on the one hand and have little experience of managing trade secrets and regulatory data on the other. Moreover, there are instances in which unregistered IPRs are the only solution available.

Because protection of CBI and regulatory data is not a right granted by a governmental authority (unlike patents and trademarks), industry and governments must engage in new discussions about the protection of CBI and regulatory data in the context of each piece of applicable legislation. Likewise, both industry and government are increasingly preoccupied with demands for total transparency. At a global level, industry finds itself confronted with a variety of approaches for establishing legitimate regulatory data and CBI protection claims and with a diversity of remedies available should such CBI and regulatory data be misused for unauthorised purposes or disseminated to the detriment of its owner.

Information on individual chemicals is a critical asset for the purposes of gaining and maintaining market access and for complying with changing regulatory requirements in existing markets. In this regard, the European Union's REACH legislation is notable because it has created by statute a sizeable marketplace for information among chemical manufacturers. It should also be noted that in addition to providing data for market access, chemical companies also provide government agencies with proprietary information to inform chemical prioritisation processes, risk assessments, the development of exposure scenarios, and for other purposes. If effective controls are not in place, proprietary information will be used by unauthorised parties to enter markets, create false assurances of product safety, or otherwise cause financial harm to manufacturers who have acted in good faith to comply with regulatory requirements.

The chemical industry supports the public availability of non-CBI information, and the OECD Council has recognised the importance of preserving CBI as crucial to innovation. Both industry and government have a common interest in balancing public interest in increased transparency with appropriate protection of regulatory data. A solution is needed that embraces the proportionality principle and in doing so recognises CBI and the ownership of regulatory data as a legitimate and necessary form of IPR, the protection of which is subject to due process of law. A single balanced approach in line with the objectives of Article 39 TRIPS Agreement on the protection of undisclosed information (see attached Annex 2) would clarify the roles and responsibilities of all parties.

IV. Metals Industry

The metals industry fully recognises the value and importance of openness and transparency on data especially for chemicals management information. The interest of this important inorganic sector stems, as for many others, mainly from the desire to share knowledge on hazard and risk data and profiles for existing chemicals.

However, rather different than for other sectors, the metals and alloys industries deal mainly with existing substances; new inorganic chemicals do occur, but are very rare. CBI in the metals sector is consequently related more to the product-specific use applications, than chemicals management information of the metal (substance) or alloy (special preparation) itself.

Another difference is in the extensiveness and comprehensiveness of the hazard and risk files prepared, or under preparation, for chemicals management purposes. The often intrinsic hazard properties of metals for different health and environmental end-points and the marked distinction between hazard and risks in the sector, due for example to exposure related factors (particle size and form, reduced exposure due to alloying, etc.), lead to the development of very extensive documentation often including testing programmes which go far beyond any regulatory requirement. This fits with the overall goal of the metals and mining sector's sustainability principles and supports materials stewardship, including the development of in-depth knowledge on the hazards and risks of metals and their use in the supply chain.

While chemicals management information is often shared between countries and regulatory agencies under the form of summaries (e.g. SIDS initial assessment profile documents under the OECD HPV programme), industry often provides, through both regulatory and voluntary programmes, deep insights into extensive reviews and data sets through the SIARs, or in the near future in Europe under the REACH registration files. In the case of metals, these often include increasingly sophisticated exposure or effects related models for assessing certain specific properties (e.g. bioavailability of metals in ecosystems). Industry promotes the use of these models by regulatory agencies in order to contribute to the better understanding of chemicals safety or risk management. Industry would, however, not wish to see the commercial sector gaining extensive advantage from them without recognition of ownership and therefore supports the principle of “exclusive use for regulatory purpose”.

As a result of regulatory chemicals management, information on (or the lack of it in other countries) chemicals hazards and risks quickly becomes a “competitive asset”. While the metals industry in general is not keen on promoting this, the sector would neither like to promote parties that did not contribute to the data/model generation, obtaining access to full details and claiming ownership - the so-called “free riders” issue. The latter is a relevant concern of the metals sector given that the materials are the same on a worldwide basis and very resource intensive to investigate.

The issue of confidential business information related to the metals sector is therefore rather an issue of *fair recognition of data ownership* and the protection of that data and avoiding unauthorised data ownership declarations for the commercial benefit or market access purposes of secondary applicants. For the metals sector, the balance between the absolute need to communicate the main conclusions on chemicals management and the recognition of data ownership is the main common challenge to address with the regulatory community. Proper balance in this respect will contribute further to extensive data gathering and enhance the quality and comprehensiveness of hazard and risk profiles of metals and alloys.

ANNEX 2:

Key principles behind the protection of regulatory data and the corresponding international agreements

Universal Declaration of Human Rights

Rights associated with property, including intellectual property, are protected in accordance with the Universal Declaration of Human Rights³ adopted by the General Assembly of the United Nations in 1948 and are set out in Articles 17 and 27 of the Declaration: -

1. *'Article 17*

- (1) *Everyone has the right to own property alone as well as in association with others.*
- (2) *No one shall be arbitrarily deprived of his property.'*

2. *'Article 27*

- (1) *Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.*
- (2) *Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.'*

International Covenant on Economic, Social and Cultural Rights

Rights concerning intellectual property were re-affirmed in the context of the International Covenant on Economic, Social and Cultural Rights⁴ adopted by the General Assembly of the United Nations in 1966 and which came into force on 3rd January 1976. Article 15 of the Covenant specifies: -

1. *The States Parties to the present Covenant recognise the right of everyone:*
 - (a) *To take part in cultural life;*
 - (b) *To enjoy the benefits of scientific progress and its applications;*
 - (c) *To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*
2. *The steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.*

³ <http://www.un.org/Overview/rights.html>

⁴ <http://www.ohchr.org/english/law/cescr.htm>

- 3 *The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.*
4. *The States Parties to the present Covenant recognise the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.'*

Paris Convention for the Protection of Industrial Property

The Paris Convention requires the members to protect industrial property rights and to provide effective protection against unfair competition. Article 10bis specifies

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited:

(i) All acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

(ii) False allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

(iii) Indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Article IV (paragraph 5) of the 1994 International Agreement establishing the World Trade Organization (WTO) ⁵ establishes *inter alia* a Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS), which '*shall operate under the general guidance of the General Council. The Council for TRIPS shall oversee the functioning of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the "Agreement on TRIPS"). These Councils shall carry out the functions assigned to them by their respective agreements and by the General Council. They shall establish their respective rules of procedure subject to the approval of the General Council. Membership in these Councils shall be open to representatives of all Members. These Councils shall meet as necessary to carry out their functions.*'

The provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) form Annex IC of the International Agreement establishing the World Trade

⁵ http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

Organisation (WTO). The objectives of the Agreement are both simple and clear and are set out in Article 7:

'Article 7

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'

Article 39 of the TRIPS Agreement links the protection of undisclosed data and data submitted to regulatory agencies with unfair business competition and as such must be prevented under Article 10 bis of the Paris Convention.

The specific provisions of TRIPS concerning CBI and intellectual property rights to data are set out in Article 39 of the Agreement:

'Article 39

- 1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.*
- 2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices⁶ so long as such information:
 - (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;*
 - (b) has commercial value because it is secret; and*
 - (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.**
- 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.'*

⁶ For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Cartagena Protocol

The Cartagena Protocol specifically relates to the safe transfer, handling and use of living modified organisms and applies to transboundary movements, excluding pharmaceutical products.

The information that a notifier must submit is protected by Article 21:

1. *The party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advanced informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.*
2. *The party of import shall consult with the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision.*
3. *Each Party shall protect confidential information received under this Protocol, including any commercial information received in the context of the advanced informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living organisms.*
4. *The party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.*
5. *If a notifier withdraws or has withdrawn a notification, the party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well information on which the party and notifier disagree as to its confidentiality.*
6. *Without prejudice to paragraph 5, the following information shall not be considered confidential:*
 - (a) *Name and address of the notifier;*
 - (b) *A general description of the living modified organism;*
 - (c) *A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and*
 - (d) *Any methods and plans for emergency response.*

Article 23 on public awareness and participation foresees that:

1. The Parties shall:
 - (a) *Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks*

to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies.

- (b) *Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.*
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.