



The Voice of OECD Business

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Balancing between the need for transparency and the protection of regulatory data

A BIAC thought starter

I. Introduction

The sectors represented within the BIAC Chemicals Committee recognize the importance of openness and transparency concerning regulatory data. At the same time, openness and transparency need to be balanced with the legitimate rights to intellectual property and be implemented in a manner that protects industry's proprietary information. The BIAC Chemicals Committee discussed this issue at its meeting in February 2008 and agreed that, while different sectors face different challenges, the need for balancing between transparency and the protection of regulatory data is an important issue for the range of sectors represented in the Committee. To help advance discussions in this area, it was decided to develop a paper for the November 2008 meeting of the BIAC Chemicals Committee and to bring its key messages to the attention of the OECD Joint Meeting. The issue was brought up at the OECD Joint Meeting in February 2008, and it was noted that the Joint Meeting bureau would review a BIAC document on proprietary data at their next meeting in November.

The objective of this paper is to respond to this request and to highlight the challenges that the chemicals, crop protection, plant biotechnology, biocides and metals sectors are facing with regard to the protection of regulatory data and to explore ways of how the OECD could help address these challenges. In addition to these sectors, it needs to be recognized that products from emerging enabling technologies, such as nanotechnology, are likely to face similar challenges in the future, which will need to be addressed. BIAC believes that the structure, expertise and economic focus make the OECD uniquely positioned to add value to these discussions.

II. The importance of Intellectual Property Rights (IPR) for innovation

Innovation drives economic growth, helps increase living standards, offers investment opportunities and is essential for addressing the major challenge of sustainable development. To realize these and other benefits from innovation, governments must create appropriate incentives for continued growth in innovation and set an overall sound policy framework that is conducive to innovation.

IPR protection is one of the central pillars on which knowledge-based industries rest. A high-quality IPR system remains a critical policy tool for a number of reasons: IPR protection stimulates innovation by providing incentives that ensure a sufficient supply of new inventions as effective IPRs promote uncertain and costly investments and enable innovation in key economic growth sectors. At the same time, IPRs promote the disclosure of inventions, which stimulates innovation across and within industries. Without the incentives provided by the temporary exclusivity generated by IPR protection, the benefits from innovation investment cannot be appropriated fully and business will not have sufficient incentives to invest in risky R&D and other value-enhancing activities. In the absence of effective IPR protection, there is a risk that business will under-invest in R&D and innovative products. Effective IPR protection is, therefore, a necessary incentive that will permit firms to invest in generating new technology in sectors where the returns to investment are longer term and involve significant risks, and where the invention may be easy to copy or to imitate.

Innovators cannot earn a profit from their risky and uncertain investments if competitors are free to appropriate their inventions without cost and gain the economic benefit of the invention before the innovator can obtain a sufficient return. In this context, the intersection between IPRs with domestic regulatory regimes and the importance of other rights closely related to IPRs need to be given due attention. Data exclusivity or data protection, which recognizes the innovators' investment in conducting rigorous toxicological and clinical trials essential for establishing the safety of new products, is of key importance to business. Such data, which must be submitted to authorities for their evaluation of the product's safety, must remain proprietary to the innovator. The cost of producing a regulatory package for a new product is a considerable investment, which does not necessarily stop with the initial approval. It is essential that data exclusivity be assured as the unauthorized use of such data for the benefit of others places the innovator at a disadvantage. While business welcomes the concept of regulatory work-sharing, the potential misuse of data provided needs to be given the highest attention.

Like any other IPR right, data protection plays an important role for the industry sectors listed hereunder. So far, when considering the relationship between IPRs and innovation, much attention was given to registered patents and trademarks, but protection of data, which is also part of the valuable assets of companies, has been less prominent. However, the effective management and exploitation of this IPR is equally important for companies. This is particularly true for small and medium-sized enterprises (SMEs) who may not have the resources to create and maintain a portfolio of registered IPR on the one hand and have little experience of managing trade secrets on the other. Moreover there are instances into which unregistered IPR are the only solution available. One of the factors that makes protection of data less well "known" than other forms of IPRs, such as patents and trademarks, is

because it is not being granted or controlled by an independent agency. Rather it is normally administered by the regulatory authority.

III. The importance of transparency – Striking the balance and application of the proportionality principle

Transparency, as used 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 in an approval process, the first stage of which is access to the information on which a decision has been proposed, followed by an opportunity to provide inputs into the final regulatory decision. Thus transparency has become a key element allowing a company to obtain the freedom to operate it needs to become successful in the commercial market place.

Transparency is not a new concept. Rules on the subject were first formally introduced in Sweden in 1766 and governments together with international organizations have continued to develop and legislate in this area, normally through freedom-of-information laws coupled with granting rights of participation. One such piece of international legislation is the UNECE Convention on Access to Information, Public Participation and Decision-Making and Access to Justice (the Aarhus Convention), which covers (1) the right of access to environmental information (2) public participation and (3) access to justice.

In the discussion 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 is, however, recognized that further access to information that is not in the public domain is another important step towards transparency.

It should also be recognized that total access to all information is not a feasible option. There are matters of commercial interests, public and state security and privacy which have to be taken into account. For the common good there have to be restrictions on transparency. In the context of this paper, two key terms describe restrictions on transparency:

1. Confidential Business Information (CBI): CBI is information that is critical to the functioning of the business and its operations, which is not generally known. It has to be kept confidential without any time limitation, unless there is a critical health or environmental implication.

2. Protection of Regulatory Data: This term refers to the obligation of regulatory authorities to ensure that the regulatory data, which are proprietary in nature, made available to it by an applicant is not used for any commercial purposes by a third party for a specified period of time. It can be made available for public inspection, but measures should be taken to prevent access from developing into misuse.

It is the protection of commercial interest coupled with the rapid development in the availability of information through electronic communication tools that is the focus of industry's concerns.

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 realize 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 the disclosure regimes allow companies to benefit from legitimate protection of their data and confidential information and ensure that objections and concerns about misuse are considered by due process of law.

IV. Challenges faced by different sectors

The following section provides an overview of the current situation in key sectors and of the challenges that these sectors are facing with regard to the protection of regulatory data and transparency.

- ***Crop protection industry***

The interest of the crop protection (CP) sector stems from the desire of the OECD countries to share the work of reviewing regulatory submissions. Work-sharing saves valuable and scarce resources in regulatory authorities, while providing industry with the opportunity of more timely decision making and, therefore, shorter 'time-to-market'. In establishing the methods of work-sharing it became obvious that regulatory authorities would need to exchange information. The basic rules for such exchanges were established by OECD in three 1983 Recommendations (C83-96/97/98). These provided a good starting point at the time for cooperation between OECD member states. However, they do not take into account regulatory developments since that time, the relatively new rules on transparency (see below), or the use of new electronic communication tools such as the Internet.

The other international rules concerning the protection of regulatory data (PRD) originate from the inclusion of agricultural chemicals in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) Article 39. This article obliges WTO members to protect CBI and not to use regulatory data submitted by an initial applicant to support a product of a second applicant unless a period of time has elapsed or the information has been disclosed.

In working with the OECD Working Group on Pesticides (WGP) and its Regulatory Steering Group (RSG) a number of issues concerning PRD and transparency emerged and recommendations to deal with them were agreed:

1. With the increasing level of information summarized in regulatory reviews and placed in the public domain, how do regulatory authorities prevent such summaries from being used for regulatory purposes by third parties?

The rules for the preparation of OECD summaries (Monographs) have been adapted to include, in a prominent position, a standard phrase indicating that the information in the Monograph should not be used for regulatory purposes unless the supporting studies are submitted or the owner of the studies has given permission to cite and use these studies.

2. How do regulatory authorities balance the increasing requirement for transparency while maintaining the IPRs of the data owner and not “disclosing” the information?

Public Access to information should be through “reading facilities” or following a legal undertaking that the information will not be used for commercial purposes by third parties, or both.

The WGP/RSG have agreed to monitor progress in the implementation of these critical points and the CP sector will raise any issues arising as the “work-sharing” process develops. Further actions which may be helpful for the CP sector in this context have been discussed in the context of the WGP.

- ***Plant biotechnology industry***

The situation of the plant biotechnology sector in terms of protection of regulatory data is characterized by a fundamental lack of consistency among countries, which determines a significant vulnerability in a sector that 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 by confidentiality in applications submitted to public authorities to obtain product authorizations. As a consequence, while the public benefits from increased transparency on product safety, the plant biotechnology sector experiences significant challenges to protect its regulatory data.

The protection of regulatory data and IPRs is especially sensitive in the area of plant biotechnology because the product is biological in nature, making it susceptible to potentially illicit competitive behaviors. In other sectors, ‘generic’ producers must create their own chemical processes or formulation facilities through the application of their own specialized forms of expertise. In contrast, ‘generic’ competitors may take possession of plant biological material (i.e., biotech seed) and multiply it without a comparable input of added expertise. As such, the protection of the information contained in product applications is fundamental.

In most OECD countries, confidentiality provisions are in place and the plant biotechnology industry protects the information deemed sensitive in product applications primarily by confidentiality. Industry must clearly identify confidential information and provide governments with a justification indicating the reason why the information must remain confidential. If governments deem this justification adequate, the confidential information will not be divulged to the public without permission from industry. While in the past confidentiality provisions granted some level of protection to regulatory data, in recent years, governments have been continually pressured to release more information to the public and to challenge confidentiality claims provided by industry, hence increasing the importance of data protection.

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 disclose any confidential information 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 confidentiality and data protection for the information submitted by the plant biotechnology industry to EU Institutions and Member States authorities to obtain product authorizations. EU Institutions are also required to comply with the principles governing the right of public access to documents received by industry. These principles were recently revisited due to the EU implementation of the Aarhus Convention.

As a result, the provisions for public access have been broadened and the amount of information currently protected by confidentiality is drastically limited compared to the past. 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, data protection provisions 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 may still be used for the benefit of other applicants in countries where data protection rules are not in place, *de facto* jeopardizing 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 and may be debatable. It becomes therefore evident that the harmonization and correct implementation of data protection provisions becomes a fundamental tool to secure companies’ IPRs and that OECD may significantly contribute to such an effort.

The plant biotechnology sector would like to add the following considerations: 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, the plant biotechnology industry is very open to the sharing of information to facilitate such progress in harmonizing decisions and minimizing the risk of trade disruptions. As this proceeds, the plant biotechnology industry believes it is important to ensure the ownership of the various regulatory authorizations remains linked to the original registrant and cannot be shifted to third parties without express written permission from the developer.

In addition to the considerations expressed above, the plant biotechnology sector would also like to draw the attention to the fact that a premature disclosure of product information in a country may seriously undermine independence and the conclusions of the scientific review and of the approval of the product in the country itself or in other geographies. In some instances, the obligation to disclose information on the locations of R&D trials has resulted in the destruction of

several field trials used to generate research and regulatory data, thereby delaying the beginning of any regulatory process and product commercialization.

- ***Chemicals industry***

The industrial chemicals sector recognizes the need for transparency in chemical management systems and the corresponding need to balance transparency with measures to prevent potential misuse of that information and provide for the respect of the legitimate IPR of chemical companies regarding data protection / CBI.

The International Council of Chemical Associations (ICCA) has developed 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 principles call for the following:

- The system should provide a sound national policy framework for chemical industry's operations in the market and be aimed at improving public confidence in chemicals.
- 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 reinforce the responsibilities of each party throughout the value chain for compliance with regulations as well as commitments to responsible action.
- 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.

As chemical regulatory programs around the world develop and mature, countries will need to take steps 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 that IPR protection as included in Article 39 of the TRIPs Agreement is not eroded.

The principle of an IPR protecting undisclosed information is firmly recognized in Article 39 of the TRIPs Agreement. However, given the many legal requirements concerning chemical data and the increasing demands for registering substances or any other type of demands to disclose data, the chemical industry considers that guiding principles on the interpretation and application of Article 39 is a must and would also ensure better understanding of the scope and content of Article 39 by authorities and stakeholders. Since this right is not granted by an authority (contrary to other IPRs such as patents and trademarks), it may cause difficulties for companies to demonstrate the existence of the right when engaging in

negotiation on new pieces of legislation or submitting required regulatory data to authorities. The general lack of knowledge of the existence of this IPR forces industry into a defensive position in view of private and public demands for placing all information in the public domain without consideration of the legitimate right of the data owner.

The chemical industry is not opposed to making information available for public inspection, particularly in the context of health, safety and environment. However, companies also seek assurance that appropriate mechanisms are in place to protect proprietary, business sensitive data. In this regard, the proportionality principle is a useful guide.¹

An example to illustrate this: In the regulatory frameworks of many OECD countries, manufacturers and importers must submit summaries of toxicological tests and exposure assessments to gain market access (registration or “new” chemical processes). For “existing” or “inventory” chemicals, manufacturers also share summaries with government agencies for various reasons. For example, through voluntary initiatives such as the ICCA High Production Volume (HPV) Program and its allied programs in individual OECD countries, chemical manufacturers are making available summaries for the Screening Information Data Set (SIDS) endpoints for hundreds of HPV chemicals.

The types of summary documents submitted to regulatory agencies are often made available to the public on agency websites. It is also appropriate to note that the regulatory frameworks of OECD countries also recognize, to varying extents, the commercially sensitive nature of information provided by chemical manufacturers and have established appropriate measures to limit access to such information. BIAAC fully supports the public availability of non-CBI information, and the OECD Council has recognized the importance of preserving CBI (C83-96/97/98). In addition, chemical manufacturers often provide regulatory agencies with proprietary information to inform chemical prioritization processes, risk assessments, the development of exposure scenarios, and for other purposes.

Chemical information is an important competitive asset. In the current regulatory environment, information on individual chemicals, whether in the form of summaries or the original proprietary studies, has become increasingly valuable for the purposes of gaining and maintaining market access and for complying with changing regulatory requirements in existing markets. For example, the European Union’s REACH legislation creates by statute a sizeable marketplace for proprietary information and a similarly sizeable opportunity for misuse if proper protections are not established. The significant increase in the volume of proprietary information shared for regulatory purposes, the ability to share information broadly and quickly through the Internet, the increasingly global nature of the chemical business, and, not least of which, the significant resources chemical manufacturers devote to developing such information creates a proportional risk that proprietary information could be misused in the market by those not authorized to use it for their own commercial purposes.

Regulatory authorities and industry must work cooperatively to prevent data misuse. If effective controls are not in place, proprietary information could be used by bad actors to

¹ The proportionality principle is a fundamental principle of European Union law that states the EU may only act to exactly the extent that is needed to achieve its objectives, and no further.

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.

- ***Biocides industry***

The biocides sector recognizes the need for transparency in regulatory systems and the corresponding need to balance transparency with measures to prevent potential misuse of the information used to support use. It has access to a fairly restricted market in terms of gross tonnage but must provide a significant range of data to enable an adequate human health and environmental risk assessment before use particularly in the EU where any use requires the fullest data package even before any market development exercise.

Further, the biocides sector believes that there should be a convergence of regulatory systems worldwide to promote greater consistency and transparency and to ensure an adequate level of demonstration of safety in use internationally. Any such systems should promote data quality and transparency and allow access to useful information to interested parties including the general public. It must, however, guarantee a fair balance between public access to data and legitimate protection of business information. A major concern to the biocides industry is that when extensive information is made available by regulatory agencies, then the subsequent regulatory use of that information by third parties can occur without demonstrating ownership rights to that information and this should not happen. Notably in Europe, the legislators have developed a system which has very high costs, provides very little protection to participants and already allows competitors access to detailed reviews.

Biocidal active and product manufacturers support the work of regulatory agencies by providing proprietary information to inform prioritization processes, risk assessments, the development of exposure scenarios, and for other purposes.

As noted previously, information on individual chemicals has become increasingly valuable for the purposes of market access and regulatory compliance. Like REACH, the European Union's Biocidal Products Directive (98/8/EC) legislation creates a marketplace for proprietary information.

Without proper protection of proprietary information, R&D activities may lack the incentive that is required to provide new tools to tackle the (new) risks that harmful organisms bring given their ever changing profile.

- ***Metals industry***

The metals industry fully recognizes the value and importance of openness and transparency on 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 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 programs 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. SIAP documents under the OECD HPV program), industry often provides, through both regulatory and voluntary programs, deep insights into extensive reviews and data sets through the SIAR reports, or in the near future in Europe under the REACH registration files. In the case of metals, these often include 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 not however, wish to see the commercial sector gaining extensive advantage from them without recognition of ownership.

As a result of regulatory chemicals management, information on (or the lack of it, in other countries) chemicals hazards and risks information becomes quickly a "competitive asset". While the metals industry in general is not keen in 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 CBI related to the metals sector is therefore rather an issue of *fair recognition of data ownership*, avoiding unauthorized data ownership declarations for own commercial or market access purposes. 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.

V. Options for OECD work and next steps

BIAC would like to thank the OECD for the opportunity to present industry's concerns to the OECD Joint Meeting delegates. As illustrated in our paper, a number of different sectors are facing challenges with regard to the protection of regulatory data and reconciling this with the need for transparency. Emerging enabling technologies are likely to face similar challenges in the future. BIAC strongly believes that the expertise of the OECD makes the Organization ideally suited to further analyze these issues and explore possible ways as to how to address them.

The OECD has a number of means by which to address key policy issues, ranging from OECD working papers, Committee reports, and guidance documents to formal OECD Council Instruments (e.g. Declarations, Recommendations, and Decisions). In this paper, BIAC therefore proposes that the OECD creates a working group, consisting of experts representing the range of concerned sectors, to explore possible future policy options and to recommend next steps to the OECD Joint Meeting. BIAC looks forward to making a constructive contribution to these discussions.