CHALLENGES OF MANDATORY DATA SHARING UNDER EU LEGISLATION ON BIOCIDAL PRODUCTS

Biocidal products are used in nearly every industry, including the chemicals, heatlhcare, food, cosmetics, textile, toys, automotive and construction sector. The coming into force of Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products (so-called "Biocidal Products Regulation", "**BPR**") in all EU Member States in 2013 caused great turmoil on the global biocides market. In the pursuit to curb animal testing, the BPR provides *int. al.* for mandatory sharing of data obtained by means of specific animal testing. The European Chemicals Agency ("**ECHA**") acts as an intermediary and connects prospective applicants with established data owners. While this helps new players to enter the market, it diminishes the economic value of data in the first place since there is no longer the appealing prospect of exclusive data exploitation.

Key issues

- Regulation (EC) No 528/2012 provides for mandatory sharing of specific scientific data between data owners, data submitters and prospective applicants, without however containing any legal definitions of these parties or of data ownership as such.
- This lack of definitions in the BPR causes significant legal and financial risks for all parties being active on the European biocides market. It is in particular debatable whether compensation for data sharing is always claimed by and paid to the legally entitled parties.
- Therefore, any data sharing under the BPR and any compensation related thereto puts agreements on data sharing in jeopardy and can cause significant controversy on the whys and wherefores of any data use and related compensation.
- This discrepancy can only be remedied by revising both the respective agreements as well as the entire correspondence between all concerned parties and competent authorities.

LEGAL CHALLENGES

The BPR aims to open up the European market by easing entry for new players. In contrast, incumbents are required, under the new rules on mandatory data sharing, to disclose valuable R&D information which they could previously exploit on an exclusive basis. In the past, numerous chemicals and biocides companies inside and outside Europe have concluded long-term data access, use, transfer and license agreements with strict exclusivity and non-competition clauses. Many players have paid a lot of money for an exclusive long-term use of specific data still before the BPR has entered into force, and they are now facing significant losses both in market share and profits after the respective data have to be shared with all other interested applicants. Most of the exclusive agreements do conflict with the new rules on mandatory data sharing. Therefore, it becomes crucial for established players to not only consider what legitimate defences might be available against requests for mandatory data sharing and how established agreements could be interpreted in light of the BPR, but also what mechanisms could be established to prevent all aforementioned legal issues from arising altogether.

Art. 62 et seq. of the BPR provide for mandatory sharing of biocidal data involving tests on vertebrates. The relevant provisions refer to four different parties involved into the process of data sharing, including the "data owner" (holding rights in the data to be shared with third parties), the "data submitter" (having submitted data to the competent authorities), the "prospective applicant" (who can request data sharing) and the European Chemicals Agency ("ECHA"). Even though the BPR contains detailed provisions on the actual process of mandatory data sharing as well as on the rights and obligations of the aforementioned parties involved into this process, it does not provide for any legal definitions of the "data owner" and the "data submitter" as repeatedly referred to in the Regulation. As to the "data owner", the BPR only sets out that it

- can agree with a prospective applicant on data sharing (Whereas 57),
- shall be filed with its contact details in a Union register (Whereas 57),
- shall receive an equitable compensation for data sharing (Whereas 58, Art. 63),
- can sign "letters of access" (Art. 3 Para. 1 lit. t),
- shall be indicated with name and contact details in all data submissions (Art. 59),
- shall be mentioned with name and contact details in letters of access (Art. 61), and
- shall be subject to mandatory data sharing (Art. 62).

However, irrespective of these rights and obligations, the BPR does not contain any specific definition of the "data owner" as referred to in the aforementioned provisions.

CONSEQUENCES FOR CONTRACT DESIGN

The aforementioned lack of definition in the BPR causes significant legal and financial risks for all parties being active on the European biocidal market. It is in particular debatable whether those "data owners" formally registered with the competent authorities or referred to in letters of access are indeed the actual data owners within the relevant legal and economic sense, and whether compensation for data sharing is always claimed by and paid to the legally entitled parties.

The ECHA and the competent national authorities try to reply to these questions by means of general recommendations on how to construe the legal notion of "data ownership". However, the relevant recommendations are non-binding, widely vague and often even inconsistent. The ECHA, for example, holds the view that the capacity of being a "data owner" primarily depends on legal ownership, property and/or copyrights (which are still subject to national legislation), and can be fully or partially transferred to third parties (e.g. by assignment of rights, data licensing, mandates, letters of access etc.). For example, according to the ECHA Guidance on data sharing under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("**REACH**") which shall apply accordingly to biocidal data sharing,

> "*ownership […] would normally be with the party(ies) who hold all the property rights over the data (data owners). These property rights are borne either automatically (because the owner is the creator of the studies or tests) or through the will of the parties (i.e. contract).*
>
> *In case the property rights over the data have been licensed by a contract (i.e. assignment of rights, license agreement, letter of access, mandate etc) the person/entity to whom those property attributes have been licensed becomes either full owner of all the property rights over that data (i.e. in case the entire property over the data has been transferred - assignment of rights) or partial owner/user (in case only certain scientific materials have been licensed or only some attributes of the property right have been granted, …)."*

In light of this recommendation, every agreement on biocidal data including R&D joint ventures, consortia, licence agreements, data access agreements, letters of access, asset purchase agreements, supply agreements etc. has a direct impact on data ownership within the sense of the BPR as well as all rights related thereto, and thus can necessitate an update on changes in data ownership to be filed with the competent authorities.

In contrast, various national authorities advance dissenting views on how the legal notion of "data ownership" shall be construed. Some even hold the view that "data owner" shall not necessarily be the one who holds rights of use either by virtue of civil law or in an economic sense (such as the sponsor of a study), but rather any natural or legal person who submitted relevant documents in the course of an application for registration. In view of this more formalistic recommendation, data ownership would rather be with the "data submitter", even though the BPR explicitly distinguishes between "data owner" and "data submitter". In summary, the legal notion of the "data owner" used in the BPR is and remains vague and undefined, irrespective of the competent authorities' attempt to provide general guidance in this regard.

Against this background, any sharing of biocidal data and any respective compensation will raise legal questions as to whether the party who (1) is formally registered as "data owner" with the competent authorities, (2) shares data with third parties and (3) receives compensation for such data sharing is actually entitled and obliged from a legal and economic standpoint to share the relevant data with third parties and to receive and keep compensation for such data sharing. In case of doubt, all these questions will have to be answered in light of the relevant agreements concluded between the concerned parties (i.e. R&D joint ventures, consortia, licence agreements, data access agreements, letters of access, asset purchase agreements, supply agreements etc.) and the national laws applicable to these agreements. However, the respective agreements usually do not either contain any specific definition of "data ownership" within the sense of the BPR, not to mention any provision as to what extent which party shall be entitled to share data and to receive compensation for any such data sharing.

NEED FOR ACTION

Therefore, any data sharing under the BPR and any compensation related thereto puts respective agreements in jeopardy and can cause significant controversy on the whys and wherefores of any data use and related compensation. This discrepancy can only be remedied by revising both the

agreements as well as the entire correspondence between all concerned parties and competent authorities.

The concerned parties should in particular explicitly set out in their agreements who shall be the actual "data owner" within the sense of the BPR and therefore be entitled to agree with a prospective applicant on data sharing, to be registered with its contact details as data owner with the competent authorities, to receive compensation for data sharing, to sign letters of access as well as to be indicated with name and contact details as data owner in data submissions and letters of access. Moreover, the parties should review their ongoing agreements as to potential conflicts with the BPR rules on mandatory data sharing, in particular with regard to contractual provisions on the exclusive use of data, non-competition, data licensing, compensation for the use of data and the ownership, property or other rights in data. They should also revise and align their agreements and templates for future agreements in light of the mandatory rules on data sharing, and conclude additional agreements on data ownership and/or (internal) compensation for data sharing with third parties, if need be. Finally, they should also deliberately pay attention to an accurate correspondence with the ECHA, all competent national authorities and other market participants, in particular where references to the "data owner" have to be made (cf. for example Art. 59 Para. 2 and 3, Art. 61 BPR: in data submissions, updates on changes in "data ownership" and letters of access).

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