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1. DATA SHARING PRACTICES: ITALY RAISES COMPETITION CONCERNS

By [Yves Botteman](#) and [Darren Abrahams](#)

Overview

The current EU regime for plant protection products (“PPPs”) set out in [Directive 91/414/EEC](#) (“the Directive”) encourages, but does not compel, sharing of vertebrate animal data amongst competitors. This approach to data sharing is common to the current [Directive 98/8/EC](#) on [biocidal products](#) (“the BPD”). The same approach applies to non-vertebrate animal data under the:

- [REACH regime](#);
- [Regulation \(EC\) 1107/2009](#) on PPPs (“the PPP Regulation”), which applies from 14 June 2011 and replaces the Directive; and
- [proposal to replace the BPD](#), which is likely to apply between 2013 and 2014.

Companies regularly share data that is required to support an active substance. This takes place through bilateral negotiations and in taskforces and consortia formed for the purpose of sharing the considerable costs of generating a dossier. In those situations where a data owner refuses to provide access to a prospective data purchaser, the reason is often a failure by the parties to agree on the correct valuation of the data rights. Whatever the reason for refusal, aggrieved data purchasers will often raise a claim that the data owner is acting in an anticompetitive manner. This is one of a

range of tactics which commonly form part of data access negotiations. These claims are rarely developed or acted upon by the relevant authorities.

On 23 February 2010, the Italian competition authority, the [Autorita Garante della Concorrenza e del Mercato](#) (“AGCM”), announced that it had opened formal proceedings concerning an allegation of an [abuse of a dominant position](#). The investigation concerns Bayer CropScience (“the data owner”) and its denial of access by competing suppliers to two vertebrate animal studies containing data necessary for obtaining marketing authorisation in Italy of formulated fungicide products used against mildew on grapevines. The proceedings were precipitated by a complaint filed in May 2009 by the Fosetyl-Aluminium Task Force (the “Task Force”), which was set up by suppliers of fosetyl-based fungicides.

Regulatory background

Under the Directive, EU member states must ensure that a PPP is only authorised if (amongst other things) its active substances are listed in Annex I to the Directive. Annex I inclusions are made when (amongst other things) an active substance is shown not to have any harmful effects on humans or animals or unacceptable influence on the environment.

The data owner participated in the evaluation process for fosetyl between 2000 and 2006, and it was thereafter [included in Annex I](#). As part of that inclusion, member states were required to review by 31 October 2007 the marketing authorisations for fungicides containing fosetyl in order to verify that holders of authorisations:

- were using active substances equivalent (both chemically and toxicologically) to that already submitted by the data owner for the evaluation and listing in Annex I; and
- owned or had access to a dossier satisfying the data requirements for the active substance (set out in Annex II to the Directive).

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If these conditions were not met the national product authorisations would be withdrawn and market access prohibited. Re-entry into the market would require the submission of a new application, requiring the production of new data, which would normally take several years to generate.

The Directive has specific rules relating to the generation of vertebrate animal data, requiring an applicant to inquire whether such studies have already been conducted by an earlier registrant. If a study has already been carried out, the earlier registrant (the data owner) and the applicant “shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals”.

Although data sharing is not generally compulsory, in circumstances where the parties cannot reach agreement member states “may introduce national measures obliging the applicant and holders of previous authorisations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned”. In Italy, a conciliation and arbitration procedure was adopted by Decree (dated February 2007), which is operated by the Italian Ministry of Economic Development (“the MSE”). (Similar national measures exist in the United Kingdom for PPPs and in Germany for biocidal products.)

Alleged abuse

The main allegation put forward by the Task Force is that the data owner deliberately delayed negotiations in order to exclude rival products from the market. The AGCM has summarised the issue in the following terms: in December 2006, the Task Force sought negotiations with the data owner in order to determine the conditions under which it would grant access to two vertebrate animal studies, invoking the conciliation and arbitration procedure before the MSE.

The data owner made robust submissions to the MSE, challenging the applicability of the conciliation procedure after the 31 October 2007 deadline had passed – at which time non-compliant products were required to be removed from the national market. At any rate, two rounds of negotiations were conducted from October 2007 to December 2008 without success.

Whilst the data owner did not reach agreement on data access with the Task Force, it did however do so with another applicant (a German producer of fungicides, Helm). The data access fee amounted to €200,000. It was calculated on the basis of the total value of data, plus a risk premium, and taking account of the length of the remaining data protection period. The data owner did not base its access terms on the number of products for which Helm was seeking marketing authorisation nor on the anticipated volume of the active substance to be marketed by Helm in Italy.

The AGCM made further findings on the appropriate relevant product market and the dominant position of the data owner. It also examined the conditions prevailing on the market following the withdrawal of the Task Force members from the Italian market for fosetyl-based fungicides against mildew on grapevines. In particular, it noted that, following the withdrawal of the Task Force members, the data owner captured about 60% of the customers previously served by the Task Force members. Between 2008 and 2009, the data owner’s share increased from 73% to 87%, with Helm left as the only competitor in the market. During the same period, the data owner’s prices went up by more than 10%. Volumes of fosetyl-based products overall declined by 5 % over the period and the volume of competing products – using alternative active substances, marketed by Syngenta and Isagro – also declined, suggesting that customers faced with the price increase did not switch to competing substances to defeat the price increase.



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Possible outcomes

If the data owner is found to have violated [Article 102, TFEU](#) on the abuse of a dominant position - which is by no means clear - the AGCM may impose fines and/or compel the data owner to supply the two studies to the Task Force on fair and non-discriminatory terms (which might be set with reference to those agreed with Helm). In addition, the Task Force might initiate an action in damages against the data owner before the Italian civil courts.

Lessons for conduct of data negotiations

The theory of competitive harm which the AGCM intends to apply in this case is the “essential facilities” doctrine. According to well established case-law, an undertaking may abuse its dominant position by engaging in an exclusionary refusal to deal with (equally efficient) competitors in relation to a resource (in this case the data) which is “indispensable” for the supply of the product in question. Indispensability means that:

- there are no actual or potential substitutes, and
- technical, economic or legal obstacles make duplication of the input prohibitively expensive. Furthermore, the refusal to deal must lead to elimination of competition in relation to the product in question.

In the case at hand, the Directive strongly encourages data sharing among competing firms in order to avoid vertebrate animal testing but stops short of mandating data sharing and preventing duplication of studies. While the regulatory framework may constitute a legal obstacle for the duplication of vertebrate studies, it remains to be seen whether this meets the “indispensable” threshold.

In examining the complaint, the AGCM will no doubt examine why it was possible to reach agreement on terms for data sharing with Helm but not with the Task Force. Comparing the two negotiations and the outcomes should help to bring into focus whether the facts disclose an abuse of a dominant position or rather an unwillingness of the Task Force to accept fair and reasonable terms for data access.

EU chemicals regulation increasingly mandates data sharing among competitors as regards vertebrate animal data and encourages sharing for other data. This trend, which has its roots in the [REACH regime](#), will become a feature of the PPP and biocides regimes in the medium term. (This model is also likely to find its way into other legislation requiring pre-market approvals.) In the period remaining, during which data owners may still refuse access to vertebrate animal data, arguments of the type raised in the case described in this article will become more common. All parties to negotiations will need to think more carefully than ever about the manner in which they are conducted. There remains scope for vigorous enforcement under EU competition rules by national competition authorities and the European Commission in situations where data owners engage in exclusionary behaviour whose object or effect is to weaken competition in the markets where they operate. Our integrated BPD, PPP, REACH and competition law practices work with clients to help them successfully manage the complex data access and valuation issues described in this article.



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2. NANOTECHNOLOGY: CURRENT REGULATORY AND BUSINESS CHALLENGES

By [Dr. Anna Gergely](#), [Tanja Ehnert](#) and [Craig Simpson](#)

Overview

Since physicist Richard Feynman first introduced the notion of nanotechnology in his 1959 lecture, [There's plenty of room at the bottom](#), its development has been dramatic. Today, many consumer products on the market involve the use of nanotechnology. As an enabling technology, nanotechnology is expected to have an impact on all industry sectors. Its emergence is, therefore, often referred to as a new industrial revolution.

There are, however, significant knowledge gaps concerning the technology's environmental and health risks. The safety of nanomaterials cannot be taken for granted. According to an [opinion](#) of the Scientific Committee for Emerging and Newly Identified Health Risks ('SCENIHR'), published in January 2009, risk assessment methodologies related to nanomaterials still require further development. With respect to food safety, the European Food Safety Authority recommended in its [opinion](#) of February 2009 that action should be taken to survey the use of nanomaterials in food and feed, to assess their exposure to consumers and to generate information on the materials' potential toxicological effects.

Regulatory pressure

To address the potential risks posed by nanotechnology, the EU currently relies on its [existing regulatory framework](#) for chemicals, worker protection, specific product legislation (such as that concerning medicinal products, plant protection products, cosmetics, food and feed additives) and environmental legislation.

At the 3rd NanoSafety Conference in November 2009, Robert Madelin, former Director General of DG Sanco,

highlighted further, equally important, challenges beyond the environmental, health and safety risks:

- First, he concluded that the EU is confronted with an *innovation risk*, referring to the danger of hampering innovation of an emerging technology by failing to build consumer trust (cf. the development of biotechnology).
- Second, he identified a *political risk*, as third countries are heavily investing into the development of nanotechnology which may potentially result in the presence of unsafe products on the European market.
- Third, industry is facing a *business risk* if consumers lose confidence in the safety of the new technology.

Nevertheless, the European Parliament ("EP") has challenged the EU's present approach towards nanotechnology regulation in its [Resolution](#) of 24 April 2009. The EP does not consider the current legislative framework as sufficient to cover nanotechnology risks. The Resolution calls on the Commission to review all relevant legislation within two years.

REACH

Specifically, the EP has focused on the regulation of nanomaterials under REACH:

- The EP heavily criticises the one metric tonne per year threshold for substance registration; to ensure safety, nanomaterials produced in quantities of less than one tonne should also be registered.
- All nanomaterials should be considered as new substances.
- A Chemicals Safety Report including an exposure assessment should be obligatory for all registered nanomaterials.
- All nanomaterials placed on the market should be subject to a notification requirement.

The first major review of the REACH Regulation is due for June 2012, and is likely to contain specific nano provisions.



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Cosmetic products

Turning its requests into practice, the EP has inserted nano-specific provisions in the scope of [Regulation \(EC\) 1223/2009](#) on cosmetic products (“the Regulation”). A definition is provided of “nanomaterial”: “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”. However, the definition will be adapted “to technical and scientific progress and to definitions subsequently agreed at international level”.

Importantly, the Regulation provides that the list of substances in Annexes III to VI (substances prohibited except subject to restrictions, and permitted colorants, preservatives, and UV filters) do not cover nanomaterials “except where specifically mentioned”.

In addition to the general notification requirement for cosmetic products, a nano-specific notification requirement has been introduced. From 11 January 2013, cosmetic products containing nanomaterials will have to be notified to the Commission by the responsible person six months *prior* to being placed on the market (except where they have already been placed on the market by the same responsible person before 11 January 2013, in which case the notification must be submitted between 11 January 2013 and 11 July 2013). The information notified must include at least the IUPAC name and other descriptors; the specification of the nanomaterial including size of particles, physical and chemical properties; an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year; the toxicological profile of the nanomaterial; the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products; and the reasonably foreseeable exposure conditions.

By 11 January 2014, the Commission will produce a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section (which are currently excluded from the

notification requirement listed above), indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions.

In addition, all ingredients in cosmetic products present in the form of nanomaterials will have to be clearly indicated in the list of ingredients, followed by the word “nano” in brackets.

Novel foods and RoHS

Nanotechnology is receiving a similar degree of attention in the context of current legislative revisions of the EU regimes on [novel foods](#) and [restriction of the use of certain hazardous substances in electrical and electronic equipment](#) (“RoHS”). Civil society is becoming increasingly aware of this debate. The Commission is under increasing pressure to act.

The way forward

The Commission has committed itself to review the relevant legislative framework by 2011. The public consultation for the new Nanotechnology Action Plan for 2010 to 2015 closed on 19 February 2010. The Action Plan is expected to be adopted in 2010. To support the regulatory efforts, the [Commission requested the SCENIHR](#) to adopt an opinion concerning the scientific basis for the definition of the term “nanomaterial” via the accelerated procedure by May 2010.

At this stage of the policy process, it is crucial to avoid the development of an immature regulatory framework that will be unduly restrictive and may well result in regulatory discrepancies between the EU, the US and other major trading partners. This is particularly true as long as there is no international consensus on definitions and appropriate testing methods. It is important to create a regulatory framework which balances the technologies’ safe development and encourages innovation and technological progress.

To reach this objective, the Commission’s response should, in our view, include an appropriate blend of



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both voluntary measures and mandatory requirements, building on a *duty of care for manufacturers* who place nanotechnology-based products on the European market.

Business challenges

The uncertain business and regulatory environment for nanotechnology raises several related challenges:

- The emerging *regulatory* framework should support the development and commercialisation of compliant nanotechnology-enabled products.
- The development, exploitation and protection of *intellectual property* rights must be supported.
- Risk assessment will have to improve in order to encourage *insurance* coverage on the commercial market.
- Potential *litigation* risks will have to be actively managed across jurisdictions.

[Step toe's nanotechnology team](#) participates in the work of different regulatory bodies to develop a suitable regulatory framework at both the EU and international levels. We are helping clients to engage with the latest legal and policy developments and to defend their products, which face ever greater scrutiny.



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