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Application of the precautionary principle: The safeguards

The *Conseil d'Etat* (Highest Administrative Court) opportunely recalled quite recently that, in the absence of scientific certainty, the precautionary principle cannot be applied without taking into account the economic consequences associated with the withdrawal or the suspension of a market authorization.

In the case at hand, the owner of the anti-inflammatory drug Ketum filed a petition with the summary judge of the *Conseil d'Etat* to request the cancellation of the decision of the French Health Products Safety Agency that had ordered the withdrawal of the market authorizations granted to certain ketoprofene-based drugs.

The summary judgment rendered by the *Conseil d'Etat* on January 26, 2010 firstly points out that there is no new scientific element that would justify a new risk-benefit assessment for Ketum:

"It appears that the adverse effect, on the basis of which the challenged decision was made, only concerns about 30 cases out of the millions of ketoprofene gels that are sold every year; this adverse effect, known since the outset, seems to be mainly attributable to non-compliance with the prescribed precautions for use; moreover, according to the information supplied to the summary judge in relation to the current status of the "Community arbitration" procedure, the Co-rapporteur appointed by Community authorities to examine the request presented by France considers that the risk-benefit assessment for ketoprofene gels remains unchanged and that none of the twenty States that have been consulted intends to withdraw this drug from the market."

The summary judgment then indicates that the urgency of the situation, a mandatory requirement to be fulfilled to obtain a decision from the summary judge, was justified by the economic consequences that a withdrawal decision would entail for the owner of the product:

“It also appears from the exhibits produced and information provided that Ketum represents the second-highest turnover of the company Menarini and that, considering how long this product has been on the market, it generates a margin that is above that of all other products marketed by this company; as such, discontinuing its commercialization would jeopardize the ability of the company to post positive earnings in 2010.”

This judgment helpfully recalls two of the safeguards created by French and Community laws with respect to the application of the precautionary principle:

- First safeguard: the decision to suspend or to withdraw a market authorization must be based on evidence that there exist new scientific elements likely to justify such decision in order to protect human health or the environment. This principle applies equally to plant protection products and drugs.
- Second safeguard: while the absence of certainty on the adverse effects of a product or on the environmental risks associated therewith does not conflict, in certain conditions, with the application of the precautionary principle, this must, however, be done at economically acceptable costs. Concerning the protection of the environment, this principle is set forth in Article L. 110-1 of the French Environmental Code.

Regarding the first safeguard, the summary judgment of the *Conseil d’Etat* can be weighed against two judgments^[1] rendered by this jurisdiction on July 24, 2009 in favor of one of our clients, BASF Agro.

These two judgments nullified the French Minister of Agriculture’s decisions to withdraw the market authorizations granted to products that contained the active substances appearing on a list of 30 active substances adopted without any prior consultation during the *Grenelle de l’environnement*^[2].

The active substances contained in such products are in the process of being included into Annex I of Council Directive 91/414/EEC of July 15, 1991 that regulates the European approval process for all active substances contained in plant protection products.

The *Conseil d’Etat* considered that none of the new scientific elements produced in addition to those examined during the approval process could justify the Minister’s withdrawal decisions, especially as the Rapporteur Member State, in the framework of the European approval process, had proposed the inclusion of the active substances contained in such products into Annex I of Council Directive 91/414/EEC (such inscription corresponding to the approval of the substance).

The third safeguard has been recalled in another decision^[3] of the *Conseil d’Etat* rendered on April 4, 2005 in favor of BASF Agro: a Minister who considers withdrawing or suspending a market authorization must give the manufacturer the possibility to present its observations and remarks in the framework of an adversary procedure.

The case in question concerned a decision to withdraw the authorization granted to Regent, a plant protection product that bee keepers had claimed to be responsible for the increased mortality rate among the bee

population. Beekeeper associations initiated criminal proceedings against the successive owners of this product. The investigating magistrate of the Saint-Gaudens Court eventually issued a full dismissal order in favor of the defendants. An appeal has been lodged by these associations and the Toulouse Court of Appeals will shortly render a decision.

The application of the precautionary principle is, therefore, subject to three safeguards: the existence of new scientific elements likely to justify the suspension or the withdrawal of a market authorization, the taking into account of economic considerations and compliance with the adversary principle before making a suspension or withdrawal decision.

In general, administrative authorities tend to fail to spontaneously respect the two last safeguards mentioned above. The incorporation of the Environmental Charter – in which the precautionary principle is mentioned – into the French Constitution in 2005 has put several legal provisions on the back burner, including that set forth in Article 110-1 of the French Environmental Code referred to above. At a time where the media permanently fuel the fear of everything that relates to chemistry or agro-chemistry, any reference to economic considerations appears almost obscene in the eyes of certain persons.

The possibility that must be offered to manufacturers to present their observations/remarks before any suspension or withdrawal decision is made is provided for in a series of texts, depending on the sector of activity and nature of the product. The adversary principle is also a fundamental principle of Community law that ought to be more often invoked before French courts, in particular when it is mentioned in EU Regulations that are, by essence, immediately enforceable.

[1] CE, June 24, 2009, n°316014 and n°316013, 8th and 3rd s.-s.

[2] Sometimes referred to in English as the “*Grenelle Environment Round Table*”: an open multi-party debate that was held in [France](#) in 2007 to define the key points of public policy on environmental and sustainable development issues for the coming five years.

[3] CE, June 24, 2009, n°266665, 8th and 3rd s.-s.

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