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Legal Requirements for a Food Alert. The ASOLIVA case and the Olive Pommace Oil Alert

In the ASOLIVA case, the Spanish Courts were called to adjudicate on the legal requirements for a Food Alert and took decisions on two very important questions, in my opinion, namely, who has standing to bring an action against a Food Alert and under which conditions the authorities can resort to this kind of mechanism.

Preliminary comments on the legal concept of a Food Alert

Before starting my comments on this particular case, I would like make a brief reflection on the legal concept of Food Alert.

What is a Food Alert in legal terms?

We know that a

Food Alert is a tool to enable Governmental Authorities

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We know that the Food Alert is confidential and that it involves several authorities, the one who issues the Alert and the one who implements the Alert and that there is no hierarchy between these Authorities, in the sense that one takes no legally-binding orders from the other.

We know that the potential impact of the use of this system can be enormous, and that the procedural guarantees offered to affected parties are few or non-existent due, precisely, to the instant nature of the Alert.

Because the alert is confidential, instant and Europe-wide, once it has been launched there is little or no defence and no contradiction is required before issuing it.

This kind of system gives rise, in my opinion, to a number of legal questions.

* Where does the responsibility for the alert lie, with the Authority who issued it or with the one who has to implement it? In other words, who do we sue?

* How do we know what obligations the Alert imposes upon individuals and companies, when most of the time an alert is a confidential recommendation addressed from one administration to another, without any real hierarchy between the issuing and

implementing authorities? In other words, what do I contest in the lawsuit?

All these questions were raised in the ASOLIVA case.

Factual background of the case

The ASOLIVA case deals with the withdrawal of all Spanish Pommace olive oil (not any specific brand) from the market, accusing the product of a high content in a substance – Polycyclic Aromatic Hydrocarbons-. This substance was not regulated by Spanish nor by European legislation at the time of the alert, so the Spanish Authorities resorted to a World Health Organisation report, dated 1991, that is, ten years before the alert. This report said that no safe level of intake could be established for this substance and advised minimising exposure to it as much as possible.

A few weeks after the Alert, a Spanish Order

maximum levels for this substance in edible oils. Almost four years later, the European Regulation on Contaminants in Food included Polycyclic

[1] was passed setting

1 Orden de la Presidencia del Gobierno de 25 de Julio de 2001, which came into force on 27 July

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Aromatic Hydrocarbons in the list of forbidden substances, above a

maximum level

The events were as follows.

* In March 2001 the Authorities of the Czech Republic announced

that they had found a high content of Polycyclic Aromatic Hydrocarbons

(PAH) in some brands of Spanish pommace olive oil. The Spanish

Authorities ordered an analysis of the pommace olive oil of four

companies. This analysis confirmed a high content of PAH in them.

* On 3 July 2001 the Health Directorate of the Ministry of Health

and Consumer Affairs decided to use the Rapid Alert System to inform

the regional authorities of a “serious but not imminent risk” posed by

Spanish pommace olive oil, recommending the withdrawal of the

product from the market.

Since at that time no specific limits to PAHs in foodstuffs were

regulated, the Health Directorate of the Ministry of Health and

Consumers based its decision on the Regulation on Olive Oil, which

states that the product should be in “perfect condition for human

consumption” and on the scientific advice provided by the WHO report

[2].

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of 1991. On these premises, the Spanish Ministry of Health invoked article 26 of the Spanish Health Act, which empowers the Authorities to adopt any measure they deem fit (including the closure of companies) to prevent an “extraordinary and imminent risk to public health”, and “recommended”

the market. This was a provisional measure to be maintained “until such time when no presence of this substance was to be detected by a duly validated analytical method and with a maximum limit of 1 ppb”.

* Almost the same day, the Regional Governments recalled all Spanish pommace olive oil, including product in the possession of distributors or abroad.

This intervention unleashed an enormous crisis in the sector. Spanish pommace olive oil almost disappeared from the market for a period of time and it took more than two years for prices and volumes to recover. There was also an acute fall in exports, and therefore member companies of ASOLIVA (Spanish Olive Oil Exporters Association) were negatively affected.

That is why ASOLIVA decided to challenge the Alert.

[3] Regional Governments to withdraw the product from

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This was the word used by Ministry of Health

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Arguments of the parties

ASOLIVA challenged the Ministry of Health’s decision on three main

counts:

i) The decision infringed the rules of due proceedings (particularly, the obligation to hear the interested parties before taking any action

ii) The Alert lacked the necessary factual premises (there was no immediate and extraordinary risk for health as required by Law

iii) The Alert was disproportionate. In relation to this, the precautionary principle, as interpreted by the European Commission infringed.

The Ministry of Health opposed the plaintiff's arguments:

[4] limiting the trade of a product),[5])[6] and the European Court of Justice had been

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A requirement of article 9 of *Real Decreto 44/1996*

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By Article 26 of Spanish Health Act, invoked by the State

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Communication of the Commission on the precautionary principle of 1 January 2000

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i) It denied that ASOLIVA had any standing for the action, since it intended to challenge a "recommendation" addressed to other authorities. The Court could only review the executing measures taken by the other authorities following the Ministry's recommendation.

ii) Furthermore, the decision was justified due to the risk posed by PAHs to public health and that, in such cases, public health considerations take preference over economic ones,

iii) This recommendation was backed by the precautionary principle.

The findings of the Court of First Instance

The case was adjudicated, in the first instance, by the High Court of Madrid

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The High Court of Madrid considered that the decision to use the Rapid Alert System was:

i) a proper administrative decision, that could be examined by the Court and that the plaintiffs had standing to challenge the

decision. In the reasoning of the Court, the Ministry of Health took a final decision: to issue a food alert and to recommend the recall of the product -“ex article 26”- of the Spanish Health Act, and therefore the Court could review whether the conditions justifying that decision were met.

ii) The Court, subsequently, takes into account the fact that the risk posed by PAHs had been known – at least - since 1991, the date of the report by the World Health Organisation, and that no measure had been taken to set any limit to this substance until 25 July 2001, a few weeks after the immobilisation of the product. The Court found that the answer to this apparent

contradiction lay in a scientific report provided to the Court by the plaintiff. This report explained that PAHs are generally accepted to be potentially harmful substances, but only in permanent doses and at a level that is several times higher than that found in the most contaminated products, and represent no danger in the case of occasional intakes. In such circumstances, no urgency existed. Urgency is required by Spanish Law in order to adopt immediate measures such as the one taken by the Ministry of Health, whose decision lacked the factual requisites that would allow the use of extraordinary measures under article 26 of Spanish Health Law. Furthermore, the Court

considered that, taking into account the wording of the WHO report and the fact that no regulation had been previously passed on PAHs, the risk posed by this substance could not be called extraordinary and could not justify the food alert in question.

This decision was appealed against

in casacion by the State.

The case in the Spanish Supreme Court

For the appellant- the State, in this case-,

i) The decision of the Spanish Ministry of Health to use the Rapid Alert System was not an administrative act subjected to jurisdictional control. In the State's interpretation, these kinds of decision are neither intermediate nor final, but a

genus

the application of the precautionary principle) that could not be

reviewed by the Court.

ii) In any case, the authorities are entitled to withdraw a product

from the market, even if there is no specific legislation because

tertium(as referred to by the Commission's Communication on

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all products must be safe and in perfect condition for

consumption.

iii) These arguments are supported by the precautionary principle.

ASOLIVA contested these arguments, with the following arguments:

i) The appellant intended to reverse the opinion of the lower

Court on the existence of an imminent and extraordinary risk,

but this is was a matter of interpretation of facts that could not

be reviewed in

of Law

casación, which only deals with interpretation.

ii) When the Ministry of Health decided to issue a food alert -

invoking article 26 of Spanish Health Act - it was taking a

decision whose consequences could not ignore, a decision

could be reviewed by a court, precisely to verify whether the

conditions set by article 26 (extraordinary and imminent risk)

were met.

iii) The precautionary principle could not support the action taken

by the Ministry of Health, since the application of this principle

requires the performance of a sound risk assessment based on

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the most recent scientific data available, can only cover

proportionate action and must strictly respect administrative

proceedings

iv) The Ministry could not justify its decision based on the general

obligation that products should be safe, since this justification

contravenes the requirements of legal certainty and was

applying the Order of 25 July 2001 (setting limits to PAH on

edible oils) retroactively, which is forbidden by Spanish Law

and the Constitution.

7.

The judgment of the 27

th of June 2007 of the Spanish Supreme Court

The Supreme Court assesses the wording of the text of the “alert”

together with the competence of the State in the matter and concludes

that, when the State takes the decision of announcing a serious risk to

health using the Rapid Alert System, it is leaving little choice to the

implementing authorities, even if it uses the term “recommendation”.

Therefore this constitutes a full administrative decision with full

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Greenpeace, Commission vs. Belgium

Cases National Farmers Union, Alpharma, Pfizer, Monsanto, Commission vs. Denmark,

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practical consequences that can be fully reviewed by a court and

challenged by the affected companies.

The Supreme Court also concludes that, although the

casacion

lower court, in this case this interpretation was correct and that the presence of a substance in a food product cannot justify urgent measures when there is no specific regulation on that substance and when its potentially harmful effects were described in a ten-year-old scientific report.

Furthermore, in the absence of regulations on the specific health risk posed by a certain substance, the authorities cannot merely resort to the general obligation that all foodstuffs must be safe, in order to act urgently against the product.

recurso deis not the place to review the interpretation of facts given by the

Conclusions and State's Liability

In conclusion, the Court deals with a very important issue, namely the conditions under which authorities can resort to the use of the Rapid Alert System. This system, important as it is to prevent real health hazards, is in potential conflict with the requirements of legal certainty. The construction of a sound scientific argument becomes essential when

taking discretional decisions with potentially serious economic effects. For the Spanish Supreme Court, the State can not justify strong invasive action on the market on the basis that products have to be safe, but only if they pose an imminent and extraordinary risk to health, and this was clearly not the case when the risk posed by a substance had been known

for ten years, without any regulatory concern on the part of the Authorities.

The second important issue tackled by the Court is whether a decision to issue a food alert is one that can be adjudicated upon by a court. In this case, the Court has no doubt that the Ministry of Health's decision had significant effects transcending internal administrative communication, irrespectively of whether it is directly executive or requires the cooperation of other authorities. A contrary decision by the Court in this respect would, in my opinion, have been a serious blow against the rule of law.

To end this presentation I must add that the case has given rise to numerous claims of State liability resolved in contradictory manner by different Courts, claims that still must be finally settled by the Spanish Supreme Court, whose present decision is an important but not binding precedent.

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Thank you,

Vicente Rodríguez Fuentes

Abogado

to react very quickly when they consider that public health is at risk.

We know that the use of the Food Alert mechanism is conditional to the existence of two premises, a risk to health that is both serious and immediate, and neither of these premises is defined by the legislation.