

More on the Hormones Dispute

A few weeks ago, I [did a post](#) relating to a summary of the recent Hormones panel meetings, by Anna-Emilia Autio and Petko Kantchevski:

- [Wednesday, September 27, 2006, meeting of Panel with parties and scientific experts](#) (notes of Petko Kantchevski)
- [Thursday, September 28, 2006, meeting of Panel with parties and scientific experts](#) (notes of Petko Kantchevski)
- [Monday/Tuesday, October 2-3, 2006, meeting of Panel with parties](#) (notes of Anna-Emilia Autio)

As mentioned there, Anna and Petko were also going to reflect on issues of the case and offer some further thoughts. Petko now has his ready -- click the link below to read them.

Some Reflections on U.S./Canada Continued Suspension of Obligations in the EC – Hormones Dispute

Petko Kantchevski

More than fifteen years there has been a ban in place against imports to EC of meat treated with hormones. After the ban was found to be inconsistent with the provisions of the SPS Agreement in 1998, the EC has claimed in the last years that it complied with the DSB's ruling and as a consequence, the US and Canada's authorization for retaliation was no longer lawful.

The Alleged Violations of the DSU

The major part of the EC's claim before the WTO in the present case concerns procedural violations of the DSU, namely Articles 22.8, 3.7, 21.5 and 23.1 "read in conjunction". It is no doubt, though some representatives at the hearing did not agree, that the new EC Directive formally falls within the meaning of a measure under Annex A 1 of the SPS Agreement and within the meaning of DSU Article 22.8 which provides that "[t]he suspension of concessions or other obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed". Since there is a new measure, this indicates that the old one has been removed though the consequences are essentially the same. The DSU underlines that the suspension of concessions is only last and exceptional resort and shall be applied only temporarily. The wording of DSU Articles 22.8 and 21.5 implies the logical conclusion that whenever there is a disagreement as to whether a measure taken to comply with a DSB's ruling is consistent with the latter, the Member *should* have recourse to the DSU and request a compliance panel. Apparently, in the present case there is a disagreement as to the consistency of the measure with the DSB's ruling. Indeed, the EC has invited several times the US and Canada to request a 21.5 compliance panel but unsuccessfully. Even though such an invitation may imply some moral considerations, the fundamental problem is that Article 21.5 does not prescribe any time-limits to initiate a compliance

panel. Hence, if Canada and the US were obliged to do this, then when this must be done? Furthermore, this provision does not even indicate some more general time-limits as, say, 'within a reasonable period of time'. Therefore, DSU Article 21.5 is without teeth and it rather provides for what would be desirable than imposing a legal obligation. In my opinion, the EC's chances on these procedural claims are quite theoretical.

The EC's Level of Protection

At some points of the second substantive meeting it was not very clear what level of protection the EC has exactly chosen for itself. Finally, it was clarified that the EC has established 'no added risk'. This means that the EC would accept certain risk from the hormones that are naturally existing in the meat but not from those that have been artificially added to the meat for growth promotion purposes. Such high level of protection fits with the Appellate Body's reasoning from 1998 that there is a fundamental distinction between added hormones (natural or synthetic) and naturally occurring hormones in meat and other food. Hence, the fact that the EC makes a ban on meat treated with those hormones for growth promotion purposes but does not adopt the same measure for import of meat which may contain naturally-occurring hormones, should not be considered as setting different levels of protection in comparable situations which are arbitrarily and unjustifiable.

The Ban on Meat Treated with Hormones

It was clear back in 1998 that the only possibility for the EC to keep a ban on meat treated with the six hormones and be in compliance with the SPS was to conduct a new risk assessment. For the EC to prove that the new measure is consistent with the DSB's ruling, it has to demonstrate in the present case that the re-introduced ban is in conformity with SPS Articles 5.1 (for oestradiol 17 β) and 5.7 (for the other five hormones). I do not agree with some opinions expressed at the hearing that the EC had merely made a 'declaration' of compliance. It is true that it is absolutely unnecessary to bring a compliance case and fall into a procedural loop every time when the losing party makes a statement that it has implemented the DSB's rulings and recommendations. However, quite some years have elapsed after the adoption of the Appellate Body report. Since then the EC has initiated numerous studies and research projects on the matter. Finally, there is a new Directive adopted by the EC's competent bodies. Hence, there is a new measure in place. The question is whether the EC's risk assessment is consistent with SPS Article 5.1 and whether it sufficiently warrants the measure that has been imposed. The Appellate Body in 1998 found that the EC's risk assessment was not specific enough. Has this deficiency been removed at the present case?

This time the EC submits that the studies on which it has based its risk assessment (and more particularly those studies referred to in EC Exhibit 6) have precisely focused on the toxicological and other adverse effects from residues in meat treated with hormones for growth promotion purposes. At the hearing it became clear that the JECFA risk assessment in 1999 relied heavily on the data that had been submitted by the USA. When conducting its new risk assessment, the EC claims that it made its best to collect these data from JECFA and the USA but unsuccessfully. Furthermore, it also tried to collect such relevant data from other states and the industry but none of them provided such information. In the light of the above mentioned, it appears that the EC has made significant efforts to collect additional data for its risk assessment.

Two contradicting statements came to light at the meeting with the experts as regards the JECFA re-evaluation of the three natural hormones in 1999-2000 (i.e., for oestradiol 17 β , progesterone and testosterone). On the one hand, the JECFA's representative said that they never received the new data from the EC which had to be considered for the re-evaluation. On the other hand, the EC claimed that at the time when JECFA was re-evaluating the three natural hormones, the EC had sent a letter requesting JECFA to defer the re-evaluation for a later meeting due to the studies that were being prepared. Nevertheless, JECFA made its re-evaluation without waiting for the new scientific data. This can easily be checked since all letters are attached to the case. In any event, since the objective of JECFA's re-evaluation was to insure that all the latest information had been evaluated, it would seem reasonable if JECFA had waited.

An Achilles' heel of the present EC's risk assessment is the dose-response relationship which is a part of step two of the four compulsory steps of the conduct of a risk assessment. The defending parties allege that the EC's risk assessment did not conduct a dose-response evaluation and as a consequence, it did not make a risk characterization, i.e., the estimation of the occurrence of potential adverse effects in a given population. Unlike the situation in 1998, this time the EC has chosen a different strategy. First, it claims that oestradiol 17 β is genotoxic and carcinogenic. Actually the genotoxicity of oestradiol is almost incontestable in the science, so the question is in what doses it is genotoxic. Second, the EC alleges that a dose-response assessment cannot be performed as this entails long-term studies of human exposure. Understandably, humans cannot be subjected to testing of this kind, can they? Moreover, since it cannot be established exactly at how low levels of exposure adverse effects would appear, the EC submits that any exposure entails a risk to human health. This makes perfect sense if a WTO Member establishes very high level of protection. In the present case the EC claims to have set a higher level of protection than the existing international standards.

The SPS Agreement requires a relationship between the risk assessment and the measure imposed so that the latter sufficiently supports the former. On the one hand, the imposed ban is the most trade-restrictive measure. A ban like the one at issue, may threaten the normal conduct of international trade if it is found to be WTO consistent, since the Appellate Body observed in 1998 that there had been a number of other products (e.g., broccoli, milk and eggs) in which the residue level of the hormones in question was the same as in the hormone-treated meat.

On the other hand, several strong arguments supporting the measure are to be considered in the present case, namely:

- 1.) the EC has presented new data on these six hormones (and more particularly, the 17 studies which were often referred to by the EC at the hearing;
- 2.) some experts stated at the hearing that the equipment and techniques used for the JECFA's risk assessment were outdated and hence not reliable as new techniques, including those used for the EC's studies, may detect metabolites which was not possible before;
- 3.) when it comes to human health, Members should be more cautious. The exceptional character of human health is confirmed by Article 5.5 of the SPS Agreement;
- 4.) the newly established fact that young children are more endangered population group as previously thought; and finally

5.) the EC is not obliged to comply with the existing international standards but may set for itself a higher level of protection.

If one takes into account these arguments, it seems that the EC's chances to prevail as regards its consistency with Article 5.1 of the SPS Agreement are not merely theoretical though perhaps still small. Nevertheless, in my view all these arguments do not justify yet the most trade-restrictive measure if all the studies referred to by the EC do not prove the specific risk – that adverse effects would come from oestradiol residues in meat from animals treated with hormones. This difficult task has to be resolved by the panel after digesting the enormous amount of scientific data submitted by the EC.

Furthermore, some of the experts confirmed at the hearing that at low doses the science does not know what happens. Hence, it is not certain that the adverse effects will occur. They may but they may not. However, there are so many other products for which we know that are dangerous but at what levels? For instance, cigarettes are dangerous but are not banned, at least not yet. Does the EC's risk assessment sufficiently warrant the imposed ban? All this entails a lack of sufficient relationship between the risk assessment and the measure in question. That is why in my view a possible solution to the dispute was for the EC to put special labels on these products.

The Provisional Ban on the Five Hormones.

There may be situations when new scientific evidence identifying a new risk comes to light but this data is not sufficient for the conduct of an adequate risk assessment. Therefore, though a risk assessment may have been possible to perform in the past, in the light of the new scientific development this may no longer be possible to perform within the meaning of Article 5.1 and as defined in Annex A to the SPS Agreement. The recently issued panel report on *EC-Biotech Products (GMOs)* has touched upon this issue though very prudently and within the context of Annex C 1 (a) of the SPS Agreement. It admitted that

...if new scientific evidence comes to light which conflicts with available scientific evidence and which is directly relevant to all biotech products subject to a pre-marketing approval requirement, we think that it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence.

Nonetheless, I find that in the present case the EC's arguments on Article 5.7 of the SPS Agreement would hardly prevail. Almost all experts confirmed that the data available for the five hormones was absolutely enough to conduct a risk assessment as provided in the SPS Agreement. Well, the science may not lead to definite conclusions, however, scientific uncertainty or divergent scientific opinion do not justify the lack of a risk assessment. Article 5.7 of the SPS Agreement requires that the scientific evidence is insufficient which is not the case. Furthermore, the Appellate Body has suggested in several cases a restrictive application of Article 5.7 of the SPS Agreement. This was also supported by the panel report on *EC-Biotech Products (GMOs)*. Although it mentioned that there might be situations when risk assessment could not be performed in the light of new scientific development, it finally confirmed a narrow interpretation of Article 5.7 of the SPS Agreement stating that the sufficiency of the scientific evidence was related to the ability to conduct an adequate risk assessment and not to a Member's level of

protection. Moreover, divergent scientific views and gaps in the scientific evidence do not necessarily mean that an appropriate risk assessment cannot be performed.

So the question still stands – if it is known that a certain substance is dangerous to human health but it is not certain at what levels it may produce its adverse effects, (hence one part of the risk assessment is impossible to be performed), can this be a justification for imposing the most trade restricted measure? Then what do we do if hormone-treated meat is really dangerous but we can be sure about its adverse effects in 30 years when they really occur?