Speech by Coen Teulings, Chairman of Merifin Capital, at the AECA Hearing Conference with David Byrne, European Commissioner for Health and Consumer Protection in Brussels on 25 November 2003

Ladies and Gentlemen,
Some time ago, although the European Union had agreed to keep its borders open for electronic components from outside, France for a while, required that all these imports go through a totally understaffed centre in Poitiers, which in effect came close to closing its borders. This shows the European Union at work. It would also suggest, there may be room for improvement. The European Union is a major challenge as well as an historic opportunity in view of so many new members. We have to live up to it and we will.

I would like to now present a number of observations some of which are general and some more specific.

General observations

1. It is widely accepted that small and medium size enterprises are the backbone and drivers of growth of our economy. Yet they often are under-represented and under-lobbied vis-à-vis the regulators as they simply cannot afford such luxuries. It therefore is imperative that regulators take especially into account the viability of rules for SMEs. This may not always be easy in view of lobbying and political pressure but sweeping regulations are no good when they appear prohibitive for the smaller business.
2. The stated policy of impact assessment and consultation, is excellent and indeed so obvious that one wonders why it was not declared earlier. It is important that regulations can work proportionately for their target communities, and consultation and impact assessment may help to achieve this outcome. However impact assessment and consultation have to be done expeditiously and done well or otherwise they may backfire. There is no better way to frustrate and bog down regulation than endless consultations. As always, execution is key. Policy statements have to be translated into effective plans of action.
3. We do not live in the world alone. In our own long term interest we also have to take care of developing countries. Regulations in the European Union should not be so complicated and demanding that developing countries effectively are frozen out from trading with the EU. They have great difficulty in implementing a myriad of regulations and really cannot follow as they often lack the mechanism and infrastructure to do the job. This is a major complaint also in the WTO. Regulators need to acknowledge this problem. This is another aspect of proportionality. If we do not enable developing countries to grow their economies, if we do not help to eliminate poverty, the world will remain unstable.

Specific observations

1. European regulations for the wine industry are very strict and European producers have to perform accordingly. Yet wine producers outside the European Union such as Australia enjoy less stringent regulations and are thus able to produce at a lower cost price which allows them to compete effectively inside the European Union against local producers. This is the more remarkable where the EU through the common agricultural policy supports the local producers who are then undercut by foreign competition let in by the same European Union.
2. A major concern for small agricultural producers in several countries is traceability in the food chain. As from January 2005 it will be compulsory for every product (apple, potato etc) that it can be traced back to a single producer. This is impossible for small producers as they bring their products to cooperatives where everything gets into a bigger pot. It is easy to trace back to an area and a cooperative but not to a single producer. Enforcing an expensive and cumbersome procedure on small producers may put them out of business.
3. A real challenge for distributors is the strict labour laws and protection for sales agents, in the European Union. This is delaying sales growth as distributors are reluctant to hire salesmen. They prefer to wait until market demand is stronger in order to cover the costs of a salesman but demand cannot grow without a salesman. Catch 22. This concerns in particular our riding boot company Ariat from California, the best riding boot producer in the world. Ariat could sell far more in Europe to the benefit of its customers if distributors were not so hesitant (this is a small commercial on the side).
4. The pharmaceutical industry and the regulators should give greater acknowledgement to the evidence that responses to drugs are different according to genetic variations among people. If big pharma would segment its drugs and marketing according to pharmaco-genomic studies, perhaps more drugs would get approval but cater to smaller, better defined types of patient. And such data may also be used to avoid toxicity in not prescribing drugs to certain patient populations who are sensitive to it. Many pills prescribed have no positive effect. This could have implications for reimbursement too. Drug development can be regulated more efficiently when data are shared with the regulators. The draft Guidance for Industry on Pharmaco-Genomic Data Submissions by the US Food and Drug Administration from

November 2003 confirms the trend. Big pharma may not like this too much as they prefer blockbuster drugs sold to everyone.

5. GMO (Genetically Modified Organism) in food is making progress. GMO is far preferable over unknown quantities of pesticides and other impurities inflicted on agriculture generally. The problem started when Monsanto tried to corner the GMO market some time ago and since then it has become a highly charged political issue. I understand that GMO food ingredients will be allowed in the European Union up to 0,9% provided it is clearly marked on the label so that the consumer has a choice. It seems however more complicated than that. GMO ingredients may be present at the beginning but later disappear in the course of a production process. If in such case a label still needs to mention "GMO", GMO may no longer exist scientifically and the result is only a paper trail and no substance. It would seem consumer protection overkill and clearly is against the interest of industry. It creates too many "GMO" food products, stifles R&D and innovation and hampers GMO science in Europe.
   In this connection I would like to add that also EU approval of new and innovative foods ("novel foods") currently takes far too much time longer than anywhere else in the world. This causes a risk that innovation and related investments move elsewhere and will be lost for the European Union.
6. For the bioscience industry a Clinical Trials Directive will come into effect in May 2004 and is intended to harmonize procedures across Europe. In practice, the Directive may instead seriously hamper EU competitiveness versus the US: it introduces new administrative and legal burdens that may raise the cost of conducting clinical trials by 30%. By reducing the modest relative advantage of doing clinical trials in the European Union that exists now, we make it more difficult to bridge the widening gap with the US biotech sector. Again impact assessment, proportionality and consultation are imperative.
7. The proposed EU Directive on Unfair Commercial Practices seems generally well received. The principles of country of origin and mutual recognition are a great achievement. It also seems wise to limit the Directive to B2C and not include B2B but it remains a challenge how to introduce the Directive into national legislations. There is a concern that the terms of the Test of Unfairness ("contrary to professional diligence" and "material distortion of average consumers' behaviour") and specific "misleading action" and "aggressive practices" should be better defined and made more consistent with each other in order to avoid different interpretation by the National Courts which might cause legal uncertainty. I suppose as always the devil is in the detail.
   Selfregulation through Codes of Conduct should be helpful also to SMEs but they have to be clear and not too complicated. The EUREP GAP protocol (Euro Retail Produce, Good Agricultural Practice Assessment) for the big distribution sector may be an example of a code too cumbersome for small producers. Yet small producers through their cooperatives often are able to guarantee better quality products than is required under the Code, with almost zero residual of pesticide, i.e. healthy products. And so healthy food may be driven out by less healthy food which is protected under a selfserving Code of Conduct drawn up by big distributors.

Conclusion

It is very important that regulations are clarified, simplified and made coherent both at the EU and national level. Key however remains execution. A lot has been achieved. A lot still has to be done if the European Union wishes to remain competitive in the world.

Thank you.

Coen Teulings 25 November 2003