## **Head-to-Head**

## Introduction to the debate: How much regulation do we want or need?

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We in Britain have seen lots of headlines about over-regulation; for example, one headline reported Europe's top motor industries bosses telling the President of the European Commission that doing business in Europe meant extra costs because of 'increasingly dense, complex and often conflicting regulations'. So how much regulation do we want or need, for we also know that absence of or inadequate regulation can have serious consequences? We do not need to be reminded about what happened over thalidomide, or more recently over the presence of the red dye Sudan 1 in some foods.

The primary purpose of regulating in the life sciences is to manage risk to human and animal health and the environment, without unduly inhibiting innovation. But this leaves several questions unanswered. Absolute freedom from risk is obviously impossible, but who decides what level of risk is acceptable? Can a balance be found between promoting safety, on the one hand, and cost, bureaucracy, invasion of privacy, and loss of innovation and competitiveness on the other? And is there a way in which we can set the drive for regulation against its costs, financial social and ethical, including the opportunity cost of options forgone or innovations suppressed?

Food safety is a major concern for all governments, food producers and retailers. Regulations are obviously essential and consumers bear the costs. There is no government subsidy, but governments should and do take responsibility for the safety of food sold in their countries, a responsibility now carried by the European Union. The EU has also decided that it is essential to provide consumer choice, causing, some will argue, endless complications and putting it into a role which is more properly exercised by the market. Others will argue that the EU has to respond to the pressure from consumers for choice so it has to be provided, but by whom?

Europe decided some years ago that all foods derived from genetic modification (GM) should be treated as 'novel'; thus they had to be assessed for their safety. Three problems arose from this. First, how should 'GM' be defined? Does it include, for example, the crude genetic surgery of applying chemical or radiation mutagenesis to the seeds of cereals — as has been successfully done, with minimal regulation and no adverse effects, for over 50 years? The answer, as you know, is no. Secondly, what should be labelled? And thirdly, what level of GM content should trigger a labelling requirement?

There appears to be in Europe an inexhaustible demand for more regulation, but this has to be paid for, and all too often there has been no consideration of the cost implications in the political discussions. Regulation, despite its appearance of being cost-free, does cost and the consumer has to pay for it. Consumers will of course meet additional costs in order to ensure safety, and also in the EU, to ensure choice. But how much will they pay, and for how long and on how many products? These questions are unresolved and the following two papers address these issues from both a North American and a European perspective.