2 The precautionary principle and false alarms — lessons learned

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Most of the cases examined in the *Late lessons from early warnings* reports are 'false negatives' — instances where early warnings existed but no preventive actions were taken. In debates surrounding the precautionary principle it is often claimed that widespread application of the principle will lead to a large number of regulatory false positives — over-regulation of minor risks and regulation of non-existent risks, often due to unwarranted public 'fears'. Understanding and learning from past false positives as well as false negatives is essential for improving decision-making about public health and the environment.

This chapter reviews incidents of 'false positives', where government regulation was undertaken based on precaution but later turned out to be unnecessary. In total 88 cases were identified to be alleged false positives, however, following a detailed analysis most of them turned out to be either real risks, or cases where 'the jury is still out', or unregulated alarms, or risk-risk trade-offs, rather than false positives.

The analysis revealed four regulatory false positives: US swine flu, saccharin, food irradiation, and Southern leaf corn blight. Numerous important lessons can be learned from each, although there are few parallels between them in terms of when and why each risk was falsely believed to be real. This is a lesson in itself: each risk is unique, as is the science and politics behind it and hence a flexible approach is therefore needed, adapted to the nature of the problem. The costs of the false positives identified were mainly economic, although the actions taken to address swine flu in 1976 did lead to some unintended deaths and human suffering, and diverted resources from other potentially serious health risks. Determining the net costs of mistaken regulatory action, however, requires a complete assessment of the impacts of the regulation, including the costs and benefits of using alternative technologies and approaches.

Overall, the analysis shows that fear of false positives is misplaced and should not be a rationale for avoiding precautionary actions where warranted. False positives are few and far between as compared to false negatives and carefully designed precautionary actions can stimulate innovation, even if the risk turns out not to be real or as serious as initially feared. There is a need for new approaches to characterising and preventing complex risks that move debate from the 'problem' sphere to the 'solutions' sphere. By learning from the lessons in this chapter, more effective preventive decisions can be made in the future.

The scarcity of genuine false positives compared to the large number of 'mistaken false positives' could partly be the result of a deliberate strategy in risk communication. Several references and leaked documents have shown that some regulated parties have consciously recruited reputable scientists, media experts and politicians to call on if their products are linked to a possible hazard. Manufacturing doubt, disregarding scientific evidence of risks and claiming over-regulation appear to be a deliberate strategy for some industry groups and think tanks to undermine precautionary decision-making.

In debates surrounding the precautionary principle it is often claimed that widespread application of the principle will lead to a large number of regulatory false positives — over-regulation of minor risks and regulation of non-existent risks, often due to unwarranted public 'fears'. Critics of the precautionary principle argue that this means losing economic, environmental and human health benefits associated with the over-regulated activities (Smith, 1997 and 2000; Within Worldwide, 2000; Bate, 2001; Bergkamp, 2002; Sunstein, 2002; Graham, 2004). The literature is replete with case studies in which researchers claim excessive or unnecessary environmental and health regulation (see for instance Claus and Bolander, 1977; Whelan, 1985 and 1993; Bast et al., 1994; Wildavsky, 1995; Lieberman and Kwon, 1998; Sanera and Shaw, 1999; Bailey, 2002).

The case studies in the first volume of *Late lessons from early warnings* (EEA, 2001) were all false negatives, where early warnings existed but no preventive action was taken. In preparing the first volume, the editorial team queried the existence of 'false positives' and invited industry representatives to submit examples of instances where action was taken on the basis of a precautionary approach that turned out to be unnecessary. No suitable examples emerged and the false positive were therefore not addressed. To address this shortfall, the present chapter contains a thorough review of the issue.

2.1 'False alarms', 'regulatory abuse' and 'regulatory false positives'

The terminology regarding false positives varies. Lieberman and Kwon (1998) call their cases of overreaction 'unfounded health scares', whereas others use terms like 'environmental hoaxes and myths' (Martin, 1990), 'eco-myths' (Bailey, 2002), 'regulatory abuse' (Cohen and Giovanetti, 1999) and 'false alarms' (Mazur, 2004). Each of these researchers uses a different set of criteria — often not clearly outlined — to define when such cases of overreaction have occurred.

Most often, the authors cited above have included any case where concerns were raised over the safety of an activity, and where they deem that these concerns were later shown to be unfounded. The mere fact that concerns were raised does not, however, imply that regulatory measures were taken. The present analysis focuses on the extent to which applying the precautionary principle leads to over-regulation and it is therefore important that regulatory measures were actually taken to mitigate the suspected risk as a result of public and scientific concerns. Clearly, concerns raised by the media or public entities can lead to changes in markets or companies ceasing activities because of concerns over, for example, liability. The present chapter focuses, however, on false positives in terms of government regulation.

Similarly, for a case to be classified as a 'false positive', scientific evidence must exist showing that a perceived risk is actually non-existent and this evidence must be generally accepted in the scientific and regulatory communities. Using the Intergovernmental Panel on Climate Change (IPCC) sliding scale for assessing the state of knowledge on climate change (Moss and Schneider, 2000; Table 2.1), we argue that there should at least be a 'high confidence' (67–95 %) in the scientific evidence indicating no harm before a case can reasonably be claimed to be a false positive. This is consistent with the strength of evidence often sought in regulatory policy before preventive actions are taken, and with the classification systems of international bodies. For example, the International Agency for Research on Cancer requires that strict criteria be applied in concluding that there is no evidence of carcinogenicity as it is often difficult to rule out the possibility of effects.

For the purpose of this analysis, regulatory false positives are defined as:

> 'Cases where (i) regulatory authorities suspected that an activity posed a risk, and acted upon this suspected risk by implementing measures aimed at mitigating this risk, and (ii) that there is at least 'high confidence' in the scientific evidence that later became available indicating that the activity regulated did not pose the risk originally suspected' (Hansen et al., 2007a).

Thus, in the absence of preventive regulatory (mandated) action and high confidence in the scientific evidence about an activity's risk, a case

Table 2.1 IPCC scale for assessing the state of knowledge

95–100 %	Very high confidence
67–95 %	High confidence
33–67 %	Medium confidence
5–33 %	Low confidence
0–5 %	Very low confidence

Source: Moss and Schneider, 2000.

cannot be considered a regulatory false positive. All types of regulatory measures — including bans, labelling requirements and restrictions — fall under the definition of preventive measures. Contrastingly, decisions to study a suspected risk further or non-regulatory actions (e.g. including a substance on a list of chemicals of concern) are not considered regulatory measures for the purposes of this chapter, although some might consider government agency programmes or statements to be *de facto* regulation.

2.2 Identifying regulatory false positives

In order to identify regulatory false positives, we followed a two-step approach.

First, we conducted a detailed literature review to identify examples of regulatory false positives in the environmental and human health fields. The search terms used included 'false positives', 'over-regulation', 'health scares' and 'false alarms'. The review involved detailed literature searches and cross-referencing, and scrutiny of relevant websites. We also interviewed experts from academia, industry, non-governmental organisations and independent think tanks. Based on the review, we compiled a list of 88 case studies that claimed to be regulatory false positives (listed in full in Table 2.3 at the end of this chapter). A limited number of references provided the majority of these cases (Mazur, 2004; Wildavsky, 1995; Lieberman and Kwon, 1998; Milloy, 2001).

In the second part of the study, we analysed the literature on each of these examples to determine whether the case could indeed be considered a regulatory false positive. This was assessed based on the definition of a regulatory false positive elaborated in the previous section and current scientific knowledge. The analysis of the literature on each of the examples was performed as follows:

1. first, scientific opinions and reviews conducted by international consensus panels or bodies such as the World Health Organization (WHO), the United Nations Environment Programme (UNEP), European Commission Scientific Committees, and the IPCC, were consulted;

2. if no recent international reviews were available, we consulted up-to-date, recent reviews conducted by national governmental institutions such as the US Food and Drug Administration (FDA), and national environmental protection agencies such as the US National Academy of Sciences or Britain's Royal Society;

3. in cases where neither international nor national reviews were available, we performed literature reviews of peer-reviewed journals.

When reviewing the cases, emphasis was first placed on whether the conclusions reached in the scientific literature and by the different scientific panels and agencies were in conflict. Differing conclusions by various scientific panels, agencies and scientists would tend to lead to dismissing the case as a false positive, whereas consistent conclusions would tend to lead to accepting the case. In cases of conflicting conclusions between different scientific panels, agencies and scientists, however, we investigated the scientific literature to identify possible explanations for those differing viewpoints. If a reasonable explanation was identified to support the claim that a case was a false positive and the explanation was found to be scientifically valid by most scientists (some dissenting scientific views were accepted) in the field, the case was accepted as an authentic false positive.

For each case, we investigated what regulatory action had been taken to mitigate the risk in question, when and why, in order to determine whether the action taken could be considered to be unnecessary or disproportionate. In the event that a case was not considered to be a false positive, which occurred frequently, the reason for this was identified.

2.3 Mistaken false positives

Following a detailed analysis of each of the 88 cases, we developed a series of 'categories' of mistaken false positives including: real risks; 'the jury is still out'; unregulated alarms; 'too narrow a definition of risk' and 'risk-risk trade-offs'. The criteria used to assign cases to each category are set out in Table 2.2, and Hansen et al. (2007a) present additional examples that illustrate the key characteristics of each category.

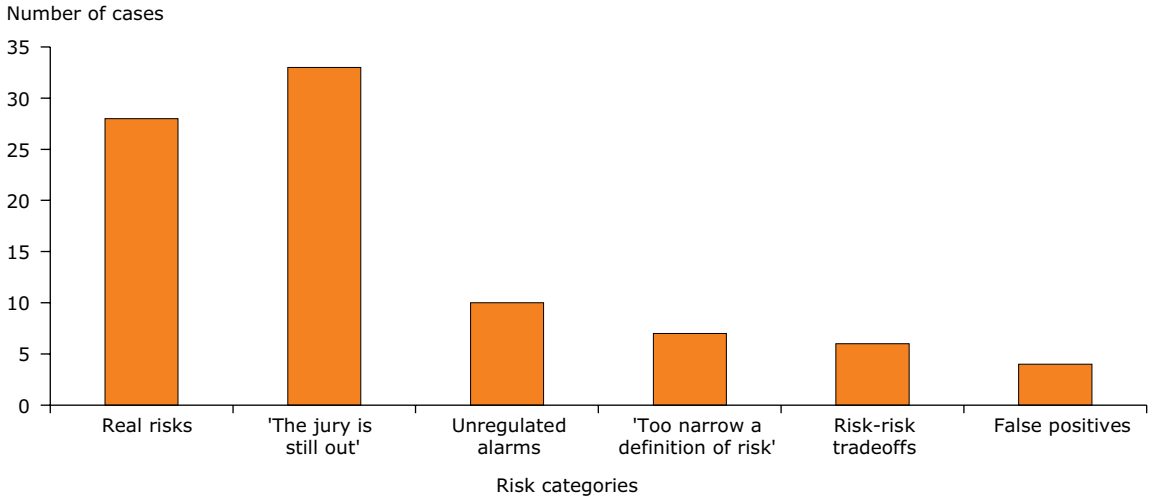
Figure 2.1 presents the distribution of cases in categories of false positives and mistaken false positives.

A detailed written analysis of each case is beyond the scope of this chapter. For a rationale for the categorisation of the cases into false positive and mistaken false positive categories, see Hansen (2004). Below, the categories are summarised.

Table 2.2 Categories of mistaken false positives and criteria for inclusion

	Criterion 1		Criterion 2		Criterion 3	Conclusion
Real risks	Hazard	and	exposure			Not a false positive
'The jury is still out'	Uncertain hazard	or	uncertain exposure	or	disputed evidence	
Unregulated alarms	Alarm raised	and	no action taken			
'Too narrow a definition of risk'	Other hazard	and	exposure			
Risk-risk trade-offs	Target risk	and	countervailing risk	and	action taken	

Figure 2.1 Distribution of 88 proclaimed false positives



2.3.1 Real risks

In about one third of the 88 cases proclaimed to be false positives, scientific evidence is available indicating that the activity in question posed a real risk. In these cases, a lack of regulatory intervention could have (and in some cases has) led to adverse effects on human health or the environment.

An example of such a case is acid rain. When exposed to bright sunshine, human emissions of sulphur dioxide and nitrogen oxides can be converted into sulfate and nitrate molecules. These particles can then interact with water vapour to form sulphuric or nitric acids, which return to Earth in rain, snow or fog. Concern was raised in the 1980s that acid rain might injure human health and the environment but according to Bast et al. (1994) and Wildavsky (1995) acid rain poses little or no threat to forests, crops, human health or lakes in America.

In response to the claims about damage caused by acid rain, the US Congress authorised a ten-year research effort called the National Acid Precipitation Assessment Program (NAPAP) (Bast et al., 1994). NAPAP acts as a coordinating office between six federal agencies including the National Oceanic and Atmospheric Administration (NOAA), the Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration (NASA) (NAPAP, 2011).

In 1996 NAPAP published an integrated assessment of costs, benefits and effectiveness of acid rain controls. NAPAP found that, although most forest ecosystems were not then known to be adversely impacted by acid deposition, sulphur and nitrogen deposition had caused adverse impacts on certain highly sensitive forest ecosystems, especially high-elevation spruce-fir forests in the eastern United States. These adverse effects might develop in more forests if deposition levels were not reduced (NAPAP, 1996). Because acid deposition has had adverse impacts on certain highly sensitive forest ecosystems in the eastern United States, this case is considered a real risk. See Semb (2001) for a discussion of sulphur dioxide and acid rain in the European context.

2.3.2 *'The jury is still out'*

In another third of the 88 cases, there is not a 'high confidence' in the scientific evidence of no harm from the activity in question. These could be categorised as cases for which 'the jury is still out' — instances where the scientific data are uncertain or disputed and no final conclusion has yet been reached.

In these cases, lack of evidence of harm has been misinterpreted as evidence of safety. This may be due to numerous factors, including the length of time the hazard has been studied, clear disagreements in the scientific literature, or limited human studies. For example, for the International Agency for Research on Cancer (IARC) to classify a chemical as 'probably not carcinogenic to humans', there is a need for 'strong evidence that it does not cause cancer in humans'. Only one substance has been listed as such.

An example of a case where 'the jury is still out' is the health risks of mobile phones (see also Chapter 21). Lieberman and Kwon (1998) argue that there is no evidence of serious health effects from routine use of cellular phones. Graham (2004) also mentions cell phones and brain cancer as a scare where qualified scientists did not replicate early studies suggesting danger. Several reviews of the scientific literature have been conducted by both international and national bodies such as the UK's Independent Expert Group on Mobile Phones (IEGMP, 2000), the British Medical Association (BMA, 2001), the Health Council of the Netherlands (2002), the Swedish Radiation Protection Authority's Independent Expert Group on Electromagnetic Fields (2003), the UK's National Radiological Protection Board (NRPB, 2003), Sweden's Research Council for Worklife and Social Science (FAS, 2003), WHO (2004) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2009). Although most reviews conclude that cellular phones probably do not constitute a health hazard after less than ten years of use, many still advise a 'precautionary approach' and recommend further research into the long-term effects on health because of the prolonged latency period of many chronic diseases (SCENIHR, 2009; WHO, 2010a and 2010b). A recent book compiling the scientific evidence on cell phone health risks (Davis, 2010), found that the there is strong enough evidence on health risks to warrant immediate action to redesign cell phones to make them safer.

According to the IEGMP (2000), the US FDA (cited in US GAO, 2001), the Danish Health Agency (2000), the Royal Society of Canada (RSC, 1999) and SCENIHR (2009), there is not enough information to conclude that cellular phones are without risk after long-term use (more than 10 years), although research to date does not show that mobile phones have adverse effects after short-term use (less than 10 years).

Several factors make it difficult to draw definitive conclusions from existing studies (US GAO, 2001; SCENIHR, 2009). Existing epidemiological studies on the health effects of radiofrequency in general have focused on short-term exposure of the entire body, not long-term exposure to the head. No studies on mobile and cordless phone use among children and adolescents have been completed so far. Additionally, most research has been conducted on the use of analogue phones instead of digital phones, which have become the standard technology. Finally, most research investigates the health effects at different frequencies than those used in mobile phones, and it is not clear how impacts from one frequency on the radiofrequency spectrum relate to other frequencies (US GAO, 2001; SCENIHR, 2009).

Studies on animal and human cells and tissues have shown that radiofrequency emissions can produce measurable responses, although it is not known whether or not these responses are harmful (Bast et al., 1994; RSC, 1999; ICNIRP, 2001). IEGMP (2000) found evidence to suggest that radiofrequency radiation might influence the ion channels and other membrane proteins of neurons in the brain under normal conditions but the significance of such effects for human health is uncertain. According to the US FDA (cited in US GAO, 2001), one type of test known as the micronucleus assay has shown changes in the genetic material, which is a common precursor to cancer. The US FDA therefore calls for additional research into the safety of mobile phones emissions. Numerous national and international research projects have been initiated across the globe to study the health risks (BMA, 2004).

The IARC has an electromagnetic field (EMF) project under way to coordinate and stimulate research and scientific discussion that can provide the basis for its reviews. IARC (2008) has established a series of multinational case-control studies (known as the Interphone study) that will potentially deliver more conclusive data on the possible health effects of mobile phones than previous research. Several studies from the Interphone study have been published (IARC, 2008) and a majority of these have found no association between cellular phone use and the risk of brain cancer. A number of small, long-term

studies did, however, find a slightly increased risk for certain types of brain tumours after long-term use of cellular phones (Lönn et al., 2004 and 2005; Hours et al., 2007; Klaeboe et al., 2007). After pooling data from Nordic countries and the United Kingdom, Lahkola et al. (2007) and Schoemaker et al. (2005) reported finding a significant increased risk of glioma on the side of the head where the tumour developed after at least 10 years of using cellular phones (IARC, 2008). See Chapter 21 on mobile phone use and brain tumour risk for an updated evaluation of this evidence.

There are a number of reasons why this case falls into the category 'the jury is still out'. First, several factors make it hard to evaluate existing epidemiological studies, as previously noted. Second, although the significance for human health is unknown, different effects on cells and tissues have been observed when exposed to radiofrequency radiation. Third, there is a vast amount of research currently under way as a result of lingering scientific concerns and uncertainties.

2.3.3 Unregulated alarms

In a number of cases, a given substance, technology or procedure was proclaimed to be a risk but no regulatory action was ever taken to mitigate it. Concerns could be raised as a result of a scientific study (which later turns out to be a scientific false positive) or public or political concern. Since the cases have not been regulated, they are not considered false positives from a regulatory point of view. Examples of cases that fall into this category include the claimed links between coffee and pancreatic cancer, between fluoridated water and associated health effects, and between the measles-mumps-rubella (MMR) vaccine and autism.

There has been great public concern about the safety of the measles-mumps-rubella (MMR) vaccine since Wakefield et al. (1998) published a small study in *The Lancet* suggesting an association between the vaccine and bowel problems and autism in 12 children. In the study, parents or doctors recalled that the first signs of autism had started within two weeks after the MMR vaccination and the researchers wondered whether these two were connected. They never claimed, however, to have conclusively demonstrated this association (IOM, 2001a). The culprit was suspected to be a vaccine preservative known as thimerosal, which contains mercury (Fields, 2004).

According to Bate (2001), this research made some pressure groups argue that a precautionary approach should be taken and that the vaccines should be withdrawn, which could lead to new disease outbreaks with severe public health consequences. According to Bate (2001) 'Precautionary vaccination propaganda that results in individual and government action harms, and sometimes even kills, children.' Guldberg (2000) calls this case an obvious example of scare-mongering and argues that damage has been done because many parents decided not to take the one-in-a-million chance of a serious reaction to the vaccine. According to Guldberg (2000) this led to falling vaccination rates in the United Kingdom, which could lead to a measles epidemic. Marchant (2003) also mentions the MMR vaccine as a case in which excessive precaution was taken.

Extensive efforts have been made to confirm the findings of Wakefield et al. (1998). A number of small studies have supported the results, whereas a series of large-scale studies have found no association between MMR vaccines and autism (e.g. Taylor et al., 1999; Meldgaard Madsen et al., 2002; DeStefano et al., 2004; Smeeth et al., 2004; Hornig et al., 2008). A number of literature reviews have also been published that have all concluded that the epidemiological evidence does not support the hypothesis of an association between the MMR vaccine and autism. These reviews further conclude that the epidemiological studies that do support an association have significant flaws in their design that limit the validity of their conclusions (CSM, 1999; IOM, 2001a, 2001b and 2004; WHO, 2003a; Parker et al., 2004). In 2004, 10 of the 12 authors of the original article by Wakefield et al. (1998) retracted their support for the findings in the study (Murch et al., 2004).

Despite the public concern about MMR vaccine and actions by many advocacy groups and parents, no regulatory action was ever taken to stop parents from getting their children MMR vaccinated. On the contrary, health agencies all over the world strongly recommended MMR vaccines at the time concerns were raised and still do (NACI, 2003; CDC, 2004; UK Department of Health, 2004; WHO, 2001 and 2003b). Therefore, this case falls into the 'unregulated alarm' category.

It is correct that the controversy about the safety of MMR vaccines led to decreasing numbers of children being vaccinated in the United Kingdom but according to the UK Department of Health (2003) the numbers are increasing again. There has been an outbreak of mumps in England and Wales but the agency has emphasised that this outbreak could not be attributed to the drop in MMR

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vaccinations caused by fears of a link to autism. The outbreak was actually largely due to young adults that missed out on the MMR programme, which began in 1988 (see Medical News Today, 2004).

2.3.4 'Too narrow a definition of risk'

Some cases proclaimed as false positives focus only on one aspect of the potential risks from a hazard. This can happen, for example, when only the human health effects of a particular hazard are examined and not the known environmental effects. Another example could be claims that a given substance is a false positive because it has been shown not to cause one type of cancer, when there is documented evidence that it increases the risk of other kinds of cancer. Examples of cases in this category include the links between hair dyes and certain cancers, and between second-hand smoke and breast cancer.

Nuclear power is another example, with some authors arguing that precautionary decisions to halt nuclear plant construction were not justified by the risks to those living near plants or the risks of accidents at the plants. For example, Graham (2004) notes that on the basis of precautionary considerations there has been a *de facto* moratorium ([1]) on the construction of new nuclear power plants in the US since the 1979 Three Mile Island incident. As a consequence, he argues that the US has become deeply dependent on fossil fuels for energy and 'now precaution is being invoked as a reason to enact stricter rules on use of fossil fuels'.

Bast et al. (1994) have further argued that the public is overly fearful of nuclear power and has been since the Three Mile Island incident. They further argue that low doses of radiation are not harmful and that nuclear power is a safe and clean technology, although they admit that accidents can happen. More recently, some have argued that nuclear power poses no risk of cancer based on a 2011 UK Committee on Medical Aspects of Radiation in the Environment (COMARE) 30 year study which found no increased risk of leukemia among children in the proximity of nuclear power plants in the United Kingdom (Ross, 2011; COMRE, 2011).

In fact, concerns about at least two other types of issues need to be considered in discussions

([1]) Since the moratorium has only been *de facto*, this case can also be discounted as a regulatory false positive because it constitutes an 'unregulated alarm'.

about risks from nuclear plants: the cost of nuclear-generated electricity and radioactive waste. Before considering them, however, it is worth asking whether the risks to those living near nuclear plants are, indeed, insufficient to justify a precautionary moratorium. There is little doubt, for example, that a major reactor accident could release large amounts of radiation into the environment, as was demonstrated during the nuclear disasters at Chernobyl, Ukraine, in 1986 and more recently at Fukushima, Japan, in 2011. Dispute seems to centre on the likelihood of such an event and there seems to be a significant disagreement between expert and lay perceptions of risk.

In 1975, the Rasmussen report assessed reactor safety in US commercial nuclear power plants. It found that the probability of having an accident like the Three Mile Island is anywhere from 1 in 250 to 1 in 25 000 reactor-years. These estimates did not take (among other factors) the possibility of human errors into consideration. US Nuclear Regulatory Commission data indicate that there is a 50 % chance of another accident occurring equal in size to Three Mile Island or larger (Shrader-Frechette, 1993).

These findings suggest that a precautionary moratorium on plant construction based on concerns about accidents and radiation leaks alone might not have been irrational. As noted, however, other factors played a role, including concerns about financial risks. Orders to construct nuclear plants had begun to decline sharply even before the Three Mile Island accident. By September 1974, 57 of 191 nuclear plants under construction, under licensing review, on order, or announced by utilities had been delayed by a year or more and a few had been cancelled altogether. Fourteen months later, 122 of the 191 projects had been deferred and nine had been cancelled. Between 1975 and 1978, US utilities ordered only 11 nuclear units. Utilities cut back on both coal and nuclear projects, but the blow fell disproportionately on builders of nuclear units because of higher capital costs (Walker, 2004). This was only partly due to public opposition.

The energy crisis of the early seventies sharply and quickly drove up the price of oil and other fuels that utilities purchased to run their plants. This again drained their financial resources. Adding to this, the serious problem of inflation greatly increased the cost of borrowing money for plant construction. An economic slump and increasing unemployment also curtailed demand for electricity, which grew at a substantially slower rate than experts had anticipated (Walker, 2004). As Giere (1991) states 'The accidents at Three Mile Island and Chernobyl dramatised the dangers of nuclear power, but the immediate cause of the demise of the nuclear power industry in the United States has been economic'. Supporting Giere's statement, the costs of nuclear-generated electricity quadrupled in the 1980s alone, and 2001 data from the US Department of Energy show that nuclear fission is more expensive per kilowatt-hour than coal, natural gas, wind, and solar thermal (Shrader-Frechette, 1993). According to Shrader-Frechette (2003) this is just another reason that no new nuclear plant has been ordered since the seventies.

In addition to accidents, radiation leaks and doubts about the financial viability of nuclear power, concerns also focused on the risks associated with radioactive waste produced as a by-product of power generation. During the 1980s radioactive waste doubled and there is still controversy surrounding how to deal with it. Although large-scale nuclear accidents might be rare, several accidents have occurred at nuclear storage facilities causing the death of hundreds of people. Clean-ups will cost hundreds of billions of dollars (Shrader-Frechette, 1993).

The example of nuclear power demonstrates that in assessing whether a decision is based on a false perception of risk, it is essential to examine all the factors motivating that decision. In this case, claims that the US moratorium represents (*de facto*) over-regulation based on disproportionate fears about accidents and radiation leaks do not bear up to scrutiny.

2.3.5 Risk-risk trade-offs

Risk-risk trade-offs can be defined as cases where efforts to combat a 'target risk' of concern unintentionally create 'countervailing risks' (also known as 'side-effects' or 'unintended consequences') (Graham and Wiener, 1995). Addressing risk-risk trade-offs (ensuring that regulatory actions do not create new risks) is an important concern in regulatory policy and several authors have written about this subject (see Tickner and Gouveia-Vigeant, 2005). The situation differs, however, from precautionary over-regulation.

One example of such a case is the use of nitrites in meat preservation. Nitrites have been used to cure meat, such as bacon, ham, hot dogs and other sausages, for several centuries. Besides enhancing

colour and flavour, nitrites inhibit the growth of *Clostridium botulinum* and other toxins. *Clostridium botulinum* causes botulism, a rare but often fatal form of food poisoning (McCutcheon, 1984). Since 1899 there have been only seven outbreaks of botulism poisoning in commercially cured meat products in the US and Canada, resulting in nine deaths. The excellent safety record of cured meat has been largely attributed to the use of nitrites (Pierson and Smoot, 1982).

In the late 1970s there was a discussion about whether or not to ban nitrites in the US. Concerns were raised after scientists found that nitrites react in the body with other food agents to form nitrosamines, which are known carcinogens (IPCS, 1978). Since attempts to discover a single alternative preservative with all the properties of nitrites have been unsuccessful, banning nitrites could result in a risk-risk trade-off between the risk of nitrosamine-induced cancers and increased risk of botulism. This argument was used by the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) and as a result nitrites were not banned (Wildavsky, 1995; Lieberman and Kwon, 1998).

Lieberman and Kwon (1998) have described the arguments against nitrites as one of the 'greatest unfounded health scares of recent times' fuelled by application of the precautionary principle. But the fact that a ban on nitrites could itself have created certain risks is not evidence that concerns about nitrites were unfounded. Indeed, the measured response of government and the food industry that ensued looks like smart management of risks, rather than over-regulation.

In 1978 the USDA required that the level of nitrite be reduced and that nitrite be used in combination with sodium ascorbate or erythorbate. Sodium ascorbate (vitamin C) or erythorbate (chemically similar to vitamin C) block or inhibit the formation of nitrosamines from nitrite (Institute of Food Technologists, 1998). The USDA took forceful steps to ensure that bacon was in compliance with the new regulations and began an extensive three-phase monitoring programme. The intent of the programme was not to stop bacon production but rather to produce bacon according to the new requirements. Plants in violation of the requirements were allowed to correct their procedures to reduce nitrosamines, and USDA offered technical assistance to plants with potential problems. The food industry responded by tightening its own quality control and nearly all bacon was free from confirmable levels of nitrosamines within one year of the start of the three-phase monitoring programme (McCutcheon, 1984).

Beyond bacon, the food industry generally made substantial changes to the cured meat manufacturing process. It stopped using sodium nitrate in major meat processes; it reduced the use of nitrite in the processing of cured meats; and it increased the use of ascorbate and erythorbate in the curing process. As a result, the food industry was able to eliminate the addition of nitrite to foods, reducing residual nitrite levels in cured meat products five-fold without compromising antibotulinal effects. Today the average level of residual nitrite is one-fifth of the amount present 20 years ago (Institute of Food Technologists, 1998). Indeed, there is a growing market for non-preserved meats due to concerns about the health implications of nitrites and antibiotics in traditional processed meats with no known safety implications to date.

2.4 Identified false positives

Of 88 cases of alleged over-regulation, only four cases fulfilled the definition of a regulatory false positive (Hansen et al., 2007a). These are the cases of:

- **Southern corn leaf blight:** the US Department of Agriculture decision in 1971 to plant more corn in the mistaken anticipation that Southern corn leaf blight would return and destroy a large part of the harvest (Lawless, 1977; Mazur, 2004; Hansen 2004);
- **saccharin:** the 1977 decision requiring saccharin to be labelled in the US because it was believed to be a human carcinogen;
- **swine flu:** the US Department of Health, Education, and Welfare decision in 1976 to mass immunise the entire American population in the mistaken anticipation of a return of swine flu (US GAO, 1977; Neustadt and Fineberg, 1978);
- **food irradiation impacts on consumer health:** the reluctance of the US Food and Drug Administration to allow food irradiation that could help reduce a large number of food pathogens and increase shelf life (WHO, 1981; 1999; SCF, 2003).

The latter two cases are presented below in greater detail. An in-depth analysis of the first two cases can be found in Hansen (2004). In the discussion that

follows, however, all four cases are referred to in drawing policy relevant lessons for decision-makers.

Each case was analysed in order to understand:

- when and why precautionary regulatory action was taken;
- when and why it was realised that this precautionary action was unnecessary;
- what the resulting cost and benefits were.

These factors are emphasised differently in each of the cases, as each has a unique historical and scientific basis. Literature is very scarce on Southern corn leaf blight, which makes it impossible to analyse and answer all of the questions in depth.

2.5 Swine flu

In late January 1976, twelve soldiers at Fort Dix in New Jersey became sick with an upper respiratory infection. One of the soldiers died after participating in a forced march. The cause of the infection was a new strain of the flu virus dubbed 'swine flu', which was antigenetically similar to the Spanish flu that had caused 40–50 million deaths worldwide in 1918–1919 (US GAO, 1977; Potter, 1998; Reid et al., 1999). Influenza epidemics result in about three to five million cases of severe illness annually and about 250 000 to 500 000 deaths, primarily among the elderly (WHO, 2010c).

Photo: © istockphoto/Sean Locke

US President Ford decided to immunise the entire American population against swine flu, dedicating USD 135 million to the production of vaccines (US GAO, 1977). The immunisation programme suffered a number of setbacks in the implementation phase, however, and only 40 million Americans (out of 200 million) were inoculated. The widespread swine flu outbreak feared by decision-makers never occurred. On this basis, the mass immunisation program appears to have been unnecessary.

2.5.1 Responses to early warnings

The initial outbreak at Fort Dix was taken very seriously by the Center for Disease Control (CDC) and other agencies for a number of reasons. Among them:

- Scientists had observed that when a new strain of the flu emerged, it would typically appear in low levels towards the end of a flu season — just as swine flu did at Fort Dix — and then return in epidemic proportions the following flu season.
- A hypothesis at the time suggested that major flu epidemics took place at regular intervals of eleven years. Because the US had experienced epidemics in 1946, 1957 and 1968, it seemed plausible that a new one would occur in 1977.
- Another theory suggested that virulent flu strains recycled themselves at intervals of sixty or seventy years. Almost sixty years had elapsed since the Spanish flu epidemic of 1918–1919 and it seemed reasonable that the swine flu virus was in the process of re-emerging.
- A new strain of flu virus had never before appeared without it leading to a major epidemic (Boffey, 1976; Colin, 1976; USDHEW, 1976; Neustadt and Fineberg, 1978; Wecht, 1979; Silverstein, 1978; Bernstein, 1985).

Knowing this, government officials held a series of emergency meetings and decided that the CDC should begin preparing to produce large amounts of swine flu antibodies. Special attention was

paid to informing the public to prevent the media portraying the Fort Dix outbreak as a 'gloom and doom' scenario (Neustadt and Fineberg, 1978; Silverstein, 1978).

Little new information on the Fort Dix outbreak was available when the CDC's Advisory Committee on Immunization Practices (ACIP) held its annual meeting in March, 1976 to review the vaccine recommendations for the next flu season. Most of the participants were in favour of recommending mass production of swine flu vaccine and inoculation of the American population as soon as possible.

One member of ACIP suggested producing the vaccine and then stockpiling it until a clearer signal of a flu pandemic emerged. According to the records, he felt that one should always be careful about putting foreign material into the human body, especially when the number of bodies approached 200 million (Neustadt and Fineberg, 1978; Silverstein, 1978). According to the minutes of the meeting, the possibility of stockpiling vaccines was never really discussed. According to some experts (Wecht, 1979), however, the option was discussed by Dr Sencer, Director of the CDC, and a few other committee members during one of the breaks of the meeting. They did not consider the option viable due to the amount of time required to distribute and administer the vaccines. Too many people could get sick and perhaps die in the time it would take for the vaccine to find its way through the delivery pipeline. The basis for not discussing this option openly during the ACIP meeting was later attributed by some to Dr Sencer's eagerness to act immediately (US GAO, 1977; Neustadt and Fineberg, 1978; Silverstein, 1978; Bernstein, 1985).

Based on the ACIP recommendations, Dr Sencer prepared a memorandum presenting the pros and cons of four courses of action:

1. No action: leave it to private drug manufacturers to produce vaccines in response to their estimates of demand, and let consumers make their own decisions on whether to get vaccinated.

2. Minimum response: the federal government would advise the drug industry to produce sufficient vaccine to immunise the general population and would undertake a public awareness programme.

3. Government programme: the federal government would advise vaccine manufacturers to embark on full scale production with the expectation of a federal government purchase of up to 200 million doses. The health authorities would carry out an immunisation programme designed to reach 100 % of the population.

4. Combined approach: the federal government would advise vaccine manufacturers to embark on full-scale production and purchase 200 million doses. However, they would leave it to state health agencies to develop plans for immunisation (USDHEW, 1976).

The memorandum recommended the 'combined approach' for a number of reasons. Previous experiences with widespread flu pandemics in 1957 and 1968 indicated that the vaccine should be produced, distributed and administered as fast as possible. In 1957 the flu outbreak came earlier than expected and only about a quarter of the vaccine doses were administered before massive outbreaks occurred, and ultimately only about half of the doses were administrated. Efforts to contain the flu pandemic of 1968 were hampered by the fact that it was realised too late that a new strain of flu had appeared, rendering vaccines in use ineffective.

A combined approach was considered to be the only way to immunise the whole population successfully before the next flu season. Furthermore full public funding was the only means of ensuring the availability of vaccines to all citizens. The cost of approximately USD 135 million would be small in comparison with the human and economic costs of past pandemics (USDHEW, 1976; Wade, 1976; Neustadt and Fineberg, 1978; Dowdle, 1997). The 1957 and 1968 pandemics caused about 45 and 50 million cases of influenza and resulted in the loss of about 70 000 and 33 000 lives, respectively. The total economic cost due to death and disease, health care costs and loss of productivity was USD 7 billion in 1957 and USD 3.9 billion in 1968 (US GAO, 1977; Silverstein, 1978; Bernstein, 1985).

The White House Office of Management and Budget (OMB) prepared a briefing paper for President Ford. It raised three main questions, relating to the probability that swine flu would reappear, the seriousness of the epidemic should it come, and whether the scientific community fully agreed with the recommendation made in Dr Sencer's memorandum (Neustadt and Fineberg, 1978; Silverstein, 1978).

Before announcing his decision on 24 March, President Ford requested a meeting with the nation's top influenza and public health experts. Many of

the scientists at the meeting thought that the vaccine was safe, that there was little to lose and that it was 'better to be safe than sorry' (Neustadt and Fineberg, 1978). Consequently, the experts voted unanimously in favour of proceeding with the immunisation campaign. Immediately after the meeting, President Ford requested Congress to appropriate USD 135 million for producing vaccines to inoculate the entire US population (US GAO, 1977; Neustadt and Fineberg, 1978; Bernstein, 1985). Later the President stated:

> 'I think you ought to gamble on the side of caution. I would rather be ahead of the curve than behind it' (Neustadt and Fineberg, 1978).

Congress approved the funds with little debate, and the final bill was signed some four months after the initial outbreak of swine flu at Fort Dix (Neustadt and Fineberg, 1978; Silverstein, 1978; Reitze, 1986).

There are some indications that the consultation process leading up to President Ford's decision did not give proper attention to alternative options and dissenting opinions. Many of the scientists consulted by President Ford noted that the discussions felt *pro forma* and that President Ford seemed already to have reached a decision (Boffey, 1976; Silverstein, 1978).

There was little doubt that Congress would respond positively to the President's request to appropriate money for producing vaccines in the face of unknown dangers (Silverstein, 1978). However, Bernstein (1985) argues that the hearings in Congress were carefully staged and that dissent was excluded. Only a few voices questioned the programme during hearings in the House of Representatives. For instance consumer advocate Ralph Nader's Health Research Group claimed that everyone was being overly alarmist, and hinted at some sort of federal-scientific plot to waste taxpayers' money. Democratic congressmen Henry Waxman of California and Andrew Maguire of New Jersey also spoke critically, implying that a potential 'rip-off' might be in the making, giving huge profits to the vaccine manufacturers (Silverstein, 1978; Garrett, 1994).

Two studies had also become available, indicating that the swine flu virus was not as virulent as had been feared. In England, Beare and Craig (1976) had injected six volunteers with the virus and only four had developed minor symptoms. They concluded that the virus was not especially contagious, a pandemic was very unlikely, and mass immunisation was unnecessary.

These results were supported by a study in the US on monkeys, which suggested that the virus would cause only a 'mild disease' (Silverstein, 1981; Neustadt and Fineberg, 1978; Edsall, 1979). According to *Medical World News* (1977), the results of the British study were known to the programme scientists, and according to Dr Sencer the programme was reconsidered three times: after the field trials; just before the President's push for money; and finally when the programme was suspended (Neustadt and Fineberg, 1978).

2.5.2 Evidence of a false positive

Although the mass immunization programme got off to a good start, the programme soon ran into a series of setbacks that delayed the inoculation process. Eventually, concerns over a possible link between the swine flu vaccination and an outbreak of a rare neurological disease, Guillain-Barré Syndrome (GBS), led the CDC to suspend the programme after only a fraction of the vaccine had been administered. By mid-December 1976, the CDC had received reports of 107 cases of GBS, including six deaths. The evidence indicated that the incidence of the disease was higher in the part of the population that had received the swine flu vaccine (one case in 100 000–200 000) compared to those who had not (one case in more than a million). An option was left open to resume immunisation if the swine flu pandemic in fact occurred in the US but swine flu did not reappear anywhere in the world during the winter of 1976–1977. The media's verdict on the swine flu immunisation programme was harsh, and allegations of incompetence and mismanagement of public funds were common (Neustadt and Fineberg, 1978; Silverstein, 1978; Dowdle, 1997; Reitze, 1986).

2.5.3 Costs and benefits

Besides the non-monetary costs in life and personal injuries due to the vaccine's side effects, the US Department of Health, Education and Welfare spent over USD 100 million on the mass immunisation programme, and state and local agencies are estimated to have spent USD 24 million (US GAO, 1977; Silverstein, 1978). In addition to these direct costs, the federal government had to pay settlements and legal fees related to the over 4 100 lawsuits that followed in the wake of the immunisation programme. Most of these lawsuits either alleged that the swine flu vaccine had caused GBS, or that it was responsible for various other illnesses including rheumatoid arthritis and multiple

sclerosis. The indemnities paid by the government totalled USD 83 million which, when added to the administrative and legal costs associated with the law suits, probably equalled the USD 100 million spent directly on the immunisation programme (Kurland et al., 1984; Reitze, 1986; Christoffel and Teret, 1991).

On a positive note, much was learned about the preparation, standardisation and administration of vaccines, as well as adverse reactions, whole and split vaccines and the adjustment of dosage according to age. Besides these benefits, some of the more puzzling findings from previous vaccine studies were clarified (Dowdle, 1997). After the events of 1976, research was initiated on the causes and possible treatment of GBS in medical institutions throughout the US (Silverstein, 1978), and a nationwide disease surveillance system was established (Neustadt and Fineberg, 1978).

2.6 Food irradiation and consumer health

Food irradiation was first applied on strawberries in Sweden in 1916 and the first patents were taken on this technology in 1921 in the US. Three kinds of radiation are typically used to sterilise food: gamma rays, X-rays and electron beams. And there are three main purposes for irradiating food: killing insects and other pests in grain, fruit, and spices; delaying ripening of fruit and vegetables; and reducing bacterial contamination of meat, chicken, seafood and spices (SOU, 1983; MAFF, 1986; WHO, 1981, 1999; SCF, 2003).

Gamma irradiation uses radioactive elements, whereas X-rays and electronic beams use ordinary electricity. However, all three perform a similar function (Environmental Nutrition, 2000; Pothisiri et al., 1991; WHO, 1993). Over the years, the FDA has issued a number of clearances to use this technology on food but in the late 1960s concerns were raised about the safety of food irradiation and no additional approvals were given for the next twenty years. At the beginning of the 1980s, the FDA authorised irradiation for several different kinds of foods, despite consumer reluctance to buy irradiated food (Meeker-Lowry and Ferrara, 1996; Adams, 2000). Consumer resistance is seen by many as the main reason why food irradiation is not widely applied (Thorne et al., 1991).

The failure of regulatory agencies to approve and accept food irradiation, despite evidence of its safety for consumers, constitutes a false positive. Similar evidence of safety was not identified for either the potential risks to worker health and safety from irradiating food, or the potential increased threat of terrorism that could follow from implementing large-scale food irradiation. Since these concerns cannot be ruled out, the perspective of this case is limited to consumer health.

2.6.1 Responses to early warnings

Serious progress in developing food irradiation technology first began in the 1950s when President Eisenhower announced his 'Atoms for Peace' programme, and extensive research and funding went into food irradiation from the US Department of Defence. Irradiation was approved for use in inhibiting potato sprouting and disinfecting wheat in 1963. Irradiation of can-packed bacon was approved in 1963 but this permission was subsequently withdrawn in 1968, after a review of the research found adverse effects in animals fed irradiated food, such as fewer surviving offspring (Webb et al., 1987).

2.6.2 Evidence of a false positive

Several international and national committees have evaluated the safety and 'wholesomeness' of food irradiation since the beginning of the 1980s, and all have concluded that irradiated foods are safe for consumers (SOU, 1983; MAFF, 1986; WHO, 1981, 1999; SCF, 1998, 2003; US FDA, 1986; NFA, 1986). However, this has not led to a general acceptance of food irradiation, and a variety of concerns have been raised through the years.

One of these concerns is about so-called radiolytic products, which form in irradiated food. Some of these radiolytic products are unique for irradiation (SOU, 1983; US FDA, 1986). Opponents of food irradiation argue that some of these chemical changes are known to be mutagenic and carcinogenic, and that free radicals — believed to be cancer promoters — are produced during irradiation (Webb et al., 1987; Public Citizen and Grace, 2002; Epstein, 2002).

Numerous toxicity studies have been performed on a range of animals, using a wide variety of different kinds of irradiated food, and examining different doses and endpoints. According to the World Health Organization, these studies have not provided evidence of harmful effects (WHO, 1981, 1994 and 1999). A number of highly controversial studies have indicated changes in the number

of polyploid cells in rats, monkeys and even malnourished Indian children fed freshly irradiated wheat (US FDA, 1986; WHO, 1994; Thayer, 1990; Vijayalaxmi and Rao, 1976; Bhaskaram and Sadasivan, 1975; Vijaylaxmi, 1975 and 1978). The WHO (1994) states, however, that 'No effects were seen showing any consistent pattern or trend, and the studies were overwhelmingly negative indicating that the consumption of irradiated food … had no toxicological effect'.

The WHO (1981, 1994 and 1999) and a British Government Advisory Committee on Irradiated and Novel Foods (MAFF, 1986) concluded that virtually all the radiolytic products found in both low- and high-dose irradiated food were either naturally present in food or produced in thermally processed food. In the US, radiation doses of up to 1 kilogray (kGy) have been approved on the basis that the concentration of radiolytic products is too small to be of toxicological significance (US FDA, 1986).

Others have argued, however, that irradiated food has never been rigorously tested (Bloomfield and Webb, 1990). It was originally thought that the radiolytic compounds could and should be tested according to the accepted protocols for food additives. This would require, however, that all of the chemicals be identified, isolated and fed separately to laboratory animals. Because of the difficulties of isolating and purifying the numerous radiolytic products, this approach is simply impossible (Bloomfield and Webb, 1990; WHO, 1994). Attempts to apply a safety margin by giving animals food irradiated at high radiation doses were also unsuccessful because the animals simply refused to eat the unpalatable food (US FDA, 1986; Bloomfield and Webb, 1990). Because of these problems testing has been done without safety margins, which may miss underlying or long-term safety hazards, according to Webb et al. (1987).

Concerns have also been raised that food irradiation could benefit irradiation-resistant bacteria, which would then grow exponentially after the food has been irradiated. It has been argued that the consequences of this are unknown (Murray, 1990; Tritsch, 2000). However, the WHO (1981, 1994 and 1999), MAFF (1986) and the Scientific Committee on Food (SCF) (2003) have all found no evidence of selective destruction and potential development of mutations. On the contrary both the WHO (1994) and the SCF (2003) state that irradiation has been found to cause loss of virulence and infectivity, as mutants are usually less competitive and less adapted.

Discussion about the safety of food irradiation has focused in particular on the chemical class of cyclobutanones and the question of whether or not they are carcinogens (Public Citizen and Grace, 2002; Epstein, 2002). Cyclobutanones are created only when fat-containing food is radiated (Delincée and Pool-Zobel, 1998; Delincée et al., 2002). Reports by both the FDA and the WHO have been criticised heavily for ignoring the issue of cyclobutanones (Public Citizen and Grace, 2002; Epstein, 2002). Concern was originally raised after studies by Delincée and Pool-Zobel (1999) and Delincée et al. (1999) found that 2-Dodecylcyclobutanone (DCB) was genotoxic. The identity and purity of the compound had not been verified prior to the studies, however, which the authors argue cast doubts on the results originally obtained (Delincée and Pool-Zobel, 1998).

A further concern relates to reducing the nutritional value of foods. Irradiation treatment does not significantly alter the nutrient value and digestibility of fatty acids and macronutrients, such as proteins, fats and carbohydrates (MAFF, 1986; WHO, 1981, 1999; Bloomfield and Webb, 1990) but loss of micronutrients does increase with radiation doses. The rate of loss differs substantially depending on the food and nutrients. Therefore these losses must be assessed for each food and for each vitamin specifically. According to the WHO (1981), thiamine (B1) is the only vitamin that should be considered in terms of dietary intake because it is radiation sensitive and the main sources of thiamine in the diet (e.g. pork) are candidates for high-dose irradiation.

In 1981, the World Health Organization (WHO) conducted a review of the studies performed with doses below 10 kGy and found that irradiated food has been conclusively demonstrated to be safe from the standpoint of toxicological, nutritional or microbiological risks to human health. This document has later been described as the culmination and turning point in the scientific evaluation of the safety of irradiated foods (WHO, 1993; 1994; Urbain, 1993). Following this report, the FDA began a systematic review of the over 400 toxicological studies on mice, rats, dogs, pigs and monkeys available up to 1982. Only five studies were considered to have been properly conducted in accordance with 1980 toxicological standards and were able to stand alone in support of safety (US FDA, 1986; WHO, 1994). Despite several years of consumer reluctance to eat irradiated food, the FDA decided to allow irradiation of spices and seasonings in 1983 while requiring that irradiated whole foods be labelled

as such. Since then the FDA has further allowed irradiation of fruits, vegetables, pork, poultry, red meat and eggs (Meeker-Lowry and Ferrara, 1996; Webb et al., 1987; US FDA, 1997; USDA, 1999a, 1999b; Epstein and Hauter, 2001).

2.6.3 Costs and benefits

Complete estimates of cost and benefits of irradiated food are not available. The costs of food-borne diseases in health and economic terms, and the potential role of food irradiation in reducing those costs, are not well documented (WHO, 1993). Robert and Murrell (1993) estimated that the economic losses in the US from food-borne pathogenic diseases are up to USD 5.3 billion annually. A number of factors affect these cost estimates, however, such as the number of estimated cases and estimated deaths, the severity of the illness and the type of food-borne disease (Todd, 1993). Cost-benefit estimates done by the US Department of Agriculture indicate that the benefits would be likely to exceed costs by a ratio of 2.2–2.8 to 1 and that the irradiation of just 10 % of poultry production would produce annual savings in the US of up to USD 50 million (WHO, 1993).

Several cost-benefit analyses have assessed the feasibility of using irradiation in developing countries. Most have indicated large potential benefits, especially with regard to increased shelf life and reduced post-harvest losses (Grünewald, 1973; Al-Bachir et al., 1993; Kahn, 1993; Moretti, 1993; Neketsia-Tabire et al., 1993). A number of challenges would have to be addressed, however, before developing countries can benefit from food irradiation. For the technology to be used efficiently requires, for instance, that the necessary infrastructure be established (WHO, 1993; Hackwood, 1991).

One of the frequently cited benefits of food irradiation is that it reduces the use of chemicals, for example use of ethylene dibromide in controlling insects and mould infestation in grain (WHO, 1993; Grünewald, 1973; Piccioni, 1987). The plausibility of this argument is, however, unclear (Webb et al., 1987; EC, 2002a and 2002b; Piccioni, 1987).

Nestlé (2007) has voiced concerns that extensive irradiation could reduce attention to the sources of pathogenic contamination of food and primary prevention. On the other hand, it could be argued that public reluctance to accept food irradiation may actually focus greater attention on improved sanitation in manufacturing and food preparation. It is unclear, however, whether or not this has been the case.

2.7 Discussion

This chapter aims to identify false positives and investigate lessons that could be learned to improve future decision-making — to minimise both false positives and false negatives. In this final section, we discuss the results of our analysis, focusing on:

1. when and why precautionary regulatory action was taken;
2. when and why it was realised that this precautionary action was unnecessary;
3. the resulting cost and benefits.

Finally, we discuss what lessons can be learned about false positives, why we were only able to identify four false positives, and the policy implications of our analysis.

2.7.1 False positives and early warnings

There are few parallels between the four cases in terms of when and why each perceived risk was falsely believed to be real. This is a lesson in itself: each risk is unique, as is the science and politics behind it. A flexible approach to science and policy is therefore needed, adapted to the nature of the problem.

In the swine flu case, concern was mainly raised because an 'early warning' of an outbreak fitted perfectly into three widely held theories about influenza cycles. Perhaps too much faith was placed on the ability of science to foresee the impending outbreak in this case. Even with hindsight, however, it is not at all obvious that the decision to mass immunise the American population was the wrong decision or an over-reaction considering the scientific understanding at the time and the stakes involved. Much contemporary scientific knowledge indicated that swine flu could return and had it done so it could potentially have killed millions. Even with the benefit of current knowledge, the science behind predicting flu epidemics remains very uncertain. One lesson from this case could be the need to be open to dissenting opinions and to discuss their validity before making decisions. Swine flu did not return and this was recognised almost immediately after the flu season, reducing the negative impact of this false positive.

In the case of saccharin, concern was triggered by new scientific knowledge indicating that saccharin causes bladder cancer in rats. There is now a general

scientific consensus that saccharin does not have the same effect on humans, although some minority opinions still exist. While it proved unnecessary, it would be wrong to say that the decision to label saccharin as a cause of cancer in laboratory animals was unjustified at the time preventive action was taken. For instance there is no way decision-makers could have known that rats would be the only species in which saccharin causes bladder cancer. Nor could they have known that scientific evidence would emerge indicating that the mechanisms by which it operates in rats appear to be irrelevant in humans. Only the often slow evolution of our scientific understanding gave decision-makers reasons to eliminate the labelling requirements for saccharin.

In both of these cases, it was virtually impossible for scientists, regulatory agencies or decision-makers to know or foresee that the potential risk was not real. The mechanism by which saccharin causes cancer in rats is so specific to this one laboratory animal that no one could have known that it would be irrelevant for humans; even today these mechanisms are disputed. Similarly, no one could know whether the swine flu would reappear or was smouldering in sub-clinical form in the public and would return in epidemic proportions when the flu season began.

The situation was similar with respect to Southern corn leaf blight (SCLB). In that case, the USDA correctly anticipated that the SCLB would return but could not have anticipated that it would not have the same devastating effect as the year before, probably due to a change in weather conditions.

Food irradiation stands out because the publication of a WHO review of existing literature in 1981 created a general consensus regarding the safety of the technology. Even before that, the WHO and others had endorsed and used food irradiation and there had been general consensus about its safety for some time. Nevertheless, the decision to withdraw permission to irradiate can-packed bacon seems completely reasonable in view of the fact that studies had found adverse effects in animals fed irradiated food. At that time there was a serious need for scientific studies investigating the safety of food irradiation.

It is also noteworthy that the false positive of food irradiation had little impact on consumers because alternatives were available to achieve the same outcome, such as improved sanitation in the manufacturing processes and good hygiene. Hence it seems that the availability of alternatives can minimise the total impact of a false positive.

2.7.2 The costs of false positives

The costs of the false positives identified were mainly economic, although the actions taken to address swine flu did lead to some unintended deaths and human suffering, and diverted resources from other potentially serious health risks. Clearly, however, determining the **net costs** of mistaken regulatory action requires a complete assessment of the positive and negative impacts of the regulation, including the costs and benefits of using alternative technologies and approaches.

The case of irradiation illustrates this point. There is no doubt that society could benefit substantially from preventing the numbers of food-borne illnesses but it is not obvious that food irradiation is the right answer. An alternative could be improving animal welfare to reduce pathogenic contamination, improving sanitation and conditions in manufacturing processes, and good hygiene (which manufacturers and governments should already be enforcing). Indeed, food irradiation provides an obvious opportunity to cover bad practices. Poor hygiene practices in food production have been widely documented (Webb et al., 1987; Bloomfield and Webb, 1990; Epstein and Hauter, 2001). And since existing regulations and requirements should guarantee that the public receives safe food even without the use of irradiation, the public would have no immediate benefit from food irradiation but would suffer the adverse health impacts if any existed (Tritsch, 2000; Begley and Roberts, 2002). Addressing the root causes of pathogenic contamination in food supply would probably lead to more sustainable prevention actions.

2.7.3 The precautionary principle, science and technological innovation

Opponents of the precautionary principle often argue that the principle stifles technological innovation (e.g. Wildavsky, 1995; Mazur, 2004). It appears, however, that the four false positives identified actually sparked innovation within industry and within government.

Innovation experts have noted that regulation may result in technological innovation because stringent regulations indirectly cause dramatic changes in technology and often allow new firms or entrants, thereby displacing dominant technologies (Ashford et al., 1985; Ashford, 1993; Porter, 1991). This phenomenon can be observed in the case of saccharin, whose existence was a major deterrent to

the development of other, more costly non-caloric sweeteners.

The mistaken actions to address swine flu likewise resulted in an unprecedented nationwide disease surveillance programme and the government learned how to mobilise resources quickly in the face of an apparent public health threat (Reitze, 1986). Such knowledge is particularly important in the context of new concerns related to bioterrorism.

In all the four cases, regulatory action indirectly sparked a large amount of research in previously unexplored fields of science. Saccharin and food irradiation are often mentioned as being some of the most tested hazards ever, and the swine flu case generated new and far better understanding of GBS — a disease that was previously little understood. The SCLB case sparked research concerning gene diversity and gene vulnerability.

Hrudey and Leiss (2003) state that:

> 'If a hazard is important enough to invoke precaution as a justification to prioritise action, it must also be important enough to understand better'.

This definitely seems to have been the case in these four cases.

2.7.4 Why so few false positives?

Given the vast amount of literature raising concerns that precautionary and preventive policies lead to false positives, it is surprising that so few were identified.

Clearly, interpreting scientific literature includes some level of subjectivity. Employing the definitions used in this study, different researchers might come up with slightly different categorisations of the 88 cases reviewed and the number of false positives could differ from analysis to analysis. But other studies might also adopt different definitions. For example, some analysts might argue that the concept of a false positive includes situations where an agency conducts a high-profile investigation, makes a public statement or runs an advocacy campaign and this results in concerns that lead to unnecessary actions.

Analysts may also vary in their interpretation of the difference between categories such as 'the jury is still out' and 'false positive', as well as in terms of the types of evidence they review and how they value uncertainties. The science informs decisions about whether a risk is real or not (does it cross some threshold of 'acceptable risk'?). But these are partly policy judgements, based on considerations such as levels of uncertainty and the economic consequences of acting or not acting.

Similarly, the question of whether a regulation is excessive to address a certain risk is a controversial and highly subjective question and difficult to characterise. For example, in current science-policy debates some scientists argue that precautionary regulation of phthalates in children's products or bisphenol-A (BPA) in items that come into contact with food may represent 'over-regulation' based on current understanding. Assessing politically defined 'safe' levels of exposure is incredibly complex given the subtle nature of many product-based exposures, lack of understanding of cumulative and interactive exposures, limited information about exposure pathways and human epidemiological data, and inadequate understanding about critical windows of vulnerability. Given significant uncertainties in such cases, a qualitative synthesis that considers the totality of the evidence of potential exposure (from body burden studies), hazard information, and information on potentially safer alternatives, may be the soundest approach to science for addressing complex risks and sufficient to spur innovation in safer materials (Sarewitz, et al., 2010).

To address concerns about subjectivity, we have attempted in this chapter to make our categorisation and evaluation as transparent as possible so that other researchers can repeat the analysis with these or other cases. Given the large number of cases examined, however, we feel confident in our core findings: that many of the cases identified as false positives are in fact 'mistaken false positives' and that the number of genuine regulatory false positives identified in the literature is small. Cox (2007) and Hansen et al. (2007b) discuss this issue in more detail. In examining the regulatory landscape, the analysis also suggests that common concerns about over-regulation are not justified, based on empirical evidence. As such, a more nuanced approach to policy analysis is needed.

The scarcity of genuine false positives compared to the large number of 'mistaken false positives' could also be the result of a deliberate strategy in risk communication. Several references and leaked documents (e.g. Martin, 2003) have shown that some regulated parties have consciously recruited reputable scientists, media experts and politicians to call on if their products are linked to a possible hazard. As an automatic response or first barrier of defence, these experts are then sent to different news

sources to denounce any risk or to manufacture uncertainty about the risk, regardless of whether the risk is real or not (Barnes and Bero, 1998; Rampton and Stauber, 2001; Michaels, 2005). Manufacturing doubt, disregarding scientific evidence of risks and claiming over-regulation appear to be a deliberate strategy for some industry groups and think tanks to undermine precautionary decision-making.

A complementary explanation could be that current decision-making processes in public health and environmental regulation have focused on minimising false positives, which increases the probability of false negatives. Shrader-Frechette (1991) argues that this preference for false negatives arises because it appears to be more consistent with scientific practice. Furthermore, many risk assessments and impact analyses are conducted by those with a vested interest in a particular technology. In such cases, Shrader-Frechette argues that assessors typically underestimate risk probabilities at least in part because it is difficult to identify all hazards and because unidentified risks are usually assumed to be zero.

According to Ozonoff and Boden (1987), institutional reasons also explain why agencies tend to favour not responding to identified effects. First, acknowledging an effect means that the public would expect the agency to do something and might even accuse the agency of not doing enough about the situation in the first place. Second, the solutions to the problem often conflict with other interests, such as economic development. Third, agencies know that affected industries may challenge the agency, accusing it of creating hysteria or negatively impacting business (Ozonoff and Boden, 1987).

In addition to the scientific and political reasons limiting false positives, several aspects of legal and regulatory decision-making in the US and EU, such as judicial review or cost-benefit analysis, greatly influence the steps that agencies must fulfil before taking precautionary actions and how much precaution can be applied. The slow pace of the regulatory process often precludes swift precautionary action on uncertain hazards, unless they pose imminent risks of severe harm. The pace is determined both by regulatory requirements and, especially in the US, by court interpretations of federal policies. The regulatory process has become more rigid and burdensome since the 1970s, leading to the 'ossification' of rule-making (McGarity, 1990).

While avoiding false positives is important, we believe that too little attention is being paid to avoiding false negatives in regulatory decision-making. Decision-makers often worry about taking too much precaution but seem to lack similar concerns about not taking enough. This tendency has developed despite evidence that the costs of not taking precautionary action are substantial — both economically and socially (e.g. EEA, 2001) and despite the many identified benefits of preventive regulation with regards to health, safety and the environment (Ashford, 1993; Ackerman and Heinzerling, 2004). Furthermore, compared to false negatives, the impact of false positives may be more short term (over-regulation can be quickly caught) and affect a relatively small number of actors.

A decision to act on limited knowledge about a hazard may ultimately turn out to have been due to a false positive. But if it spurs innovations, stimulates new economic forces, and raises awareness about sustainability then it may still be judged to have been worthwhile. As a result, there is a need to develop more nuanced policy analysis methods that give equal weight to avoiding both false negatives and false positives. Combining a more precautionary approach with proper assessment of impacts and alternatives in a more flexible management process could minimise the number of false positives and negatives and maximise society's benefits from false positives.

2.7.5 Lessons learned

Understanding and learning from past mistakes is essential for improving decision-making about public health and the environment. Numerous important lessons can be learned from each of the false positives identified. Some are specific to the case and cannot easily be transferred to other risk situations. The focus here is on experience that is applicable to other cases and can be generalised. These lessons are important to avoid both false positives and false negatives.

Lesson 1: the cases of swine flu and saccharin show how important it is to **be open and honest about disagreement and not suggest that there is consensus when there is not**. Even though scientists and others might think that reaching consensus is a goal in itself, disagreement can help provide the decision-maker with a broad picture of alternative explanations of the science, what is at stake and which options and alternatives are available before making a decision.

Lesson 2: following on the previous lesson, it is important to **be transparent about what is known or not known and about uncertainties and make sure that these are apparent in communication** between scientists, regulatory authorities, politicians and the public. Alternative courses of action should be

considered with an open mind and limits should not be placed on the range of alternatives in advance.

Lesson 3: the cases of food irradiation and saccharin indicate that **the availability of options minimises the total impact of false positives**. An alternatives assessment that considers the pros and cons of other courses of action (including no action) is critical to avoid risk-risk trade-offs. To reduce the potential negative impact of committing false positives, adequate resources should be made available to consider alternative courses of action. In conducting assessments attention must be paid to defining 'safer' alternatives.

Lesson 4: **particular care is needed when introducing a new substance or technology at a large scale** because of the risk of 'unknown unknowns'. In two of the four cases (swine flu and Southern leaf corn blight), the precautionary action initially taken had unintended consequences because of events that could not have been anticipated and had severe consequences because of its widespread application.

Lesson 5: **initiating and funding research to increase understanding and reduce uncertainties should supplement other risk-reducing regulatory measures** and not be seen as a regulatory measure in itself. In none of the cases could more scientific research have prevented the false positives from happening; indeed, in some of the cases too much trust was put on the capability of science to demonstrate effects.

Lesson 6: **precautionary actions (both necessary and unnecessary) can lead to innovation in science, policy and technology**. Decision-makers should take this into consideration when they consider regulating a potentially harmful technology and choose regulatory measures that can spark innovation even if the precautionary action proves unnecessary.

Lesson 7: it is necessary to **be flexible in decision-making processes**. The decision-making process should be designed with re-evaluation as a key component, so that decisions can be altered in the light of new knowledge. It is also important that the regulators are prepared to alter their initial decisions about risks.

In conclusion, the analysis has shown that fear of false positives should not be a rationale for avoiding precautionary actions where warranted. False positives are few and far between as compared to false negatives and carefully designed precautionary actions can stimulate innovation, even if the risk turns out not to be real or as serious as initially feared. Overall, the analysis has demonstrated the need for new approaches to characterising and preventing complex risks that move debate from the 'problem' sphere to the 'solutions' sphere (Sarewitz, et al., 2010). By learning from the lessons above, more effective preventive decisions can be made in the future.

Table 2.3 Overview — the 88 case studies claimed to be regulatory false positives

	Subject	Risk category
1	Acid rain (Bast et al., 1994, Wildavsky, 1995)	Real risk
2	Acrylamide (Löfstedt, 2003)	'The jury is still out'
3	Aflatoxins (Majone, 2002)	Real risk
4	Agent Orange (Milloy, 2001)	Real risk
5	Air pollution in the USA (Whelan, 1993)	Real risk
6	Alar (Fumento, 1990; Wildavsky, 1995; Lieberman and Kwon, 1998)	Risk-risk trade-off
7	Amalgam dental fillings (Lieberman and Kwon, 1998)	Unregulated alarm
8	Antibiotics cause breast cancer (Kava et al., 2004)	'The jury is still out'
9	Asbestos in hair dryers (Lieberman and Kwon, 1998)	Unregulated alarm
10	Asbestos in schools (Lieberman and Kwon, 1998)	Real risk
11	BAM (From, 2004)	'The jury is still out'
12	Ban of Coca Cola (Whelan, 1999)	'The jury is still out'
13	Bendectin (Marchant, 2003)	Unregulated alarm
14	Benzene in Perrier Water (Lieberman and Kwon, 1998)	Real risk
15	Bovine Somatotropin (bST) (Lieberman and Kwon, 1998)	'The jury is still out'
16	Breast implants (Fumento, 1996; Milloy, 2001)	'The jury is still out'
17	BSE and vCJD (Adams, 2000)	'The jury is still out'
18	Busy streets and childhood cancer (Milloy, 2001)	'The jury is still out'
19	Cellular phones (Lieberman and Kwon, 1998; Graham, 2004)	'The jury is still out'
20	Cheeseburgers and Cardiovascular Disease (Kava et al., 2004)	'Too narrow a definition of risk'
21	Chemical Mace (Mazur, 2004)	Unregulated alarm
22	Chemicals in cosmetics (Kava et al., 2004)	'The jury is still out'
23	Chlormequat and Cerone (IMV, 2003)	'The jury is still out'
24	Coffee and pancreatic cancer (Lieberman and Kwon, 1998)	Unregulated alarm

Table 2.3 Overview — the 88 case studies claimed to be regulatory false positives (cont.)

25	Cyclamates (Lieberman and Kwon, 1998)	'The jury is still out'
26	DDT and malaria (Wildavsky, 1995; Lieberman and Kwon, 1998)	Real risk
27	DEHP (Milloy, 2001)	'The jury is still out'
28	DES in beef (Lieberman and Kwon, 1998)	Real risk
29	Destruction of the ozone layer (Bast et al., 1994)	Real risk
30	Dioxin (Gough, 1994)	Real risk
31	Electric blankets (Lieberman and Kwon, 1998)	'The jury is still out'
32	Electromagnetic fields (Lieberman and Kwon, 1998)	'The jury is still out'
33	Endocrine disrupting chemicals (Maxeiner and Miersch, 1998)	'The jury is still out'
34	Ethylene dibromide (Lieberman and Kwon, 1998)	Risk-risk trade-off
35	Fen-Phen and heart value disease (Milloy, 2001)	Real risk
36	Fluoridated water (Lieberman and Kwon, 1998)	Unregulated alarm
37	Food irradiation (Lieberman and Kwon, 1998)	False positive
38	Formaldehyde (Maxeiner and Miersch, 1998)	Real risk
39	Functional food (Marchant and Mossman, 2002)	'The jury is still out'
40	Genetically modified organisms (Miller and Conko, 2001)	'The jury is still out'
41	Global warming (Bast et al., 1994; Wildavsky, 1995)	Real risk
42	Hair dyes and cancer (Lieberman and Kwon, 1998)	'Too narrow a definition of risk'
43	Homocysteine causing atheroschlerosis (Milloy, 2001)	Real risk
44	Hormone replacement therapy and breast cancer (Milloy, 2001)	Real risk
45	Hypoxia: dead zones in the Gulf of Mexico (Avery, 1999)	Real risk
46	Laundry detergents (Mazur, 2004)	Unregulated alarm
47	Love Canal (Wildavsky, 1995; Lieberman and Kwon, 1998)	Real risk
48	4-MBC in sun-lotion (Politiken, 2001)	Risk-risk trade-off
49	Mercury in fish (Mazur, 2004)	Real risk
50	MMR vaccines (Bate, 2001)	Unregulated alarm
51	Monarch butterfly and Bt corn (Marchant, 2003)	'The jury is still out'
52	Monosodium glutamate (MSG) (Mazur, 2004)	Real risk
53	Nightlights and leukemia (Kava et al., 2004)	'The jury is still out'
54	Nitrilotriacetic acid in detergents (Mazur, 2004)	Risk-risk trade-off
55	Nitrites (Sodium Nitrite) (Lieberman and Kwon, 1998)	Risk-risk trade-off
56	Nuclear power (Bast et al., 1994; Graham, 2004)	'Too narrow a definition of risk'
57	Oral contraceptive pill scare (Adams, 2000)	Real risk
58	Perce in a Harlem school (Lieberman and Kwon, 1998)	'The jury is still out'
59	Pesticides (Whelan, 1993)	Real risk
60	Phenolphthalein (Milloy, 2001)	'The jury is still out'
61	Polybrominated biphenyls (Whelan, 1993)	'The jury is still out'
62	Polychlorinated biphenyls (Whelan, 1993)	Real risk
63	PVC blood bags and cancer (Milloy, 2001)	'The jury is still out'
64	Radon gas in houses poses a health risk (Miloy, 2001)	Real risk
65	Red dye number 2 (Lieberman and Kwon, 1998)	'The jury is still out'
66	Saccharin (Lieberman and Kwon, 1998)	False positive
67	Second hand smoke and breast cancer (Milloy, 2001)	'Too narrow a definition of risk'
68	Second hand smoke and lung cancer (Matthews, 2000)	Real risk
69	Second hand smoke causing hearing problems (Milloy, 2001)	'The jury is still out'
70	Soda causes esophageal cancer (Kava et al., 2004)	'The jury is still out'
71	Spermicides and birth defects (Mills, 1993)	Unregulated alarm
72	Superfund's abandoned hazardous waste sites (Milloy, 2001)	Real risk
73	2,4,5-T (Lieberman and Kwon, 1998)	'The jury is still out'
74	Taconite pollution (Mazur, 2004)	'Too narrow a definition of risk'
75	Teflon causes health problems in humans (Kava et al., 2004)	'The jury is still out'
76	The 'Cranberry Scare' of 1959 (Wildavsky, 1995; Lieberman and Kwon, 1998; Mazur, 2004)	'The jury is still out'
77	The baby bottle scare (Kamrin, 2004)	'The jury is still out'
78	The Dalkon Shield (Milloy, 2001)	Unregulated alarm
79	The Peruvian outbreak of cholera (Bate 2001; Milloy, 2001)	'The jury is still out'
80	The Southern leaf corn blight (Lawless, 1977)	False positive
81	The swine flu (Marchant, 2003)	False positive
82	Three Mile Island (Lieberman and Kwon, 1998; Graham, 2004)	'Too narrow a definition of risk'
83	Times beach, Missouri (Wildavsky, 1995; Lieberman and Kwon, 1998)	Real risk
84	Toxins in breast milk causing harm to babies (Ross, 2004)	Risk-risk trade-off
85	Trichloroethylene (TCE) (Jaeger and Weiss, 1994)	Real risk
86	Tris (Lieberman and Kwon, 1998)	Unregulated alarm
87	Video display terminals (Lieberman and Kwon, 1998)	'Too narrow a definition of risk'
88	Water contamination in Sydney (Clancy, 2000)	Real risk

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