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Artus GmbH has recently entered a licensing agreement with Swiss pharmaceutical company (F Hoffmann-La Roche — for manufacturing and marketing of a wide range of PCR — polymerase chain reaction) products. Apart from opening doors for global markets of the diagnostic products, this agreement has rendered Artus the largest real-time PCR kits provider in the world.

As one of the most important in vitro diagnostic screening tools in the near future, PCR already dominates the detection sector of the healthcare service for diseases (such as infectious diseases, genetics, oncology, tissue typing) as well as therapeutic drug monitoring sector.

According to Dr. Ulrich Spengler, Managing Director of Artus GmbH, this acquisition of the broad PCR license is of great importance. Currently, Artus is marketing more than 60 PCR assays. To date, there are only five companies holding broad license for PCR commercialization. These companies are namely Abbott, Bayer, Johnson & Johnson, ABI and Altana.

“The awarding of the broad PCR-license by F. Hoffmann-La Roche plus our cooperative marketing agreements with such established companies as Abbott and QIAGEN emphasize the quality of our molecular diagnostic assays”, said Dr. Spengler.

From December 2003, all companies producing and distributing in vitro diagnostics in the EU have to comply with the IVD guideline by the EU on in vitro diagnostics. “Artus has already labeled 25 of its RealArt™ PCR Kits with the CE-mark within the time-frame and more assays will be CE-marked soon”, added Spengler.

About PCR Technology

Dr. Kary Mullis, who received the Nobel Prize in 1993, developed PCR technology in the 1980s. Subsequently, F. Hoffmann-La Roche patented the technology. In 2002 Mullis also became a member of the Board of Advisors at Artus. PCR enables specific fragments of genetic material to be amplified a million-fold in order to generate enough copies for the fast and reliable detection of infectious diseases, cancer cells, and hereditary diseases.

About Artus

Artus GmbH develops and distributes diagnostic assays to detect viruses, bacteria and parasites through the use of modern PCR technology. The main areas of application for these procedures are human and veterinary medicine. Artus was established as a spin-off of the Bernhard-Nocht-Institute for Tropical Medicine in 1998. With the headquarters in Hamburg, and subsidiaries in San Francisco and Kuala Lumpur, Artus offers worldwide sales and service support also through local distribution partners in more than 30 countries within Europe, Asia, Latin America and the Pacific. The company has grown from six to around more...
The sudden emergence of mad cow disease has sent government officials and researchers in US scuttling to prevent a repeat of the infamous health crisis experienced in Europe 10 years ago, amid strong criticisms that a mad cow scare would not have occurred if the US’ food regulatory system had committed itself to necessary reforms.

The alarming news broke just before the Christmas holidays that near Yakima, Washington, a slaughtered Holstein dairy cow had tested positive for the deadly mad cow disease, or bovine spongiform encephalopathy (BSE), in early laboratory results.

During the 1980s and 1990s, the deadly disease had spread through 180,000 livestock in Europe and took the lives of more than 100 people. Soon enough, information confirming the first such case in the United States started building up into a widespread panic, as countries including Japan, Russia, South Korea, Malaysia and Singapore hastened to make announcements that they were banning imports of beef from America.

While the occurrence of mad cow disease did not have much of a direct effect on the consumer confidence of the American public, an air of uncertainty clouded over the beef industry in those few weeks.

All of a sudden, the reputation of American beef and — more importantly — the standards of food safety regulations in US were left in tatters. Many questions were raised, as American consumer groups flamed their critique of the food regulatory regime. How did the cow get infected in the first place, and could there be any more contaminated meat out there in the food supply? Where had the food regulators failed in ensuring a more comprehensive screening for infected cattle?

**Swift Responses**

Government officials acted immediately to address the issue before the mad cow scare escalates further and got out of hand, with prompt actions taken by the US Department of Agriculture when the discovery of BSE was first announced. The authorities ordered a voluntary recall for more than 10,000 pounds of beef to trace the contaminated meat to where the cows were slaughtered and processed. The farm from which the sick cow came from was quarantined.

The agriculture secretary, Ann M. Veneman, assured the American public that the meat supply was safe because necessary precautions were already in place to keep the nerve tissue of slaughtered beef out of the food supply — as it is believed that BSE can only be spread to humans through the brain, spinal cord and nerve-related parts of the cattle. The risk of other cattle contracting the disease from the sick cow was also played down, as the disease cannot be transmitted upon contact.

US Food Regulatory Regime Draws Criticism for Mad Cow Scare
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Mad Cow Origins

First diagnosed in Britain in 1986, mad cow disease or BSE is a transmissible and degenerative disease affecting the central nervous system of adult cattle, while there is a BSE-related disease, which affects humans. Known as variant Creutzfeldt-Jakob Disease (vCJD), this disease found in human has been associated with the consumption of foods produced from BSE infected animals. Both BSE and vCJD cause brain tissue to become spongy and full of holes. There is strong scientific evidence to suggest that the agent that causes BSE in cattle is the agent that causes vCJD in humans.

When BSE first surfaced among cattle in UK in 1986, there were great worries about a major outbreak of the disease and that the disease would be spread to humans or rather, beef consumers. At the height of the epidemic, almost 1,000 new cases were identified per week in January 1993.

It is widely held that the outbreak of the disease in cattle was accelerated by the feeding of bovine “meat-and-bone meal” to young calves. The transmissible agent in BSE is believed to be a modified form of a normal cell surface component known as a prion, an abnormal protein that accumulates in cells and damages the brain; how exactly this substance produces the disease is as yet unknown. A theory is that prions form a chain reaction that ultimately destroys brain tissue.

BSE “Imported” from Canada

As the authorities combed through cattle sales records at two state companies to trace where the infected cow came from, it was later speculated that the diseased cow was likely to be related to a BSE case reported in Canada earlier last year.

In May 2003, a single case of BSE was found in Alberta, Canada, which had led the US to restrict the import of Canadian beef for a period of time. Subsequently, the ban was eased and imports of boneless cuts and from cattle younger than 30 months were allowed back into US.

Through genetic tests, it was later confirmed that the sick cow was indeed born on a dairy farm in Alberta, Canada — making it the second mad cow case found in cattle born in Alberta. It was established then that this case of mad cow disease entered US as part of a herd of 74 cattle that came from Alberta in 2001. Meanwhile, a second quarantined herd of 129 dairy cows linked with infected cow will be killed.

The news that the sick cow originated from Canada brought some reprieve to the American beef industry and agricultural officials from US used this information to persuade trading partners to lift their bans on American beef imports. For if can be confirmed that the sick cow had came from Canada, the perceived likelihood of a widespread outbreak of BSE in US will be dramatically reduced.

Not surprising, the Canadian officials were not too pleased about how the mad cow case was handled by the Americans. They pointed out that heavy trading of dairy, beef and breeding cattle in the past few years had already created an integrated cattle market between the two countries. Hence it would be unfair for the United States to attempt to characterize mad cow disease as a Canadian problem.

Impact on American Food Industry

Between the two countries, the beef industry has already lost more than US$1 billion in sales since May 2003 due to mad cow disease. With the general apprehension over American beef unlikely to blow over right away, the latest mad cow scare is certain to deal another hefty blow to the American food industry.
Beef exports make up 10% of the American beef production. With many countries banning the import of American beef, two thirds of the export market was immediately affected. The resulting worldwide ban on American beef — more than 30 countries have banned US beef — certainly made its presence felt on the cattle markets in those few weeks, with US cattle prices tumbling and the agricultural department’s estimates for beef exports in 2004 falling by as much as 90%.

The mad cow scare in the US also sparked a public relation frenzy as giant conglomerates in the food and agricultural industries rushed to assure the public that safeguards against the disease were in place and that their products had not been tainted. McDonald’s, Burger King and Wal-Mart Stores immediately produced media releases to declare their food products safe for consumption, having not received contaminated meat. Officials from the National Cattlemen’s Beef Association publicized their endorsement of more rapid meat testing. The association is the representation of most cattle producers in US.

The Cattlemen’s Turnaround

After the discovery of the infected cow, the National Cattlemen’s Beef Association said that it would back a ban on “downer” cattle — sick cattle that are unable to walk properly ( for human consumption. No doubt, the association wanted to be recognized for taking the initiative in supporting more thorough screening of cattle.

The irony is that the proposed restriction on downer cattle, among other proposed safeguards against BSE, is a legislative bill that the cattlemen’s association had a long history of opposing successfully in Congress for years through aggressive lobbying, supposedly to defend its interests on meat regulations against excessive bureaucratic interference on the issue.

Consumer groups are now pointing the finger at the cattlemen’s association for having delayed numerous plans to tighten safety precautions in the past. The association is being accused of placing emphasis on making profit at the expanse of safety for the consumers.

With a potential mad cow crisis at hand, the cattlemen’s latest turnaround is dismissed as a calculated move to entice foreign countries to lift restrictions on American beef imports. On 30 December 2003, the Department of Agriculture formally announced that downed cattle would no longer be allowed into the human food supply.

Opponents of the cattlemen association also lambasted the amount of influence wielded by the cattlemen, alleging that the close connections between the cattle industry and federal officials has severely handicapped food regulators’ prerogative to ensure food safety standards are met.

New Measures to Improve Food Safety

The regulation of meat products is becoming a significant issue and more screening of meat is recommended. The first case of mad cow disease in US dealt a serious blow to the credibility of the food regulators. The growing perception is that there are clearly not enough safeguards to prevent sick cattle from reaching consumers. Some consumer groups are outraged that the authorities had decided to step up food safety measures only after the first mad cow case was discovered.

In the wake of the mad cow scare, the US Department of Agriculture is considering whether to do more screening of meat and changing the way meat from questionable livestock is handled. Currently, testing is limited almost exclusively to downed cattle. In the last nine years, only 30,000 of the estimated 300 million animals slaughtered are
screened and these animals are screened only after slaughter, with the results to be obtained only days or weeks later.

Dr. Ron De Haven, the agricultural department’s chief veterinarian, acknowledged that the American screening system was not designed to absolutely prevent sick animals from reaching the public, but rather to serve more of a surveillance role.

American inspectors screened specifically for animals showing signs of sickness (twitching, displaying aggression, showing signs of brain damage) to give officials a 95% certainty that they would be able to detect diseases if it appeared in one animal in a million. Nevertheless, critics railed at the inadequacy of such a screening system that decidedly falls short of providing unqualified food safety for the public.

In contrast, countries like Japan test all the cows it slaughters for consumption each year. In Europe, 19 million cattle were tested last year and 4,200 cases of mad cow disease were found. And apparently, Japan and some European countries screened animals using advanced testing methods that are fast enough to stop infected cattle from being processed into food.

The Department of Agriculture had instituted several other new measures to further ensure the safety of American beef products. “While we are confident that the United States has safeguards and fire walls needed to protect public health, these additional actions will further strengthen our protection systems,” Veneman said.

The additional actions will include an outright ban on the slaughter of sickly cattle and the implementation of a revamped national tracking system to identify for disease cattle more readily during outbreaks of disease.

Carcasses singled out for BSE testing will now be kept until the results are out, instead of being sent to the consumer market immediately. Changes will be made to machines used in meat scraping to keep high-risk tissue parts out of meat products. During slaughtering, the old practice, which involves blasting air into cattle skulls, to render the animal unconscious, will be banned.

Paranoid about Meat

Still, meat patrons in US certainly have cause for concerns. Some are asking serious questions about the beef they are purchasing — the risk that they might be eating contaminated meat looms large and plays mind games of paranoia on the consumers.

Many speculations followed that farmers have perhaps failed to obey federal regulations, which forbade the use of proteins derived from processed cattle as feed for cows. Financial constraints forced cattle producer to make the most out of what they have. Advanced technology such as hydraulic pressure is used to force extra pounds off carcasses to produce filler meat for processed food products such as hamburger and hot dogs. The worry is that bone tissues may get into these recovered meat products. In 1997, federal officials found spinal cord tissue in some of the meat.

Irresponsible agricultural practices as such have prompted understandable concerns that the disease might already exist in American beef, and are left undetected because too few animals are tested. The infected cow is (believed to be) slaughtered on 9 December 2003 and two weeks lapsed before the beef recall order was issued. The worst case scenario — and a scenario that was not entirely unimaginable — that there are, very likely, more contaminated meat existing in the food supply.

In the minds of many people, something was amiss in the whole affair of how their food was screened. How could the carcass of the sick cow be comprehensively presumed as safe and allowed to slip into the food supply, weeks before the release of its test results?
Again, this raised the issue of how American food regulators are really shooting themselves in the foot. There is a long perceived lack of cohesion between the various agencies in charge of regulating food product, especially when the process of assigning inspection responsibilities can become very convoluted.

One of the reasons why a suspect cow could slip into the food supply while its test results are pending is because BSE testing falls under the Animal and Plant Health Inspection Service (APHIS) and not the Food and Safety Inspection Service (FSIS). Meanwhile, APHIS’s responsibility is confined only to ensuring that the animals are healthy.

There were other flaws the American food regulatory system needed to address. Critics suggested that the government needed a quicker and more efficient way to trace infected cattle, especially after authorities originally suggested that it might take as long as weeks or even months to trace where the BSE infected cow was born.

The time lag and obstacles encountered in tracking the cow demonstrated just how much the US needed a more comprehensive system for tracking cattle from birth to slaughter, if new cases of sick cows are to emerge in the future. Federal officials foresee fitting electronic ear tags on the animals for tracking purposes in the future.

**Are Consumers Really at Risk?**

But what conceivable risks does the recent occurrence of mad cow disease really pose to consumers? American officials are certainly confident that the consumers are safe: they maintained that even if the beef was eaten, the risk to humans is extremely low. And a bit of history and science ought to allay some of the consumers’ anxieties too. Consider that over 200,000 cows were infected in Britain and millions of people still ate beef without an outbreak of a major epidemic.

Back in 1996, Britain issued a caution about an increase in vCJD cases, and experts warned that an outbreak that would kill millions. Fortunately, the ominous predictions did not hold true; though there were about 20 people who die of vCJD each year.

Furthermore, scientific research has showed that some people are genetically predisposed toward the disease and are therefore more at risk. And essentially, there has been no direct link between human contracting vCJD and the consumption of contaminated beef. So despite the uncertainties being drummed up by the media, health authorities in US have been quick from the start to provide assurance that public health is still protected.

Dr. Elsa Murano, the under secretary for food safety, had stated that even if it was possible that the contaminated beef were distributed, its consumption will pose little safety risk to consumers because the processed parts did not include the tissue carrying the disease. These disease-carrying parts mainly concerned the brain and spinal cord, which are not commonly used as food.

So far, mad cow prion had never been found in solid muscle meat consumed by humans either. However, some scientists are of the opinion that the prion could also be found in other tissues of an infected cow. On the other hand, Dr. Stanley B. Prusiner, a neurologist at the University of California and the researcher responsible for developing the theory behind prion, believes that infection in young animals may not show up in the brain tissues for at least 30 months.

Instead, low levels of contamination can be present in other tissues including the muscles and higher levels can be found in the lymph glands of calves — though it cannot be established whether these levels are enough to infect consumers. There is also the possibility for brain tissue to be mixed and driven into muscles when the cattle are slaughtered.
Furthermore, there are already concerns over some potentially BSE infected animals could still be undetected by inspectors, especially after Japanese researchers had discovered that BSE can be found in healthy-looking animals too.

Consumers expect and demand a quick and efficient testing method. However, testing for BSE is more complex than testing for other more typical infections mainly because prions are extremely elusive. Containing no DNA or RNA, prions cannot be detected under a microscope or cultivated in a laboratory.

Another problem is that mad cow disease takes between 20 months to 15 years for infectious prions to surface in an animal’s brain stem after eating contaminated feed. Researchers had not been able to determine whether prions do accumulate in small amounts in other tissues in the early stages of infection.

To improve the current screening methods, Dr. Prusiner has recommended a more liberal approach of BSE screening. The procedure would involve infecting calves and killing them at different ages, each time removing at least a dozen types of organ tissues including the muscle, heart and kidney. These organ tissue parts are then to be placed into mice engineered to have the normal cow prion. This will allow researchers to determine where, if any, the infection exists outside of the brain.

**Americans Still Eating Beef**

Not that the alarm and commotion are going to keep beef consumers in US away from their meat. Despite the projected uncertainties brought forth by the mad cow scare, consumer confidence in beef remains high, according to a survey conducted by the National Cattlemen’s Beef Association.

Without evidence that the disease has spread, Americans have continued to purchase beef products. According to the survey, 89% of the 1,001 non-vegetarian adults interviewed said they were confident American beef was safe from mad cow disease and 75% said they were eating as much beef as a month earlier.

Experts explained that consumers were convinced enough with the assurances that the chances of human infections were remote. The fact that the sick cow really did come from Canada does help the American consumers to diminish the potential risks as well, i.e. unless a second infected cattle does crop up in the country.

And reflecting the fresh optimism that US had weathered the mad cow scare, cattle prices are slowly climbing up again, though prices are still some way below the US$90 per 100 pounds paid before the mad cow incident.

Nevertheless, this minor brush with the deadly mad cow disease has brought some much needed changes to the food regulatory system in the US, as the authorities seek out and explore more efficient means of screening meat for the sake of the consumers’ wellbeing.