International Supply Arrangements

Charles F. Wilkinson
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International Supply Arrangements
Foreign Manufacturing

- Contract Production (i.e. tolling contract).
- Ownership interest (i.e. joint venture, wholly owned subsidiary).
- These arrangements have different benefits and risks.
- Each method will affect your brand differently.
- Which entity is responsible for the finished product?
- Contract requirements to produce to your specifications.
- Can you trust your contract manufacturer?
- Can you trust your business partners?
- Do you understand local and national consumer protection laws?

Contract Production

- We hire you to produce in accordance with our specifications.
- Preferably a non-exclusive contract.
- Specifications include containers and labels approved by us.
- Allow for no or little variances to specifications.
- Quality control requires our right to inspect and audit.
- Failure to perform = our ability to terminate the contract.
- Grant only necessary limited rights in use of trade names and marks.
- Contractor is responsible for having all necessary permits and licenses.
- Action that negatively affects the brand name is grounds for termination.

Contract Production in The Peoples Republic of China

- Insist on a written contract.
- Adequately protect intellectual property; i.e. formulae.
- Ascertain contractor's compliance with environmental laws.
- Conduct a site review just like you were setting up your own plant.
- Are goods for resale in the PRC, for export, or both?
- Does the toll manufacturer have sufficient supplies of raw materials?
- Do you need or want to furnish raw materials?
- Sample, audit, sample, audit. Your brand is on the line.
- Is the manufacturer contractually responsible for rework?

Ownership of Production in The Peoples Republic of China

- Alone or with a local partner?
- Do you have in-country resources to establish a presence?
- If not, have you conducted due diligence on prospective partners?
- Many concerns are similar to contract manufacturing.
- Are the rewards equal to or greater than the additional risks?
- Are there consumer regulatory requirements for your products?
- Are you and/or your partner capable of handling consumer issues?

Anthology of Chinese Laws

- Regulations on Industrial Product Quality Responsibility - 1986
- Standardization Law of the People's Republic of China - 1989
- Rules for the Implementation of the Standardization Law of the People's Republic of China - 1990
- Regulations on the Administration of Product Quality Certification - 1991
- Decision of the Standing Committee of the National People's Congress on Punishing the Crimes of Production and Sale of Fake or Substandard Commodities - 1993
- Law of the People's Republic of China on Protection of the Rights and Interests of the Consumers - 1994
- Provisional Regulations on Banning Excessive Profiteering – 1995
- Product Quality Law of the People's Republic of China - 2000
- Notice of the Supreme People's Court on Legally Punishing the Crimes of Seriously Undermining the Order of the Market Economy - 2004

How Your Brand Can Be Affected
Story Line September 2011 (Part 1)

Foreign brands accused of cheating China Daily 09-09-2011

BEIJING - The global retail giant Wal-Mart said on Wednesday that consumers who bought ordinary pork sold as higher-quality pork will get double their money back.

"Wal-Mart's unalterable responsibility is to safeguard consumers' interests. The relevant people in this case will be seriously dealt with, and we will further enhance our staff training and food management processes," the company said in a statement sent to the media.

Since the beginning of this year, more than 1,000 kilograms of ordinary pork were sold as green pork, which is manufactured in line with rigorous production standards and sold at a higher price, at three of Wal-Mart's outlets in Chongqing, according to the municipal market watchdog.

How Your Brand Can Be Affected
Story Line September 2011 (Part 1)

Law enforcement officials from Chongqing's industrial and commercial bureau raided eight Wal-Mart branches in the city on Aug 25, after receiving tip-offs from consumers, and found three of the stores were selling ordinary pork as green pork. The falsely labeled pork did not contain the official green stamps.

The officials also found the amount of "green pork" that had been sold and was for sale was more than the purchase volume after checking with the green pork supplier.

The company said in response that it will establish a daily inspection mechanism of green and ordinary pork, strengthen checks of purchase and sales volumes, and separate the two types of pork in the whole process from supplier to sales.

Experts also warn that consumers should be rational about foreign brands.

How Your Brand Can Be Affected
Storyline September 2011(Part 2)

Another US company, Nike, was also facing criticism after Wang Hai, the manager of a consultancy company in Beijing known for his fight against counterfeit products, said he bought a pair of basketball shoes that were not the model claimed.

"There is only one air cushion at the heel. However, the model sold in the United States with that name has two air cushions," Wang said.

A man from Nike's service hotline said the company had activated an investigation process, and is cooperating with the industrial and commercial department.

"We will inform the public of the results and get in touch with the consumers who complained," said the man surnamed Jiang.

How Your Brand Can Be Affected
Storyline September 2011(Part 2)

But Wang is not satisfied with the company's response.

"Nike deleted the description of the two air cushions on Wednesday, which showed they realized they were cheating Chinese consumers with false advertising," Wang said. "They are just prevaricating instead of apologizing or compensating consumers."

Consumer-rights experts said the incidents unmasked problems in the attitude of some foreign enterprises.

"Some businesses change their business model and integrity in China. But consumers everywhere should be treated the same," said Qiu Baochang, head of the lawyers group of the China Consumers' Association.

"Instead of arrogance, big brands should cherish their fame and consumers' trust," said Yi Shenghua, a lawyer at Beijing Ying Ke Law Firm.

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Product Safety in Europe

Caroline May
Partner
Norton Rose LLP
London
25 October 2011

Product Safety in Europe

- Single market
- Level playing field
- Uniform approach
- Policy and legislation
- Enforcement
- Consumer protection

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Potential Hurdles

- Consumer Policy not in EEC Treaty 1957
- Market expansion – proliferation of goods and services
- 1975 – Consumer Action Programme
- 1985 – “New approach” to harmonisation of consumer policy
- 1992 – General Product Safety Directive [92/59/EEC] (GPS Directive)
- Consumer protection official Community Policy
- 1994 General Product Safety Regulations – UK
- General safety requirement all consumer products placed on the market must be safe

GPS Directive – Key Features

- Producer/Importer obligation
- All necessary information
- Appropriate checks
- Sampling

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GPS Directive – Key Problems

- Member State discretion on implementation
- Differing sanctions
- Consistency of enforcement

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Product Information

- Notification of non-conforming products
- Exchange of information
- EH LASS
- Emergency procedures – Rapid Exchange of Information System (RAPEX)
- Notification via RAPEX where a “serious risk” is in issue
- Article II Notification, where Member State does not believe the effects of a risk beyond its territory
- Article 12 Notification – where risks can go beyond Member State’s territory
- Member States can give notification before any recall action has been taken

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Rapid Exchange of Information System (RAPEX)

- Notification to Regulators
- Must include:
  - Information enabling the precise identification of the product or batch of products
  - A full description of the risk of the defective product
  - All available information for tracing the product
- Product information
- Risk assessment
- Member State action
- Duty to notify not engaged where relates to functional quality, not safety

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Product Recall: Legal Issues

- Privilege
- Incident investigation
- Monitoring the recall
- Managing liability issues: criminal/civil
- Commercial liabilities: strict liability
- Brand protection
- Jurisdictional variations

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Product Recall General Issues

- Voluntary action
- Internal Investigation
- Consider best methods of reaching consumers who may have brought the product
- Establishing who will take responsibility for the recall (i.e. if product is manufactured by one company for sale under another brand)
- Corrective actions
- Formal notifications Distribution/supply chain
- Regulatory liaison
- Insurance
- Business continuity
- Reputational Issues

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Related Regulation

Product Liability Directive 85/374/EEC

- In force 25 July 1985
- Establishes common rules for governing liability for defective products in the EU
- Imposes liability on the producer of a defective product for damage covered by the defect.
- Strict liability: no requirement for the injured party to prove fault or negligence on the part of the producer
- Harmonising measure: Member States cannot enhance the protection provided by the Directive

Classification, Labelling and Packaging of substances and mixtures (CLP) Regulation

- In force 20 January 2009
- Implements the Globally Harmonised System (GHS) of classification and labelling of chemicals into EU

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Related Regulation

CLP Regulation Continued

- Direct implementation into Member States (provisions phased in until 1 June 2015)
- Manufacturers/importers notify substances to ECHA within one month of placing on market (unless supplied under REACH registration)
- Extension for “on the shelf” substances or mixtures
- All substances/mixtures irrespective of volume
- Harmonisation classification – agreed at EU level
- Self classification – classified by supplier

Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation

- EU regulatory regime for chemical substances which are manufactured in, or imported into, the EU in quantities of 1 tonne or more per annum
- Registration began 1 December 2008
- Pre-registered substance benefit from registration extension deadlines
- Join SIEFs for preparing registration dossiers
- Only representatives

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Our international practice

* Associate office

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Science For A Better Life

Session 205: Commercial Aspects of Regulated Products

ACC Meeting – Oct. 25, 2011

Cynthia Hughes-Coons, Assistant General Counsel

Bayer HealthCare LLC

Products for US Market & Consumer Safety

- 8/14/2008 - CPSIA provides new provisions impacting import safety
- Not all products subject to CPSA
- CPSIA creates a Working Group - 12 federal agencies with directive to increase safety of imports
- Lack of communication between US government agencies
- Lack of harmonization – every country is a sovereign nation
- Compliance with myriad of laws and regulations – complex commercial issues for global business

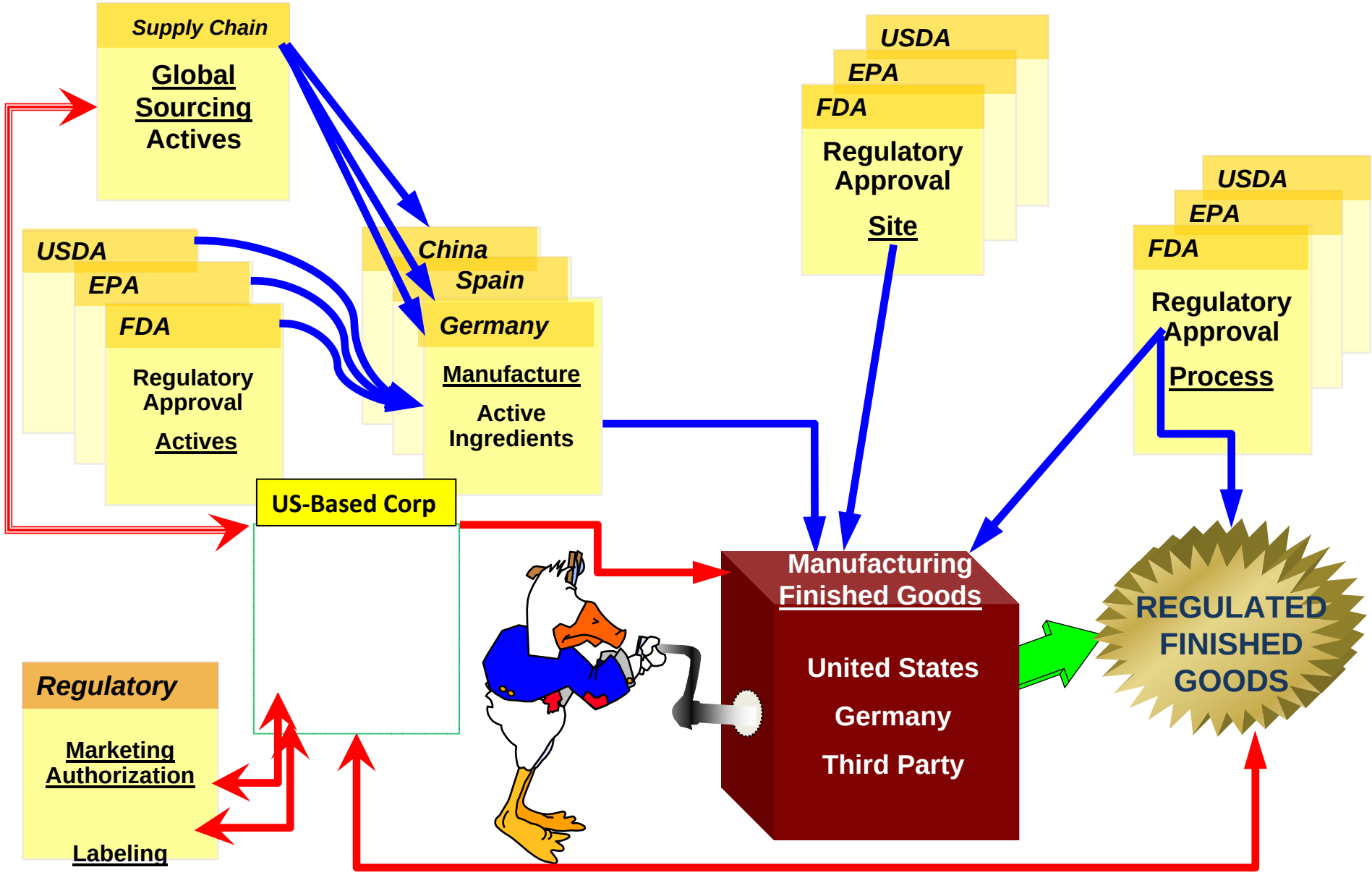
Case Study – Animal Health Products

- Impact on Global Brand Strategies with various Manufacturing Sites and sources of Materials, Actives, Raw Materials for distribution and sale to consumers in the US?

- Products for the U.S. animal health market
  - Manufacturing sites located around the world
  - In US, regulation by several agencies, different requirements import notice of actives, research materials, samples and finished goods
  - FDA – CVM
  - EPA (Federal & State requirements)
  - USDA – CVB and APHIS

- Common Objectives - Product Safety (Animal and Consumer) & Efficacy

Global Brands – Sourcing, Manufacturing, Labeling, Registration, & Distribution



Country of Origin
US Customs & Border Protection (CBP)

- **19 C.F.R PART 134 – Country of Origin Marking,** Designed to inform consumer – a product contains material of non-U.S. origin.
  - *"Made in ____" or "Product of _____".*
  - **§ 134.11 Country of origin marking required.** Section 304, Tariff Act of 1930 (19 U.S.C. 1304), requires every article of foreign origin (or its container) . . . be marked . . . to indicate to an ultimate purchaser . . . the country of origin of the article

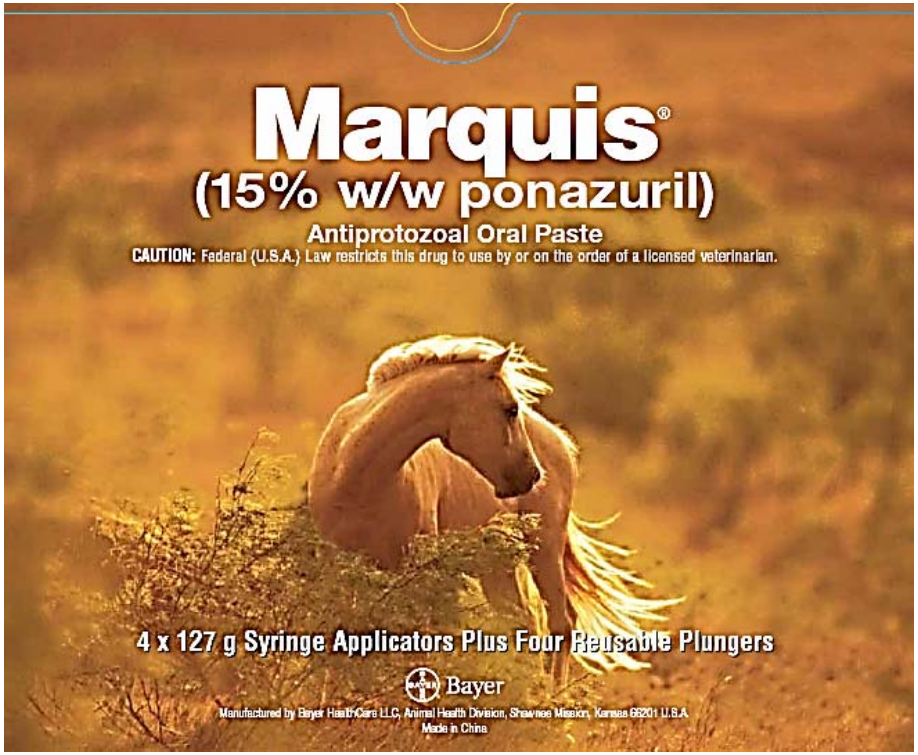
  § 134.1(b) Defines **Country of Origin** - the country of manufacture, production of growth of article of foreign origin - unless substantial transformation.
  - Creative rulings by Customs on what constitutes "substantial transformation" - requires expert review on a case by case basis

- **Impact on labeling requirements of other Agencies?**
  - Creates additional requirements
  - **§ 134.31 Requirements of other agencies.** Nothing in this subpart shall be construed as excepting . . . the particular requirements of marking provided for in any other provision of any law [of] . . . other agencies
  - Under **FTC Act**, a product cannot be marked "Made in U.S.A." unless it is made in the United States and all or substantially all of the product originates in the United States

Origin & Marking

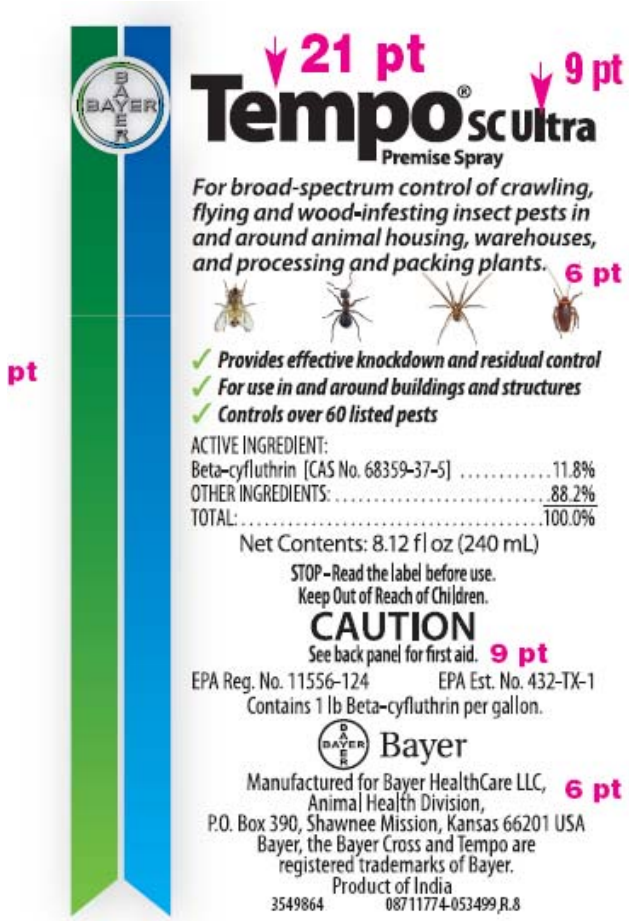
Source of Active(s) (AI)	Number of Actives	Place of Manufac-ture	Substantial Transformation?	Marking
U.S.	1 or more	U.S.	NA	*"Product of/Made in USA" (FTC)* "Manufactured by" [US location](FDA/EPA) *No marking required (CBP)*
Foreign	1 or more	U.S.	Yes	~~*Product of/Made in USA (FTC)*~~ "Manufactured by" [US location](FDA/EPA) *No marking required (CBP)*
Foreign	1	U.S.	No	~~*Product of/Made in USA (FTC)*~~ "Manufactured by" [US location](FDA/EPA) *"Product of/Made in"[AI Source] (CBP)*
Multiple Foreign	1	U.S.	No - blending of AI's not equal to substantial transformation	~~*Product of USA (FTC)*~~ "Manufactured by" [US location](FDA/EPA) *"Product of/Made in" [AI Source] (CBP)*
Foreign	1 or more	Foreign	NA	"Manufactured by" [location](FDA/EPA) *"Product of/Made in" [AI Source] (CBP)*

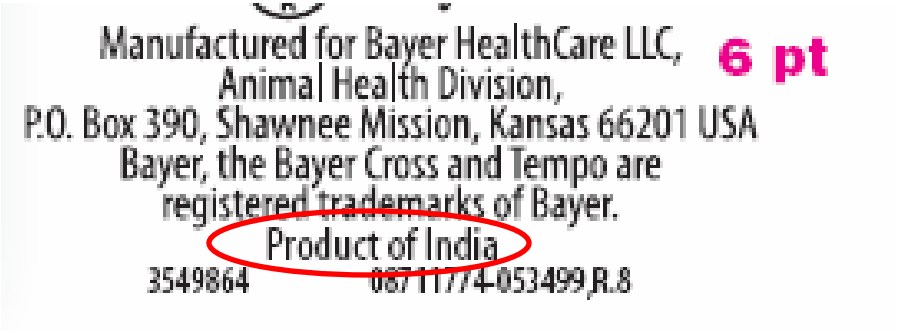
FDA - CVM


Marquis®
(15% w/w ponazuril)
Antiprotozoal Oral Paste
CAUTION: Federal (U.S.A.) Law restricts this drug to use by or on the order of a licensed veterinarian.
4 x 127 g Syringe Applicators Plus Four Reusable Plungers
Bayer
Manufactured by Bayer HealthCare LLC, Animal Health Division, Shawnee Mission, Kansas 66201 U.S.A.
Made in China


Bayer
Manufactured by Bayer HealthCare LLC, Animal Health Division, Shawnee Mission, Kansas 66201 U.S.A.
Made in China

EPA Product –Multiple Sources of AI





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The Regulated World:

Linking Countries and Continents through Consumer Product Safety Legislation: Canada and South Africa

Martha A. Healey
Partner
Dispute Resolution
October 25, 2011

CANADA

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Canada – Consumer Product Legislation

Legislation	Description
Canada Consumer Product Safety Act	Consumer products excluding certain products that are otherwise regulated (such as food, drugs, motor vehicles but possibly including vehicle accessories and food packaging)
•*Food and Drugs Act* •*Food and Drug Regulations* •*Medical Devices Regulations* •*Natural Health Products Regulations*	*Food, drugs, cosmetics, medical devices, natural health products*
Imported Food Sector Regulatory Proposal	Imported food and food ingredients (Proposed regulations expected Fall, 2011)
•*Meat Inspection Act* •*Fish Inspection Act* •*Canada Agricultural Products Act*	Importation requirements and procedures
Motor Vehicle Safety Act	Motor vehicles
•*Electricity Act, 1998* (Ontario) •Ontario Regulation 438/07	Electrical consumer products
•Provincial consumer protection legislation	Consumer protection requirements and “Consumer Beware List” in Ontario

Canada Consumer Product Safety Act

Purpose and Application

"The purpose of this Act is to protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products in Canada, including those that circulate within Canada and those that are imported."

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Canada Consumer Product Safety Act

7 Key Objectives

1. Protect the public by addressing dangers to human health and safety posed by consumer products.
2. Increase consumer protection in relation to the growing number of consumer products that flow across the borders in an increasingly global marketplace.
3. Recognize that individuals and suppliers of consumer products have an important role to play in addressing dangers to human health and safety.
4. Foster cooperation within the Government of Canada between the levels of government in Canada and with foreign governments and international agencies.
5. Create a regulatory system regarding consumer products that is complementary to the regulatory system regarding the environment, due to the impact consumer products can have on the environment.
6. Recognize that a lack of scientific certainty is not a reason for postponing measures that prevent adverse effects on human health if those effects could be serious or irreversible.
7. Apply effective measures geared to encourage compliance with federal regulatory system for consumer products.

Canada Consumer Product Safety Act

Operation of the CCPSA

- Interrelated system of prohibitions against, among other things, manufacturing, importing, advertising or selling a consumer product that is a danger to human health and safety combined with:
- mandatory record keeping and reporting obligations
- recall powers for the Minister of Health
- international scope for due diligence
- limited ability to challenge regulatory action
- substantial penalties
- expanded compliance and enforcement team(s) within Health Canada – but without qualification criteria
- broad media (including social media) reach

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Canada Consumer Product Safety Act

Prohibitions

- May not sell scheduled products (i.e. products for babies that are put in the mouth when used and contain a filling that has in it a viable micro-organism) (s. 5)
- Main prohibition against manufacturing, importing, advertising or selling a consumer product that does not meet the requirements set out in the regulations. (s. 6)
- Further prohibition against the manufacture, importation, advertisement or sale of a consumer product that is a danger to human health or safety, is the subject of a recall order or is the subject of a measure that the manufacturer or importer has not carried out but is required to carry out. (s. 7)
- No person shall advertise or sell a consumer product that they know is a danger to human health or safety, is the subject of a recall order or is the subject of a measure that has not been carried out. (s. 8)

Canada Consumer Product Safety Act

Prohibitions

- Prohibition against the packaging or labelling of a consumer product in a manner – including one that is false, misleading or deceptive – that may reasonably be expected to create an erroneous impression regarding the fact that it is not a danger to human health or safety. (s. 9)
- No person shall advertise or sell a consumer product that they know is advertised, packaged or labelled in a manner referred to in s. 9. (s. 10)
- No person shall knowingly provide the Minister with false or misleading information. (s. 11)

Canada Consumer Product Safety Act

Prohibitions

- Prohibitions apply not only to manufacturers, distributors and importers (previously the main focus of enforcement action) but also to advertisers and retailers.
- Greater regulatory focus on retailers.
- How involved will retailers become in monitoring national/international reports concerning products sold by them?
- Impact on mass retailers?
- Impact on international and/or internet sales?

International Cooperation

- Close economic connections and trade links place an emphasis on regulatory cooperation between Canada and the United States.
- Greater Canada/US harmonization is regularly a topic of political discussion and speculation.
- 2005 Memorandum of Understanding between Health Canada and the United States Consumer Product Safety Commission provides for information sharing: http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpb-dgps/pdf/intactiv/us-eu-cooperation-eng.pdf
- Purpose of the MOU:

  - to enhance and strengthen the sharing and exchange of regulatory, risk assessment, risk management, emergency management, and public health and safety information and existing public health and safety protection cooperative activities between them related to the safety of consumer products, and

  - without reducing the level of safety or of protection of human, animal or plant life or health, the environment or consumers, and taking into account international standardization activities, to the greatest extent practicable, to make compatible their respective standards-related measures.

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International Cooperation

- *Canada Consumer Product Safety Act* provides for sharing commercial and personal information across borders and to the public (sections 15, 16 and 17 of the CCPSA).
- The Minister of Health may disclose personal information to a person or a government that carries out functions relating to the protection of human health or safety without the consent of the individual to whom the personal information relates if the disclosure is necessary to identify or address a serious danger to human health or safety.
- The Minister may also disclose confidential business information to a person or a government that carries out functions relating to the protection of human health or safety or the environment — in relation to a consumer product — without the consent of the person to whose business or affairs the information relates and without notifying that person if the person to whom or government to which the information may be disclosed agrees in writing to maintain the confidentiality of the information and to use it only for the purpose of carrying out those functions.
- Finally, the Minister may, without the consent of the person to whose business or affairs the information relates and without notifying that person beforehand, disclose confidential business information about a consumer product that is a serious and imminent danger to human health or safety or the environment, if the disclosure of the information is essential to address the danger.

SOUTH AFRICA

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South Africa – Consumer Protection Act, 2008

Background and Application

- Omnibus *Consumer Protection Act, 2008* (CPA) came into effect in April, 2011
- Prior to the CPA there was no overarching regulatory framework regarding product quality or consumer protection; there was some sector specific safety regulation (eg. foodstuffs, and cosmetics) but inconsistent enforcement mechanisms.
- National Consumer Commission tasked with enforcement of the CPA
  - NCC may require an importer or producer of a product to conduct a recall where the NCC has reasonable grounds to believe that goods are unsafe, and the producer or importer of the goods has not taken the necessary steps to ensure public safety

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South Africa – Consumer Protection Act, 2008

Background and Application

- Draft Product Safety Recall Guidelines published for comment in June 2011
  - Suppliers are required to adopt a system to ensure the efficient and effective recall of unsafe consumer products from consumers and within the supply chain – tailored to the type of product and the risk posed to consumers
- The guidelines set out detailed legal requirements as well as notification, recall strategy, retrieval of the product and reporting on the recall
- Link to draft Product Recall Guidelines for the NCC under the CPA: http://greengazette.co.za/notices/consumer-protection-act-68-2008-consumer-product-safety-recall-guidelines-draft_20110718-GGN-34471-00486/

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South Africa – Consumer Protection Act, 2008

Application and Enforcement

- The CPA affects all areas of business in South Africa. It applies to all sectors and all suppliers (including importers, distributors, retailers and others in the supply chain) in South Africa.

- Returns policies, advertising, marketing contracts, standard terms and conditions, pricing policies, labelling, information retention, promotional competitions, franchises and business names and no-fault liability for harm caused by goods are just some of the areas that are radically affected by the provisions of the CPA.

- Recent report of order made against automobile companies to fix or replace vehicles sold prior to the coming into force of the legislation.

- Compliance notices also issued to telecommunications companies concerning customer contracts, retailers regarding pricing display and returns policies, and municipalities regarding billing errors on rates (subsequently fined for non-compliance)

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Product liability – product recall and liability insurance in South Africa

Product Liability

A brief history of South African common law

As late as 1972 a South African court was reluctant to allow a delictual (tort) claim for product liability in cases of pure financial loss because of concerns that to allow such a claim would expose a manufacturer of the product to duplicate claims for the same defects (in contract by the purchaser and in delict (tort) by an injured third party), and a concern that allowing claims for pure economic loss might open floodgates of liability (See *Combrinck Chiropraktiese Kliniek (Edms) Bpk v Datsun Motor Vehicle Distribution (Pty) Ltd*, 1972 (4) SA 185). That is no longer the law.

A significant development of product liability law in South Africa was the judgment in *A Gibb & Son (Pty) Ltd v Taylor & Mitchell Timber Supply Co (Pty) Ltd*, 1975 (2) SA 457, which is the first South African case in which a merchant seller was sought to be held delictually liable for damage caused to a third person for a defect in the merchandise. The court determined there is no reason in South African law why such a liability should not arise in accordance with common law principles.

There are very few reported decisions dealing with product liability in delict. There are a few more decisions, but not many, that deal with product liability in contract, particularly in the context of strict liability of the expert seller or manufacturer.

Of interest are a series of judgments dealing with strict liability for breach of implied warranty in the case of the sale of seed for agricultural use. See for example, the Supreme Court of Appeal in *Ciba Geigy (Pty) Ltd v Lushof Farms (Pty) Ltd en Ander*, 2002 (2) SA 447.

The Supreme Court of Appeal handed in *Wagener v Pharmacare Limited* / *Cuttings v Pharmacare* 2003 (4) SA 285 (SCA), dealt with the issue whether the manufacturer was strictly liable in delict for harm caused by defective manufacture. The court declined to develop the common law so as to impose strict delictual liability for defective products.

It was contended that South African law had reached a stage of development where strict liability should be imposed, and that imposition of such liability was appropriate in circumstances where the Constitution placed an obligation on the courts to develop the common law to give effect to constitutional rights and values, and that physical injuries through the manufacture of defective products constituted an unlawful contravention of the right to bodily integrity in the Bill of Rights.

The court held that the constitutional right to bodily integrity is provided sufficient protection in product liability cases by way of the delictual action described above. To the extent that there were calls for the imposition of strict liability in delictual cases for product liability such law reform was held to be the primary task of legislation and a social economic question which had to be answered by the legislature.

Under the common law, there were prospects in the case of contractual liability of the court jettisoning the common law restriction against strict liability for damages arising from latent defects to sellers who profess skill and expert knowledge in relation to the particular goods (see *Langeberg Voedsel Bpk v Sarculum Boerdery Bpk*, 1996 (2) SA 565 (A)). Given the opportunity and the appropriate facts the courts may have accepted an invitation to impose damages arising from latent defects in contract on the ordinary seller without prospects of negligence.

It has been suggested that in the delictual action the doctrine of *res ipsa loquitur* (the facts speak for themselves) could be used to alleviate the difficulty an injured party has in proving fault on the part of the manufacturer or seller by putting the onus on the defendant to refute the inference of blame.

While the appeal court indicated that it was not, in principle, opposed to the application of that doctrine when policy considerations justified it, no South African court applied the doctrine in a delictual product liability case.

We now, however, have the Consumer Protection Act of 2008 (“the CPA”) which makes provision for no-fault product liability. The Act came into full operation on 1 April 2011.

The implementation of that Act will probably obviate the need for a Court to consider and embark on the development of our law to apply the doctrine of *res ipso loquitur* to infer negligence where the injured party can prove injury or lost cause by a defective product and that the product was in that defective state when it left the control of the manufacturer when the facts do speak for themselves.

Common law principles

South African law adopts the concept that, as a general principle, a delict can arise from a breach of a contractual obligation.

The Aquilian action, from the Roman Law, is a general remedy for civil wrongs to patrimonial interest. The action requires proof of both wrongful conduct and fault on the part of the defendant.

Wrongful conduct usually consists of the production of a defective article that causes physical or purely economic damage to any person or property. Fault is satisfied by showing that the plaintiff's damage was reasonably foreseeable; that the reasonable person would have guarded against it; that the defendant failed to do so; and the failure to guard against it caused damages, i.e. that the defendant is negligent be caused the loss.

The manufacturer or seller of a defective product would be liable to the purchaser or any other person who suffers harm if the injured parson can prove that:

- the product was made by the manufacturer or purchased from the seller;
- the product was defective;
- a reasonable person in the position of the manufacturer or seller ought to have foreseen the likelihood of the product being defective and causing harm to that person;
- a reasonable person in the position of the manufacturer or seller would have taken steps to prevent the harm from occurring;
- the seller did not take the steps that a reasonable person in that position would have taken to prevent the harm; and
- the failure by the manufacturer or seller to take these reasonable steps to prevent the harm caused the damage to the injured party.

In most cases, manufacturers are corporate entities and are vicariously liable for the negligence of an employee who causes a product to be defective while acting in the course and scope of that employee's employment with the manufacturer.

The liability referred to above arises from the negligence of the manufacturer, the seller or their employees. A claim will also lie for intentional conduct which causes damage.

There is no reported South African decision which founds product liability for breach of statute although such a cause of action is recognised. Breach of a statutory duty usually constitutes evidence of negligence rather than an independent cause of action.

The common law principles referred to above apply equally in situations where:

- the product is unfinished and has to be assembled by an intermediary;
- the product consists of separate components;
- the product is negligently serviced by an intermediary or the intermediary negligently fails to discover a defect;
- the product is inherently dangerous;

- the product is harmless unless used abnormally;
- the product suffers from an undetected patent defect; and
- the product is incorrectly labelled.

The seller or manufacturer will also be delictually liable for a negligent misrepresentation made to the purchaser or third party user concerning a product where it can be proved that:

- the person in the position of the seller/manufacturer ought to have foreseen that the purchaser or third party user would have relied upon the statement and would have suffered harm as a result; and
- the purchaser or third party user was entitled to rely, and did rely, upon the statement and suffered patrimonial loss as a result thereof.

The law allows for an apportionment of liability between the negligent seller, manufacturer or intermediary and the negligent injured party.

Where there is a contractual nexus between the seller and purchaser, South African Contract law allows, in the case of a defective product for:

- rescission of the contract and return of the purchase price at the purchaser's election; or
- reduction of the purchase price; or
- damages for breach of contract usually limited to the damages directly caused by the breach.

There are a number of situations where a seller would be liable in contract for not only direct, but also indirect but foreseeable damages arising from a defective product.

These are:

Fraud on the part of the seller

- the purchaser suing the seller for fraud arising from a concealment of a defect in a product would have to prove that:
- the defective product was purchased from the seller;
- the purchaser did not know of the defect;
- the seller knew of the defect in the product and intentionally concealed it;
- the purchaser, if the defect had been known, would not have purchased the product; and
- the concealment of the defect resulted in the purchaser suffering harm.

Breach of express warranty

the purchaser may sue for breach of contract where the seller breaches a specific term or warranty in the contract. The warranty usually relates to a particular characteristic of the product sold;

the breach would entitle the purchaser to cancel the contract and recover any direct and consequential damages that ought to have been contemplated by the parties.

Breach of implied warranty

in circumstances where the seller publicly professes skill and expert knowledge in the product sold, or where the seller is the manufacturer, the purchaser may claim consequential damages for an injury caused by a product with a latent defect without proving fault on the part of the seller, on the basis of an implied warranty or in delict.

in the case of an ordinary seller who does not profess to have skill and expert knowledge, or is not the manufacturer, the purchaser will only be able to recover foreseeable consequential damages if it can be shown that the breach of the implied warranty against the latent defects occurred intentionally or as a result of negligence, including a negligent misrepresentation. This is delictual.

to succeed in an action for damages based on negligence, the purchaser will have to prove the various elements of liability of sellers discussed in respect of delictual liability earlier.

a manufacturer or seller may contract out of liability for the defective products and, in such circumstances, the injured party could not seek to avoid the exemption by suing in delict, where the exemption is appropriately worded. The exemption is not binding on a third person injured by a defect in the product where there is no contractual nexus between the manufacturer/seller and that party.

The Consumer Protection Act

In this context, the Consumer Protection Act protects all natural persons suffering injury, illness or death or damage to property. Corporations are protected against damage to property. It includes not only the buyer but also a user of the goods.

Product liability

Section 61 of the Act as dispenses with the common law requirement for a Claimant to establish fault, usually in the form of negligence, on the part of the producer and importer or distributor and retailer in respect of a defective product causing harm.

All a claimant now need to do is prove harm, as defined in this section (see below), caused wholly or partly as a consequence of:

- Supplying any unsafe goods;
- A product failure, defect or hazard of any goods; or
- Inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from or associated with the use of any goods.

Liability

Suppliers cannot contract out of the section 61 liability.

Section 61 has been in forced since from 1 April 2011. However, it does apply to goods that were first supplied to consumers on or after 24 April 2010.

While section 61 provides for no-fault liability it does not provide for absolute liability. There are limited exclusions to liability which benefit distributors or retailers but not producers or importers.

Any supplier will escape liability:

- The unsafe product characteristic, failure, defect or hazard that results in harm is wholly attributable to compliance with any public regulations;
- Were the unsafe product characteristic, failure, defect or hazard:
  - Did not exist in the goods at the time it was supplied by that person to another person alleged to be liable; or
  - Was wholly attributable to compliance by that person with instructions provided by the person who supplied the goods to that person which precludes the manufacturer.

A distributor or retailer who will escape liability:

- Where it is unreasonable to expect the distributor or retailer to have discovered the unsafe characteristics failure defect or hazard having regard to the person's role in marketing the goods;

A general three year time-bar prescription period (in various forms) is applied to claims.

In terms of section 61, the supplier of services who in conjunction with the performance of those services applies, supplies, installs or provides access to any goods is also regarded as a supplier of those goods for the purposes of the section.

A limiting feature of the section is the definition of "*harm*" which is:

- Death of or injury to a natural person.
- Illness of any natural person.
- Any loss of or physical damage to any property whether movable or immovable.
- Economic loss resulting from any of those forms of harm

No mention is made of pure economic loss which causes economic loss without injury or physical damage. In our view, the context in which "*harm*" is used in this section does not allow for such an extension.

Pure economic loss is economic loss that does not arise directly from damage to property or person but in consequence of the conduct complained. Such as a loss of profit, being put to extra expenses or the diminution in the value of property (Telematrix (Pty) Limited t/a Matrix Vehicle Tracking v Advertising Standards Authority 2006(1) SA 461 (SCA) [2006] 1 ALL SA 6).

Because pure economic loss falls outside the ambit of the product liability provisions of section 61, a claimant who suffers pure economic loss because of a defective product, will have to consider whether the common law described above provides any remedy in the circumstances.

Of course where the claimant is able, and has the foresight of regulating its contractual relationship with a product manufacturer, supplier or distributor, to provide for a remedy, in such circumstances, the question is easily answered.

The Supreme Court of Appeal in a judgment of 31 March 2011 in AB Ventures Limited v Siemens Limited held that where the claimant suffers pure economic loss and was in the position or capable of having avoided the loss contractually, there are no grounds to extend the remedy to another legal basis, for example, there is no delictual claim.

If the activities engaged in are itself the product of a contractual arrangement, then generally the very contract that brought about the engagement will be capable of regulating exposure to loss.

The situation is different where it is not possible in any practical sense for a consumer to protect itself against pure economic loss caused by the negligence of the manufacturer.

In Freddy Hirsch Group (Pty) Limited v Chickenland (Pty) Limited, a Supreme Court of Appeal judgment of 17 March 2011, Nandos Chicken international distributors suffered pure economic loss when products in which the spice packs containing Sudan One (a substance not fit for human consumption) were recalled.

Those distributors stood in no contractual relationship with the supplier of the spice packs and were accordingly not in the position to protect themselves by contract or other means in respect of those losses.

The question was whether our common law allowed the claim for pure economic loss in the circumstances.

Our courts are reluctant to allow pure economic loss claims. Liability is not simply imposed once there is proof of fault, usually in the form of negligence by the manufacturer. The court also requires policy factors to be in favour of imposing such a liability.

To decide whether the conduct is wrongful and therefore actionable, the court takes into account such as whether there are a limited number of possible claimants, whether there will be a multiplicity of actions, whether the damage suffered by the claimants was foreseeable by the manufacturer.

On the Chickenland facts, the Court found that the nature of the distributor relationships was such that:

- The spice manufacturer was aware of the role played by the distributors in their clients' business.
- Liability would not bring a multiplicity of actions.
- The imposition of liability imposed no additional burden on the manufacturer than already imposed by law or good practice internationally.
- The manufacturer's client and the distributors were innocent victims of the manufacturer's illegal conduct and a duty to withdraw the contaminated product from the market to mitigate their losses.

On the Chickenland facts, the court determined that fault on the part of the manufacturer had been established.

So, in the case of a claim for pure economic loss, arising from a defective product, the default position is recovery at common law because such claims fall outside the benefits afforded by section 61 of the CPA.

Right to safe quality goods implied warranty and remedies

In terms of section 55 of the CPA, consumers, who are individuals, or juristic persons with a annual turnover or asset value at the time of the transaction less than the promulgated threshold (currently ZAR2million), have the right to receive goods that are:

- Reasonably suitable for the purpose for which they are generally intended;
- Are a good quality and in good working order and free of any defects (both of these requirements do not apply if the customer has been expressly informed that particular goods were offered in a specific condition and the consumer has expressly agreed to accept the goods in that condition or knowingly acted in a manner consistent with accepting the goods in that condition);
- Will be useable and durable for a reasonable period of time, having regard to the use to which they will normally be put and to all the surrounding circumstances of the supply;
- Comply with any applicable standards under the Standards Act 1993 or any other public regulation.

If a consumer has specifically informed a supplier of a particular purpose for which they wish to acquire or use the goods, and the supplier ordinarily offers to supply those goods or acts in a manner consistent with being knowledgeable about the use of those goods, then the consumer also has the rights to expect that those goods are reasonably suited for that specific purpose.

Any transaction as contemplated in the circumstances referred to above contains an implied warranty (section 56) that the goods comply with those standards. That is except to the extent that the goods have been altered contrary to instructions after leaving the supplier's control.

If the goods do not satisfy the safe quality goods requirements, then the consumer may within six months after delivery of the goods to the consumer, return them to the supplier and the supplier must, at the direction of the consumer, either:

- Repair or replace the failed, unsafe or defective goods;
- Refund the consumer the price paid.

If the supplier repairs the goods and within three months after that repair, the failure, defect or the unsafe feature has not in fact been remedied or a further defect or unsafe feature is discovered, then the supplier must, at the consumer's direction, either:

- Replace the goods; or
- Refund the consumer the price paid for the goods.

The implied warranty and the right to return goods and obtain a refund are in addition to any other warranty or condition imposed, or by common law, the CPA and any other regulation or any other express warranty which the producer or importer, distributor or retailer provides.

A service provider also warrants every new or reconditioned part installed during any repair or maintenance work and the labour required to install it for a period of three months after date of installation or a longer period if a supplier has specified this in writing.

That warranty is:

- concurrent with any other deemed, implied or express warranty;
- void if the consumer has subjected the part or the goods or property in which it was installed to misuse or abuse; and
- does not apply to ordinary wear and tear, having regard to the circumstances in which the goods are intended to ordinarily be used.

At common law, recourse lies in the law of contract or, perhaps, delict.

Climate for litigation

The Constitution allows for class actions but only in respect of claims based upon alleged breaches of constitutional rights and duties. The new Companies Act and the CPA allow for class actions. The law in respect of class actions and the rules for class actions need, however, to be developed. Class actions may be pursued by accredited consumer bodies.

There is currently legislation allowing for contingency fee arrangements, for example in personal injury cases.

The general principle in civil litigation is that the unsuccessful party pays the successful party's costs according to a prescribed tariff applicable to the relevant court in which the litigation is conducted. While the tariff does not necessarily allow the successful party to recover all their attorney and client costs from their opponent, the costs that are recoverable would usually mean that the unsuccessful party bears the risk of having to make a significant costs payment to the successful party if the case is lost.

A contingency fee arrangement does not protect that unsuccessful litigant from an adverse costs order.

The significant costs implications to any unsuccessful litigant reduces frivolous litigation, and may also act as a hurdle to a legitimate but impecunious plaintiff.

The Constitutional Court will usually not make an adverse costs order against a losing litigant who is bona fide pursuing a human rights issue.

The combination of class actions and contingency fees will increase the risk to manufacturers or to suppliers of defective products of exposure to liability for injury caused by the defective products in circumstances where previously the injured individual could not afford the costs and risks of litigation.

South Africa has a system of providing legal aid to impecunious claimants.

The Legal Aid Act 1969 establishes a Legal Aid Board, the object of which is to make legal aid available to indigent persons. The Board has laid down a means test for the purpose of determining the indigence of an

applicant for aid. In civil matters the income and assets of the applicant and the applicant's spouse are both taken into account, with certain exceptions, for the purposes of determining the indigence of the applicant.

Assistance is provided by way of a number of legal aid clinics and justice centres.

Legal aid will cover the claimant's legal fees of litigation, subject to a specified tariff. Legal aid does not cover the costs that an unsuccessful litigant is ordered to pay to the opposing party. In the high court of South Africa, a litigant who is assisted by legal aid is exempted from providing security for the opposing party's costs of the litigation, unless ordered to do so by the court.

An agreement in terms of which a person provides a litigant with funds to litigate in return for a share of the proceeds of the litigation is neither contrary to public policy nor void. Third party funding rarely occurs and generally occurs on an ad hoc basis. There has been at least one instance of a foreign funder entering this market. Legal expenses insurance is available on a relatively limited scale.

The Courts and trial procedure

Product liability claims, whether at common law or under the CPA will proceed in our civil Courts, usually the High Court.

The Supreme Court of Appeal functions exclusively as a court of appeal and sits in Bloemfontein in the central province of the Free State. Save for constitutional issues, it is the highest court of appeal.

Cases are heard by a bench of between three and five judges.

There are provincial divisions of the high court the provinces in the country and three local divisions in the commercial centres of Durban, Johannesburg and Port Elizabeth. Each high court has unlimited monetary civil jurisdiction and territorial jurisdiction over its defined geographic area. Civil trials are heard by a single judge and there is no automatic right of appeal. If permission to appeal is granted by the court, then such appeal is heard either by a full bench of three judges in the relevant provincial division or, with the permission of the court, by direct referral to the Supreme Court of Appeal. If leave to appeal is refused, the unsuccessful applicant may petition the Supreme Court of Appeal for permission to appeal. Rarely, direct appeal access to the Constitutional Court may be granted on constitutional issues.

Magistrates' courts are the lower courts of the land that have civil jurisdiction to entertain claims of up to ZAR300,000 in regional courts (approximately US$42 000). Each magistrates' court has jurisdiction over a designated geographic area and these courts are situated in urban and rural areas throughout the entire country. There is no automatic right of appeal. Application for leave to appeal must be made to the court. The appeal lies to the high court in whose jurisdiction the magistrates' court lies. If leave to appeal is refused, application for such leave can be made directly to the relevant high Court. Both the high courts and the magistrates' courts have jurisdiction over persons (including corporate entities) that are resident or carry on business or are domiciled within the geographic jurisdiction of the court. The courts will also entertain proceedings if the cause of action arose exclusively within their jurisdiction.

With some minor differences the basic pleadings in both high court and magistrate's court cases are as follows:

First, a summons commencing action must set out all the necessary allegations to found the cause of action relied on by the plaintiff, and second a plea by the defendant in response to the summons setting out the defence.

In the magistrates' court, the defendant may request particulars before pleading, calling for information reasonably necessary to enable it to plead.

In the high court, either party may call for such further particulars as are necessary to enable it to prepare for trial.

In theory a high court trial date may be allocated in as short a period as six months after the date of issue of the summons. In practice a period of one year to 18 months will lapse between the issue of process and the trial date. In some divisions of the high court that delay may be extended. In complex high court product

liability litigation, the period between issue of process and the commencement of the trial is frequently two to three years, dependent upon the extent of the discovery of documents and the complexity of the issues requiring evidence from expert witnesses.

Trials are conducted before the judge or magistrate, and follow the common law adversarial system. There are no juries and the initial hearing will proceed before a single judicial officer. The party bearing the onus of proof on the issue in dispute will generally have the duty to begin. Witnesses are led and cross-examined in turn.

At a trial there is no deposition process. Hearsay evidence is usually excluded, but may be admissible in exceptional circumstances.

The parties are entitled to present expert evidence. The rules of the trial courts require the parties who intend to lead expert evidence to provide the opposing party with a summary of each expert witnesses' opinions and reasons, prior to trial. As a matter of practice, there is a meeting of opposing experts prior to trial, and compilation of the minutes of the experts' meeting. The purpose of that meeting is to determine whether issues between the experts can be narrowed and points in dispute clarified. The court may, but rarely does, use experts in an advisory role.

While the section provides for a no-fault liability it does not provide for absolute liability. There are limited exclusions to liability which benefit distributors or retailers but not producers or importers.

In both courts the judge or magistrate, as the case may be, is generally allocated on the hearing date. The rules of court make provision for pre-trial conferences between the parties with a view to limiting the issues in dispute and encouraging settlement discussions. Different divisions of the high court have different practice rules designed to facilitate the limitation of issues and to curtail the duration of the trial. At the close of the hearing judgment may be, and frequently is, reserved by the presiding officer and is delivered at a later date.

The duration of the trial will depend on the complexity of the issues, the number of witnesses called and the length of the legal argument. The duration of trials is anything between a few days to a number of weeks or, occasionally, months.

The Promotion of Access to Information Act 2000 allows for presummons access to records in certain circumstances. There is no deposition procedure. In certain circumstances documentary evidence may be preserved by way of a court order where there is a real threat of the evidence being destroyed.

The rules of court empower a party in any civil action to call for discovery of documents and electronic records relevant to any matter in question in the proceedings which are or have at any time been in the possession or control of the other party or its agent. Discovery may only be called for after the close of pleadings in the action. In exceptional circumstances a court may, on substantive application made before it, authorise early discovery. The rules of court also provide for the giving of notice in respect of the use of eg, photographs, videos, plans, diagrams and drawings, and an inspection thereof prior to trial.

The procedural rules relating to discovery of documents were adopted from English law and are broadly similar to discovery rules applying in England. A party upon whom a request for discovery is served must respond within the stipulated time period (20 court days in the high court) by service of a discovery affidavit, listing and identifying the documents in its possession that are relevant to the issues and the documents in respect of which it claims privilege. The concept of legal professional privilege conforms broadly with the law on that topic applied in common law jurisdictions and is protected.

Damages and penalties

Damages awarded by courts at common law are:

- in the case of breach of contract, a monetary award to place the plaintiff in the patrimonial position it would have occupied if proper performance in terms of the contract had taken place;

And

- in the case of delictual actions, a monetary award to place the plaintiff in the position it would have been but for the wrongful conduct.

At common law damages are compensatory, not punitive.

An indemnity is provided for actual loss. The Constitutional Court has considered the position of what is termed constitutional damages in the case of human rights violations, although no such award has to date been made.

In contractual claims it is not possible to sue for general damages, that is damages for pain and suffering, disability, discomfort, loss of amenities of life, and disfigurement.

In delictual actions where there has been personal injury, general damages are awarded. South African courts adopt a conservative approach in awarding of damages. The quantum of such awards is generally lower than courts in the United Kingdom.

Special damages are those that are quantifiable either by reference to incurred expenses or with the assistance of expert opinion as to costs that will be incurred in the future in treating the injury and its consequences. Those damages would include loss of past and future income.

In general the test for damages is foreseeability, which allows an award for bodily injury and psychological injury in certain circumstances as well as damage to material property plus foreseeable consequential loss reasonably contemplated.

Subject to the proviso below, section 61 of the CPA is not likely to change in the normal course of events the nature of damages awarded by our Courts.

Provided that a Court is required to make appropriate orders to give practical effect to the consumer's rights of access to redress, including any innovative order that better advances, protects, promotes and insures a realisation by consumers of the their rights in terms of the CPA.

An activist Court may take that to be an invitation to introduce punitive damages in appropriate cases.

In determining the appropriate administrative fine, factors such as the nature, duration, gravity and extent of the contravention and loss or damage suffered as a result of the contravention are considered.

Under the CPA, suppliers are also exposed to an administrative penalty for breach of the Act – a fine which may not exceed the greater of 10% of the supplier's annual turnover during the preceding financial year or a million rand. There is also exposure to criminal sanction, including imprisonment for breaches of certain sections of the Act.

In terms of the Court's retaining the authority under the section to assess:

- whether any harm has been proven and adequately mitigated;
- determine the extent and monetary value of any damages including economic loss; and
- apportioning liability among persons who are found to be jointly and severally liable.

Product Recall

Until the commencement operation of section 60 of the CPA on 1 April 2011, there existed no legislation governing product recall in South Africa.

In terms of section 60, the National Consumer Commission by the CPA must develop, adopt and apply industry-wide codes of practice providing for efficient systems to, among other things conduct investigations into the nature, course, extent and degree of any risk presented to the public by any failure, defect or hazard in goods; and if the goods are unsafe, recall of those goods for repair, replacement or refund.

If the Commission has reasonable grounds to believe that any goods may be unsafe, or that there is a potential risk to the public from the continued use of or exposure to the goods, and the producer or importer

of the goods has not taken any steps required by the applicable code (including those in respect of recall), then the Commission may, by written notice, require the producer to:

- Conduct an investigation;
- Carry out a recall programme on any terms required by the Commissioner. Provided that a producer or importer affected by such a notice may apply to the Tribunal to set aside the notice in whole or in part.

The section 60 requirements, accordingly, create significant exposure to producers and importers of goods and they are likely to see an increase in product recall claims.

Damages for pure economic loss suffered as a result of a product recall need to be dealt with by the common law as discussed in respect of the Chickenland judgment referred to above.

Products Insurance

South African insurers provide a variety of cover both in respect of product liability and product recall.

Normally, however, product liability insurance excludes cover in respect of product recall, loss of use or inefficacy.

Insureds who seek such cover would need to make appropriate arrangements with their insurer.

With the advent of the CPA, insureds do need to ensure that the operative clauses of their product liability policies would respond to the entire range of the exposure to no-fault liability, and also where appropriate provide an indemnity for claims for pure economic loss if desired.

The latter is also often excluded from cover.

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