TEST AND MEASUREMENT CONFERENCE 2009

The Impact of Technical Competence on Reliable Measurements

Development of Chemical Testing Laboratory Capacity to Expand the Scope of Good Laboratory Practice Compliant Testing Facilities

by
Herman Wiechers and Tshenge Demana

ABSTRACT

The Customized Sector Programme for Chemicals and Chemical Summit Agreement identified the need to address constraints that affect the development of appropriate geographically spread laboratory service necessary for the growth of the chemical sector and to align these to economic growth in SA. To investigate these needs the Department of Trade and Industry launched an investigation to identify problems experienced by industry of routine testing of products requirements; Identify gaps and opportunities for the provision of chemical testing facilities in South Africa; and, develop a strategy to address the identified gaps and opportunities in the chemical testing sub-sector of laboratory services.

BACKGROUND

The Accelerated Shared Growth Initiative of South Africa (ASGISA) has identified the chemical sector as one of the key priority sectors that has a potential to create jobs. There is a need to address constraints that affect growth and geographical spread of laboratory services and to align these services with economic growth in South Africa. In addition, adequate chemical testing capacity will help South Africa to comply with its obligation in terms of the Multilateral Environmental Agreements (MEAs) and national legislation, all of which require a range of chemical tests to verify characteristics, hazards and pollution of chemicals, or, emissions as the result of industrial process. In view of the foregoing, it is important for South Africa to extend the number of laboratories performing chemical testing and also expand the scope of laboratories that are accredited or compliant with *Good Laboratory Practice* (GLP). For these reasons Department of Trade and Industry (***the dti***) has launched a study with the following aims, i.e. to:

a) Identify problems experienced by industry in terms of routine testing of products requirements;

b) Identify gaps and opportunities in the provision of chemical testing facilities in South Africa; and

c) Develop a strategy to address the identified gaps and opportunities in the chemical testing sub-sector of laboratory services.

The study comprised *two phases*, i.e. a *Situation Analysis* phase and a *Strategy Development* phase, with the following tasks:

Phase 1 - Situation Analysis:

1. Review of current national and future international legislation (such as REACH) that addresses chemical testing.
2. Identification of products which require chemicals testing and laboratory services in each sub-sector and whether these products can be registered and accepted in other countries.
3. Identification of laboratories that are available to undertake the necessary testing, and whether there are sufficient laboratories available for this purpose.
4. Estimation of what the financial implications are for upgrading and accreditation of existing laboratories and the establishment of new ones.
5. Identification of potential investors and funding options for the aforementioned laboratory services.
6. Establishment of the need for possible Centres of Excellence for testing laboratories, as well as identifying timescales for such initiatives and possible funding options.

Phase 2 - Strategy Including Mechanisms to Address Situation Analysis Issues

1 Development of a framework for a sustainable communication mechanism between identified sub-sectors and regulators.

2 Development of a strategy to promote the use of accreditation and good laboratory practice in the identified sub-sectors.

3 Development of an implementation plan of the strategy and an estimate of resources required for implementation.

This paper sets out the findings of the investigation as well as the strategy developed to address the identified shortcomings.

METHODOLOGY

The methodology used to assess the current situation was as follows:

Phase 1: Situation Analysis

Review of Legislation: Relevant national legislation and international conventions which deal with, or require chemical testing, as well as national legislation still under development, were reviewed. Although no specific testing requirements are provided for in the South African Acts or the Regulations, chemical testing is implied through a number of requirements, for example, classification of chemicals requires testing to, for example, determine physico-chemical, health and environmental hazard characteristics. Testing requirements in respect of foreign markets were also reviewed.

Identify Products Requiring Testing: Products which require chemical testing and the type of laboratory services required in each sub-sector, were identified. This was done by interviewing (directly or by telephone or e-mail) representatives of the relevant sectors and sub-sectors, using a brief questionnaire. The questionnaires were used as a basis for compiling illustrative lists of chemicals and chemical products that need to be tested.

Identify Existing Testing Laboratories*:** Existing chemical testing laboratories were identified based on guidance from ***the dti and a Project Counterpart Group (CPG), as well as through a search on the internet and other relevant databases. A supply/demand analysis of chemical testing laboratories, with an appropriate geographic spread over South Africa, was undertaken.

***Financial Implications*:** Criteria and requirements were established for upgrading and accreditation of existing laboratories, as well as for establishment of new ones, and an estimate was made of the associated costs. This investigation estimated the financial implications for upgrading and accreditation of existing laboratories, as well as for establishment of new ones.

***Investors and Funding Options*:** Based on the foregoing information, potential investors and funding options for upgrading and accreditation of existing laboratories, as well as for establishing of new ones, were identified.

***Centres of Excellence*:** The need for Centres of Excellence for chemical testing laboratories, and the associated time scales for such initiatives were established and recommendations were made.

Phase 2 - Strategy Development

The *strategy development process* comprised three tasks:

1. Development of a framework for a sustainable communication mechanism between identified sub-sectors and regulators;
2. Development of a strategy to promote the use of accreditation and good laboratory practice in the identified sub-sectors; and
3. Development of an implementation plan of the strategy and an estimate of resources required for implementation.

REVIEW OF LEGISLATION

Relevant national legislation and international conventions which deal with or require chemical testing were reviewed, as well as legislation under development. Some testing requirements in respect of foreign markets were also reviewed and are reported on.

National Legislation: A brief review of national legislation, as well as associated regulations and national standards, which refer to chemical testing requirements, was undertaken. The acts and regulations reviewed were the following: Hazardous Substances Act; Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act; Occupational Health and Safety Act; Explosives Act of 1956; South African Drugs and Drug Trafficking Act No 140 of 1992; The Non-Proliferation of Weapons of Mass Destruction Act No 87 of 1993; National Road Traffic Act No. 93 of 1996; NEMA and the EIA Regulations; National Environmental Management: Air Quality Act; National Water Act; and, the Foodstuffs, Cosmetics and Disinfectants Act. Table below summarises the key findings detailed above on testing requirements as specified in National Legislation.

Summary of National Legislation

LEGISLATION	TESTING REQUIREMENT	METHODOLOGY	TEST FACILITIES/ COMPETENCY
Hazardous Substances Act (HSA), Act No. 15 of 1973 **Regulations** Government Notice R452 of 1977 Group I Hazardous Substances	Classification	Not prescribed **GHS** Physico-chemicals: prescribed Toxicity: Internationally recognised methods not prescribed	Competency not prescribed
Government Notice R1382 of 1994 Group II Hazardous Substances: Classification		Not prescribed **GHS** Physico-chemicals: prescribed Toxicity: Internationally recognised methods not prescribed	Competency not prescribed
Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, Act 36 of 1947	Determination of Toxicity and Potential Hazards of Agricultural Remedies	Not prescribed **GHS** Physico-chemicals: prescribed Toxicity: Internationally recognised methods not prescribed	Competency not prescribed
Regulations Government Notice R935 in GG 29225 of 22 September 2006 Sub-Regulation 8: Government Notice R956 in GG 29241 of 29 September 2006: Part 4A of Annexure C: Laboratory Studies Requirements	Laboratory studies on toxicity	Summaries of the validation of methods of analysis must be included. Summaries of the methods of analysis or references for the methods must be included	All laboratory studies conform to *Good Laboratory Practices* (GLP) which must be reflected in the data produced.
Explosives Act (EA), Act 26 of 1956 has been repealed by section 34(1) of the Explosives Act 15 of 2003 **Regulations** Sub-Regulation 14.5 requires testing for authorisation	Physical properties and chemical composition	Not prescribed	Competency not prescribed
South African Drugs and Drug Trafficking Act No 140 of 1992 Schedules 1 and 2 of the Act list the scheduled substance	By implication, the capacity to analyse to identify scheduled substances	Not prescribed	Competency not prescribed
The Non-Proliferation of Weapons of Mass Destruction Act No 87 of 1993 The Council may cause a sample obtained in terms of subsection (1) (a) or taken under section 12 (7) to be examined, tested or analysed	Goods comply with conditions of permit; by implication, the capacity to analyse samples to identify scheduled substances	Not prescribed	Competency not prescribed

LEGISLATION	TESTING REQUIREMENT	METHODOLOGY	TEST FACILITIES/ COMPETENCY
National Road Traffic Act No. 93 of 1996 Regulations under the Act refer to Dangerous Goods , which in turn reference SANS 10228 describes the tests to be undertaken on Dangerous Goods	Physical & chemical characteristics	Not prescribed **GHS** Physico-chemicals: prescribed	Competency not prescribed
National Environmental Management Act (NEMA), Act 107 of 1998 Environmental Impact Assessment: GN R386 sets out the list of activities and competent authorities in respect of which a 'basic assessment' needs to be undertaken GN 387 contains a list of activities and competent authorities requiring "scoping and environmental impact assessment" Regulations	Air pollutants	Methodology in the process of being prescribed	Competency not prescribed
National Environmental Management: Air Quality Act National Air Quality Framework		Measurement of air emissions	
National Water Act, Act 26 of 1998 Government Notice R509 of 2001 (GG 22355 of 8 June 2001)	Inorganic and organic constituents of water and wastewater	Some prescribed Methodology must be registered with DWAF as part of licence application	Competency not prescribed
Water Act 1956 No. 991 - 18 May 1984 **Regulations** Specifying quality standards	Inorganic and organic constituents of water and wastewater	Some prescribed Methodology must be registered with DWAF as part of licence application	Competency not prescribed
Foodstuffs, Cosmetics and Disinfectants Act No 54 of 1972 **Regulations** Chemical quality requirements	Wide variety of chemical additives and contaminants	Not prescribed	Competency not prescribed

INTERNATIONAL INSTRUMENTS

The following *international instruments* were reviewed: the Basel Convention; the Montreal Protocol; the Rotterdam Convention; the Stockholm Convention; the Chemical Weapons Convention; and, the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Chemical testing requirements in terms of these instruments are briefly discussed below.

Basel Convention on the *Control of Trans-boundary Movements of Hazardous Wastes and their Disposal* aims to protect human health and the environment against the adverse effects resulting from the generation, management, trans-boundary movements and disposal of hazardous and other wastes.

Montreal Protocol *on Substances that Deplete the Ozone Layer* is an international treaty designed to protect the ozone layer by phasing out the production of a number of substances believed to be responsible for ozone depletion.

Rotterdam Convention is a multilateral agreement *to promote shared responsibilities in relation to importation of hazardous chemicals.*

Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs). POPs are chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to humans and wildlife.

Chemical Weapons Convention *on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction* is an arms control agreement which outlaws the production, stockpiling and use of chemical weapons. .

UN Convention Against Illicit Traffic in Narcotic Drugs & Psychotropic Substances is one of three major drug control treaties currently in force and provides additional legal mechanisms for enforcing the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

A summary of the key findings related to testing requirements as specified in above iinternational conventions is set out in the Table below.

Summary of International Conventions

International Convention	Schedule/ Section	Testing Requirement	Examples
Basel Convention	Annex I: Categories of Wastes to be Controlled	Waste Streams Wastes Having as Constituents	Y1: Clinical wastes from medical care in hospitals, medical centres and clinics Y19: Metal carbonyls
	Annex III: List of Hazardous Characteristics	Explosive	An explosive substance or waste is a solid or liquid substance or waste (or mixture of substances or wastes) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings.
Montreal Protocol	Phasing out of Group I of Annex A controlled substances, between 1991 and 1996	Chemical Identity	$CFCl_3$ (CFC-11), CF_2Cl_2 (CFC-12), $C_2F_3Cl_3$ (CFC-113), $C_2F_4Cl_2$(CFC-114), C_2F_5Cl (CFC-115)
	Phase-out to zero by 2010 of other substances	Chemical Identity	Halon 1211, 1301, 2402; CFCs 13, 111, 112, etc) and Carbon tetrachloride; 1,1,1-trichloroethane
	Phasing-out of the less active HCFCs by2030	Chemical Identity	Less active HCFCs
Rotterdam Convention	Annex III: Chemicals covered by the Convention subject to PIC	Chemical Identity, Content and Residues	*Pesticides, e.g.* aldrin, captafol, chlordane *Industrial Chemicals, e.g.* crocidolite, polybrominated biphenyls (PBB), polychlorinated biphenyls (PCB)
Stockholm Convention	Annex D to the Convention, Information Requirements and Screening Criteria	Chemical identity Persistence Bio-Accumulation	Aldrin, hexachlorobenzene (HCB), dioxins E.g. half-life of the chemical in water is greater than two months; E.g. Evidence that the bio-concentration factor or bio-accumulation factor in aquatic species for the chemical is greater than 5,000
Chemical Weapons Convention	*Schedule 1 chemicals* have few, or no uses outside of chemical weapons	Chemical identity	Sarin, Tabun, VX, Sulfur mustards
Chemical Weapons Convention	*Schedule 2 chemicals* have legitimate small-scale applications.	Chemical identity	Amiton, PFIB, Methylphosphonyl dichloride
	Schedule 3 chemicals have large-scale uses apart from chemical weapons	Chemical identity	Phosgene, Cyanogen chloride, Phosphorus oxychloride
	Discrete organic chemicals	Chemical identity	Chemical containing phosphorus, sulfur or fluorine
UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	Article 12: Categories of controlled illicit drug precursor substances	Table I Table II	N-acetylanthranilic acid, Ephedrine, Ergometrine Acetic anhydride, Acetone, Ethyl ether

FOREIGN MARKET LEGISLATION

EU REACH Legislation: The EU is the largest foreign market for exports of chemicals for South Africa and has the most comprehensive chemical legislation, and was therefore used as an illustration of the challenges faced by exporters. The European Commission's new regulatory system for chemicals, REACH (*Registration, Evaluation and Authorisation of Chemicals)* came into effect during 2007. Non-EU manufacturers exporting to EU who export greater than 1 tonne of substances to the EU are legally bound to comply with REACH Legislation. Article 10 of the REACH Legislation specifies *Information Requirements* for registration, make it obligatory for all importers to the EC to register the goods. Registration of chemical substances involves *inter alia*, the identification of the substances*:* Including the provision of the composition of each substance, e.g. degree of purity; nature and percentage of impurities; high pressure liquid chromatogram; and description of analytical method.

REACH, OECD GLP and GHS Requirements

REACH Legislation and OECD GLP	Schedule/Section	Testing Requirement	Examples
EU REACH Requirements	Article 10: Information Requirements	Identification of the Substances	Degree of purity; Nature and percentage of impurities; High pressure liquid chromatogram; Description of analytical method
		Information on the Manufacture and Use of Substances	Overall manufacture quantities; Precise details of the process; Form and physical state; Information on waste quantities and composition; Uses advised against
		Classification and labelling	Hazard classification; Hazard label of substance; Specific concentration limits
	Article 13: General Requirements for generation of Information on Intrinsic Properties of Substances	Requirement 4 requires that that all eco-toxicological and toxicological tests and analyses be carried out in compliance with the principle GLP (or other approved international standards)	
	Annex I: General Provisions for Assessing Substances and Preparing Chemical Safety Reports,	Chemical Safety Reports	Human Health and Environment Hazard Assessment for dangerous substances; Exposure Assessment and Risk Characterisation.
OECD Good Laboratory Practice (GLP) Requirements			
Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Requirements	second revised edition of the GHS, which was published in July 2007	***Physico-Chemical Test Methods***	Explosives, Flammable Gases, Flammable Aerosols, Oxidizing Gases, Gases Under Pressure, Flammable Liquids, Flammable Solids, Self-reactive Substances, Pyrophoric Substances, Substances and mixtures that, on contact with water, emit flammable gases, Oxidizing substances and mixtures, Organic Peroxides, Corrosive to Metals, Radio-Active Materials, Pesticides, Fertilizers, Ammonium Nitrate Fertilizer and Lithium Batteries, and Others
		Human Health Hazard Test Methods	Acute toxicity, Skin corrosion and irritation, eye damage and irritation, Respiratory and skin sensitization, Germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ systematic toxicity (single and multiple exposure), Aspiration hazards, and Others
		Environmental Hazard Test Methods	Aquatic toxicity; Degradation, Bioaccumulation; Metals and Metal compounds; and Others.
		Polluting Aquatic Emissions (Effluents) From Industry Processes	
		Physical-Chemical Test Methods	Total dissolved Solids, Total suspended solids, pH, Electrical conductivity, Calcium; Magnesium, Potassium, Chlorides; Sulphates; Phosphates; Ammonia; Nitrate; and, Others.
		Microbiological Test Methods	Escherichia coli; Faecal Coliform Bacteria; Total Coliform Bacteria; Standard (Heterotrophic) Plate Count; and, Others
		Air Polluting Emissions from Industry Processes Physico-Chemical Test Methods	Particulates; Sulphur; Sulphur Dioxide; *Green House Gasses (GHSs) (*Carbon Dioxide (CO_2), Carbon Monoxide (CO); Methane (CH_4)); and, Others
		Solid Waste Polluting Streams From Industry Processes Physical-Chemical Test Methods:	Sulphur; Moisture content; Volatile matter; Ash content; and, Others

OECD Principles and Guidance for Compliance Monitoring[1]: Chemicals control legislation in OECD member countries is founded in a proactive philosophy of preventing risk by testing and assessing chemicals to determine their potential hazards. The requirement that evaluations of chemicals be based on safety test data of sufficient quality, rigour and reproducibility is a basic principle in this legislation. The *OECD Principles of Good Laboratory Practice* (GLP) have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemical products.

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[2] addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. It aims at ensuring that information on physical hazards and toxicity from chemicals be available in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals. The GHS also provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level, an important factor also for trade facilitation.

HAZARDS AND TESTING REQUIREMENTS FOR CHEMICALS PRODUCT

In South African legislation tests for hazardous chemicals are currently prescribed either by reference or by description. However, the actual test methods are mostly not prescribed in the appropriate Regulations or Standards. The common practice is to use what is considered the best methodologies or practices, but these are not prescribed. Hence there is a need for the specification of the best test methods or practices. The Department of Water Affairs and Forestry (DWAF) and the Department of Labour (DOL)[3] do specify the test methods to be used for the testing of raw and potable waters, as well as for effluents and wastewaters. The test methods specified are those of the South African Bureau of Standards, e.g. *SABS 241: Standard Specification for Water for Domestic Supplies*. The DWAF South African Water Quality Guidelines[4] extensively references the American Public Health Association (APHA): *Standard Methods for the Examination of Water and Waste Water* (17th Edition). There are three types of requirements:

- Physical/chemical hazards and testing requirements, test and test methodologies, e.g. explosives flammable liquids oxidising substances and organic peroxides.
- Health hazards tests requirements, test and test methodologies, e.g. acute toxicity and carcinogenicity.
- Hazards to the aquatic environment test requirements, test and test methodologies, e.g. acute aquatic toxicity and bioaccumulation.

REGISTRATION REQUIREMENTS FOR EXPORT CHEMICALS

European Union REACH Registration Requirements: Under REACH each producer and importer of chemicals in volumes of 1 ton or more per year (to the EU) (for an estimated 30,000 substances), will have to register them with a new EU Chemicals Agency. Producers/importers have to submit information on the chemical product properties, uses and safe ways of handling them.

OECD Registration Requirements: The *Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decisions in OECD Countries[5],* provides guidance to applicants wishing to have particular active substances approved or plant protection products (pesticides) registered.

---

[1] OECD 2005 *Good Laboratory Practice: OECD Principles and Guidance for Compliance Monitoring*, Organization for Economic Co-Operation and Development, ISBN 92-64-01282-6

[2] UNECE 2007 *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)* Webpage, http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

[3] GN No. R728 in Government Gazette of 3 June 2003, Draft Facilities Regulations, 2003, Department of Labour, Occupational Health *and* Safety Act, 1993 (Act N0.85 of 1993) specifies *SABS 241*

[4] DWAF (1996) South African Water Quality Guidelines: Volume 1: Domestic Use: Department Of Water Affaires and Forestry, 2nd Ed.

[5] Revision 1, March 2001 *OECD Environment Directorate*

TESTING LABORATORIES: REQUIREMENTS AND STATUS QUO

The review of international instruments, and foreign market and national legislation identified the need for a range of requirements for laboratories testing chemical products for export purposes. These requirements include: Mutual Acceptance of Chemical Safety Data (MAD); the accreditation of laboratory testing methods and/or techniques, and Good Laboratory Practice (GLP) procedures.

OECD Mutual Acceptance of Data: The testing of chemicals is labour-intensive and expensive, and testing the same chemical in several countries adds to the cost in time, resources and laboratory animals. Because of the need to relieve some of this burden, the OECD Council adopted a Decision in 1981 stating that "data generated in a member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment." Since GLP compliance is related to the tests performed by a facility, the area(s) of expertise of the test facilities inspected should be included in the annual overviews, using the following broad categories: Physical-chemical testing; Toxicity studies; Mutagenicity studies; Environmental toxicity studies on aquatic and terrestrial organisms; Studies on behaviour in water, soil and air; bioaccumulation; Residue studies; Studies on effects on meso-cosms and natural ecosystems; Analytical and clinical chemistry testing; and, Other studies (to be specified).

Good Laboratory Practice: Chemicals control legislation in OECD member countries is founded in a proactive philosophy of preventing risk by testing and assessing chemicals to determine their potential hazards. The requirement that evaluations of chemicals be based on safety test data of sufficient quality, rigour and reproducibility is a basic principle in this legislation. The OECD Principles of Good Laboratory Practice (GLP) have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemicals products.

***Accreditation of Testing Laboratories*:** Tests of chemical products for export/import have been undertaken by testing laboratories which are internationally accredited. The *ISO/IEC 17025:1999 International Standard* is used by accreditation bodies world-wide as the basis for recognizing and accrediting competence of testing laboratories[6]. This International Standard specifies the general requirements for the competence to carry out tests, including sampling. It covers testing performed using standard methods, non-standard methods, and laboratory developed methods. It is applicable to all organizations performing tests, which include, for example, first-, second- and third-party laboratories, and laboratories where testing forms part of inspection and product certification. In South Africa the process for accreditation for the *Testing, Medical, Calibration Laboratories and Proficiency Testing Schemes* is undertaken by SANAS[7]. It plans and conducts assessments of laboratories accredited to the requirement specific scopes of activity supported by ISO/IEC 17025, ISO 15189, or other relevant standards/guides, where applicable, as well as set out in the SANAS and International Laboratory Accreditation Co-operation (ILAC) regulatory documents.

Testing Laboratories-Status Quo: An assessment was made of the capacity of laboratories in South Africa to provide the testing services required for the export and import of chemical products from and to the country. The key findings on chemical testing laboratories are presented addressing: Background, accreditation, laboratory clients, barriers and constraints to upgrading and expanding laboratories, and suggestions by the laboratories surveyed.

FINANCIAL IMPLICATIONS

Based on the type and number of Chemical Laboratories required, an estimate of the financial implications for upgrading and accreditation of existing laboratories, as well as for establishment of new ones, was made. Both capital investment (e.g. new buildings and analytical equipment) and operating and maintenance cost (e.g. staff salaries, chemical reagents, services and on-going staff training) were considered.

Need for Laboratory Capacity: This investigation has indicated that South Africa has significant laboratory capacity, both within Government and the Private Sector. However, this resource is gradually being eroded by a lack rigour and enthusiasm within government to implement and enforce current legislative requirements, and with limited planning for future needs as this relates to laboratory capacity. Private laboratories are driven by demand for their analytical testing services and profit. Both sectors are currently inadequately prepared for or planning for the immediate and longer-term chemical testing needs of the Chemical Industry.

---

[6] ISO/IEC 17025 (2005) *General requirements for the competence of testing and calibration laboratories*, ISO/IEC 17025:2005(E), Second Edition, 15 May 2005

[7] SANAS P 04-09 (2004) *Accreditation of Laboratories and Proficiency Testing Scheme Providers*, The South African National Accreditation System, Pretoria, Nov 2004

Laboratory Costs: The laboratories interviewed provided order of magnitude costs estimates for the various costs associated with establishing and running a testing laboratory.

Drivers for Extending Existing Services and New Laboratories: Existing laboratories are usually cash strapped and looking at way to minimise costs, rather than expanding services. Laboratories are considered service providers and often are not perceived as core to the function of a government department or industry. Commercial Testing laboratories are market and profit driven. Key to their expansion planning is a sustained demand for the service with sufficient throughput to justify the capital investment and expenditure, and a reasonable return on investment within 3 -5 years.

Funding of Laboratory Expansions and New Laboratories: Where a critical need arises within government, provision can be made for the funding of laboratory expansions and new laboratories, following normal government processes. Funding will only be made available if the need and priority can be demonstrated to be both essential and high. In cases where the need falls outside government's direct sphere of responsibility, but it is still within its core interest, it may undertake joint ventures with the public sector. Funding by overseas funding agencies, e.g. DANIDA, SIDA, UNEP, GEF or the World Bank will probably be limited to need assessment and feasibility studies, for areas of particular interest to these agencies, i.e. targeted funding.

CENTRES OF EXCELLENCE

There are a number of *Centres of Excellence* for chemical testing in South Africa. These organisations have extensive experience on, and are undertaking on-going research into testing methods to meet international export/import requirements. Centres of excellence are experiencing similar problems to the chemical testing laboratories. In addition, they have the problem of retaining their mostly highly trained staff, who are drawn to more lucrative positions in industry. Furthermore, over the last 15 years the funding of centres of excellence has remained static or in some cases has decreased. Centres of excellence are not being used sufficiently to develop chemical testing methods appropriate to the needs of the SA chemical export/import market. Notwithstanding the abovementioned problems, various initiatives are underway to reverse the current situation.

RECOMMENDATIONS

Based on the findings of the investigation, it is considered important for South Africa to extend the number of laboratories performing chemical testing and also expand the scope of laboratories that are accredited or compliant with *Good Laboratory Practice* (GLP). Specific recommendations in this regard are:

- *National Interest:* Issues of national interest that need to be addressed are to protect South African export markets by rigorously addressing the new needs and requirements of its main trading partners, i.e. EU, USA, East; and to protect the South African consumer from substandard imports.
- *Public–Private Partnerships*: Where there are significant constrains to get chemical testing initiatives off the ground, Government and the Private Sector should enter into partnerships, building on the combined strengths of the partners: e.g. by expanding existing Centres of Excellence to specifically address export/import chemical testing research and development needs; and, developing a POPs laboratory that could service the SADAC and/or rest of Africa.
- *Commercial Laboratories:* Incentivise commercial chemical testing laboratories to expand their services to include the possibly less profitable low volume chemical testing requirements for the export/import of chemical, Government should consider developing and actively promoting a range of financial mechanisms, such as tax incentives and rebates, as well creating funding opportunities, e.g. seed funding for strategic projects.
- *Training Institutions:* Universities and Technikons should give consideration to the following: Provide more practical training for graduates to build up their experience in analytical chemistry; and, the quality and standard of analytical training which appears to have deteriorated over the last ten years.
- *Staff Training and Skills Development*: Government should consider increased funding through grants and/or subsidies for analytical chemistry training and skills development by the Universities and Technicons. Laboratory staff with relevant potential and initiative should be given opportunity and financial support to study further by their employers.
- *Role of State Testing Facilities:* The role of State funded analytical chemical testing laboratories in providing competitive commercial services is problematic and should be debated and place on a sustainable basis. Their function should be to assist the state management e.g. water, health agriculture. This is a complex issue of state involvement in the private sector should be debated by interested parties.

- *Accreditation:* To reduce cost and time associated with the accreditation of laboratories investigate forming a consortium of laboratories with multiple sites, which could be accredited as satellite laboratories.
- *Centre of Excellence:* Existing Centre of Excellence for POPs analysis could assist the development of a POPs analytical laboratory and undertake the training of analytical staff, research and development work, monitoring and quality control. However, such a Centre of Excellence could not run it as a sustainable commercial entity and would require the development of a partnership with a commercial laboratory/ies.
- *Laboratory Database*: Develop a central South African laboratory database.

THE WAY FORWARD

Phase 2 of this Project comprised the development of a strategy and mechanisms to address issues identified in the Situation Analysis, i.e.: Developing a framework for a sustainable communication mechanism between identified sub-sectors and regulators; Developing a strategy to promote the use of accreditation and good laboratory practice in the identified sub-sectors; and, Developing an implementation plan for the strategy and an estimate of required resources.

Framework for a Sustainable Communication Mechanism

The project has identified the major role players associated with chemical testing laboratory capacity in regard to export and import of chemicals to South Africa. These are:

- *The Regulators,* including the following National Government Departments: The Department of Trade and Industry (***the dti***); The Department of Science and Technology (DST); The Department of Health (DoH); The Department Minerals and Energy (DME); The Department of Water Affairs and Forestry (DWAF); The Department of Labour (DoL); and The National Treasury (NT).
- *Accreditation and Good Laboratory Practice Organisations*: The South African National Accreditation System (SANAS); and, The National Laboratory Association (NLA).
- *Sub-Sectors requiring the services include:* Organisations being regulated, Training Institutions, Centres of Excellence, Public Interest Groups and NGOs. These stakeholders should be reviewed at regular intervals, to ensure that all appropriate key stakeholders are: kept up to date with developments on-going activities in this field, are invited to participate when key issues and approaches are discussed, and are invited to make input where specific projects or initiatives are launched.

In order to ensure sustainable communication between the *regulators*, the *identified sub-sectors requiring the services* and the *chemical laboratory service providers*, it is proposed that the following mechanism be put into place:

- *A Laboratory Capacity Action Committee* be appointed which will identify and develop an appropriate mechanism(s) for communication ensuring that the *Strategy Implementation Plan* is launched, implemented and monitored against agreed actions and timeframes, including that a communications programme. Do we really want to establish a new committee? Responsible agencies in the strategy should just do what is assigned to them.
- *Stakeholders are well informed* of new requirements, guidelines and progress with the implementation of the Strategy, by the regulator using various communication mechanisms, e.g. direct letters, webpage announcements and articles, meetings and workshops; whichever is the most appropriate.

STRATEGY FOR CHEMICAL TESTING LABORATORIES AND FACILITIES

Key strategies are proposed to address the needs, challenges, barriers and constraints to developing chemical testing laboratory capacity to meet current and imminent requirements associated with export and import of chemicals.

Protection of Export Market and South African Consumer: On an ongoing basis (say annually or when appropriate): identify and assess the new needs and requirements of our main trading partners (e.g. the European Union (EU), the United States of America (USA), South America and countries in the East). Develop appropriate action programmes to address these needs and requirements; and, identify international norms and standards for importation of chemical to South Africa. Rigorously apply these norms and standards to protect the South African consumer and the chemical industry from substandard imports.

Public–Private Partnerships: Government and the Private Sector need to enter into partnerships, building on the combined strengths of the partners where there are significant constrains to get chemical testing initiatives off the ground. Areas to be considered in the short to medium term are: Expanding existing Centres of Excellence to

specifically address export/import chemical testing research and development needs; and, Developing a national POPs laboratory.

Incentives for Commercial Laboratories: Develop and actively promote a range of financial mechanisms, such as tax incentives and rebates, and creating funding opportunities to incentivise commercial laboratories to expand their services to include the less profitable low volume essential chemical testing requirements for the export/import of chemicals.

Staff Training and Skills Development: Address analytical chemistry training and skills development needs by increasing funding (e.g. through grants and/or subsidies) the academic universities and universities of technology (Technikons) through the CHETA. Industries should provide opportunities and financial support for their laboratory staff (with relevant potential and initiative) to study further in the field of chemical testing.

Training Institutions: Through the CHIETA, assist training institutions to meet the chemical industries crucial training needs in regard to analytical chemistry (e.g. improve the quality and standard of analytical training, and encourage graduates to build-up experience in analytical chemistry).

Role of State Testing Facilities: Task the National Laboratories Association to investigate the role of state-funded analytical chemical testing laboratories (e.g. the CSIR and MINTEK) in providing 'cheap' commercial analytical services in competition to the private sector. These Laboratories currently rather than assisting the state in managing crucial national resources, e.g. water, health and agriculture, by offering subsidised rates for these services. This creates unfair competition.

Burden of Accreditation on Smaller Laboratories: Task the National Laboratories Association to investigate the impact of accreditation and maintenance of accreditation status by small and medium chemical testing laboratories, as well as to develop practical solutions to lighten the financial burden on the smaller laboratories.

Expanding Role of Chemical Testing Centre of Excellence: Encourage and finically assist existing Centres of Excellence (CoE) for chemical testing to assist with: The development of analytical methodologies; Undertake the training of analytical staff; Undertake research and development work, as well as monitoring and quality control; and development partnerships with commercial laboratories.

Laboratory Database Expanding Role of Chemical Testing Centres of Excellence: Develop and maintain a centralised database of South African chemical-testing laboratories, and including GLP compliant and accredited laboratories.

Funding of Laboratory Expansions and New Laboratories: Where a critical need arises within government, provide funding of laboratory expansions and new laboratories, following normal government financial processes. Only provide funding where the need and priority are demonstrated to be both essential and high. In cases where the need falls outside government's direct sphere of responsibility, but is still within its core interest, undertake joint ventures with the public sector (e.g. by government providing funding for capital equipment and development of the laboratory, and the private sector covering the running and maintenance cost). Encourage and lend support proposals for funding of chemical testing facilities by overseas funding agencies (e.g. DANIDA, SIDA, UNEP, GEF or the World Bank), for assessment and feasibility studies related to chemical testing facilities. However, for major capital expenditure and running costs encourage the government and the chemical industry to cover these costs.

IMPLEMENTATION PLAN FOR CHEMICAL TESTING LABORATORIES

Based on the strategy, an implementation plan was developed that addresses the key elements of the strategy. Detail tasks and activities deliverables, responsibilities, resources and timeframes have been proposed.

REFERENCES

the dti (2008) *Development Of Chemical Testing Laboratory Capacity To Expand The Scope Of Good Laboratory Practise Compliant Testing Facilities:* Final Situation Analysis Report, ***the dti***, 5 January 2008

the dti (2008) *Development of Chemical Testing Laboratory Capacity to Expand the Scope of Good Laboratory Practise Compliant Testing Facilities - Phase 2: Strategy for the Development of Chemical Testing Laboratory Capacity to Expand the Scope of Good Laboratory Practise Compliant Testing Facilities, Department of Trade and Industry*, Final Strategy Report, ***the dti***, 15 February 2008