

## *Croatia Preparing for EU Accession*

### *Enhancing Trade Facilitation and Export Competitiveness through International MAS-Q Recognition*

*Trip Report - June 2006*

*Prepared by*

*Ed Nemeroff and Sani Daher*

#### **Introduction**

In the fall of 2005, the USAID funded “Enhancing SME Performance” project (ESP) completed an assessment of the state of Metrology, Accreditation, Standards and Quality (MAS-Q) infrastructure and quality management services in Croatia. The findings were presented in a report titled “Metrology, Accreditation, Standardization and Quality activities in Croatia”, by Ed Nemeroff dated December 2005. The report identified a number of shortcomings that have to be addressed as soon as possible for Croatia to have an effective MAS-Q infrastructure that would enable Croatian companies to compete in EU and other global markets. The report made a number of recommendations that included the elimination of the 12,000 outdated Yugoslav standards, and the development of a model for the creation and the publication of new technical regulations meeting EU requirements. The report also referred to a communication gap between the public and private sector, with the private sector expressing dissatisfaction with the lack of information on proposed changes to MAS-Q and the subsequent impact. Thus, the report recommended the organization of an international MAS-Q conference focused on EU accession, which would open up a dialogue between the Government, MAS-Q public institutions and the private sector, and proposed the establishment of a “Center for Excellence”, which would coordinate and conduct formal programs relating to quality and would be a resource center for businesses to obtain information. The idea for a “Center for Excellence” was fully supported by the 1<sup>st</sup> March 2006 workshop organized by the National Competitiveness Council (NCC) and the World Economic Forum (WEF), sponsored by USAID, which recommended the formation of a Quality Center for the coordination and implementation of official quality programs at the national level.

In its work with Croatian industries, ESP has encountered numerous cases, which draw attention to the needs of enterprises resulting from inadequate information, lack of quality conformity assessment services, and existence of technical barriers to trade. Following the publication of the Nemeroff report, a number of discussions were held within ESP and outside on the further development of the “Center for Excellence” concept and other initiatives aimed at building a platform for a dialogue between the public and private sectors, as well as a basis for launching services tackling the issues described above and meeting market needs. As a result of these discussions, a concept has evolved for an organizational structure and associated services. This concept has so far been discussed with a number of stakeholders including representatives of the Ministry of the Economy, EC delegation in Zagreb, General Manager of IBM (who is also a member of the NCC), Executive staff of the Croatian Employers Association, the Secretary General of the Croatian Exports Association, and others.

In June 2006, Ed Nemeroff returned to Croatia, together with Sani Daher a DAI, Principle Development Specialist, the two with members of ESP and Mr. John Martin (short term consultant – expert in the boat building industry) visited more than 35 private and public

sector organizations. Private sector companies were from different industry sectors including pharmaceuticals, cosmetics, food processing, automotive, boat building, industrial equipment, electrical components, and consulting. In addition the team visited the major public sector organizations involved in conformity assessment activities. Specific objectives for the team included:

- ✓ Determining the progress that they have made by the Government of Croatia (MAS-Q agencies) in complying with international MAS-Q requirements since the initial assessment conducted in the fall of 2005.
- ✓ Evaluation of options for setting up a Center and engagement of all stakeholders in the process through discussion and demonstration of how modern MAS-Q infrastructure works in developed and emerging economies, including new members of the EU.
- ✓ Selection of the best solution for a Center of Excellence and recommendations on mission, ownership and objectives, processes and services and organizational structure.

## **Summary Findings**

### Public Sector

- ✓ The obsession with EU accession by the government and the demands being made on those agencies involved has caused them to divert their resources toward compliance. Impact: Long term, (2-3 years) most of this will benefit the private sector, but presently the information GAP between the public and private sector has widened and the real needs for export growth are not being addressed.
- ✓ Needs of the private sector basically falling between the cracks.-impact –many SME’s could go out of business
- ✓ No firm Croatian plan or date for transition of EU requirements
- ✓ EU accession is the driver for government actions – Top Priority, government MAS-Q agencies under high pressure to harmonize their activities and procedures with EU accession requirements.
- ✓ New legislation, new agencies, and reorganization of MAS-Q activities: on the surface in line with EU technical principles and requirements. Still a lot to be accomplished – could be years
- ✓ The European Union (CARDS program) is providing assistance to Croatian government MAS-Q organizations, objective: bring legal, regulatory and technical requirements in compliance. - The focus: protect EU member countries.

### Private Sector

- ✓ There is a communication gap between public and private sector – don’t know where to get information
- ✓ Not being kept informed on how EU accession will impact them.
- ✓ Language is a barrier to understanding requirements
- ✓ Croatian “Quality Mark” – “CE Mark” The Croatian mark is a quality mark, the CE mark is a safety mark – obtaining CE mark in Croatia is not available.
- ✓ There is a lack of private third party accredited testing and calibration labs

### Progress –Public Sector

- ✓ Croatia is now starting to understand the importance of MAS-Q in the development of economic policies.
- ✓ The newly created government agencies are being structured, adopting and implementing the necessary standards and regulatory procedures required by EU and (WTO) international MAS-Q organizations
- ✓ The State Office of Standardization and Metrology” has been dissolved, the new agency; the State Office for Metrology” has been created, this is still government body under the Ministry of Science. It has a new director and recently became the newest associate member of the *Bureau International des Poids et Mesures* (BIPM) and the European Metrology Cooperation (EUROMET)
- ✓ The Croatian National Standards Institute and the Croatian Accreditation Agency have been created as separate, autonomous non-profit public institutions. Independence is a requirement of international MAS-Q rules.
- ✓ 3,000 of the 12,000 documentary standards left over Yugoslavian times have been made obsolete
- ✓ The Croatian Accreditation Agency (HAA) has been granted full membership in the European Accreditation Cooperation (EA). This is major step to achieving Mutual Recognition of accreditation and certification activities. This will eliminate re-testing and re-certification, reduce cost and eliminates non-tariff barriers to trade and market access delays for products being exported and imported. .
- ✓ The HAA has signed MOU with MOH for cooperation on laboratories and training of technical specialist to become qualified assessors
- ✓ The National Standardization Body (HZN) has developed a “Standards Awareness program” promoting benefits of standardization in trade facilitation- There have been 340 private organizations that have become voluntary fee paying members of the HZN in 6 months. The following is a quote from their program:
 

***“Description of the problems and desirable situation***  
*In the transition process, big companies came under the domination of global companies. Numerous newly established SME’s thus do not have a developed awareness of the role of standards in their development and market promotion. Therefore, the role of the HZN is to establish a cooperating relationship with its natural partners in the economy. The Croatian Chamber of commerce has a similar problem. i.e .it also has to influence raising the total awareness of standards in society”.*
- ✓ The HZH has become an associate member of the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC)

#### Progress - Private Sector

In general, the none-exporters were eager to export but did not know where to start, and did not know what standards they need to comply with to satisfy market entry requirements or buyer requirements.

The exporters on the other hand, usually had some sort of a quality management system in place, but relied heavily on a sister or parent company abroad or a major buyer for guidance on all quality issues. Large companies are interested in integrating more inputs from supplier in Croatia, but in general characterize small companies as low productivity, low technology,

poor sustainability, and quality ignorant to some extent. But this is not true for all companies and there is evidence of increasing efforts for value chain linkages between large companies and small suppliers in Croatia.

Our assessment revolved around the question how does the existing quality infrastructure facilitate or constrain trade. In other words do the companies have in country access to consulting, testing, calibration, and certification services they need to comply with market entry requirements, more importantly do they know where to get information about market entry requirements.

### **Information**

While Croatia's quality infrastructure poses several constraints to export growth, the key constraint is access to information about requirements. As explained in previous sections, state bodies like the Croatian Standards Institute have been so overwhelmed with the requirements of EU accession that their linkages with the private sector companies and associations have suffered. In turn the private companies are not kept informed of changes within the quality infrastructure, they do not understand the challenges they will face as a result of EU accession. The day that Croatia accedes to the EU, Croatian products covered by the EU safety directives, will require CE marking or they won't be able to sell even in the Croatian market.

CE marking will require testing be carried out by labs that are accredited, this will require certification by notified bodies recognized by the EU. These services are almost none existent in Croatia, and at the moment there is not enough demand for such services due to the lack of awareness driven by poor planning of the Croatian Government.

Companies in Croatia that export today almost completely rely on their sister companies or buyers abroad in Germany, Austria, Italy for information on market entry requirements, and the means to comply with requirements. Many rely on international certification or testing services to meet these requirements. As the quality manager of one automotive parts manufacturer, Feroimpex, puts it, "I hate being so dependent on my buyer for information on quality requirements. I should be able to get this information from an agency in Croatia".

This information handicap directly affects the ability of companies to export as the Manager of Palace Delekatose, an ISO 9000 and HACCP certified producer of frozen ready meals, has experienced first hand. He told us; "I had a contract at hand with a U.S importer that distributed products to 150 shops in the U.S, and I had no idea where to go for information, it took me seven weeks to only know what is required!"

For small companies, the difficulty goes beyond finding information. Technical regulations per the New Approach reference standards. The standards are predominantly in English, some have official translation in German, French or Spanish. Many small and medium size companies don't speak any of these languages good enough to interpret these standards or the relevant parts of them.

### **Metrology and Calibration**

Most of the calibration needs of the companies we visited can be satisfied locally. Croatia as explained earlier has a fragmented metrology system but seems to satisfy most present needs of existing industries. In some cases, equipment or a standard used in internal checking or calibration is sent abroad for inspection and calibration. The University of Zagreb and other

academic institutions are part of the national metrology infrastructure; they host of many of the country's primary standards and provide calibration services to companies and other calibration labs.

There seem to be very few private sector testing and/or calibration labs. To our knowledge, none of the calibration labs in Croatia are internationally accredited yet. However we expect great progress in this area given the progress being made by the Croatian Accreditation Agency.

### **Testing Labs**

Private sector labs are key for industrial development. As companies get more sophisticated and attempt to access new markets, recognized third party testing become more crucial. There are virtually no private sector labs in Croatia with few exceptions. The few private labs that exist are set up to serve one or a group of companies of the same owner as that of the lab, rather than providing services to all companies.

State labs carry out all legally (national system) required testing and inspection of products. None of the labs have internationally recognized accreditation, but again we believe this is soon to change given the EU assistance and progress made by the accreditation body. Despite the lack of accreditation, buyers are accepting local test results in most cases. However, in the cases where CE marking is needed, test data by accredited labs is required and products are tested abroad or locally by accredited agencies that come out to the companies.

### **Certification**

Access to recognized third party certification services and consulting for compliance is very important to facilitate business to business contracts and market access. Quality management system certifications are quite important to international buyers. It assures the buyer that the supplier has the ability to consistently produce the same quality product. Consultancy services in this area including ISO 9000, ISO 14000, HACCP, EUREPGAP, GMP etc are quite adequate, but in many instances companies find these services to be cost prohibitive. All internationally recognized certification bodies present in Croatia can provide this kind of certification services. DNV, SGS and BV are just few among the companies that can provide such certification.

Product certification on the other hand is very much lagging. For example CE mark certification is almost none existent in Croatia. In talking with Bureau Veritas about this issue, they explained that there is not enough demand for them to open up CE mark certification departments, train and certify auditors. The poor demand for these services is a result of the lack of awareness among companies on the requirements for exports in general and regulatory impact of EU accession.

Thus, when companies need CE mark certification they must bring companies from abroad to do that. One company, BHS Corrugated told us "The bid I got from TUV Slovenia was cheaper than the bid from TUV Croatia, because TUV Croatia has to bring the experts from Germany!" The lack of internationally recognized product certification services in the market is a constraint to industrial and export growth.

On the other hand the proximity of Croatia to Slovenia and Hungary, and the basically free movement of people with these neighboring countries make it reasonable and not too cost prohibitive for the Croatian companies to contract recognized certification bodies in Slovenia

to do the work. So in the end the impact of the lack of these services locally may not be as catastrophic as one would imagine for a country well on its way to accede to the EU.

### **Private Sector Summary and Recommendations**

While we have highlighted above several quality infrastructure constraints to export growth, the number one constraint is lack of product specific, market specific information on entry requirements. The standards body has been consumed in accession compliance related activities that their information services have been virtually none existent. Companies at the moment have no place to turn to for information on what they need to comply with in order to export to a certain market. Companies do not seem to comprehend the impact of EU accession on their market regulations and what that means to them in terms of compliance and thus sustainability.

This surprising lack of awareness, results in low demand for certain consulting services, and accredited testing and product certification services. It is therefore imperative for ESP to immediately launch the following interventions:

- 1) Improve private sector awareness of quality related requirements for new market entry and quality compliance requirements for improved supply chain backward integration within Croatia.

MAS-Q related EU assistance to Croatia is focused on TBT compliance issues, and largely neglects the private sector needs to deal with the changes in the regulatory environment. The day that Croatia accedes to the EU, every product that is covered by the EU New Directives must comply. Examples are all electrical products, toys, machines, pressure vessels, automotive products and assemblies, recreational boats etc.

ESP should organize sector focused workshops inviting companies, consulting firms with experience in quality management systems and product certification requirements, as well as notified certification bodies to present to firms within the sector, the requirements of CE marking based on the different product categories, and the ramifications of not having product certification as they accede to the EU or attempt to export. By giving the consulting and certification firms the opportunity to outreach to a huge number of companies, we should be able to get their contribution to the workshops at no cost to the project or at very little cost.

ESP should also consider as a result of these workshops, providing technical assistance to companies interested in product certification and or quality management system certification.

- 2) Improve backward supply chain integration by providing quality related technical assistance :

Recognizing that many of the multinational companies in Croatia are looking to expand their in country supply chain input, ESP should consider working with a group of multinational firms from different complex industries like automotive, boat building, machinery and others to increase their production inputs from suppliers in Croatia. ESP is in a position to provide technical assistance to suppliers to improve their quality management systems and product quality in line with buyer requirements, while the

companies should be responsible to invest in the necessary upgrades to improve quality and productivity.

- 3) Provide firms with access to information on market entry requirements by developing an information center preferably hosted at the National Standards Institute.

ESP must leave behind a sustainable information center that continues to reach out to companies to help them with their quality related queries on market access. The Center must at a minimum have the capacity to provide the following information to clients:

- Market entry requirements, per industry, product category and for each country.
- Sources for the relevant consulting and training services
- Source for accredited testing, inspection, calibration and certification services.
- Contact information for export and import license issuing agencies by country.

## Organizations visited

### **Pharmaceutical and Cosmetics Companies**

1. Medika, Zagreb  
Mr. Damir Kustrak CEO,  
Mr. Boris Matulovic, Manager of Development  
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Medika is one of the largest suppliers of wholesale pharmaceuticals and medical supplies with a share of 31% of the local market (31% of 600 million Euro). 70% of their stock is imported and the rest is from local production. Their operations include

three warehouses, and a chain of pharmacies. The company employs about 390 workers. Their warehouses are not checked by the health department; their main foreign producers audit their warehouse operations regularly and have the responsibility of drug registration in Croatia. Registration is a cumbersome procedure taking on average 2 years per application.

The Chinese are mounting a fierce competition in the medical supplies arena, and the company believes the imports and the market are not adequately regulated to check the quality of medical supplies. The company was ISO 9000:2000 certified in 2001 and is currently pursuing ISO 14000 certification. Mr. Kustrak and Mr. Matulovic both attest to the competence of local consultants in ISO 9000 and ISO 14000.

2. Biovitalis

Durdica Zagorec, Director Manager

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This is a small, 10 employees, cosmetics company with yearly revenues of about half a million Euro. Products range from cough syrups using herb extracts and honey mix, to ointments, creams, and shampoos. All products are formulated by the company and are registered with the ministry of health. I am guessing in most cases they copy branded products formulations. According to the owner none of her products have any active ingredients and thus no bio equivalence studies are needed. At the moment they do not comply with any specific production standard. Ms. Zagorec made the comment that the industry is not heavily regulated, the sanitary Dept. of the Ministry of health rarely checks on them. When they do, they check against a certain standard, but she did not have a copy of it! All current production goes to the local market and Bosnia. The owner is very interested in the export markets but does not know where to start from a quality point of view. Bosnia does not require any quality certifications aside from the Croatian product registration. The Croatian product certificates are based on tests in state laboratories. The state does not recognize any other private lab to conduct the tests. There are few small private labs, but they are not recognized. We looked at few of her products, the cough syrups and ointments were tamper proof, had batch numbers and expiration dates on them, which tells you there appears to be some level of control. The owner would not allow us to see productions. I am guessing it is mostly done by hand.

Her number one need was access to information about markets and the technical entry requirements. Language is a barrier. She does not know English, French or German. She also stated that for companies her size consulting firms are too expensive. I promised to send her the U.S FDA regulations related to her products. She was quite excited about this and the prospect of a quality center that would provide such information.

4) Supera Consulting

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Ms. Peterlic has over 15 years of experience in the pharmaceutical and medical device quality control field. She has previously worked for the largest pharmaceutical company in Croatia, Pliva, as the head of the quality control department. She has experience in working with the EU EMEA and U.S FDA on GMP certification.

The Croatian GMP standard has been the same as the EU GMP standard since 1999, except now it needs to be updated to reflect the changes to the EU GMP that occurred in 2005. The center for Drug Control and State labs carry out the needed inspection and testing. All companies have their own labs with varying degree of sophistication depending on the product.

According to Ms. Paterlic, Bioequivalence studies are all carried out abroad. The local demand is not enough to justify the cost of setting up a local bioequivalence study clinic. Registration of product in the U.S or EU market requires that bioequivalence studies be carried out there, inspection of the facility by the FDA or EMEA, and the presence of company representative in the country of export. (The cost of a bioequivalence study per product is a staggering one million USD).

Croatia has five producing companies, Pliva the largest exports to the U.S and EU, another company exports to the EU, the rest are smaller and serve mainly the local market.

## **Food Processing Companies**

### 5) Biotechnicon, Zagreb

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Biotechnicon is a Food Consulting Firm. Their quality related consulting expertise span agriculture, food processing, and restaurant food preparations. They have to this date provided consulting work to over 150 companies, and training to over 5000 individuals. Mr. Srjan believes his company commands about 45% market share.

Their training and consulting work focuses on HACCP, EUREPGAP, BRC, IFS, Codex Elamentarius standards, organic, and most recently ISO 22000. They have also helped one company gain access to the U.S market by working with the U.S FDA.

As HACCP is a requirement for food processors by local regulations, companies are HACCP certified. Some for export purposes are certified by internationally recognized certification bodies such as BV DNV, but mainly SGS. The main problem he sees in certification is the company's lack of knowledge in maintenance and management of documentation per the HACCP guide. Most recently two large companies have become ISO 22000 certified (Frank is one of the companies). They had to bring an accredited certification body from abroad for the process.

Almost all food testing labs both chemical and biological are state owned with the exception of two. The Ministry of Health owns about 23 labs scattered in the different counties. The Ministry of agriculture has their set of labs. There are many overlaps in the inspections and testing of the two ministries. None of the labs are internationally accredited, which puts in question all the testing data used as part of the certification process of any company or product for export purposes.

- 6) Hermes International  
Chad Henry, Co-owner, Croatia Director  
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Hermes International is a U.S company that worked on exports of Croatian food products to the U.S for the last eight years. Their products include fig spread, olive spread, plum spread and some jams. Their U.S clients are among the largest buyers such as Whole Food Market, BJs, Schaws etc. They have one established brand in the U.S Damatya, some of the products are sold under private labels.

He had mostly so far worked with one Croatian producer, but have ran into many quality related problems with them, that he decided with his two U.S partners to open up their own production line. The producers here do not want to invest money nor effort into HACCP, Organic. Most recently he found out that his producer had included ingredients into production that were not on the label. Some products were rejected by U.S customs after the FDA ran their random tests. Whole Food was not happy with the documentation and sent their quality assurance team that failed his producer on simple but yet important hygiene and documentation issues. His new production line had its first dry run a couple of weeks ago and seemed to function properly. His factory will immediately employ 10 workers plus admin staff. They will double that in September. They expect revenues of 2.5 million euros in 2007.

Entry to the U.S market is relatively easy for his product category. The U.S Customs with the FDA run random shipment tests. They do not require facility visits. If the product fails, the U.S customs may send the shipment back or destroy it. If this happens again and again, they may ban the producer from shipping again until proving by documentation that the situation has changed. Products that are qualified as low acid or acidified have more stringent inspections than the products they export.

It is the big Buyers that require adherence to HACCP and GMP. They conduct facility inspections as needed based on the documentation provided. Producers accept local test results of state labs, even though the labs are not internationally accredited. Test data are mostly chemical analysis looking for metals and other contaminants as well as microbiological tests. In the new company he is setting up, they are following HACCP procedures but are thinking of getting ISO 22000 certification right from the start. He is also perusing USDA 95% organic certification according to the National Organic Program (NOP) standards. This allows them to affix the USDA 95% organic label. He can get this certification locally through a company called BIOINSPEKT that is acting as an agent for IMO in Switzerland that is recognized by the USDA. The approximate cost is about four to five thousand Euros.

He thought that the key services of a Quality Center would be to provide *very* specific information for the market entry requirements for the specific product of each company or client, bearing in mind the language barrier in some cases. This will require more than just access to website type of information (I think linkage with the various U.S and EU technical regulation enforcing agencies.) Aside from that he thinks that companies are low on working capital due to late payments which average 220 days. Thus there is little money to be invested in quality programs and associated consulting fees, and then marketing and export development. The industry also suffers from low productivity due to old technology, over staffing.

7) Emos

Ms. Vladimir Mesanic CEO

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EMOS is a cattle and pig farm. They have 22- 25 thousand pigs and produce 8000 tons of feed annually. 99% of the pigs go to a meat processor Vajda cakouec. Their revenues are 5-6 million euros and have 18 to 20 employees. Regulations in this industry in Croatia are quite loose. They do get inspected by Agroinspekt of the state inspector. Ms. Mesanic could not tell us to what standard or regulation they are inspecting. Both her company and the processor are working together to prepare for exporting. They think the process will be straight forward and will not need much help. For a while they were not able to export because of some vaccination they had to give the pigs.

One of the current issues they may need help with is waste water management. As a by product of the animal feed, you get high level nitrates in the water. The nitrogen can be extracted for energy purposes, and the process can yield some profits. She thinks in few years they will not be able to dispose of the water on Ag. Land as they do now. They are working with a German company on this, but would appreciate any outside assistance. In conclusion, their level of awareness in standards is low, and clearly she stated there is no communications with the National Standards Institute.

8) **Palace Delikatese**

Ramon Spoljar

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Palace Delikatese is a hand made frozen food manufacturer. Their investment is roughly 1 million Euro, with 23 employees and can produce about 3000 boxes per day. They have 15 different types of meals that are already on the Croatian market. The product is vacuum packed and frozen. According to local test results from state labs the food has no preservatives and is good for six months if kept frozen, four days if kept in the fridge. The company is HACCP and ISO 9000 certified by SGS. They used local consultants and find their assistance/competence satisfactory. The consultants were provided through the USAID ACE project.

Palace Delikatese most recently with USAID assistance through our project attended Anuga trade show in the U.S and was able to close a deal with a U.S company and a

Saudi Arabian company. He has been having difficulty with obtaining the export permit/ license.

- a. He does not know where to start to find information on the requirements to export to the U.S for his product category.
- b. He did not know what is required or who to turn to get an export license number from the Croatian Authorities. It took him 7 weeks to find out that he first needed a Vet. Certificate and can then apply for the export certificate.
- c. To bypass the regulations for these permits, bribes have to be paid. After seven months of follow up, they finally have the Vet certificate, but still have to get an export permit.
- d. According to his research the U.S market requires on site inspection by the U.S FDA for his food category, on top of all other requirements including registration of the importer in the U.S and the various lot testing in the U.S. (I will check that). It is extremely hard for a person like him who speaks good English to sift through hundred of pages to know what is required exactly and how to do it.

Mr. Spoljar thinks that the Quality Center to be valuable it has to have the expertise to provide very specific information about process by which companies can get the needed certificates and gain market access.

## **Boat Building Industry**

- 9) Companies visited by John Martin, U.K.  
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Mr. Martin is on an STTA for DAI/Nathan to look at the boat building industry in Croatia. We agreed to work together on export related requirements. He had visited 14 companies in and around Split. Of the 14 companies, only one is able to export to the EU market. One exports through its sister company in Italy that handles much of the certification process. Four other companies export east where requirements are less stringent and no internationally recognized certification is required.

AD. Boat the only EU exporter that Martin met has a Class A ocean going certification from Germanischer Lloyd. He sells boats to UK and Portugal. For certification of one boat design, the cost is roughly 25,000 USD, and it costs about 10,000 USD for yearly random inspections after that. Testing of various parts is carried out by Lloyds in their own labs.

Most of the boat building operations in Croatia are small and fragmented. The engine and sophisticated parts are mostly imported with the required certification. Production is focused on making the hull and assembly.

Mr. Martin main findings on quality related issues can be summarized by the following: Companies do not have much knowledge of TQM, and proper inspection during production. For example as a company is making the hull, a test piece made

exactly as the hull is made for each ship is required for testing purposes. This is not done in Croatia. Furthermore documentation is practically none existent.

His recommendation is to assist the more promising companies with TQM technical assistance and attempt to broker joint ventures among the producers to raise productivity and specialization to improve competitiveness.

## **Automotive Industry**

### **10) Feroimpex**

Ivan Darap, Quality Manager

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Feroimpex is a manufacturer of automotive bearing rings. Their production is about 20,000 rings per day. Their main customer is a German Automotive part supplier from Austria FAG and they sometime supply FAG Germany. On a daily basis, for just in time manufacturing, their customer contacts them with the number and type of parts needed. The producer, machines the parts and heat treats it before shipping. The automotive industry is very demanding in terms of quality and efficiency. The customer requires zero percent failures, as they would like not to do any quality inspection on receiving the goods.

For that reason, the customer has been guiding the supplier on required calibrations, certifications and requires proper quality documentation for all batches of production.

The Company first got ISO 9002 certified in 1998, in 2000 they were certified to QS 9000, and in 2005 they were certified to ISO/TS 16949 by BVQI Austria (Even though they could have been certified by BVQI Croatia). They are now working to get ISO 14000 certified by BVQI Croatia. They have done most of this work by learning from attending various training seminars and some guidance from the customer. They got no help from any governmental agency and have no contact with the Standards Institute.

In terms of Metrology, they have several measurement devices that require calibration including an electronic contour measurement device, a hardness measurement device, and electronic and mechanical length measurement devices in addition various other basic instruments for temperature etc. The customer FAG accepts all proof of calibration services done by the Mechanical Engineering Dept. of University of Zagreb. However the Contour measurement device and the hardness device both require external calibration. The contour device is calibrated by the device manufacturer who comes out from Germany. The hardness machine is checked using a reference plate that is calibrated by a lab in Germany as recommended by FAG. For these calibrations FAG would not accept local results due to lack of accreditation. The precision of measurement required is on the order +/- 0.03 mm. It seems this level of instrument calibration can be done reliably locally.

With regards to ISO 14000, their two main byproducts are oil and metal shavings. They separate the two. The metal (13 tons per day) is shipped to Germany for recycling and the oil is recycled on the Croatian authorities.

Mr. Darap was excited about the prospect of a quality center, he told us that he does not like the fact that they are so dependent on their client for quality related development and information. He would like to see the Governmental agencies engage with the private companies provide information specific to each company and product on new standards, and assist with translating bits and pieces of documents. He also thinks the center should lobby and provide the governmental agencies with feedback on their services.

He went on to say that consultancy services are very expensive and they either learn on their own or attend training but do not have the resources to bring in consultants. He provided me with a couple of examples of valuable American guides on failure analysis, measurement analysis and other topics issued by the top three auto manufacturers, but again the English language is somewhat a barrier. He tries to make the most of it, but on their own.

## **Other Industries**

### 11) Zrinski

Ms. Ines Lukman, Managing Director  
385 42 684 461  
[Ines.lukman@zrinski-technologija.hr](mailto:Ines.lukman@zrinski-technologija.hr)

Zriniski is a CNC machining company that makes high precision metal parts that are used in the airline industry, robotic machines, and telecom manufacturing machinery. Zriniski Croatia is the sister company of Zriniski Germany, and much of the production is being transferred to Croatia, while the R&D, engineering and marketing functions will remain in Zriniski Germany. Zriniski Croatia has been in business just over 11 months, has 24 employees, working in most cases 3 shifts to meet demand. All design drawings for parts, quality requirements, operating procedures come from Zriniski Germany.

The company has the usual micrometers that are checked using internal measurement standards, and calibration is done at the University of Zagreb when needed. They have one computerized dimension checking machine (Zeiss) that require calibration by experts from Austria.

They have no quality management certification, but their mother company does and all parts are shipped to Zriniski Germany before being shipped to customers. They are going to get into manufacturing implantable medical devices such as metal plates, and vertebrae. This will require a separate facility and a more controlled environment and quality inspections by third parties.

### 12) BHS Corrugated

Mr. Ante Beljan, Manager  
Tel 042/684 305  
[ABeljan@bhs-corrugated.hr](mailto:ABeljan@bhs-corrugated.hr)  
[www.bhs-corrugated.hr](http://www.bhs-corrugated.hr)

BHS is a sister company of BHS Germany, BHS Croatia assembles production lines for the production of corrugated cardboard. A single production line takes 8 weeks to

build. At any one time they work on up to three production lines. Each production line can sell for up to 12 million Euros.

They source 40% of all parts locally through 5 to 6 main local suppliers. Main problem with suppliers is their productivity level. The technologies they use are old and their working capital is low, many are going bankrupt. All of their suppliers are ISO 9000 certified, and they have worked with them for a while now and the suppliers are said to deliver good quality parts. BHS Croatia, on a daily basis has engineers working with suppliers to ensure quality parts and prompt delivery.

The product for the EU market has to comply with several EU directives including the low voltage directive, the pressure vessel directive and machine directive. Their product is certified by TUV Slovenia. TUV Croatia could have done the certification but it turned it out to be more expensive as the local office would have to bring the inspector from German.

One of their Suppliers TMT d.o.o which makes the steam cylinder which has to withstand pressures up to 36.5 bars, gets its own product certification again from TUV Slovenia (EN 13445)

In terms of calibration, again all length measurement equipment is calibrated locally. Except for micrometers that have a precision of .001 mm are calibrated in Germany. (TUV requires that, as the University of Zagreb is a not accredited for this precision.) That level of precision is need on some rollers.

They have not needed any local consultants, since much of their needs are answered by BHS Germany.

### **13) Koncar –Electrical Engineering Institute**

Mr. Darko kittler –Head of Certification Department

Large company, > 10 K employees – This operation produces electrical components, transformers, generators and motors. They are ISO 9001 certified according to national system, no intentions for go for internationally recognized certification. But they do export their products into EU. Presently conform to New Approach Directivities for Low Voltage Devices and EMC. CE marking a problem, feels that they meet requirements but unable to obtain CE in Croatia.

### **14) Eurocable Group**

Mr. Tomisiav Hren – Production & Development Manager

Mr. Alen Andric –Director Quality Management

Company formed in 1999, started with 2 employees, now 115, runs four production shifts, annual sales > 40 million € Has ISO 9001 certification by DNV –recently has been recertified. The company produces electrical cable made of copper and aluminum, primary usage in building construction and telecommunications. Production line is fully automated. Some products have CE marking, this was obtained via Austria.

### **15) ESCO d.o.c.**

Mr. Ksenofan, General Manager

Mr. Marijan Muzar, Quality Management

ESCO is a producer of metal springs, one of the largest metal spring manufacturers in Croatia. 95% of their market is in EU. They are quality oriented organization, having been certified to ISO 9001, (Quality Management) OSHAS 18000 (Safety Management), TS 9000 (Automotive industry version to ISO 9000) and ISO 14000 (Environmental Management). They have both national certification and international certification. Recently renewed their certifications

## **Certification Bodies**

### 16) Bureau Veritas Zagreb

Mr. Goran Kliskic, Technical Manager

Tel 385 1 65 29 398

[goran.kliskic@hr.bureauveritas.com](mailto:goran.kliskic@hr.bureauveritas.com)

Bureau Veritas in Zagreb has 22 employees of which 16 are surveyors and Auditors. Their primary business is Marine Certification to BV classification system (65%), and quality management system certification, ISO 9000, ISO 14000, HACCP, OHAS 18000 (30%). They are not notified to do any CE marking. CE marking certification requests require assistance from external BV offices in France or Prague. In terms of access to labs, Mr. Kliskic thinks that calibration can be done locally; sample testing is also done locally even though labs are not accredited. Main concern he has is as Croatia nears accession to EU, the majority of companies that need to be CE marking are not CE marked, and to this day there is no certification body that is notified to do CE marking in Croatia

### **Croatian Metrology Society**

Prof. Dr. Mladen Borsic, Past President

Mr. Mladen Jakovcic, President

The Croatian Metrology Society is a voluntary association concerned with metrology, testing, accreditation and technical regulations. The Society is registered in the Register of Associations with the Ministry of Administration. The HMD is a non-profit making, non-governmental organization having about 300 members and about fifty laboratories as associate members. It is a member organization of the Croatian Engineering Association. *Objectives* of the Croatian Metrology Society are:

- to bring together parties involved in metrology and testing activities with the aim to improve profession, exchange of expertise and co-operation; concern for the members and protection of their interests;
- to improve metrology and testing infrastructure and to adjust them to the European practices;
- to promote the development of science, technology, human resources and publishing;
- to co-operate on scientific projects with recognized scientific organizations, both domestic and foreign, with other societies and related associations with the aim to exchange information and expertise;
- to observe the development of metrology, testing, standardization, accreditation and certification practice;
- Education in the field of metrology, testing and related activities.

Comment: This organization truly represents metrology activities in Croatia. I have personally know Mladen Borsic for many years and aware of the activities of the organization. It is internationally known that there is a “conflict” between this

organization and the National Metrology Institute. We could do a major service if we could somehow bring these two organizations together to cooperate in metrology activities that are of importance to the country.

### **Government organizations**

#### **State Office for Metrology**

Mr. Mirko Vukovic, Director

The Director is newly appointed (March 2006), he has been a long-time member of the staff. This organization is the National Metrology Institute, by law it is responsible for all metrology functions, Legal, Scientific and industrial. Until March of 2005, Croatian metrology was within the "State Office of Standardization and Metrology" The old organization fulfilled technical requirements of the entire scope of activities including standardization, accreditation, and all metrology functions, but this was not compliant with the European system requiring independent organizations, specifically in the area of accreditation and standardization. At present the State Office of Standardization and Metrology" has been dissolved, the new agency the State Office for Metrology has been created, with this new director, accreditation and standardization functions have been moved and new independent agencies with their own directors have been created. The State office is divided into two main bodies. The DZM is the in the National Metrology body dealing with scientific and industrial metrology, the HMI deals with legal metrology ie: weights and measures –these borders on consumer protection.

The national metrology system is fragmented and is going through a re-definition of its functions, activities and responsible. Examples: The State Agency for Metrology is an administrative operation only; there is not a national metrology institute. Local universities under an MOU operate, maintain and provide scientific metrology functions.

#### **Croatian Accreditation Agency (NAA)**

Ms. Biserka Bajzek Brezak, Director General (acting)

This organization is the National Accreditation Agency (NAA), as stated in the previous report, the HAA has over the last year been in process of restructuring, developing new procedures, to bring the national system in line with the European Accreditation Cooperation (EA), and international accreditation procedures. Much progress has been made.

- ✓ Organizational and operating procedures: ISO 17011 is the international standard that establishes the rules on how an accreditation body operates and details their functions. The HAA has been restructured and the present organization is in full compliance with the standard.
- ✓ As of January, 2006, the HAA is only accrediting laboratories in accordance with the international standard ISO 17025, the national standard is no longer used, again in line with international requirements.
- ✓ In November, 2005 the NAA was granted full membership in the European Accreditation Cooperation (EA). This is a major step toward achieving mutual recognition (EA-MLA) for testing, certification and accreditation activities. The NAA hopes to become a signatory of the EA by January, 2007.
- ✓ Major efforts are in place to train technical specialists to become recognized and qualified assessors to perform accreditation in accordance with international

standards. The staff of the HAA has increased from 7 to 17 members in 8 months; plans are to have 20 by January 2007.

- ✓ The NAA has entered into a formal agreement with the Ministry of Health to bring their laboratories into compliance with EU requirements. In addition, the NAA will train MOH inspectors to become accreditation assessors.
- ✓ The market demand for accreditation services is growing at the rate of almost 100% per year.
  - 2002 =19
  - 2003 =27
  - 2004=46
  - 2005=62
  - 2006 =63 as of end April, projected to be 100

### **Croatian Standards Institute (HNZ)**

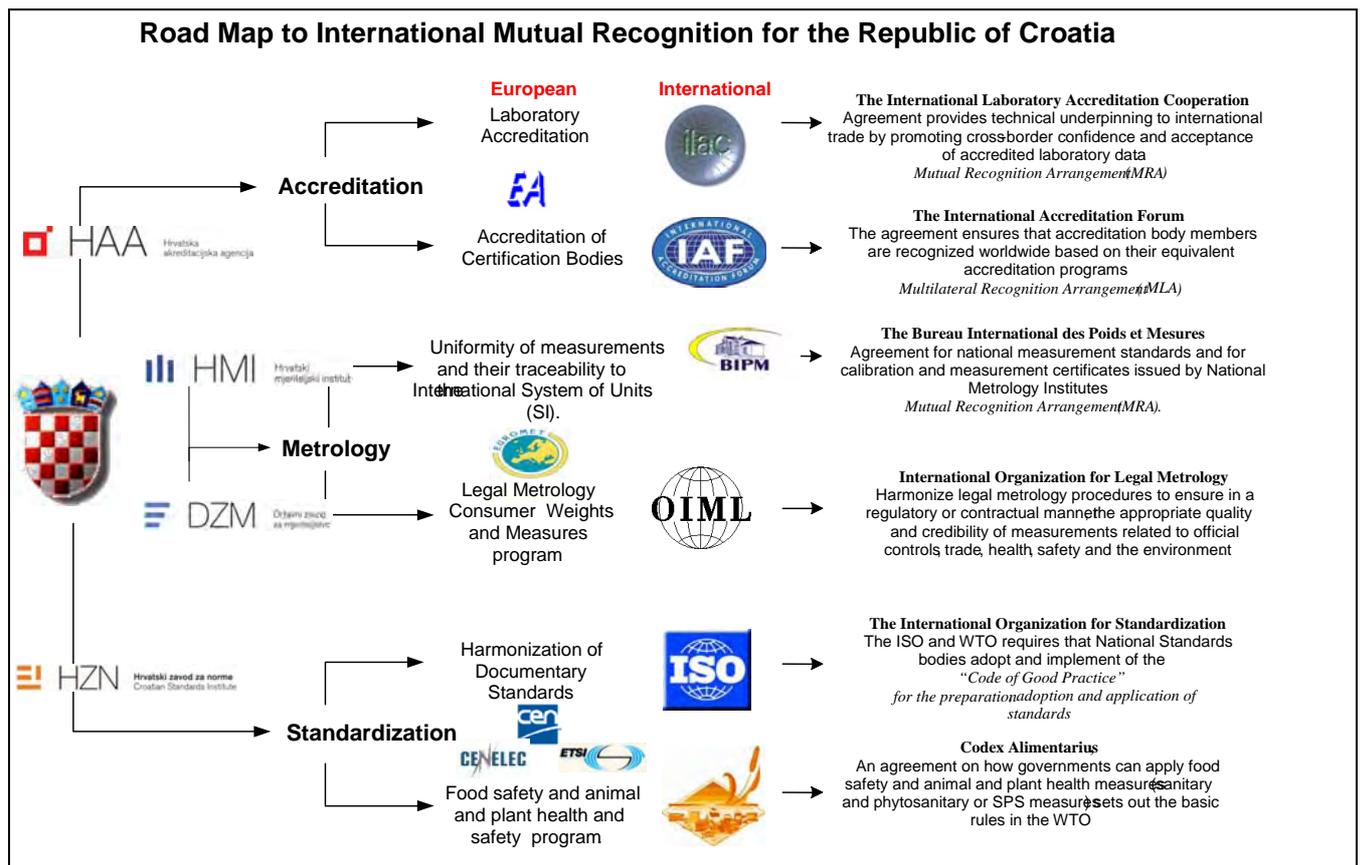
Ms. Snjezana Zima, Director General (acting)

As in the Accreditation Agency, the Standards agency has made great progress

- ✓ The National Standardization Body (HZN) has developed a “Standards Awareness program” promoting benefits of standardization in trade facilitation- There have been 340 private organizations that have become voluntary fee paying members of the HZN in 6 months.
- ✓ The HZH has become an associate member of the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). The HZH through support of the EU CARDS program is in process of becoming a full member of both of these organizations.
- ✓ 3,000 of the 12,000 documentary standards left over Yugoslavian times have been made obsolete – there is a plan to continue this effort and remove thousands more, assistance is needed here, we have been asked to participate by comparing these old standards to new international standards and make recommendations for revision, replacement or make obsolete.

Note: The recent activities of the three National MAS-Q organizations in participating as associate members and members of these various European organizations is a major step in achieving mutual recognition for testing, metrology, accreditation and certification activities in Croatia. This will minimize and in many cases eliminate re-testing and re-certification requirements. It will reduce cost to SME's and eliminate many non-tariff barriers to trade and market access delays. The next step will be to achieving Mutual recognition at an international level –see diagram below.

Recommendation: ESP activity support and provide assistance to these Croatian MAS-Q agencies in their quest for achieving international recognition.



**World Learning Center – USAID**

Ms. Cynthia Rogers –Country Director

Ms. Morana Kovacevic - Program Officer

Ms. Ondian Obradovic –Program Assistant

The following is a memo provide by Cindy Rogers

*Summary of the issues we discussed in the meeting for up coming study tour.*

*We will aim for the week of September 18, with a Sunday departure and return the following Saturday. Proposed meetings could begin in Slovakia on Monday, Paris on Wednesday, and England on Friday. (Ed could then travel back to US from England). Travel days Tuesday/Thursday, with some room for meetings if needed.*

*Ed will contact organizations, set the meetings, and at some point prepare the agenda. He will arrive in Zagreb in time to attend the pre-departure orientation meeting, will facilitate the meetings during the training, and will also follow up with the group post training to ensure that their „action plan“ (the lessons learned report they will prepare) will be done. He will also recommend participants for the training.*

*Morana and Ondina will reserve the hotels; based on recommendations from the host organizations (Ed will ask them when he contacts them). Arrange for airport/hotel van transport. Reserve airline tickets (Paris to London could be by train, we will check on this).*

*We need to have the names at least one month prior for the reservations, but Ed will try and have them by mid-July.*

*Issues to resolve:*

*A person should travel with Ed and the group to do the logistics. This can be an ESP staff person or World Learning can either send a staff person or hire someone to do this. (Jim, you let us know what you decide) English language: We either have to language test the group in our office or Fred would have to sign a waiver. We will check with Fred to see which he prefers. He might be willing to sign a waiver based on Ed's recommendations if Ed meets with them and confirms they speak English. Ed will also double check that the Slovaks will speak English.*

*Per Diems: We usually pay 75% of USG rates. We will check the rates and determine if this will be adequate or if we should pay the full USG rate.*

*Forms: We will need the „nominator section“ completed by ESP. We gave Ed and Hana samples. Participants will need to complete a bio-data form, which we also provided samples of. We will also ask for their CVs so that this information can be provided to the host organizations. We also gave Ed and Hana samples of the Action Planning forms, and explained how Action Planning is linked to our Small Grants program (grants of \$5,000).*

*Monitoring Call: We explained that we are required to conduct monitoring calls with the group while they are in training.*

*Evaluation: We explained that we will ask the person doing the logistics to have participants complete the evaluation forms on the last day.*

*Training Implementation Plan (TIP): We explained that this is a document that has the participants listed; full daily agenda, all flight and hotel information, all logistics, plus the budget. USAID has to approve this at least a week prior to departure (Cindy, Rebecca, Fred, Brad). We will work with Ed to get the information needed to put this document together.*

*That's all I can think of. Please let me know if I am forgetting anything. We are delighted to work on this with you, ESP and Ed's role is making this one a „peice of cake“ for us!*

## **Present activity**

Target date for tour: Week of Oct 16 Or 23<sup>rd</sup>

EN will be meeting with representatives of the host organizations week of Aug 6(during NCSL conference in USA) to finalize meeting agenda and arrangements

## **Participants:**

Preliminary list of participants for the European tour. This list is subject to change, major factor is the dates for the tour. I'm trying to get agreement with the host countries and the participants, there are some conflicts and we might not be able to satisfy everyone. Hopefully we can get agreement soon, at present we're looking at mid October at earliest.

I'll keep you all posted, I intend to pick a date ASAP, and shortly there after lock-in the final list of participants.

1. State Office for Metrology - Mr. Mirko Vukovie, Director
2. The Croatian Accreditation Agency- Ms. Biserka Bajzek Brezak Director (acting)
3. The Croatian Standards Institute - Ms. Snjezana Zima, Director General (acting)
4. The Croatian Metrology Society - Mr. Mladen Jakovic \_President
5. Croatian Chamber of Economy-Center for Quality- Mr.Trpimir Zupic, Managing Director
6. ESCO D.O.C - Mr. Ksenofan, General Manager
7. Croatian Exporters Association - Mr. Dubravko Miholic -Secretary General
8. Ministry of Economy - Mr. Leo Begovic - Assistant Minister

Other possible candidates - individuals to be appointed

1. Croatian Employers Association
2. National Competitiveness Council
3. EURO-Cable Group
4. Palace DelkattesE
5. Feroimpex

**Croatian Chamber of Economy –Center for Quality**

Trpimir Zupic, Managing Director

A government agency which requires all companies in Croatia to become a member, membership fees are based on the size of the company. The agency publishes a catalog of quality products produced in Croatia. The products selected appear to have no technical basis for being chosen. The positive point of the agency is that they sponsor many seminar and workshops on quality and related activities. (Certification and accreditation)

They provide services for a fee, pricing lower than private sector firms, they train their own people, and there are 18 local offices in the country. Appear to have well qualified staff.

They are in favor of participating in our proposed “Center for Excellence”. They see a need and do not consider it competitive.

**“Center for Excellence”**

Based on the team’s findings, we recommend that USAID through a Public-Private Sector Partnership Program with key stakeholders help create a “Standards Awareness Information Center” It is recommended that the center become department within the Croatian Standards Institute. This is a natural fit, since the perceived activities of the information center are directly related to the normal activities and functions of the Standards Institute. Discussions have taken place with the head of the Institute, a positive dialog has commenced.

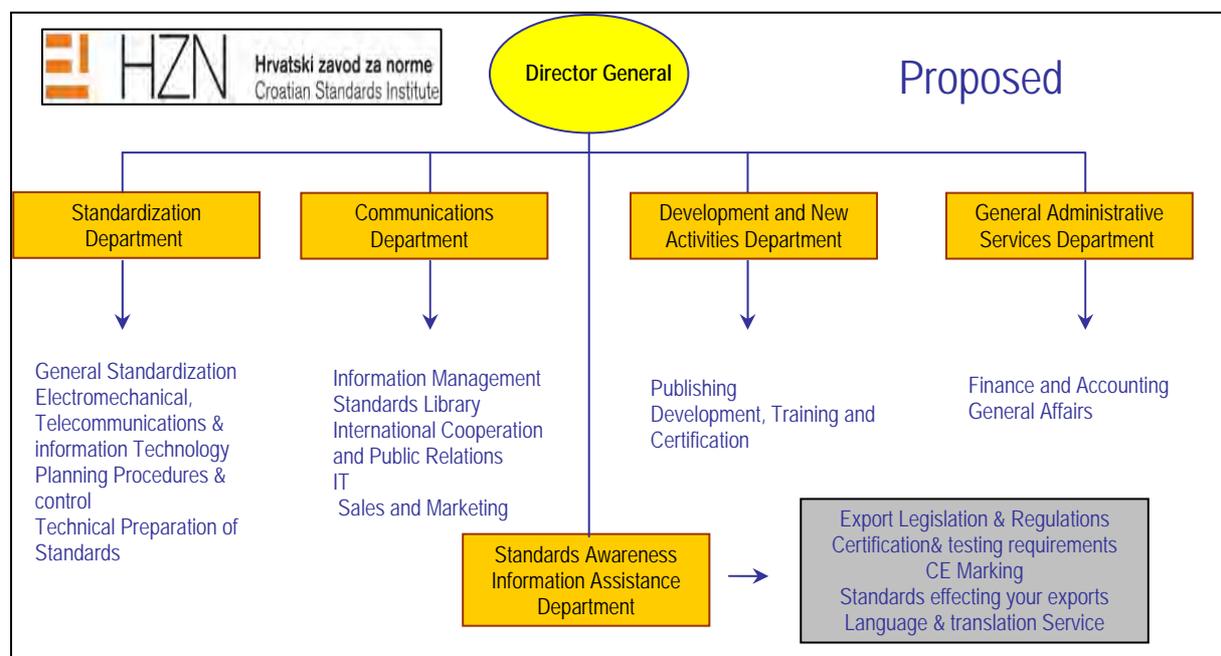


Figure 2 –proposed Standards Awareness Information Assistance Department within the Croatian Standards Institute

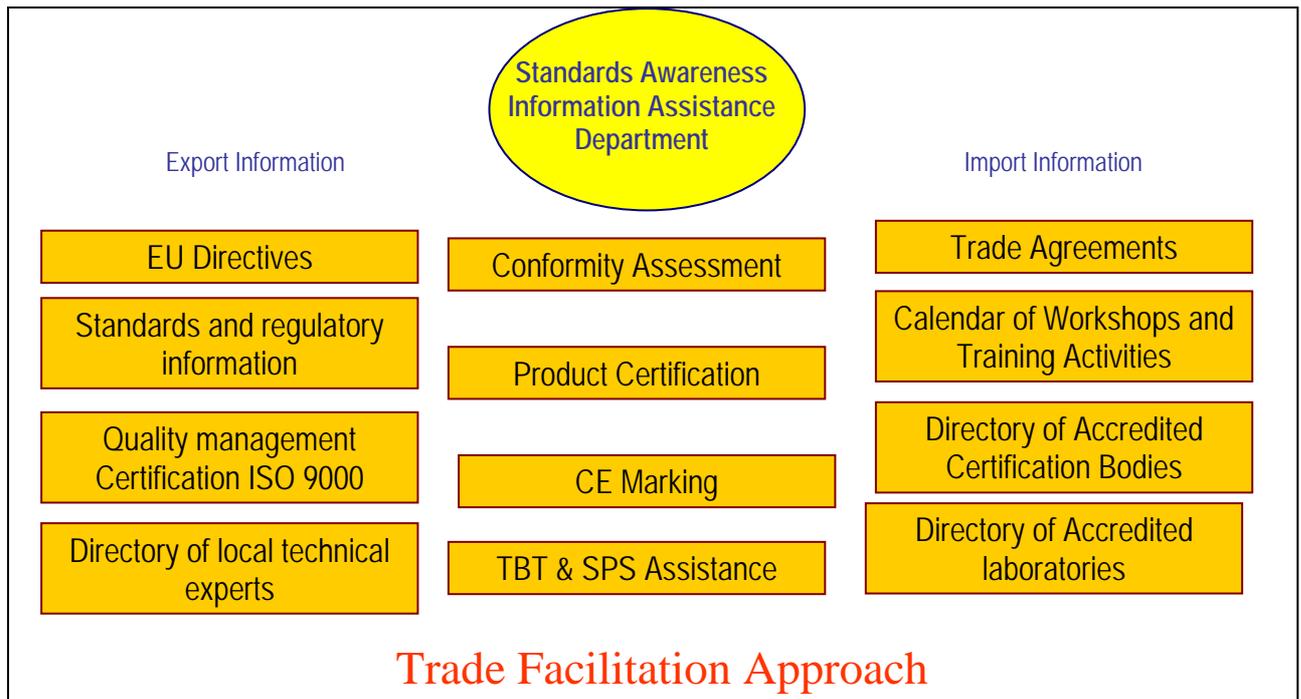


Figure 3 –functions of the Standards Awareness Information Assistance Department

- The Standards Information Center will provide quality Information on:
  - Market entry requirements per industry, product category and country
  - Sources for consulting and training on requirements. (Croatian Calendar of Quality related Training and Seminars)
  - Sources for accredited testing, inspection and certification
  - Sources for Equipment Calibration
  - Contact information for export and import license issuing agencies by country

Budget: The team estimates that a budget of \$200,000 over two years will be required.

Note: The Croatian Metrology Society has expressed a sincere desire and interest to have the information center located within their facilities. The team visited their offices and met with their senior management. The society is our second choice; it is recommended that they be actively involved in the center activities within the Standards Institute. The metrology Society has experience in providing training and awareness workshops. It would be a valuable asset to the Standards Institute if there could be a formal arrangement between the two organizations for cooperation.

### **Proposal from the Croatian Metrology Society**

#### ***Croatian Metrology Society***

*Croatian Metrology Society, Berislavićeva 8, 10000 Zagreb*

*Phone: +385 1 48 72 485; +385 1 49 21 074; Fax: 48 72 487*

*E-mail: [hmd@hmd.hr](mailto:hmd@hmd.hr)*

*URL: [www.hmd.hr](http://www.hmd.hr)*

#### ***Proposal***

#### ***of the establishment of a “MAS-Q Center for Excellence” at HMD***

*HMD is interested to become the MAS-Q Center of Excellence“ in accordance with the document,,Scope of work development of business plan and related programs for a quality management center“ proposed by US expert Ed Nemeroff and USAID staff. HMD has a good*

*experience in organizing national and international training courses and gatherings, and has a fine reputation in Croatia and abroad. With the support of the USAID it will become a regional centre for the dissemination of knowledge in the field of metrology, accreditation, standards and quality (MAS-Q) infrastructure.*

#### **Organizational Structure of the „MAS-Q Center of Excellence“**

- *Ownership: Non-profit, non-governmental organization.*
- *Location: at HMD, Berislavićeva 8, Zagreb.*
- *Staff: three employers of the HMD; foreign and Croatian experts; one or two workers more if needed.*
- *Management Board: Representative of HMD, USAID, and National Competitiveness Council.*

#### **Objectives**

- *Become the Regional “Center of Excellence of MAS-Q” capable to:*
- *Promote the European Foundation Quality Management Excellence Model. Training on TQM methods and tools. Provision of Benchmarking & Best Practices information.*
- *Act as inquiry point on applicable regulations & standards, and other metrology services.*
- *Prove up-to-date information on EU and GoC funds supporting quality initiatives.*
- *Facilitate delivery of education on quality standards.*
- *Advocate for systemic change & policy, and acting as the business community’s spokesman on MAS-Q.*
- *Provide Technical Assistance for development of conformity assessment service providers for mandatory and voluntary certification.*
- *Brokering of QM consultants and conformity assessment services, and monitor of the quality of services.*
- *Monitoring of industry competitiveness.*

#### **Activities**

- *The study: Identification and prioritization of the Croatian market’s needs for modernization of the MAS-Q infrastructure, information and related services.*
- *Organization of training courses covering different aspects of MAS-Q.*
- *Organization of National Conference together with 20<sup>th</sup> International Metrology Symposium – presentation of the MAS-Q Center of Excellence.*
- *Creation and editing of the internet page as the information centre.*
- *Develop E-learning center for distance learning through internet.*
- *Publishing the teaching material and proceedings for training courses.*
- *Development of a business plan leading to start-up of operations in 2007.*

#### **Partners**

*Foreign partners:*

- *USAID*
- *“World Learning”*
- *„Work Place Training – WPT“*
- *...*

*Croatian Partners:*

- *State Office for Standardization*
- *State Office for Metrology*
- *National Competitiveness Council*

- Faculty for Electrical Engineering and Computing
- Metrology Consulting
- Society for Quality Management
- Croatian Chamber of Commerce.

### **Needs**

- Equipment: computer (server) in HMD; software for E-learning management; two personal computers; two projectors
- US and European experts at disposal
- Training for HMD staff and some selected specialists (“teaching the teachers”)
- Joint seminars with World Learning and WPT for Croatia and the Balkan Region
- Copy, translation and publication rights
- Translators
- Communication and internet costs
- Office costs.

### **HMD Background**

**Croatian Metrology Society (HMD).** HMD is a non-profit making, non-governmental organization having about 300 individual members and about fifty testing and calibration laboratories, private and public as associate members. It is a voluntary association concerned with metrology, testing, and technical regulations.

**International Position.** • Corresponding member of EUROMET (European Collaboration in Measurement Standards); • Stakeholder Member of ILAC (International Laboratory Accreditation Co-operation); • Member of NCSL International; • Associate Member of EUROLAB.

**Activities:** See Attachments A, B, and C.

Attachment A: Activity Report of the Croatian Metrology Society amid two assemblies (2004–2005)

Attachment B: Plans for 2006

Attachment C: Detailed plan of seminars which are going to be held in the first half of the year 2006.

### **Recommendation**

ESP staff needs to continue the dialog with the heads of Standardization and accreditation concerning the implementation of the Standards Awareness Information Center” Ms. Zima did commit to providing us with her suggestions in writing for the center, please follow up on this. After reviewing her comments we can set a plan to go forward.

*End of report*