

Health and safety – Latest findings

Knut Soraas, EUROBITUME, Brussels (B)

Good morning, all of you!

I am pleased to have the opportunity to speak to you this morning about the latest progress on the Health, Safety and Environment (HSE) side. HSE is always on top of our agenda, this year as it was also in September last year at your meeting in Vienna. This confirms the importance and priority, which the Executive Committee of EMAA wishes to inspire amongst its members. We applaud this leadership.

You will recall from last year that I spoke about three business fundamentals that were needed to be successfully in place in order for the business to thrive:

- A license to operate
- The freedom and incentive to innovate
- An image to attract new employees

Today I will speak about the first one only, A License to Operate I will speak about the important work which has been done in our joint HSE group and some of their deliverables studies and my speak will be about Health related issues. Since last year, industry has not developed a lot of new, ground breaking health data. Our progress has been in the organisation of the preparations for the IARC Monograph and the design, funding and initiation of important studies as a part of those preparations, and I will spend more time on the what I believe is the most important single issue for our business today: The up-coming IARC cancer classification of bitumen and bitumen fumes and aerosols and what Industry is doing to prepare. Towards the end, I will also say a few words about a new legislative initiative, which is coming, REACH.

But firstly, let us briefly re-cap what our goals with these activities are, and look at some of the important deliverables which have been accomplished by our Joint HSE group.

Society rightly demands that our products and the way they are applied are safe to the individual both in situ and in the workplace and safe to the environment.

Attention to this requirement is a pre-requisite before we start work and before we are invited to the negotiating table. It is our "license to operate".

The HSE issue is worked at three levels, which is useful to keep in mind when defining our own roles and tasks. Very simplified, one can say that:

- Each supplier of a product has a responsibility for providing sufficient data and applicable labelling and warnings so that his product can be safely handled and applied. Of course, that also implies that he has to control his raw materials and production so that his information is correct for each batch he is supplying. This, in brief, is product stewardship.
- Worker Protection: Each employer has the responsibility for the safety of his workers that they can work safely with the material they use, the tools, the tasks, i.e. that they can do the jobs they are asked to do, safely over time. The employer will need data for the products provided to him by his suppliers for that.
- Authorities develop and install regulations to ensure that a minimum protection of the workers and the environment is established, and is applied by all. The absence of regulations does not exempt the employers and suppliers from their responsibilities. In the case of bitumen, there is no cancer classification at EU level, and bitumen is under so called self-classification. In other words, it is the responsibility of each supplier to classify the products he put on the market. To assist the industry, Eurobitume has developed a

guideline for the classification of bitumen and recommend that Safety Data Sheets (SDS) will be developed, even if the product is not classified.

Industry's responsibility to be active in asking questions and developing information in HSE related matters will increase in the future. That is why I want to say a few words about REACH at the end of this presentation.

Within this framework, industry has defined clear and simple goals and objectives. We want to:

- Provide relevant information to promote the safe use of bitumen
- Provide data to answer key health and regulatory questions
- Provide data that is accepted by the broad scientific community

The importance of the latter one should not be underestimated. Our information and advice should always be based on sound scientific data, which means we need to be open and transparent in our assessments and research studies. For example, only peer reviewed studies and material will be considered for the important IARC Monograph review for cancer classification.

It was in line with these simple goals and objectives that our joint HSE group was established a few years back, and we are pleased to see that important progress has been made.

Our joint HSE group has now developed, ready to be dispatched, three important documents about Mastic Asphalt

Two documents providing answers to questions, which are frequently asked about mastic asphalt. One of these is a simplified version aimed at the general public providing simple and easy to understand answers to general questions people ask about mastic asphalt health and safety.

- The other one is more advanced; it is a Specialist Advice for mastic asphalt suppliers and customers. It is designed for the mastic asphalt focal points to assist them in providing consistent and correct answers to more difficult questions often asked by users and other specialist groups.
- The third document, which is now ready for distribution, is a Safety Data Sheet, SDS for mastic asphalt. The SDS provides important information about the product for those who prepare it, store it, transport and apply it, or in any other way handles the product.

Do not be misled to believe the development of these three documents has been "plain sailing" even if they have been modelled after similar documents, which were already available for bitumen. Mastic asphalt is a preparation and is not the same as the substance bitumen; mastic asphalt is a blend of bitumen and a number of other components. Besides providing reliable and accurate information about mastic asphalt to their readers, the development of these documents have provided important learning to those involved, and mark a good start for the joint HSE group and represent an important step forward for the mastic asphalt business in the HSE field.

But the work is not finished by this, next to come, already started in fact, is the tying in to the Eurobitume Exposure Reduction Project which is aimed to provide specific advice on best practices in the field in order to reduce the exposure to bitumen fumes and aerosols, and, another quite important activity is the preparations for the IARC Monograph. I will spend some time explaining the IARC Monograph and what industry is doing to prepare.

Today, bitumen is not classified at EU level with respect to cancer:

- EU regulators [1993] deferred classification of bitumen, awaiting outcome of WHO (IARC) epi-study. IARC is the International Agency for Research on Cancer and is the branch of the World Health Organisation which develops cancer classifications

- German regulators - AGS - deferred a “local” classification of bitumen pending outcome of animal inhalation studies

This situation of awaiting better information and deferred decisions will of course not continue indefinitely, we have to bring it to an end. Authorities will eventually regulate, and it is in everybody’s interest that this is done on the best possible knowledge and sound scientific data. Industry has therefore designed and commissioned large and advanced studies to fill the data gaps, which have been identified.

I will only briefly mention the most important of these projects before turn to the IARC process for developing cancer classifications, the so called IARC Monograph, because that is probably the most authoritative one in the world.

Human epi-study IARC Nested Case Control, or NCC study

Does exposure to bitumen cause lung cancer in humans? You will recall that Phase I of this study found a small, but statistically significant overrepresentation of lung cancer in asphalt workers, but that a causal link to bitumen could not be established due to possible effects of confounding factors. I. In May this year Industry signed the contract to start Phase II of this study, the Nested Case Control study, in an attempt to Identify effects of confounding factors from Phase I. The study will take three years. Please note that this study is done by IARC, but a different part of that organisation than the one, which does the cancer classification. A watertight wall separates the two parts of the organisation.

Animal 2 year study Fraunhofer

Does exposure to bitumen fume cause cancer in animals? Identify dose response relationship, and threshold level for health effect. This study was started in March 2003; it is now running into its last 6 months period. No alarming results have been seen so far, but most of the analytical work remains to be done.

Animal mechanistic study Fraunhofer

Clarify possible mechanisms of action and provide data on possible biological exposure markers. This study is run as an integrated part of the Animal 2 year inhalation study. It is too early to predict results.

Human mechanistic studies BGFA

Link mechanistic work in animals with human exposure data. It has been a lengthy process to design the protocols and secure the funding for this project. As of mid this year there were still some unresolved issues, although there were good possibilities these can be resolved so that the project can be started and deliver in time to be considered for the IARC Monograph.

I will now turn to the IARC Monograph itself and how industry is preparing for it.

IARC is the World Health Organisation’s International Agency for Research on Cancer. It develops and issues cancer classifications on substances which by European and many non-European legislators are considered authoritative and therefore applied as basis for regional or national health regulations:

- The IARC Monographs have been the scientific basis in the past for EU classification decisions for Petroleum Products
- In the US, Occupational Safety and Health Agency (OSHA) views IARC determination as conclusive

The opinion of IARC is therefore of the outmost importance for the industry in EU as in USA, and we need to understand how and when it will be developed.

From the IARC web site, one can see that bitumen is a high priority item in the IARC program, and it is assumed that it will take place in 2007.

The date of the official review is selected well in advance and posted on the IARC website. The year 2007 is currently posted, but there is no guarantee this will not change. Further, we are not sure how long time in advance the review date will be announced, practices have been variable. However, two years ago we received signals that IARC may await important

scientific data to become available through deliveries from important research. Our current planning basis is therefore that the Monograph will take place in 2007 when the IARC NCC and the Fraunhofer Inhalation studies are planned to deliver.

A group of scientists knowledgeable in the subject matter to be reviewed is selected by IARC approximately 6 months prior to the meeting. They are primarily experts on cancer, not necessarily on bitumen.

Industry is usually allowed one or more observers at the review. They participate fully but do not vote.

During the review, drafts of the various chapters are finalized and a classification is reached by simple majority vote.

The Monograph review is done on a global basis. Information about the product to be reviewed is solicited from all over the world, its manufacturing, composition, use, exposure situations and exposure data. The assessment is a global assessment, not regional, not national; it is a global assessment of the carcinogenicity of bitumen. Note that their assessment is an assessment of the hazard, not the risk. Which means that protective measures in the work place to reduce risk of cancer through exposure reduction measures is irrelevant, it is the inherent hazard of the subject product that is assessed.

For all sections of the monograph other than Chapter 1 (Production, Use and Occurrence) only peer reviewed scientific literature is considered. This is a very firm rule. Our preparations need to reflect this point, which means that all the scientific data we generate to fill gaps in the knowledge base need to be developed, reported and also peer reviewed before the monograph takes place. The peer review process itself will often take one year.

Industry is often asked to provide information to complete Chapter 1 and this information need not be peer reviewed. Chapter 1 is a description of the industry, how is the product manufactured, used, and its occurrence. Chapter 1 is often put together by an external consultant. It is natural that industry itself prepares by making sure that relevant and true data is available. How, or to which extent industry will be asked to provide such information, is not clear in the moment, but it is wise to ensure it exists and is available to all interested parties.

As the focus of the monographs is human health, epidemiology data are deemed most significant. The full monograph is published by IARC in a book. It will include all the relevant data and the final assessment.

Industry has formulated three different tasks for the Monograph preparations:

- Chapter 1: Industry description. Since we know that some of the data that will be looked at by the scientists panel dates back to times when industry practices were different, we need to outline these practices and describe the changes that have taken place over time. Since the IARC review is global, regional differences must also be outlined. The challenge in Chapter 1 is to balance the amount of information to provide and to structure it so that it is easy to read and use for the scientific team in the context of the Monograph. A too large amount of details, however accurate, may not only be unnecessary, but may also reduce the penetration of the important information and as such reduce the total value of the Chapter 1. Chapter 1 needs to be comprehensive enough to provide all the important messages about the industry, while short and simple enough so that it is read and understood. Finding this balance and agreeing upon the main messages is our challenge.
- Bibliography: Quite a lot of literature and scientific data have been written over the past 10-20 years on bitumen and health. It can be difficult to find it all, but various sources exist and also some literature lists. The Bibliography is about developing one comprehensive list available to all, also IARC. One main purpose is to identify gaps in the

literature and data, which is available to and will be studied by the monograph scientist team. There may be knowledge or data that we think should be important to have, but which for some reasons may not have been developed yet. We may still have time to develop such data by new research, or simply find them amongst the large amount of unpublished data. And it is important to review all existing papers; we need to ensure that industry experts are aware of all the literature and data, which are available. A complete and unbiased database may also be adopted by IARC as a useful tool for the monograph scientific team.

- Communication, internally between the industry sectors as well externally, between industry and the outside world, is so important that it has been identified as a separate task. We need to communicate industry practices and all other information we believe is important to be included in Chapter 1, we need to express views on existing scientific data and communicate new data which will be developed. There are various ways of doing this; we still have to decide on which ones will serve us best. And above all, industry needs a good communication between the various business sectors and geographical regions to reach agreements on basic issues related to our preparations. A consistent industry approach and messages are imperative for a fair assessment of the carcinogenic potential of bitumen by the IARC Monograph.

The IARC Monograph is a global exercise and industry is preparing on a global basis.

Eurobitume has taken a natural leading position in the industry preparations. We are working closely with all the most important industry sectors in our preparations, in Europe, European Asphalt Pavement Association (EAPA), the Bituminous Waterproofing Association (BWA), and yourself, the European Mastic Asphalt Association (EMAA), in USA the Asphalt Institute (AI), the National Asphalt Pavement Association (NAPA) which is the contractors association in the US, similar to EAPA in Europe, the Asphalt Roofing Manufacturers Association (ARMA) and the National Roofing Contractors Association (NRCA). We have also liaisons with the Australian Asphalt Pavement Association (AAPA) and with Southern African Bitumen Association (SABITA). The main trust of the preparations will be by Eurobitume and the AI, who, after all, manufacture the product to be classified. But specific information about bitumen applications will have to be provided by the bitumen users.

I will speak a little bit more about Chapter 1 because that is where EMAA input is expected.

This chart is a simplified block diagram showing the manufacture and application of bituminous products.

The box to the left is called Bitumen Manufacturing. Bitumen is manufactured in refineries, and when done according to the description in one of the nine EINECS entries, the product is what we call a bitumen substance. The bitumen substance can be a pen grade bitumen, an oxidised grade, or a soft grade. Chapter 1 will include some description of the manufacturing process and the characteristics of the bitumen substances.

Most of the bitumen substances go directly to a user for his application as shown by the big arrow. Some typical applications are shown in the box on the right hand side, paving, roofing, other waterproofing, mastic, the list is really quite long, only the most important are shown here. Please note that the product applied on the road or the roof, is not a bitumen substance. In these applications, bitumen is always blended, and what is applied is a preparation in which bitumen is only a component.

Some of the bitumen substance manufactured in the refineries goes into some blending process before being used. Through blending processes products like soft bitumen, cut backs, polymer modified binders, emulsions and bitumen paints and primers are produced, to mention only a few. These products are not substances; they are what can be called bitumen preparations and derivatives.

Some of the most important data, which the IARC Scientific team will study, is worker exposure data and the resulting effects on the workers. They will study the effects on the

workers, in the past and now, from exposure occurring during the application of bituminous preparations, which is on the right hand side in this diagram, in order to classify the substance bitumen which comes out of the refineries, to the left in this diagram. In order to do that, they need to understand what goes on in between, from the bitumen leaves the refinery until the worker is exposed, in order to understand the exposure effects which they see. That has to be explained in Chapter 1, and that is why it is so important for industry to ensure that relevant and true information is available about our practices, current and past, for the different application segments.

Most of the bitumen, which is used by our customers, is unblended, in other words a bitumen substance, especially in the road segment. But there are important exceptions, many workers in the EPI study database which the IARC Scientists will study, have also been exposed to additives which have been blended in, or have been exposed to other materials, some of the most important ones are mentioned in the diagram: Emulsifiers / Polymers / Adhesion Agents / Fluxes / Solvents / Filler / RAP / TLA / Coal Tar...

This chart describes the over-all picture and the framework for Chapter 1 and you may rightfully now ask who is going to explain all this to the scientists, who is going to do what, and when, who is putting all this together, and lots of other good questions. I do not pretend to have all the answers yet, but let us start with the simple things.

Only the refiners can explain the refinery processes and the characteristics of the bitumen substance, which means that Eurobitume and the AI will be in charge of the refinery information in Chapter 1. This is already indicated in the diagram.

On the other side of the diagram you have the applications, and only the contractors can describe those properly, which means EAPA and NAPA will have to do something on paving applications, and only the mastic asphalt people can describe the mastic asphalt applications and practices.

The box in the middle, Intermediate Blended Products, the answer is that we do not really know yet, probably AI and Eurobitume will have to take a lead since these products are manufactured by refiners as well as contractors.

The need for IARC Monograph preparations and the role of EMAA has been brought to the attention of and discussed in the EMAA & Eurobitume Joint HSE group as well as the EMAA board. It was agreed by the Joint HSE group to start collecting already existing information about mastic asphalt applications and practices. It is expected that a lot of the descriptions, which are needed for Chapter 1, actually has already been written and can be found in handbooks, product specifications, standards or brochures. We talk about description of practices, before and now, products and formulations/composition, application, and exposure data. No need to start from scratch, the group will find out what we have, how it fits the needs, and go from there.

Same with the bibliography. The Joint HSE group will look at the literature lists we already have and ask if there are some important studies or data, which is not there. Does any member have data of interest in their files, which is not known to the public? No need to design studies to generate new data if we have data already that can just be published.

Our Joint HSE Group has already started this work, they met in Marseilles for a full day just before this meeting, and their efforts fall within what we can call the industry Global Monograph Preparation Program.

I have spoken about some of the preparations, which are underway for the IARC Monograph, under the headings Chapter 1, Bibliography, and Communication. This timeline shows some of the sub-projects, the yellow bars, and decision points, the red stars.

In its preparation, Industry is working under the assumption that the Monograph will take place mid 2007. Some time before, may be one year before that, IARC will start their preparations, start collecting information, that means mid 2006. If industry wants information about itself and its practices to be publicly available by then, such information needs to be finished and ready for communication by end 2005. That is what we have shown on this timeline for Chapter 1.

A first version of the Bibliography has now been put together and will assist Industry to identify the gaps in the knowledge base, which needs to be closed. New projects for that purpose need to be identified and decided upon shortly in order to deliver peer reviewed results in time to be considered by the Monograph, i.e. by mid 2007. You see that some projects have been identified on the chart:

- The BGFA Human Exposure study
- Fraunhofer 2 year animal inhalation study
- The IARC NCC
- and some possible American paving and roofing studies

Under Communication, four sub-projects have been identified, you will recognize the communication of Chapter 1 here, and communication of the bibliography. You will also see that the idea of a Health Forum is being studied as a means to communicate.

Our plans and timeline are shared between all the industry organisations. However, both plans and schedule will evolve as we move forward. Our process is open, all industry organisations involved will be consulted, heard, and kept informed. Everybody cannot, and should not, participate in everything. But it is important that all participants see and understand the overall picture, what we are doing and why. We firmly believe that the open and transparent process we are putting in place is the best way to achieve this, and that we will be successful in our preparations for the IARC cancer classification of bitumen.

Let there be no doubt that the HSE issue is high on everybody's agenda in EU, and the issue is not likely to go away even if a successful outcome of the IARC cancer classification. It is realised though that the current EU HSE regulations for the Chemical Industry is quite complicated and neither as efficient nor as effective as desired and in order to improve the situation, the Commission has developed a proposal for a new Regulation, it is called REACH.

I thank you for your attention and the opportunity to come and tell you about the over-all situation in this important area, and I will appreciate to answer any questions you may have. REACH stands for

- Registration
- Evaluation
- Authorisation and Restriction

of

- Chemicals

The proposal replaces the current ineffective and inefficient system of about 40 existing Community Directives and Regulations on chemicals with different rules for existing and new substances, by a single regulation with one consistent approach to controlling risks from both existing and new substances.

It aims at maintaining and enhancing the competitiveness of the EU chemicals industry as well as the protection of human health and the environment. It contains rules about chemical substances on their own, in preparations and in articles.

To adequately control the risks arising from the manufacture, import, placing on the market and use of substances, the RAECH proposal reverses the burden of proof from the authorities to industry for gathering information on chemical substances and using this information to assess the safety of chemicals and select appropriate risk management measures. To reflect this new approach, the Regulation states in Article 1 that it is based on the principle that it is up to manufacturers, importers, and downstream users of substances to ensure that they manufacture, place on the market or import or use such substances in a way that does not adversely affect human health or the environment.

It is too early to explain exactly how REACH will impact our HSE work, but it seems clear that some additional work or research may be required, especially on the possible effects of bitumen on the reproducibility of living organisms, and that there is an increased liability put on the shoulders of the industry. If the companies or individuals for that sake, being manufacturers, importers or users of a substance do not have sufficient information, that individual or company is responsible to find out or develop all the information or take all the measures which may be needed in order to ensure that human health and the environment are not adversely affected.

I thank you for your attention and the opportunity to come and tell you about the over-all situation in this important area, and I will appreciate to answer any questions you may have.