PRODUCT APPROVALS AND CERTIFICATION:
GETTING NEW PRODUCTS TO MARKET

Jeanette A Drysdale
Consultant
PO Box 72 275
Papakura 2244
Auckland
New Zealand

Tel: (+64) 9 299 9435
or (+64) 21 939 728
Fax: (+64) 9 299 6434
Email : drysdale_ja@xtra.co.nz
PRODUCT APPROVALS AND CERTIFICATION:
GETTING NEW PRODUCTS TO MARKET

Jeanette A Drysdale
Consultant

Introduction

The on-going acceptance of preservative treated timber and wood products as an acceptable and reliable material is important to the future of this industry. However this will increasingly demand chemical suppliers and timber treaters to be mindful of the performance requirements for their products in-service. Treated products must meet or exceed the requirements of national legislation or regulations in each country. In addition, there may be desirable attributes such as appearance, dimensional stability, health, safety and environmental related factors that satisfy the expectations or influence the choice of timber products by users. The user groups include merchants, builders, and home owners. Companies seeking an approval of new or modified timber preservative products tend to focus on the durability (to biological agents) properties. However achieving fitness for purpose for timber in-service covers a far broader performance requirement, the significance of which often appears to be overlooked.

Approval or certification systems by external independent organisations recognise manufacturer’s proprietary products, processes or systems as being fit for the intended use as defined in Building Codes. This is a means of differentiating from generic specifications in standards and can give consumers more confidence in what they are purchasing. However there is a risk of ‘self-certifying’ quality assurance schemes only covering part of a process or a specific product property. For treated timber, an assessment of the product through to installation at a construction site and then in-service is also desirable. The handling and storage of the product, painting, gluing and corrosion characteristics, and compatibility with other materials commonly used in construction, may be significant factors affecting performance in the expected in-service conditions. These factors can be just as critical fitness for purpose criteria as protection from biological deterioration agents. It is noted that ‘man-made’ products seem to be more likely to have been through a product certification scheme and have an Appraisal document or equivalent. There is an increasing variety of differentiated preservative treated timber options, often with the same active and within the same Hazard class. It begs the question as to whether it is acceptable for such products to be ‘tested in the market place’ for acceptability/performance.

This paper provides an overview of existing approval systems and how product certification may become an increasingly favoured option. Regulators and user groups such as architects, builders and approving authorities, can be expected to seek verification or an assurance of fitness for purpose for products.
Approval of preservatives

In New Zealand, any ‘substance’ that has hazardous properties exceeding the thresholds as set out in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 is required to be approved under the NZ Hazardous Substances and New Organisms (HSNO) Act, 1997. This Act has replaced the Dangerous Goods Act 1974, the Explosives Act 1957, the Pesticides Act 1979, the Toxic Substances Act 1979 and the Regulations that went with those various Acts. Timber preservatives and Antisapstain products (trade name products) previously approved under the Pesticides Act 1979 had already been transferred in 2004. In July, 2006, the Environmental Risk Management Authority (ERMA) completed the transfer of remaining substances notified prior to July 2001 over to the HSNO Act. These legislative and regulatory changes have had a significant impact on the approvals of new timber preservatives and antisapstains in New Zealand and how these products are required to be managed in the wood protection industry.

Perhaps the most significant change for New Zealand under the new regime of the HSNO Act is that any approval is for a ‘substance’ and this is not necessarily for a specific trade-name product. A substance may be a single chemical component, e.g. a new active, or a mixture, e.g. a formulated product, and can include a concentration range for the active(s) and/or other formulating chemicals. Furthermore the specification for a formulated product can be quite broad (provided hazardous classifications are same) so the ERMA register approval number can cover more than one commercial product being offered into the wood protection market. This change offers flexibility to the chemical manufacturers which is undoubtedly welcomed. However another aspect of the approval is that once a substance is on the ERMA Register, a request can be submitted to determine if the formulation of another supplier (importer or local manufacturer) or of a potential new product is covered by any existing approval. This has significantly reduced the timeframe and cost for new entrants or the introduction of new products. A down-side is for those companies that invest over many years to prove a novel preservative system is that while confidential information in the initial application may be protected, there is little protection from the immediate market entry of image or look-a-like products unless there is patent protection.

The situation in Australia is somewhat different and follows a more traditional approach. Active constituents, i.e. actives, must be approved (and approvals are specific to a manufacturer/site) unless on the exempted chemical list, by the Agricultural Pesticides and Veterinary Medicines Authority (APVMA). Formulated (end-use) products are then approved by the APVMA and these are for trade name products and are again specific to the registrant. Outcome for a registered product is an approved (stamped) label. Any other supplier wishing to offer identical or similar products must also go through an approval and registration process although the timeframe and data requirements are less. Applications for new wood protection products are required to be supported with efficacy data. This is unlike New Zealand where biological efficacy data is not required for approval under the HSNO Act.
Efficacy data

Demonstration of the biological efficacy of a preservative whether an active, formulated mixture or protection system, is a critical factor in getting approval for inclusion in the preservative Standards relevant to both countries. While it is desirable to have long term data from in-service performance, it is recognised that the timeframe is commercially unrealistic. Accordingly an efficacy data package that may encompass laboratory and accelerated field tests is typically prepared for review by the approving authority/committee. Guidance on acceptable test methods for different Hazard classes and biological hazards is set out in an Australasian Wood Preservation Committee (AWPC) document. However these are the minimum requirements and more comprehensive data is desirable and may be critical for approval of novel new systems.

A key criterion for assisting the data assessment is for the benchmarking of performance of the candidate preservative to a known approved preservative of similar type, i.e. water based or solvent based and already approved in the target Hazard class(s). A dilemma of this approach is that the performance in short term trials (laboratory and accelerated field trials) may not lead to a valid extrapolation of long term performance of the candidate preservative in-service. This has implications when considering the users’ requirements and expectations for performance of treated timber products under the minimum performance requirements of either country’s Building Codes.

Preservative Standards

The respective Australian and New Zealand Standards organisations manage the development of Standards on a variety of products and services. Timber treatment standards may define specifications or test methods for checking compliance, or processes. Committee members would be expected to represent interested parties to ensure the resulting document meets the expectation for quality, practicability and usability. Compliance to standards can be voluntary but is mandatory when cited in legislation or regulations such as the respective Building Codes.

NZS 3640:2003 Chemical Preservation of Round and Sawn Timber and subsequent amendments is the timber preservative specification applicable to solid wood products in New Zealand. AS1604.1:2005 Specification for preservative treatment- Sawn and round timber is the equivalent Australian Standard. However other products; namely reconstituted wood-based products, plywood, laminated veneer lumber (LVL), glued laminated, all fall within the requirements of AS/NZS 1604 Part 2 to 5 inclusive and apply to both New Zealand and Australia.

Generally the wood preservation standards list the approved biologically active compounds (or combination of actives) for the hazard class(s), the minimum concentration required in the timber, define the minimum penetration to be achieved and the analytical zone to check for compliance, and include how the treated timber is to be identified (branded).

In New Zealand, once a new preservative product is approved under the HSNO Act, and if the active(s)/preservative type is not already covered by NZS3640, an application for amendment of
the timber preservative standard is required. This requires initiating a contract with Standards New Zealand and for the submission of efficacy data to support the approval of the new active(s), formulation type, and concentration for the relevant Hazard class(s).

In Australia, the APVMA requires efficacy data to be submitted for new products as part of the approval process. Once through that process, approval is then still required through Standards Australia for inclusion in the relevant AS1604 standards and separate to the relevant State authorities under the Queensland Timber Utilisation and Marketing Act, 1987 and New South Wales Timber Marketing Act, 1977.

**Limitations of Standards**

The timber preservative Standards in each country are of limited scope beyond an assessment of biological durability expectations. The Standards do however serve as the default benchmark and have provided some assurance of durability (insects, termites, decay) to the industry and users. These are however generic approvals for preservatives (actives or combinations of actives). User groups would therefore assume any treated timber or wood products (for specific Hazard classes) to have a similar generic performance for product properties; durability to biological agents and for the minimum service life to be met or exceeded.

The efficacy data to gain approval may be generated over a relatively short timeframe when compared to expected (or in the case of the NZBC, required) minimum service life performance. No provision is made to call up preservative systems for re-assessment or to require annual or periodic updates of data/performance for new systems. Historically this would not be a problem as funding for ‘public good’ research that in the past allowed preservative treated timber to be in long term field and commodity service trials, provided a source of external and independent authoritative information. This lack of continuity in funding of independent trials to maintain this knowledge base is a consequence of changing government polices. Neither the regulators nor industry bodies have yet acted on managing potential future risk of product performance deficiencies or failure. However there is a growing awareness of the shortcomings of the present system in New Zealand.

The preservative treatment systems impregnated into timber may not be generic except for having a common active(s). Yet, the treated products have a common Hazard class identification so should be expected to have an equivalent durability performance. There is no assurance this is the case. This is not necessarily a deliberate oversight of the Standards process but the consequence of a rapidly evolving situation arising from a changing and competitive market as new preservative products and systems are developed.

There are also some unique differences between the preservative standards in each country. An obvious difference is that compliance of treated timber to NZS3640 is determined at the treatment plant gate whereas for the AS1604 series this is determined either on the timber at the treatment plant or in the marketplace.
Building Codes

The main building controls in New Zealand are the Building Act 2004, the Building Regulation Controls and the Building Code (NZBC). Compliance documents to meet the NZBC, e.g. Clause B2 Durability, are produced by the Department of Building and Housing. Many of the documents reference New Zealand Standards as a means of compliance. It is the treaters responsibility to ensure that products being manufactured to a standard do comply. This can mean convincing the regulators’ that there is an effective quality assurance system in place. The use of any timber in buildings (to comply with NZBC Durability requirements) is described in NZS 3602:2003 Timber and wood-based products for use in building and within this document references are made to treated timber by Hazard class only (not preservative type) for which a full definition and list of approved actives is covered by NZS 3640.

It seems inevitable that a situation will arise where the regulator will require independent proof or certification that a product complies. This external independent product certifier can be expected to test for conformance against the performance requirements of just a single Standard or single Code Clause or for all aspects of the Building Code, then issue a logo or certificate of performance to the producer/manufacturer. However it is also possible to ‘self-certify’. This might by the individual treatment site or company or through an organisation. The New Zealand Timber Preservation (TPC) and Agriquality are examples of organisations that have quality assurance schemes and cover almost all treated timber produced in New Zealand. The checking of treated timber products is presently voluntary not mandatory, but the pressure to change this may increase with more emphasis on a product certification scheme and accreditation of certification bodies under a harmonised system covering New Zealand and Australia.

Where a situation arises that a product, material or system is outside the descriptions in the Compliance document then it is termed to be an ‘Alternative Solution’ and this will require other means to support compliance with the Building Code. New products or innovative approaches for existing systems can provide a dilemma as Compliance documents and Standards can take quite a time to come up for review or amendment. In addition the make up on standards committees can also serve as potential blockages to change and sometimes with justifiable reason.

Organisations that have been traditionally associated with the issuing of Appraisals to provide a statement of compliance with the Australian or New Zealand Building Codes (BCA or NZBC respectively) are CSIRO www.cmit.csiro.au/services/appraisals/ and BRANZ www.branz.co.nz. Appraisals can cover all type of products, materials and building systems from design through to construction. The products may comply with a Standard but may also be an ‘Alternative Solution’. The Appraisals would be expected to require evaluation and testing of the product, but would likely also include reviews of technical literature, quality control methods and procedures, installation, service performance and maintenance requirements and have a an on-going monitoring commitment for verification of compliance. Increasingly one might expect users of products to seek the reassurance of such documents as a statement of fitness for purpose and compliance with relevant regulations or codes. For producers/manufacturers such documents can mean faster acceptance of products in the marketplace and can be a helpful reference point for
approving authorities. Under the NZ Building Act 2004 it will be very difficult to get any ‘Alternative Solution’ accepted.

A building product certification scheme for Australia and New Zealand has been previously publicised as CodeMark™. Under this scheme third part certification bodies (not the regulator) would evaluate and certify that products meet the specified requirements of the BCA and NZBC. Products could include building materials and forms of construction and design and would be required to be revalidated annually. In Australia the scheme is managed by the Australian Building Codes Board (ABCB) and in New Zealand by the Department of Building and Housing (DBH). It is the long term intention that product certification for materials would then be assured acceptance by building control authorities but this has meant some legislative changes to allow this to progress. When the NZ Building Act 2004 was passed, previous accredited products were transferred to the new Act under transitional provisions. The NZ product certification scheme currently under discussion and still to be implemented might not continue with the word CodeMark™. In time, certified bodies and certified products are to be listed on the respective organisations web sites. The certification bodies are, or are proposed to be, accredited through the Joint Accreditation System of Australia and New Zealand (JAS-NZ).

Conclusion

A review of the scope of the preservative standards, particularly NZS 3640, may be necessary given the broad fitness for purpose performance criteria for preservative treated timber. This may become justified if there is a possibility of failure arising with products and as a response to mitigate this possibility. A product certification scheme would/should not be a generic approval. It is an opportunity for the manufacturer to have their product certified through a single agency that covers both Australia and New Zealand. This would overcome or circumvent some of the obvious deficiencies in the scope of current standards approval process. Potentially there may be a downstream advantage of streamlining the approval processes for Territorial/Local Authorities by avoiding duplication of effort. However it is understood only one product has been certified under the new Australian scheme and only 12 in NZ under the old scheme.

The impetus or need by regulators or authorities to want more scrutiny of products or to introduce systems may lay with the industry itself and its ability to effectively self regulate. User groups including consumers are key stakeholders in the future acceptance of all timber including preservative-treated wood products. Keeping timber as a preferred material in the construction market lies with attention to understanding and demonstrating fundamental fitness for purpose performance requirements. Timely and sensible communication of relevant information is required to all those stakeholders who need to know and not through marketing hype.