

Keeping up with standards changes

By Martin Keay, Technical Consultant

In the past two years we have not only seen changes to all the main directives which affect processing and packaging machines but also a large number of changes to the many European and International standards which support this legislation.

There is always a steady trickle of new standards being published and the latest of these in our sector is the product specific standard EN 415-8: 2008 Safety of packaging machines – Part 8: strapping machines. Developed by the PPMA in conjunction with the British Tensile Strapping Association and European colleagues it is the latest in the EN 415 series of safety standards for packaging machines. However it is the revision and renumbering of basic concept standards (e.g. EN 292, now EN ISO 12100), which has caused the most consternation. These changes are the result of the Vienna agreement between the European Standard Organisation CEN and the International Standards Organisation ISO to turn the basic EN safety of machinery standards into EN ISO standards.



Revisions may not always be required, but complex standards like EN 60204-1 (electrical equipment on machines) are regularly revised and republished, so if you are still using the 1997 version you should be aware that it has been replaced by a 2006 version and that work has already started on the next revision.

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The latest product of the Vienna Agreement is EN ISO 13857: 2008, Safety of machinery – Safety distances to prevent danger zones being reached by the upper and lower limbs which merges probably the best known EN standard, EN 294 (upper limb reach distances) with EN 811 (lower limb reach distances). While this change will not alter the design of guards, it will mean that every company involved in making and modifying machines will need to purchase a new standard and to revise their Declarations of Conformity.

Another reason for change is that EN standards have to be routinely reviewed for revision every five years. This periodic revision process has recently begun for EN 453 (Dough mixers), EN 12041 (bread moulders), EN 415-2 (preformed rigid container packaging machines) and EN 415-4 (palletizers and depalletizers) but the revisions are unlikely to be published before 2010.

However there are a lot more changes to standards in prospect. One of the consequences of changing the Machinery Directive is that all of the standards linked to the Directive have also got to change. For most Directives there are only a handful of so called harmonised standards, but for the Machinery Directive there are over 600 harmonised standards all of which need to be checked and amended in some way in theory before the new Machinery Directive comes into force on 29 December 2009.

Three types of amendment apply to the new Machinery Directive:-

Type 1 The majority of standards will undergo what is termed a **type 1** amendment where the only change is to annex ZA which currently refers to the existing Machinery Directive 98/37/EC - this Directive number will be changed to 2006/42/EC (important for legal but not practical reasons).

Type 2 amendments involve changing not only annex ZA but also the so called “normative references” which are the numbers of the other standards referred to in the document - provided you are aware of the changes to the numbers of the different standards used as normative references you will not find any technical changes in a type 2 revised standard.

Type 3 A small number of standards need to be completely revised so that they can comply with the new Machinery Directive, termed a **type 3** revision and when these are eventually published they will contain technical changes.

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For those of you whose companies are ISO 9000 registered you will immediately understand the importance of having the current version of each standard that you use but it is also important for everyone else as well. If suppliers quote the old standard numbers in a Declaration of Conformity it immediately begs the question “How seriously does this company take safety?” and similarly if purchase documents make reference to out of date standards, suppliers will begin to wonder how much the purchaser knows about the subject.

Old No.	New No.	New Title/Date	Comparison of new and old Standards numbers
EN 292-1	EN ISO 12100-1	Safety of machinery – Basic concepts, general principles for design – Part 1: Basic terminology, methodology - 2003	Comparison of new and old Standards numbers
EN 292-2	EN ISO 12100-2	Safety of machinery – Basic concepts, general principles for design – Part 2: Technical principles and specifications. 2003	
EN 294	EN ISO 13857	Safety of machinery – Safety distances to prevent danger zones being reached by the upper and lower limbs 2008	Comparison of new and old Standards numbers
EN 418	EN ISO 13850	Safety of machinery – Emergency stop; – Principles for design 2006	
EN 563	EN ISO 13732-1	Ergonomics of the thermal environment - methods for the assessment of human responses to contact with surfaces - Part1: Hot surfaces (ISO 13732-1: 2006) 2006	Comparison of new and old Standards numbers
EN 811	EN ISO 13857	Safety of machinery – Safety distances to prevent danger zones being reached by the upper and lower limbs 2008	
EN 954-1	EN ISO 13849-1	Safety of machinery – Safety related parts of control systems – Part 1: General principles for design 2006	Comparison of new and old Standards numbers
EN 1050	EN ISO 14121-1	Safety of machinery – Risk assessment –Part 1: Principles 2007	
EN 1088	EN 1088 + A1	Safety of machinery – Interlocking devices associated with guards – Principles for design and selection 2005	Comparison of new and old Standards numbers
EN 60204-1	EN 60204-1	Safety of machinery – Electrical equipment of machines – Part 1: General requirements 2006	

Certificates for food contact materials

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The current flavour of the month is a certificate for food contact materials. Retailers are asking food manufacturers to produce them and in turn food manufacturers are asking their suppliers for evidence that the materials or articles they have supplied are suitable for use in contact with foods.

The immediate cause of these requests is the Plastic Materials and Articles in Contact with Food Regulations 2008 which came into force on 1 July 2008 as the UK implementation of EC Regulation No 1935/2004 on materials and articles intended to come into contact with food.

The previous legislation (Directives 80/590/EEC and 89/109/EEC) obliged food suppliers to ensure that only those chemicals mentioned in the Directive are used to make plastics for use in contact with food and that the migration levels of permitted chemicals are below the limits prescribed for different types of foodstuffs, but placed no obligations on suppliers of plastics. The legislation now recognises the simple facts that as a purchaser you do not know what a piece of plastic has been made from unless the supplier tells you and that if you don't require plastic suppliers to keep records, it is impossible for an enforcing authority to trace where a particular batch of plastic has gone.

“ *In many ways the new Regulations change very little from the current situation, apart from the need for certificates and documentation, because they replace previous legislation on the same subject which has been in force since 1 January 1993.* **”**

Suppliers of plastic materials and articles (inc. plastic mouldings or conveyor belts) now have a duty to pass on information about the product they are supplying in the form of a certificate or label on the product and to improve traceability to keep records on where particular batches of plastics have gone, which can be requested by an enforcing authority if required. This mirrors two features of the Machinery Directive which has applied to machine suppliers since 1995, the **EC Declaration of Conformity** and the **technical file** which has to be made available to an enforcing authority in the event of a question about the conformity of a machine.

The **EC Declaration of Conformity** which is sent out with a machine, covers all of the components that go to make that machine and if the manufacturer intends the machine to be used to process or pack food, confirms that the plastic parts that come into contact with the food will comply with the plastic in contact with food legislation. This is because the Machinery Directive (98/37/EC), in essential safety requirement 2.1, requires manufacturers to ensure that “materials in contact, or intended to come into contact, with the



Multipond's MP 28-400/400-A weighing machine

Although food manufacturers should already know that the plastic components they are using in contact with food comply with this legislation (a requirement since 1993), many food producers are using the new Regulations as a reason for requesting certificates not only for new plastic components but also for components supplied on machines that are ten or fifteen years old.

foodstuffs must satisfy the conditions set down in the relevant Directives.” In the case of plastic materials these relevant Directives are 80/590/EEC and 89/109/EEC which are now being revised.

In addition the Machinery Directive requires machinery suppliers to hold a **technical file** which must contain information to demonstrate that the machine conforms to the relevant essential health and safety requirements of the Directive. In the case of food contact materials this would be documents provided by the supplier of the plastic components to demonstrate that the plastic complies either with the European Directives or the equivalent American FDA regulations. So it is a reasonable assumption that any machine supplied since 1995 with a Declaration of Conformity to the Machinery Directive and intended for use with food will have been equipped with plastic materials that comply with the plastic in contact with food legislation and that the manufacturer will have the documentation to back up this claim in the technical file for this machine.

From a machine manufacturer's point of view the advantage of the new legislation is that plastics suppliers will now be obliged to supply them with a certificate for the plastic, whereas up to now it was up to the purchaser to establish if it was suitable. So certificates are certainly a good improvement to the legislation for both food manufacturers and machine builders, but it is always worth remembering the importance of practical measures like labelling the components or materials when they are in store, because once the plastic becomes separated from its certificate or label you are back to the original problem of not knowing what it is made from.

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