



News Summary

March - April 2012

This *News Summary* covers March and April 2012. A summary list appears on this page, of sectors / issues covered. Details start on page 2 and include, for each item, the essence of the news, brief comments on its significance, and the main free of charge Internet sources of data and background.

Sectors and issues covered in this *News Summary*

Data protection regulations: all products
All **CE Marking Directives** and the *New Legislative Framework*
Eco-design: household appliances
Chemicals and REACH
Toy safety
Automotive
Energy efficiency of buildings
Smart grids / smart meters
Radio spectrum policy
EMC (electromagnetic compatibility)
EMF (electromagnetic fields) at the workplace
RTTE

Climate change: measurement of greenhouse gas emissions
National technical regulations in EU countries
Nanomaterials
Medical devices
Maritime (ship) safety
Fertilisers
Food safety
Pressure equipment
Machinery
Textiles
Tobacco products
Detergents

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Sector/issue/essence of the news	Comments and sources
<p>Data protection – all products and all suppliers. The <i>European Data Protection Supervisor</i> (EDPS) has publicly announced concerns about the recent EU proposal to reform the entire body of data protection regulation, which was presented in February and is currently under discussion. Sample quotation: <i>The proposed rules for data protection are unacceptably weak.</i> Examples of personal data covered by the proposal include names, photos, e-mail addresses, bank details, posts on web-sites, medical information, and computer IP addresses.</p> <p style="text-align: right;">120404</p>	<ul style="list-style-type: none"> • The proposed reform is important to all traders in Europe who store or distribute data on private individuals in any form. The new rules will also apply to companies which trade inside the EU but store data outside. • Broad goals are to combine administrative simplification with increased transparency for consumers. • The reservations expressed by the EDPS are likely to be taken up by consumers and other stakeholders concerned that the powers given to government are too intrusive. • Additional interest comes from a parallel announcement that the EU and US governments plan to increase cooperation in this area. <p>Sources: The latest opinion from the EDPS: link..... The announcement of EU-US cooperation in this field: link..... The earlier 2012 data protection reform package link..... A portal to broader data in the same area: link.....</p>

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<p>CE Marking Directives: 3 more texts have appeared of revisions to CE Marking directives to adapt them to the <i>New Legislative Framework</i> adopted in 2008. The 3 new texts are electromagnetic compatibility (EMC), non-automatic weighing instruments, and fireworks / pyrotechnics.</p> <p style="text-align: right;">120417</p>	<ul style="list-style-type: none"> • The NLF aims to achieve administrative consistency between the procedures of applying CE Marking directives – for example, in the content of conformity assessment modules – with evident benefits to suppliers affected by more than a single directive. The NLF does not aim to change substantive technical requirements. • 10 Directives had previously been listed as targets for this “no technical change” revision. The 3 latest now bring the number of proposed texts to 7. Others already issued are LVD, ATEX, Explosives, and Lifts. Those remaining to be issued in the programme are Gas Appliances, and the 2 Pressure Equipment Directives. • Although in principle adoption of the revised texts should be straightforward, concerns have been voiced over the EMC text, which is claimed to include substantive changes despite official EU claims to the contrary. <p>Sources: The 3 new texts: Fireworks/ pyrotechnics <i>link</i>..... EMC <i>link</i>..... Non-automatic weighing instruments <i>link</i>..... Portal, with list of target directives for revision. <i>link</i>.....</p>

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<p>All products, especially electrical: <i>Eco-design</i> programme: 1) a new implementing regulation on air-conditioners <12 kw has been ratified and published; 2) a new working draft has appeared of an implementing regulation for coffee-machines; 3) a new <i>Green Paper</i> proposes a framework for accelerating the introduction of SSL (solid-state lighting), linking the plans to the eco-design programme and the related EPBD Directive (Energy Performance of Buildings). See also next row for news of EPBD.</p> <p style="text-align: right;">120406</p>	<ul style="list-style-type: none"> • The new regulation on air-conditioners was expected, and demonstrates the increasing convergence between test methods for eco-design (which imposes mandatory energy consumption limits), and energy efficiency labelling, which imposes no limits but requires transparent labelling. • Coffee machines were included in the previously announced <i>Working Plan</i> • The <i>Green Paper</i> on SSL contains a helpful compendium of policy initiatives in this field aimed at improved energy efficiency. <p>Sources: 1) the regulation on air-conditioners <i>link</i>..... the parallel regulation of 2011 on energy-labelling of air-conditioners <i>link</i>..... 2) the draft regulation of a regulation for coffee-machines <i>link</i>..... 3) The Green Paper on solid-state lighting: <i>link</i>..... Portals and overviews. <i>links</i>.....</p>

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<p>Energy efficiency of buildings. 1) A methodology and (separately) guidance to its application have been published for calculating energy efficiency of buildings under the EPBD (Energy Performance of Buildings Directive). 2) A public consultation has been opened, which asks for views on financial support mechanisms suitable for encouraging energy efficiency improvements.</p> <p style="text-align: right;">120412</p>	<ul style="list-style-type: none"> • The new methodology plugs one of the major gaps in the EPBD programme, which seeks to make <i>nearly zero-energy buildings</i> mandatory, but failed to define exactly how to calculate their performance. But its publication is nine months later than planned, and a parallel definition is still awaited of exactly what <i>nearly zero-energy</i> means. • The consultation on financial support mechanisms is of evident interest to promoters of specific types of technology suitable for the programme <p>Sources: The new methodology for calculating energy performance, and supporting link..... andlink..... The public consultation on financial support mechanisms link..... Portal to Directive (not updated for 244/2012) link.....</p>
<p>Climate change / measurement of GHG emissions. The EU is about to publish mandatory, harmonised procedures for measuring GHG in the agricultural and forestry sectors. Initially they will affect only governments.</p> <p style="text-align: right;">120411</p>	<ul style="list-style-type: none"> • This measure has no direct impact on traded products or suppliers of them, but could in theory herald a new wider change: new mandatory measurements of GHG output by individual operators in the sector. <p>Sources: The announcement of the imminent publication of new requirements: link..... and link..... Portal to EU policies and regulations of forestry in climate change programmes link.....</p>

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<p>Toys. 1) a new Directive tightens limits on cadmium. 2) A new decision allows Germany to continue temporarily national limits on various hazardous substances, tighter than those in the Toy Directive, until the EU can agree on harmonised limits.</p> <p style="text-align: right;">120402</p>	<ul style="list-style-type: none"> • The decision on the German national regulations can be linked to the separate public consultation on lead limits in toys reported in February. <p>Sources: 1) new limits on cadmium<i>link</i>..... 2) decision authorisation temporary continuation of German national bans<i>link</i>..... Portal to EU regulation of toys.<i>link</i>.....</p>
<p>Tobacco. A new directive adapts EU requirements for health warnings on tobacco products to make them compatible with the latest WHO guidelines.</p> <p style="text-align: right;">120403</p>	<ul style="list-style-type: none"> • Current EU requirements for tobacco labelling date from 2001 • The new directive maintains the current number of 14 mandatory warnings, which must be rotated on labels, but changes some to adapt them to WHO guidelines; e.g., a previous statement that <i>smoking can cause slow and painful death</i> has been removed. <p>Sources: The new directive:<i>link</i>..... A supporting statement on the link to the WHO:<i>link</i>.....</p>

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<p>Automotive sector:</p> <p>1) Tyres: a list has been published of test laboratories which are authorised to conduct mandatory tests under the Directive which imposes labelling of energy efficiency of tyres.</p> <p>2) CO2 emissions for light commercial vehicles. Monitoring and reporting procedures have been clarified under the regime which imposes <i>fleet average</i> emissions on each manufacturer.</p> <p>3) A new proposal would reduce maximum noise limits for both light and heavy vehicles, in 2 phases, and impose new measurement methods. One of the announced benefits is a 25% reduction in the number of <i>highly annoyed people</i>.</p> <p>4) Two new consultations on road traffic safety, open until June. One covers information programmes to user groups (e.g., children on way to school) rather than technical regulations. The second seeks views on what kind of safety-related traffic information should be made available to all users (e.g., safety messages relayed to cars).</p> <p>5) Routine updates are made to type-approval rules for cab protection, registration plates, and AEBS (advance emergency braking systems)</p> <p>See also separate row on biofuels later in this report</p> <p style="text-align: right;">120405</p>	<ul style="list-style-type: none"> • Except for item 4 (consultations on possible new regulations), all items are routine updates in known programmes. • One of the consultations in item 4 will be of wider interest, outside the automotive sector, to any provider of traffic-related information services. <p>Sources:</p> <p>1) Tyres: the new list of test laboratorieslink.....</p> <p>2) CO2 emissions: the latest procedures:link..... The 2011 regulation which it implements:link..... Portal to EU regulation of CO₂ emissionslink.....</p> <p>3) New noise regulations for vehicleslink.....</p> <p>4) Consultations:</p> <p>i) on road traffic safety programmes to target user groupslink.....</p> <p>ii) on safety-related universal traffic informationlink.....</p> <p>5) Type-approval updates:links.....</p>

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<p>Medical devices.</p> <p>1) a new regulation stipulates when electronic user information may be used to replace paper (which products and which applications), to comply with the existing technical requirements for medical devices;</p> <p>2) a new consultation requests comments on a proposal to extend, to manufacturers outside the EU, the requirement to use GMP (Good Manufacturing Practice) in the manufacture of active substances;</p> <p>3) a first official scientific report has been published on the implications of the scandal of sub-standard breast implants from the French company PIP, but it is inconclusive.</p> <p>4) Routine updates have been made to standards under all 3 Medical Devices Directives. They include, notably, new texts on good clinical practice (ISO 14155) and labelling of in vitro devices.</p> <p style="text-align: right;">120407</p>	<ul style="list-style-type: none"> • All news items are routine but significant updates to the evolution of regulation in this sector. <p>Sources:</p> <p>1) Electronic user information<i>link</i>.....</p> <p>2) consultation on GMP<i>link</i>.....</p> <p>3) Scientific report on breast implants<i>link</i>.....</p> <p>4) Standards – updated lists: 90/385<i>link</i>..... 93/42<i>link</i>..... 98/79<i>link</i>.....</p> <p>The newly added texts are clearly identified in the above OJ publications.</p> <p>Portal to data on EU regulation of medical devices: Official data on EU regulation in this sector is among the best of all sectors in EU technical regulation, in both quality and ease of access.<i>link</i>.....</p>

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<p>Smart grids. 1) a new, non-binding recommendation takes a first step towards harmonisation of connection rules for smart metering systems, including minimum requirements for functionality and data protection; 2) a new consultation on radio spectrum allocations explicitly requests comments on the implications for smart metering and smart grids; 3) a more formal <i>Radio spectrum policy programme</i> treats broadly the issue of allocating broadband spectrum to smart grids.</p> <p style="text-align: right;">120408</p>	<ul style="list-style-type: none"> • Although none of these announcements has direct, immediate impact, they all propose fundamental ground-rules of wide relevance to all interested in smart grid deployment. • Examples of issues raised: minimum functionalities, privacy protection, information and transparency, economic assessment criteria. • <i>Radio Spectrum Policy Programme</i> goes far beyond smart grids, but mentions them explicitly and gives priority to broadband. • Announcement are consistent with public EU efforts to harmonise regulatory oversight in this field internationally, notably with the USA. <p>Sources:</p> <p>1) Recommendation on smart meters<i>link</i>.....</p> <p>2) consultation on radio spectrum allocations<i>link</i>.....</p> <p>3) Radio spectrum policy programme<i>link</i>.....</p> <p>Portal to smart grids, which lists this latest recommendation among other documents<i>link</i>.....</p> <p>The home-page for EU radio spectrum policy<i>link</i>.....</p>
<p>Radiocommunications and radio spectrum management.</p> <p>1) For smart grids, see items 2 and 3 in previous row</p> <p>2) A new list has been published of standards recognised under the RTTE Directive (radio and telecommunications terminal equipment). All new texts except one are ETSI standards. The exception: a CENELEC standard for EMF for fixed transmitters (EN 50401)</p> <p style="text-align: right;">120408 120421</p>	<ul style="list-style-type: none"> • See previous row for comments on smart grids • Standards update for RTTE is routine. • News is still awaited of the planned revision of this directive, announced in 2011 <p>Sources:</p> <p>1) For smart grids, see items 2 and 3 above</p> <p>2) The new list of standards for RTTE<i>link</i>.....</p> <p>The portal to other information about the RTTE Directive<i>link</i>.....</p> <p>The most recent, but now old, report on directions for revision of the RTTE Directive:<i>link</i>.....</p>

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<p>EMC Directive (electromagnetic compatibility): a routine update has been issued to the list of standards recognised, but fails even to mention the festering problem with the core standard for radio interference of in-home PLC (power-line communications) equipment.</p> <p style="text-align: right;">120422</p>	<ul style="list-style-type: none"> Perhaps surprisingly, the “festering problem” is not discussed in public by the EU. It concerns EN 55022 which, in its current recognised version, contains radio disturbance requirements too restrictive for many PLC products; the same is true of its latest IEC parent standard (CISPR 22). An older 1998 version of the standard, no longer recognised, was more PLC-friendly. The PLC sector has lobbied hard against the latest versions. Debate goes on behind the scenes. The latest unofficial news is that the European Commission may impose a more PLC-friendly regulation. <p>Sources: The dedicated sectoral page for EMC standards identifies the new texts:<i>link</i>.....</p> <p>Portal to data on the EMC Directive:<i>link</i>.....</p>
<p>EMF (Electromagnetic fields) at the workplace. The entry into force of tighter limits, announced in 2004, has been postponed for a further year, until 2013. The measure is in the <i>Health & Safety</i> category.</p> <p style="text-align: right;">120423</p>	<ul style="list-style-type: none"> Implementation of the tighter limits, announced in 2004, was delayed until 2012 in order to allow MRI (magnetic resonance imaging) medical equipment to continue to be used while a new regulation was prepared. A new text was proposed in 2011, and was expected to be adopted before the April 2012 deadline. But it has not been ratified, leading to this decision to continue the old limits for a further year. <p>Sources: Official data on this category of regulation (H&S) is poorly presented. The latest text postponing the implementation of the 2004 limits for a further year:<i>link</i>..... The latest draft of the measure intended to replace it, but which failed to achieve ratification by the April 2012 deadline<i>link</i>..... A list of other <i>Health & Safety</i> Directives in the same series as this latest proposal<i>link</i>.....</p>

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<p>Fertilisers. A routine update has been made to the list of substances approved for pan-EU use in fertilisers</p> <p style="text-align: right;">120409</p>	<ul style="list-style-type: none"> Because of climatic differences affecting agriculture, only limited harmonisation of fertiliser approvals has been applied so far in the EU, based on a 2003 regulation. <p>Sources: The latest update <i>link</i>..... A portal to the sector, hopelessly out of date <i>link</i>.....</p>
<p>Food sector.</p> <p>1) Two routine updates have been made to the EU’s positive lists of approved food additives;</p> <p>2) a fresh update has appeared to emergency EU food safety rules applicable to imports from Japan following the Fukushima disaster.</p> <p>3) Procedures have been defined for lodging objections, on grounds of a perceived risk to food safety, to approvals of vitamins and minerals authorised for use in <i>fortified foods</i>.</p> <p>4) EU standards for describing fruit juices and their sugar content have been aligned with the <i>Codex Alimentarius</i>.</p> <p>5) A new report on <i>irradiation</i> of foods confirms that the EU has no intention of changing current rules, which leave authorisation almost entirely to national governments, without EU harmonisation.</p> <p style="text-align: right;">120410</p>	<ul style="list-style-type: none"> Only two of these developments stand out as other than routine: item 2, which updates emergency rules following the Fukushima disaster; and item 4 which, while of little impact, is evidence of a growing willingness by the EU to use Codex standards, which it still frequently rejects as the exclusive basis for regulation. <p>Sources: 1) the latest updates to food additive regulation <i>link</i>..... and <i>link</i>..... A portal to data on EU regulation of food additives: <i>link</i>..... 2) the update to emergency food safety rules in response to the Fukushima disaster <i>link</i>..... 3) the update to the regulation on <i>fortified foods</i>: <i>link</i>..... 4) EU regulations and standards for fruit juices <i>link</i>..... 5) the latest report on irradiation of <i>link</i>..... Portal to all EU regulation of food safety: <i>link</i>.....</p>

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<p>Machinery Directive. In a routine update, new standards have been added to the list of those approved under the Directive. Earth-moving machinery and industrial trucks are among those affected by the additions. 120413</p>	<p>Sources: The latest list of standards, clearly identifying new texts: <i>link</i>..... Sectoral portal, leading to comprehensive guidance and reference documents: <i>link</i>.....</p>
<p>Pressure equipment. 1) The first European Approval for Materials (EAM) since 2006 has been issued under the Pressure Equipment Directive. 2) A single addition (EN 287-1) has been made to the list of standards recognised under the Simple Pressure Vessel Directive. 3) 12 new standards have been added to the list of those recognised under the PED (Pressure Equipment Directive), which covers most of the sector. 120414</p>	<ul style="list-style-type: none"> • The first item (EAM) illustrates the semi-paralysis of EU regulation in this sector. The EAM process is one of three processes defined in the PED for approval of materials; the main one is use of a material meeting a harmonised standard. But in practice, EAMs have been rarely issued, despite a number of applications for materials outside the scope of EN standards. Published data is out-of-date and hard to interpret. Case-specific evaluation by a notified body is the only other option. The separate data on standards is also less than transparent: for example, new texts in each new announcement are not highlighted, and must be sought laboriously. <p>Sources: 1) The latest EAM: <i>link</i>..... Reference list of EAM's not updated for this latest one: <i>link</i>..... A page which also leads to a list of applications for EAMs, including those not yet approved. <i>link</i>..... 2) Simple Pressure Vessels Directive: Standards: <i>link</i>..... Portal to simple pressure vessels directive <i>link</i>..... 3) Pressure Equipment Directive Dedicated standards page, which unlike 2009/105 above, does identify the new texts. <i>link</i>..... Portal to PED <i>link</i>.....</p>

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<p>Detergents. A newly ratified regulation reduces maximum levels of phosphates permitted in most detergents.</p> <p style="text-align: right;">120415</p>	<ul style="list-style-type: none"> The proposal to do this was presented in 2010, and its adoption is no surprise. Its justification is environmental: phosphates harm the aquatic environment. An adequate replacement chemical is reported to be available. <p>Sources: The new regulation: link..... Portal to regulation of detergents link.....</p>
<p>Textiles. In routine technical updates, a new type of textile has been added to the EU's positive list of permitted textile names, and analysis procedures have been modified.</p> <p style="text-align: right;">120416</p>	<ul style="list-style-type: none"> This update is within the frame of the 2011 update to ground-rules for use of textile names in the EU. Amends several annexes, covering the list of approved descriptions, and the technical methods of analysis and composition of textile fibres. [Under the regulation, textile names used in the EU must respect technical specifications contained in this regulation, but are otherwise subject to no approval procedure.] Other categories of technical regulation applicable to textiles include: restrictions on the use of dangerous substances including dangerous dyestuffs; flammability; metrological accuracy of textiles sold in bulk. <p>Sources: The latest amendment link..... Portal to sector: link.....</p>
<p>Biofuels. One more voluntary certification scheme, covering Ensus bioethanol, has been recognised as complying with EU rules for classifying biofuels as fit for inclusion in renewable energy calculations.</p> <p style="text-align: right;">120424</p>	<ul style="list-style-type: none"> This is the latest in a series of announcements of schemes approved within the frame of the RES (Renewable Energy Sources) Directive, which imposes percentage targets for the use of renewable fuels. To be counted, biofuels must meet <i>sustainability criteria</i>, and approved certification schemes offer proof of that. <p>Sources: The latest decision recognising the Ensus voluntary scheme for certifying biofuels link..... Portal to data on sustainability criteria of biofuels: link.....</p>

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<p>Chemicals and the REACH programme:</p> <p>1) The core regulation on <i>dangerous preparations</i> (combinations of chemical substances sold as a single product, which represent a high percentage of sales in the sector) has been aligned with the <i>REACH</i> regulation. The only significant change is to give more power to the European Commission to use its delegated powers to issue new regulations directly.</p> <p>2) New guidance has been issued on the safety assessment of chemical substances which take the form of nanomaterials; the guidance is integrated into the broader REACH procedures for safety assessment of chemicals.</p> <p>3) New or updated guidance has been issued on monomers and polymers</p> <p>4) New guidance has been issued on the application of CLP regulations (Classification, Labelling, Packaging) of chemicals.</p> <p style="text-align: right;">120418</p>	<ul style="list-style-type: none"> • The announcements shown here are only the most striking in a constant stream of updates of EU regulation of chemicals, most of which are connected with the <i>REACH</i> programme, the core programme adopted in 2006 for the sector. For specialists in the sector, constant monitoring of the site of the European Chemicals Agency is recommended. • The new guidance on nanomaterials is likely to be of particular interest because of the novelty of this field, and the relevance of nanomaterials in a wide range of sectors. • The update of the regulation on dangerous preparations illustrates the steady progress in the EU towards aligning regulations for chemical substances and the myriad of products which use them outside the chemicals sector. <p>Sources:</p> <p>1) the re-issued core regulation on dangerous preparations link.....</p> <p>2) New guidance on nanomaterials appears in three separate texts links.....</p> <p>All 3 texts are integrated into broader guidance on chemicals safety assessment shown on: link.....</p> <p>3) New guidance on monomers/polymers link.....</p> <p>4) New guidance on CLP link.....</p> <p>Key portals and access pages on the programme</p> <p style="padding-left: 20px;">Legislation, including both REACH itself and the related GHS/CLP texts: link.....</p> <p style="padding-left: 20px;">The most comprehensive portal to guidance documents link.....</p>

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<p>Ship safety. A new, public consultation has been launched, open until July, which seeks opinions on how the safety requirements of the present Directive on ship safety could be improved.</p> <p style="text-align: right;">120420</p>	<ul style="list-style-type: none"> This follows an announcement earlier in the year that the EU would examine all possible ways of improving passenger safety on ships, in response to the <i>Costa Concordia</i> shipwreck in Italy. No specific directions for reform have yet emerged. <p>Details of the consultation and how to submit commentslink.....</p> <p>Portal to maritime safety regulations in the EU:link.....</p>
<p>National technical regulations for all products. For the first time in two years, the EU has issued a report on the operation of its clearing-house for national technical regulations and standards, which operates largely as a more rigorous regional version of the WTO <i>Enquiry Point</i> system globally.</p> <p style="text-align: right;">120419</p>	<ul style="list-style-type: none"> Compared with the WTO, the EU has greater legal powers to intervene when national technical regulations are proposed: in essence, WTO members may <i>threaten</i> action against a proposed technical regulation, but the EU may <i>take</i> action, for example by imposing a standstill. While the report indicates official satisfaction with performance, it reveals that the number of national technical regulations in the EU is not declining significantly, and acknowledges the need for greater speed and transparency in EU-level responses. <p>Sources:</p> <p>The latest report on the operation of the systemlink.....</p> <p>A portal to date on the EU systemlink.....</p> <p>A searchable data-base of EU notificationslink.....</p>