

Materials Compliance: Just as Critical As Electrical Safety & EMC

by Kevin Parmenter, Chair, and James Spangler, Co-chair, PSMA Safety and Compliance Committee

For most power electronics engineers, and perhaps for hardware designers in general, environmental regulations have not been high on the list of design considerations. Other compliance requirements have usually demanded more attention. But that situation may be changing and now even power supply designers may need an awareness of the regulations governing restricted materials. At a recent webinar on materials compliance in electronics, an expert on environmental compliance weighed in on the importance of materials compliance.

“From a recall perspective, restricted materials compliance should be given equivalent priority to electrical safety, and more than EMC compliance,” said Bruce Calder VP Consulting Services at Claigan,^[1] a company specializing in environmental compliance. The materials compliance area is expanding in scope and the repercussions of not meeting the standards are higher than ever before.

Just as an example of the widening scope of regulations, consider that the toxicity issues are not only a concern in the electronics and component manufacturing processes, they are also a consideration in the recycling process at product end of life. In other words, your design choices will affect how the end customer is allowed or required to dispose of your product.

Power electronics designers have long had numerous compliance demands to think about. We’ve had to consider the electrical safety of our products providing isolation and minimizing shock hazards. Plus we’ve designed to meet EMI-EMC standards for conducted and radiated emissions and susceptibility. Now on top of all that, we have to make sure the product meets global hazardous material standards. And the list of standards, which are codified as regulations, directives, or similar legalistic titles, is long.

These include EU RoHS 2, RoHS 3 (phthalates), REACH SVHC, REACH Restrictions, EU POP, Swedish Flame Retardant Tax, EU Packaging Directive, WEEE Directive and EU Medical Device Regulation. Then, in North America we have Prop 65 and U.S. Toxics in Packaging. In Canada, we have iMERC (Hg) in Canada and the Canadian Prohibition. Finally, in Asia we must meet China RoHS; UAE RoHS in the UAE, and lastly Taiwan RoHS in Taiwan.

So, to obtain certifications and customs clearances to ship into these regions RoHS 3, for example, becomes the law in the EU starting in July of 2019—just around the corner. Of course, everyone wants the CE mark for products because in the EU if your product does not have a CE marking certification you cannot ship it into the country and customs will typically reject the shipment. In order to meet the CE marking directive you now must meet RoHS 3 levels.

If you’re familiar with the previous version of RoHS, EU RoHS 2 (2011/65/EU), you may wonder what has changed in RoHS 3? RoHS 2 set maximum levels on Pb and Cd content at 100 ppm; while Hg, Cr6+, PBB, and PBDE were banned at 1,000 ppm.

Now for RoHS 3, there are added restrictions on a class of chemicals known as phthalates. Per EU RoHS 3 (phthalates) (2015/863), DEHP, BBP, DBP, and DIBP are banned at 1,000 ppm. The deadline for compliance with these restrictions for most products is July 21, 2019. However, for products classified as Medical, IVD, monitoring and control, the deadline is pushed back to July 21, 2021. This is now the law of the land.

From a design engineering perspective, the new regulations mean you must maintain close communications with your purchasing and manufacturing teams. Here’s an example to illustrate why.

Let’s say you have designed your product to meet all the requirements and you certify that your product is now in compliance. All it takes is for someone in purchasing to toss in an accessory cable, say a USB cable, from a supplier that is not compliant and suddenly your product is not compliant. Thus tight restrictions on part substitutions for even mechanical and electromechanical parts must be specified and rigidly controlled to insure non-conforming and non-qualified materials are not used. That applies even to accessories like cables and external power supplies. Believe it or not wire, cables and strain reliefs are causing many of the problems.

Now what to do after you insure compliance to the standard and the mistake by someone in purchasing has caused your product to be noncompliant? If you discover it yourself you have to self-report and specify the

corrective action taken. If you don't self-report and it's discovered, big fines and penalties await including potential recalls.

This leads to a broader question: what regulatory landscape are we operating in? The standards have been evolving. Essentially EN 63000:2018 replaces EN 50581:2012 and it's based on IEC 63000:2016. Now, EN 63000:2018 is basically the same as the previous EN 50581 but aligned with international standards and it has an implementation deadline (on the CENELEC website) of June 7, 2019.

Having said that, the replacement of EN 50581 by EN 63000 has not been cleared through the EU Commission. So, according to the EU commission, EN 50581 is still the standard with a transition timeline of five years. So, what do you have to do as a supplier of electronic equipment?

There are two choices by July 2019. Option one: use both standards EN 50581:2012 and EN 63000:2018 and meet both standards. Or go with option two: stay with just EN 50581:2012 as supposedly, there is a five-year transition period. Either one would not be incorrect, but you must do one or the other, otherwise you risk large fines and having your product denied entry by a customs organization.

You must have either supplier declarations, confirming that the restricted substance content of the specified material, part, or subassembly is within the permitted levels and identifying any exemptions that have been applied. Or you can have signed contracts confirming that the product specification for the maximum content of restricted substances in a material, part, or subassembly is fulfilled. The intention of the EU approach is elimination of restricted compounds above certain levels.

In contrast California Proposition 65, which in the U.S. is probably the closest comparison to the levels of restriction imposed in Europe and elsewhere, combines a reduction in the amounts of certain chemicals along with labeling requirements. For instance, a product may carry a label like the following: "WARNING: This product can expose you to chemicals including arsenic, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov."

Both the state of California and the EU can impose severe fines on the offending supplier of product in the market, so the risk of violating either one's regulations is substantial. So make the materials evaluation process part of the supplier and component qualification process. Ask suppliers about their components to ensure they are compliant to the required standard(s), especially when selecting new suppliers or components. Also, review your product design early in the development process at the same point in the new product introduction (NPI) process as EMC testing and make a restricted materials test report necessary for the product to reach the manufacturing phase.

As you go through this process, be aware that there is a new screening test technique validated for orthophthalates to test and see if a product meets RoHS 3, REACH SVHC, and Prop 65 phthalates requirements. The technique is called Fourier-transform infrared spectroscopy (FTIR) screening and it's best to call in experts to assist with the process, test the product and offer guidance on testing and product labeling requirements. Then, if your product is found to contain certain chemicals and/or if those chemicals are at or below a certain level, labeling will be required for P65.^[2]

In general, it is recommended that you bring in experts to assist, recommend and test early as you would with EMC-EMI testing during product development as violating one of the hazardous materials restrictions globally can have severe consequences. These include steep fines and/or denial of permission for you to ship your product to various countries or regions, or—even worse—costly recalls.

References

1. Claihan [website](#)
2. OEHHA's [Proposition 65 in Plain Language](#)
3. The Office of Environmental Health Hazard Assessment (OEHHA) [website](#).

About The Authors



Kevin Parmenter is an IEEE Senior Member and has over 20 years of experience in the electronics and semiconductor industry. Kevin is currently director of Field Applications Engineering North America for Taiwan Semiconductor. Previously he was vice president of applications engineering in the U.S.A. for Excelsys, an Advanced Energy company; director of Advanced Technical Marketing for Digital Power Products at Exar; and led global product applications engineering and new product definition for Freescale Semiconductors AMPD - Analog, Mixed Signal and Power Division.

Prior to that, Kevin worked for Fairchild Semiconductor in the Americas as senior director of field applications engineering and held various technical and management positions with increasing responsibility at ON Semiconductor and in the Motorola Semiconductor Products Sector. Kevin also led an applications engineering team for the start-up Primarion where he worked on high-speed electro-optical communications and digital power supply semiconductors.

Kevin serves on the board of directors of the [PSMA](#) (Power Sources Manufacturers Association) and was the general chair of APEC 2009 ([the IEEE Applied Power Electronics Conference](#).) Kevin has also had design engineering experience in the medical electronics and military electronics fields. He holds a BSEE and BS in Business Administration, is a member of the IEEE, and holds an Amateur Extra class FCC license (call sign KG5Q) as well as an FCC Commercial Radiotelephone License.



Jim Spangler is a Life Member of the IEEE with over 40 years of electronics design experience and is president of Spangler Prototype Inc. (SPI). His power electronics engineering consulting firm's priority is helping companies to place products into production, assisting them to pass government regulations and agency standards such as UL, FCC, ANSI, IES, and the IEC.

For many years, he worked as a field applications engineer (FAE) for Motorola Semiconductor, On Semiconductor, Cirrus Logic, and Active Semiconductor, assisting customers in using semiconductors. He published numerous application notes and conference papers at a variety of conferences: APEC, ECCE, IAS, and PCIM. Topics included power factor correction, lighting, and automotive applications. As an FAE, he traveled internationally giving switch-mode power supply seminars in Australia, Hong Kong, Taiwan, Korea, Japan, Mexico, and Canada.

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For further reading on power supply-related safety and compliance issues, see How2Power's special section on [Power Supply Safety and Compliance](#).