How many directives shall be applied to household appliances?

[TPS Comment]
For CE marking the following Directives apply: EMC; LVD
However, the RTTE Directive may also apply if, for example, the household appliance contains a GSM modem. Note: the RTTE Directive invokes LVD (with the lower voltage limit removed) and EMC Directives.
There are also non CE marking Directives that will apply: General Product Safety, REACH, RoHS, WEEE and EuP.

If your product is a complex component that is integrated into a product by the OEM, does the ‘component’ still need CE marking?

[TPS Comment]
It depends on the type of component and the specifics of the OEM. Components are covered by the regulations provided they fall within the scope of the regulations. E.g. a resistor being a passive device and falling outside the scope of the regulations is NOT subject to CE marking. A dc-dc converter module is covered by the regulations and therefore CE marking applies.
If the OEM is located outside of the EU then they may legally purchase components / modules from elsewhere outside the EU and CE marking does not apply. However, if the OEM then sells the final product into the EU they take overall responsibility for the complete product including the component / module.
If the OEM is based within the EU it is illegal for component / module suppliers to sell them these items without CE marking PROVIDED that the regulations apply.

Should Glowsticks be CE marked?

[TPS Comment]
There is no applicable EU Directive covering glowsticks unless they are sold as toys in which case the Toys Directive applies and CE marking is required.

If I have product such as reactor (filter) used only in power distribution systems that is not common place on the market, is this product shall be affix CE mark? What is the reason?

[TPS Comment]
It depends on the specific details of the “reactor”. If there is an appropriate Directive which applies then CE marking applies. The fact the unit is not common place on the market is not relevant in this case.
• My company supplies products to OEMs who usually wish to label the product with their own details. What are the labelling requirements? What do we need to put on our product label?

[TPS Comment]
The labelling requirements are the same. The CE marking must be affixed provided the products fall within the scope of an applicable Directive along with any other markings required for the device in question (e.g. manufacturer, model number / type reference, crossed wheelie bin). If the OEM replaces your label with their own it is their responsibility to ensure the correct markings remain and moreover to ensure adequate information remains to make sure it correlates with the Declaration of Conformity.

• Hi, is there a formal (legal) document that specifies the need for a DoC?

[TPS Comment]

You can view the text here (scroll down the page or click on html under the EN tab): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0068:en:NOT

• If a product was developed prior to the existence of a Directive but still on sale, does CE marking apply?

[TPS comment]
Yes, CE marking applies if the product is still on sale.

• If I build a product from CE marked components and sub-assemblies can I create a DoC without further test?

[TPS Comment]
Unfortunately “CE + CE does not equal CE”. Testing will almost certainly be required to demonstrate that the components and sub-assemblies are still compliant when connected together as a system.
- Can you use other country requirements (e.g. FCC emissions) to cover part of EMC directive?

[TPS Comment]
You can use other rationales to demonstrate compliance but you need to explain the rationale. Be aware that by not testing in accordance with EN standards you will not benefit from a presumption of conformity with the Essential Requirements of the Directive. In this specific case also be aware that the mains supply voltage / frequency may be different for FCC.

- You mentioned imported components in a product - if they are not CE marked in their own right (e.g. a PSU) are you saying I definitely can't use it in a larger product, or if I have the product data, can I make my own assessment?

[TPS Comment]
If you use a component or sub-assembly that is subject to CE marking then it should be made available to you with the appropriate CE marking and Declaration of Conformity supported by a Technical File. You can use it but you take responsibility for the compliance of that component or sub-assembly within the complete product. Be aware however that this is not always very straightforward; i.e. you may have an EMC failure as a result of this part or you may have to obtain detailed constructional information which you may not have access to.

- Hi I have read that any product can have a CE marking if we/I feel that the product complies with all the relevant UK/EU Regulations/Laws, Is this correct that we can label anything for sale within EU?

[TPS Comment]
You can only apply CE marking where there is a relevant CE marking Directive and where you can demonstrate compliance. If there is no relevant CE marking Directive then you must not apply CE marking.
We import a Chinese product and we are the primary company who placed the product on the market. We have no technical file, DoC etc only a CE certificate from the manufacturer. Is this sufficient or should we build up all the information covered in this broadcast DoC, technical file etc.

[TPS Comment]
The responsible organisation based in the EEA is the first point in the supply chain who can:
- apply CE marking
- produce the Declaration of Conformity (DoC)
- compile and hold Technical Documentation

Where the manufacturer is not established within the EEA they can apply CE marking, produce the DoC and compile Technical Documentation. If they have an authorised representative within the EEA that representative should hold the DoC and Technical Documentation. For manufacturers outside the EEA with no authorised representative the DoC and Technical Documentation should be held by the first supplier of the equipment within the EEA.

How can I find the example of TF?

[TPS Comment]
You can download some very useful documents from the BIS website: http://bis.ecgroup.net/Publications/BusinessSectors/EnvironmentalTechnicalRegulations.aspx

For example URN 07/616 (Electrical Equipment (implementing the Low Voltage Directive)) gives some useful guidance in Annex D.

What is the difference between CE mark and GS mark?

[TPS Comment]
CE marking is your own declaration that the product complies with all applicable CE marking Directives. Generally there is no necessity to involve a 3rd party in the process (albeit recommended).
The GS Mark is a 3rd party certification issued by a Certification Body (such as TÜV SÜD) which is based on independent testing and ongoing surveillance of the production facilities in which the product is manufactured.
- **What is the meaning of presumption of conformity?**

  [TPS Comment]

  You do not have to test to European Harmonised standards but then you lose the benefit of the presumption of conformity and have to explain your compliance rationale in the technical file.

- **If say TÜV advise on what directives and standards your product needs to comply with, who is liable if a standard is missed etc?**

  [TPS Comment]
  Unfortunately you are ultimately liable. However I would always advise consulting with a testing / certification organisation or Notified Body for advice and recommendation.

- **What about components; are they subject to CE marking?**

  [TPS Comment]
  Components are covered by the regulations provided they fall within the scope of the regulations. E.g. a resistor being a passive device and falling outside the scope of the regulations is NOT subject to CE marking. A dc-dc converter module is covered by the regulations and therefore CE marking applies. If we take the case of the Low Voltage Directive only components which are “electrical equipment” need to comply with the regulations. Interestingly and unfortunately the term “electrical equipment” is not defined in the regulations and as such we suggest you use the standard dictionary definition: Electrical – “operated by means of electricity” Equipment – “the things collectively necessary to perform an activity or function”

- **What about “one off” and prototypes; do they need CE marking?**

  [TPS Comment]
  “One offs” and prototypes need not have CE marking applied. However you must still ensure that they meet the appropriate Essential Requirements; i.e. must be safe, must not interfere with or be interfered by.
• Isn’t it better to be safe and apply CE marking to all my products?

[TPS Comment]
It depends. If all your products are subject to one or more CE marking Directives then CE marking applies and must be carried out. If there is no relevant CE marking Directive or Directives applicable to your product then CE marking must not be applied.

• Can the declaration of conformity by someone outside of the EU?

[TPS Comment]
The responsible organisation based in the EEA is the first point in the supply chain who can:
- apply CE marking
- produce the Declaration of Conformity (DoC)
- compile and hold Technical Documentation

Where the manufacturer is not established within the EEA they can apply CE marking, produce the DoC and compile Technical Documentation.

If they have an authorised representative within the EEA that representative should hold the DoC and Technical Documentation.

For manufacturers outside the EEA with no authorised representative the DoC and Technical Documentation should be held by the first supplier of the equipment within the EEA.

• Where must the technical file reside?

[TPS Comment]
see Question above

• How long must the technical file be kept for?

[TPS Comment]
For 10 years after the last manufacture date of the product(s)
How does CE marking apply to second hand and refurbished equipment?

[TPS Comment]
CE marking does not apply to second hand equipment provided that second hand equipment has been previously placed on the market within the EU. If you are importing it into the EU for the first time then CE marking applies. Where equipment is refurbished in accordance with the original specification the requirements for second hand equipment apply. If however the refurbishment incorporates updates or upgrades such as different types of components the equipment is subject to CE marking and must be re-assessed.

We recently had a PC custom built for us from separate bits. Should that be CE marked? We manufacture small (<5) runs of unique or variants. When does this cease to be 'prototype'?

[TPS Comment]
Yes a PC built from custom parts is subject to CE marking. Small production runs are also subject to CE marking as they don't fall under either a prototype for evaluation or a "one off".

END.