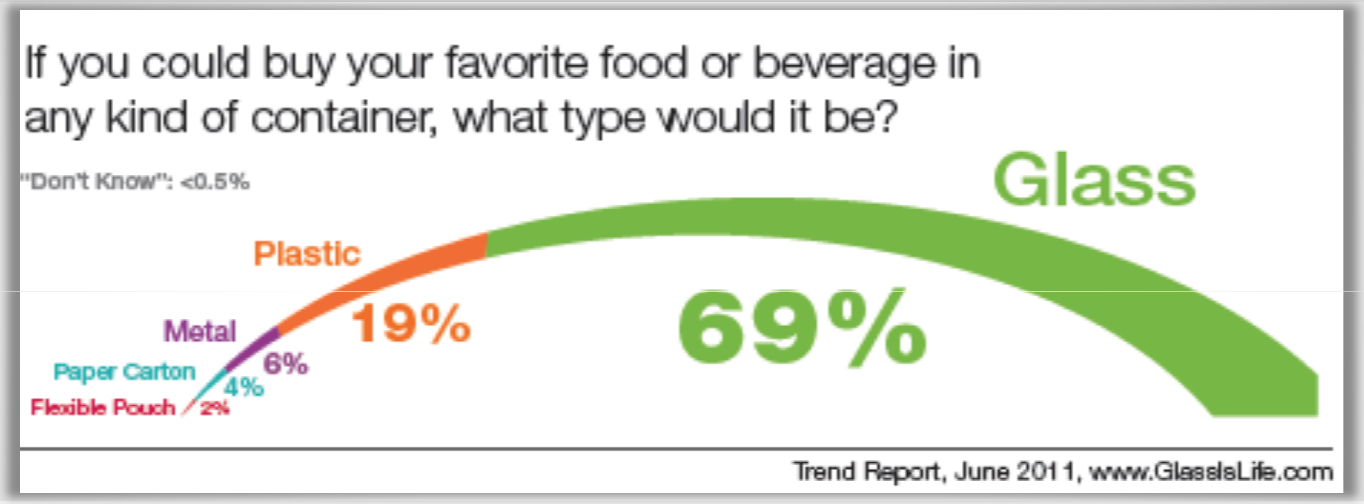
BENGAL GLASS

An ISO 9001:2008 Company



Glass Packaging

Issues with PET

Made from nontoxic raw materials - sand, soda ash, limestone, and up to 70 percent recycled glass or "cullet" - glass is the only packaging material accepted worldwide as "generally recognized as safe". Glass has **no chemical interaction**, ensuring that the products inside a glass bottle keep their strength, aroma, and flavor. Glass **does not deteriorate, corrode, stain or fade**, so products inside a glass container remain as fresh as when they were bottled. Glass packaging gives people confidence that their food is pure.

Key Features	Benefits
Inert and chemically inactive	- Does not undergo any transformation when subjected to chemical reactions
Pure and safe	- Does not contaminate content even if it is acidic - Can be hermetically sealed - Is nontoxic and impermeable
Odorless	- Does not emit any odor
Sterilizable	- Allows sterilization, as well as pasteurization
Longer shelf life	- Protects products against the effects of temperature and light
Nonpolluting	- Has least pollution impact compared to other packaging options (eg. PET)

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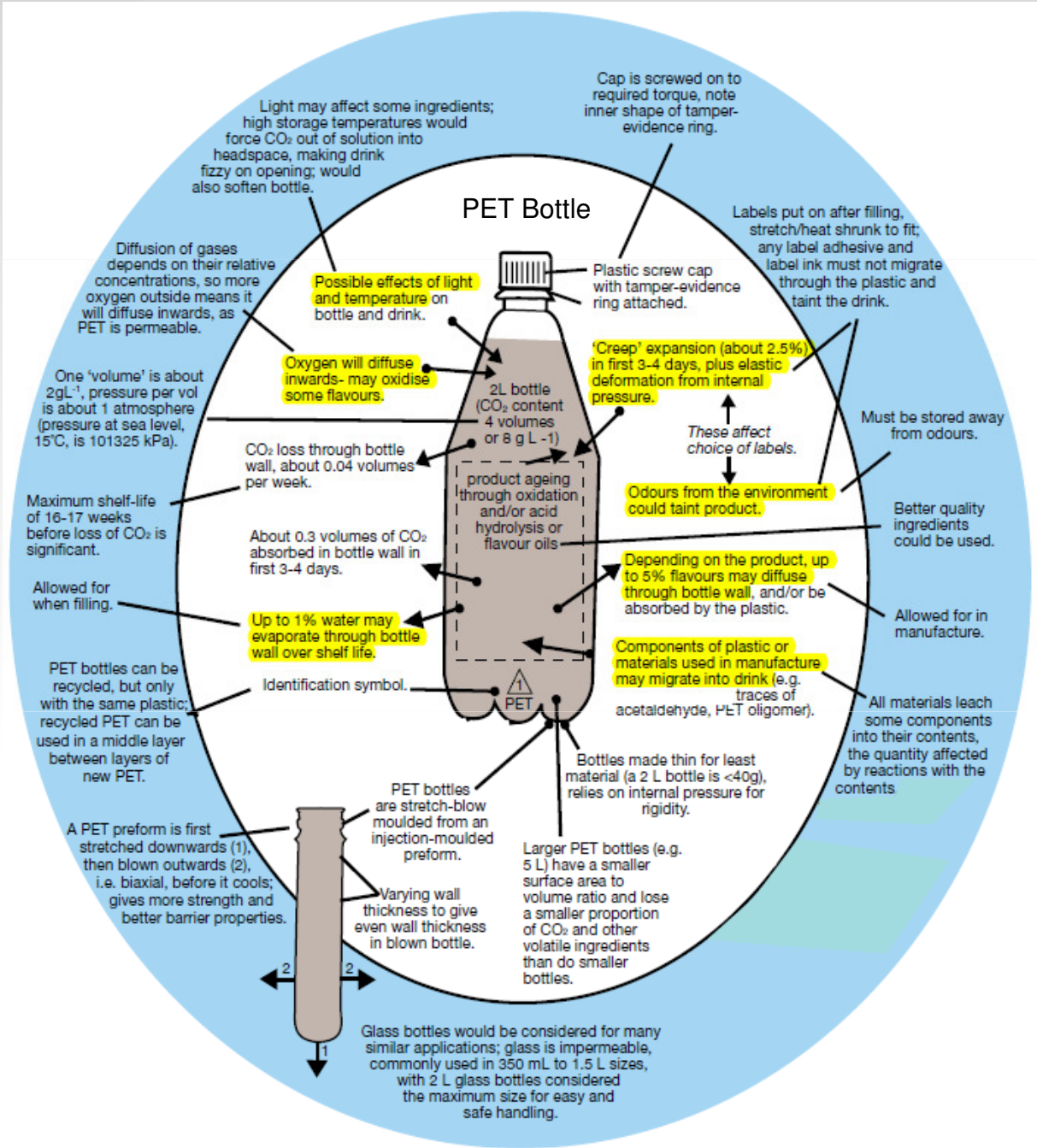
Issues with PET

- •Shelf Life
- •Hot filling
- •Safety
- •Environment
- •Price

Shelf Life:

1. Over time, oxygen diffuses through the PET wall into the container and reduces the shelf life of the contents by oxidizing the contents. Glass on the other hand is impermeable.
2. The amber color of the PET is often not dark enough – for oral drug purpose bottles greater than 50ml, light transmission must be less than 10% at wavelengths ranging from 290-450nm, as per US Pharmacopoeia.
3. PET allows through significant UV radiation above 320nm (Natural sunlight has UV wavelength between 315-400nm) if proper amber color is not used, whereas glass is opaque to UV radiation.
    i. Color of the content can change if synthetic food coloring is used (upto 80% concentration reduction in 2 hours)
    ii. In 2 hours of UV radiation, the concentration of ingredients degrade as follows and effect strength and flavor of medicine:

Vitamin	Degradation
A	100%
B6	75%
B12	77%
B2 (Riboflavin)	55%
Folic Acid	100%


PET Bottle
Light may affect some ingredients; high storage temperatures would force CO_2 out of solution into headspace, making drink fizzy on opening; would also soften bottle.
Cap is screwed on to required torque, note inner shape of tamper-evidence ring.
Diffusion of gases depends on their relative concentrations, so more oxygen outside means it will diffuse inwards, as PET is permeable.
Possible effects of light and temperature on bottle and drink.
Plastic screw cap with tamper-evidence ring attached.
Labels put on after filling, stretch/heat shrunk to fit; any label adhesive and label ink must not migrate through the plastic and taint the drink.
Oxygen will diffuse inwards- may oxidise some flavours.
'Creep' expansion (about 2.5%) in first 3-4 days, plus elastic deformation from internal pressure.
One 'volume' is about 2gL^{-1}, pressure per vol is about 1 atmosphere (pressure at sea level, 15°C, is 101325 kPa).
2L bottle (CO_2 content 4 volumes or 8 g L -1)
These affect choice of labels.
Must be stored away from odours.
CO_2 loss through bottle wall, about 0.04 volumes per week.
product ageing through oxidation and/or acid hydrolysis or flavour oils
Odours from the environment could taint product.
Maximum shelf-life of 16-17 weeks before loss of CO_2 is significant.
Better quality ingredients could be used.
About 0.3 volumes of CO_2 absorbed in bottle wall in first 3-4 days.
Depending on the product, up to 5% flavours may diffuse through bottle wall, and/or be absorbed by the plastic.
Allowed for when filling.
Allowed for in manufacture.
Up to 1% water may evaporate through bottle wall over shelf life.
Components of plastic or materials used in manufacture may migrate into drink (e.g. traces of acetaldehyde, PET oligomer).
PET bottles can be recycled, but only with the same plastic; recycled PET can be used in a middle layer between layers of new PET.
Identification symbol.
1
PET
All materials leach some components into their contents, the quantity affected by reactions with the contents
Bottles made thin for least material (a 2 L bottle is <40g), relies on internal pressure for rigidity.
PET bottles are stretch-blow moulded from an injection-moulded preform.
A PET preform is first stretched downwards (1), then blown outwards (2), i.e. biaxial, before it cools; gives more strength and better barrier properties.
Varying wall thickness to give even wall thickness in blown bottle.
Larger PET bottles (e.g. 5 L) have a smaller surface area to volume ratio and lose a smaller proportion of CO_2 and other volatile ingredients than do smaller bottles.
2
2
1
Glass bottles would be considered for many similar applications; glass is impermeable, commonly used in 350 mL to 1.5 L sizes, with 2 L glass bottles considered the maximum size for easy and safe handling.

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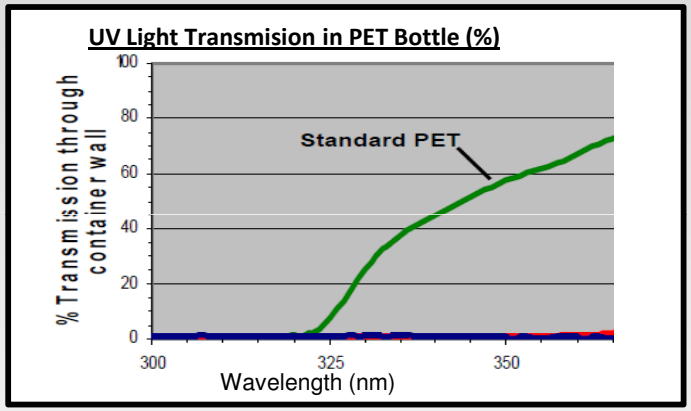
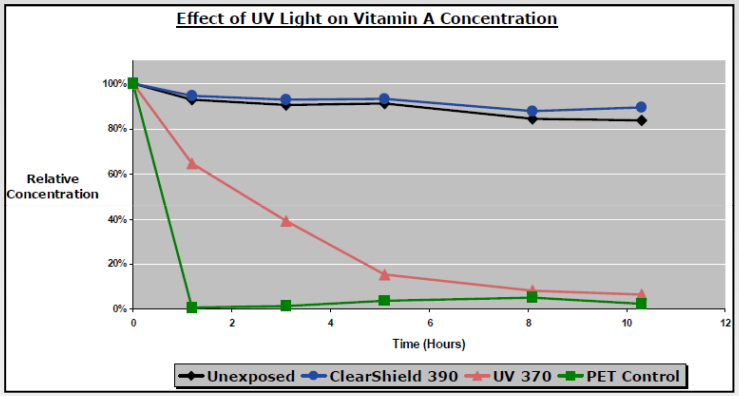
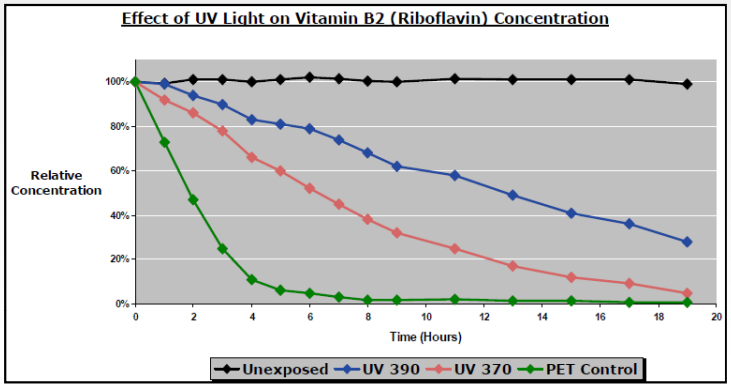
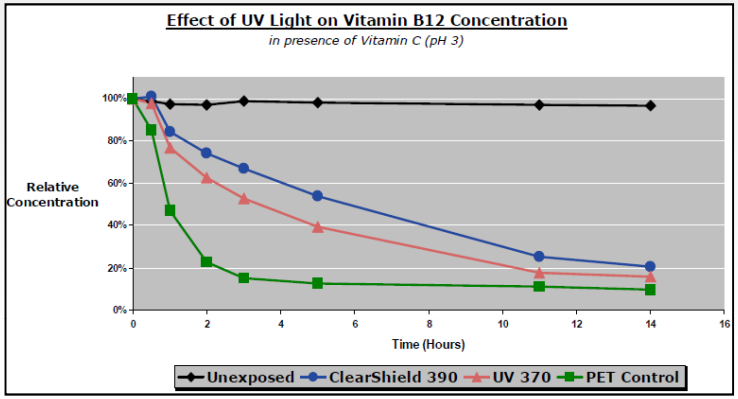
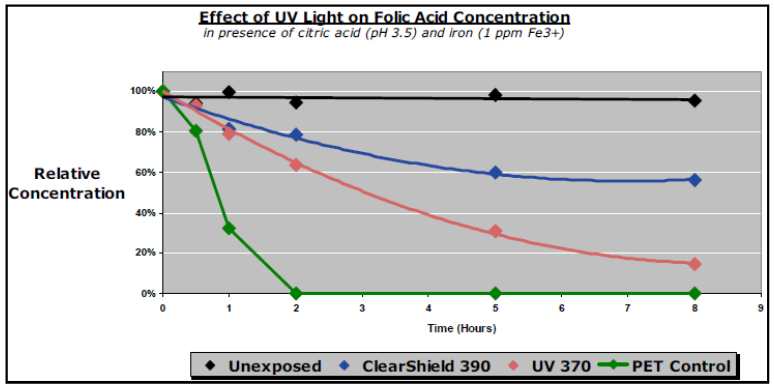
UV Light Impact on Content of PET Bottles

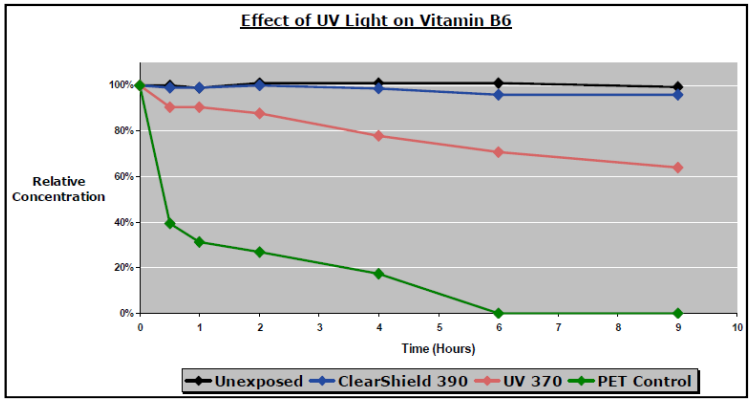












Source: Milliken Chemical, 2003

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Issues with PET

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- •Hot filling
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Hot filling:

Recent reports suggest that endocrine disruptors may leach into the contents of bottles made from polyethylene terephthalate (PET), which is the main ingredient in most clear plastic containers used for beverages and condiments worldwide. According to Leonard Sax, MD, PhD, temperature appears to influence the leaching both of phthalates and of antimony from PET, with **greater leaching at higher temperatures.**

Thus, one must address how products may interact with PET packaging material during the **hot-filling process**. Since some products are packed in a plastic container before high-pressure, heat processing - which can reach boiling **hot temperatures of 100 degrees Celsius** - certain products have already reached elevated temperatures in contact with the container in the filling process that far exceed temperatures found when microwaving foods. The plastic and the product contained within may also remain at elevated temperatures for some time after filling. This may **alter the packaging structure** and consequently its **mechanical and mass transfer (barrier and migration) properties** as well, posing a potential **health concern**.

Source: Sax, L, "Polyethylene Terephthalate May Yield Endocrine Disruptors", Environmental Health Perspectives, Vol. 118, no. 4, April 2010

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Glass Packaging

Issues with PET

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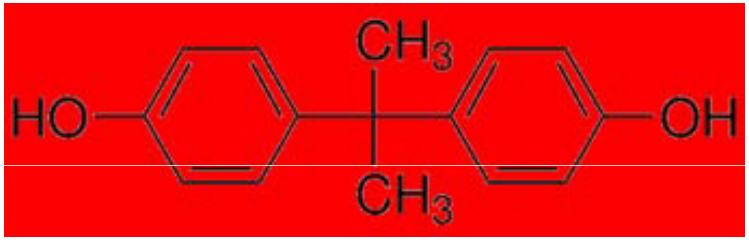
Safety:

1. PET is **not inert** like glass and therefore has potential to interact chemically with the medicine and make it unsafe for the consumer of the medicine.
2. Components of plastic or material used in manufacturing process migrate into contents like traces of acetaldehyde or PET oligomer.
3. The main chemical found in polycarbonate plastic, called **bisphenol A (BPA)**, causes neural and behavioral effects in fetuses, infants, and children. BPA works as an **endocrine disruptor** and interferes with natural hormone balance and can cause:
    i. Early puberty in both male and female
    ii. Altered prostrate and urinary development in infant males
    iii. Variety of cancers
4. PET bottles also contain additives such as **phthalates** (DMP, DEHP, etc) which are a group of chemicals used to make toys, detergents, lubrication oils, etc. and also act as endocrine disruptors and cause abdominal obesity and insulin resistance which leads to Type 2 diabetes and cardiovascular disease.

Source:
Muncke, J "Exposure to endocrine disrupting compounds via the food chain: Is packaging a relevant source? Science of the Total Environment.
Barrett, J. ,"Estrogens in a Bottle?", Environmental Health Perspectives, vol 117 , no. 6, June 2009

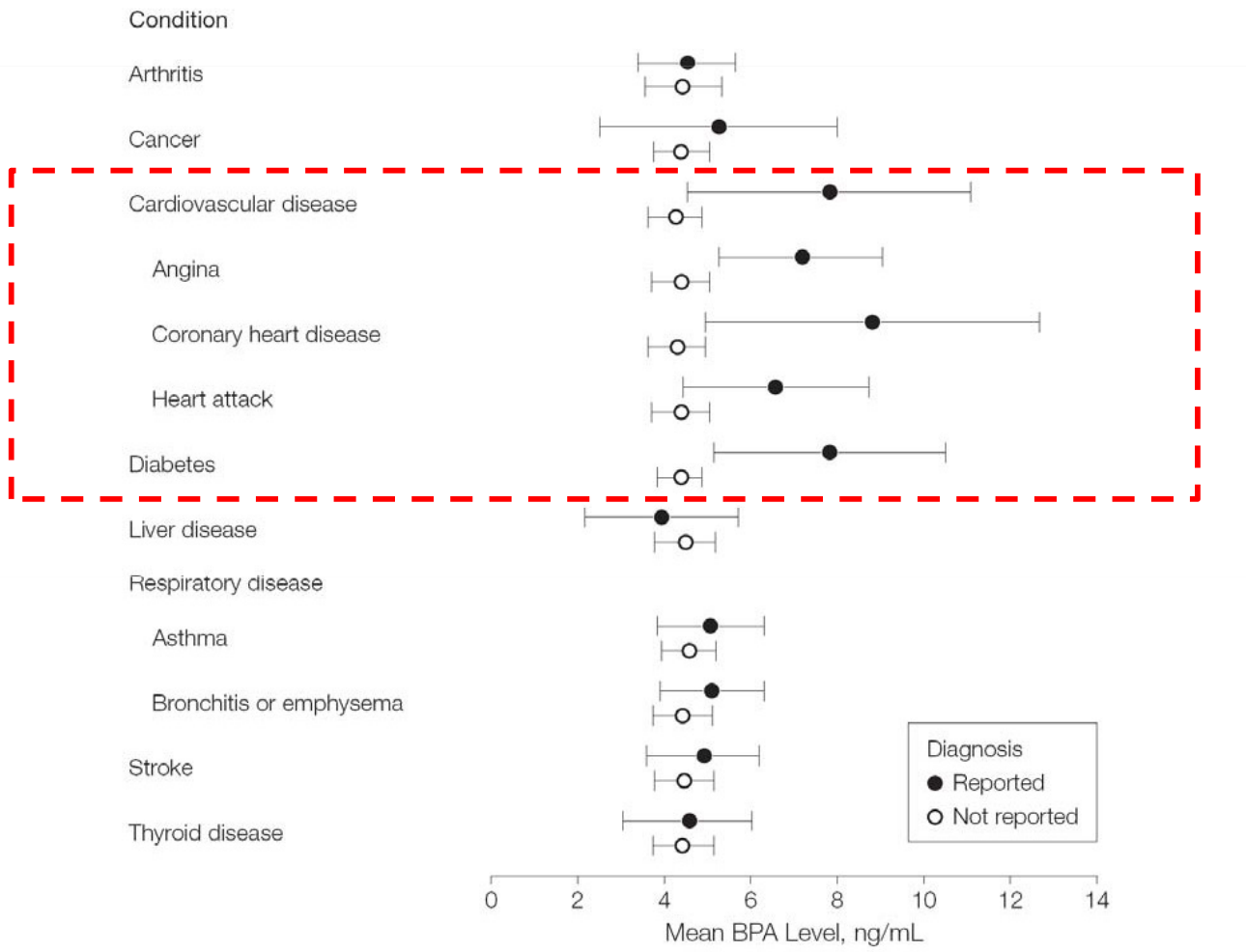
About BPA



- Bisphenol A
- High production volume chemical
- 1938: found to be estrogenic in vivo
- 1953: polymerization with phosgene into polycarbonate (PC)
- Since 1958 industrial production and use
- Endocrine Disrupting Chemical (EDC) - mimics biological effects of natural hormones
- 2006: global production > 4 M Tons (estimated)
- Uses:
    - Polycarbonate Plastics - 65-70%
    - CDs, DVDs; electronics, household appliances; baby bottles–Epoxy Resins - 25-30%
        - Coatings, adhesives, electrical laminates, food+beverage can linings, metal closures coatings
    - Other Uses - 5%
        - Thermal paper, PVC+rubber additive, precursor for other chemicals, dental sealants

Source: Friends of the Earth Europe (2008); Horn and Schnieders (2008) Kunststoffe 10; Dodds and Lawson (1938) Proc. Royal Soc. London B, 125, 222-232.

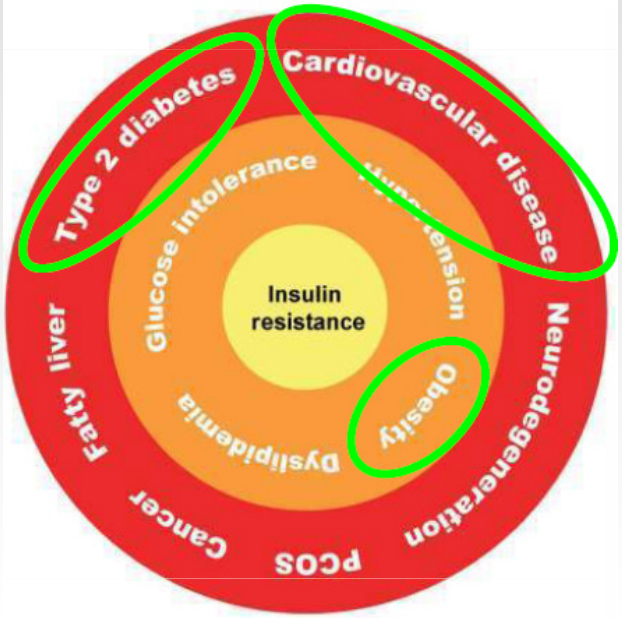
Figure. Estimated Mean Bisphenol A (BPA) Concentrations in Relation to Reported Diseases and Conditions



Estimates adjusted for age and sex. Error bars indicate 95% confidence intervals.

Source: Lang et al.(2008) JAMA 300 (11); Diabetes http://diabetes.niddk.nih.gov/dm/pubs/statistics/

Insulin resistance is at the beginning of many chronic diseases that are increasing



Source: Biddinger and Khan (2006) Annu. Rev. Physiol. 68:123-158

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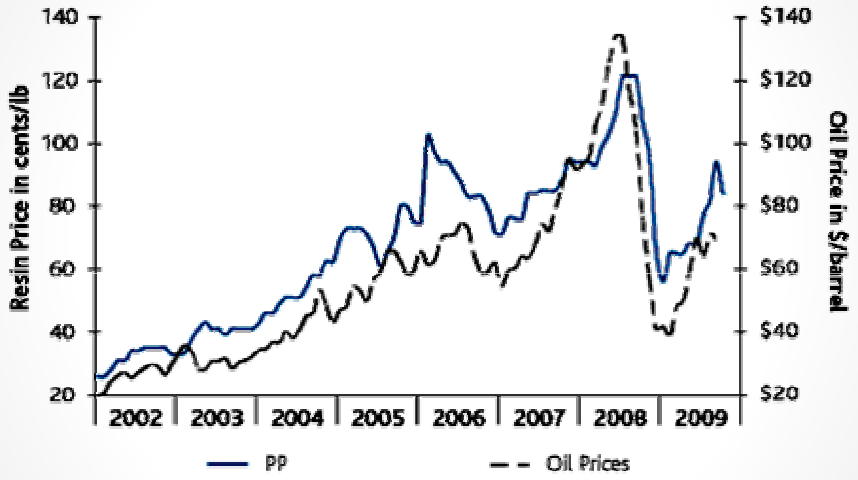
Environment:

1. A small percentage of PET bottles is recycled back into new bottles – a modernized nation like the US recycled only 28% of total PET bottles manufactured in 2009.
2. Even if it is recycled, plastic has a limited feasible number of cycles before it would have to be scrapped, since the strength of recycled PET bottles reduces every time when it is recycled.
3. PET bottles can only be recycled with the same plastic and can be used in a middle layer between layers of new PET.
4. On the other hand, broken glass is recycled endlessly by melting and reforming into glass and does not require additional processing when recycled.
5. PET is non-biodegradable and has a life expectancy of a 1000 years before it biodegrades.

Source: Parthasarathy, P, "Thermal and Mechanical properties of recycled PET and its blends", Annual Technical Conference 2005 Proceedings, Boston, MA.



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Price:

1. PET is a petrochemical product therefore the price of plastic resins is linked to the global oil price which is risky since the price can fluctuate drastically over time and can affect the profitability of the medicine.
2. In comparison, the primary raw material for glass is sand and its cost is highly stable.
3. Price of PET vs. BGW prices in Taka, as of October 2012, are as follows:

ITEM	BGW Price	PET Price	Difference
30 ml R/A	2.26	3.10	37%
60/70 ml R/A	3.02	3.17	5%
100 ml R/A	3.48	3.78	9%

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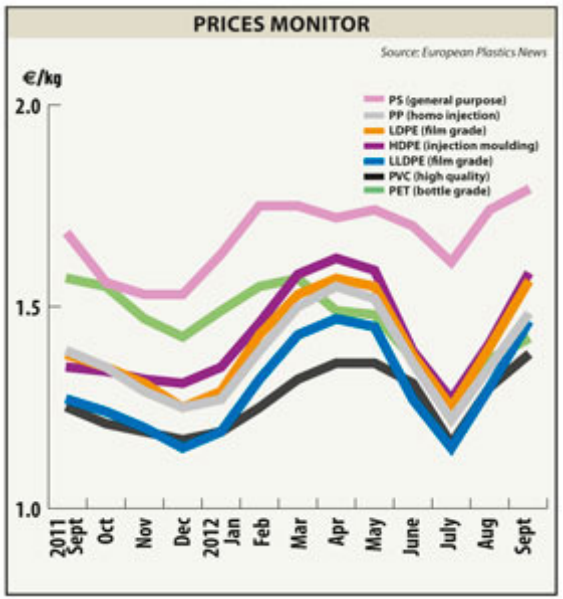
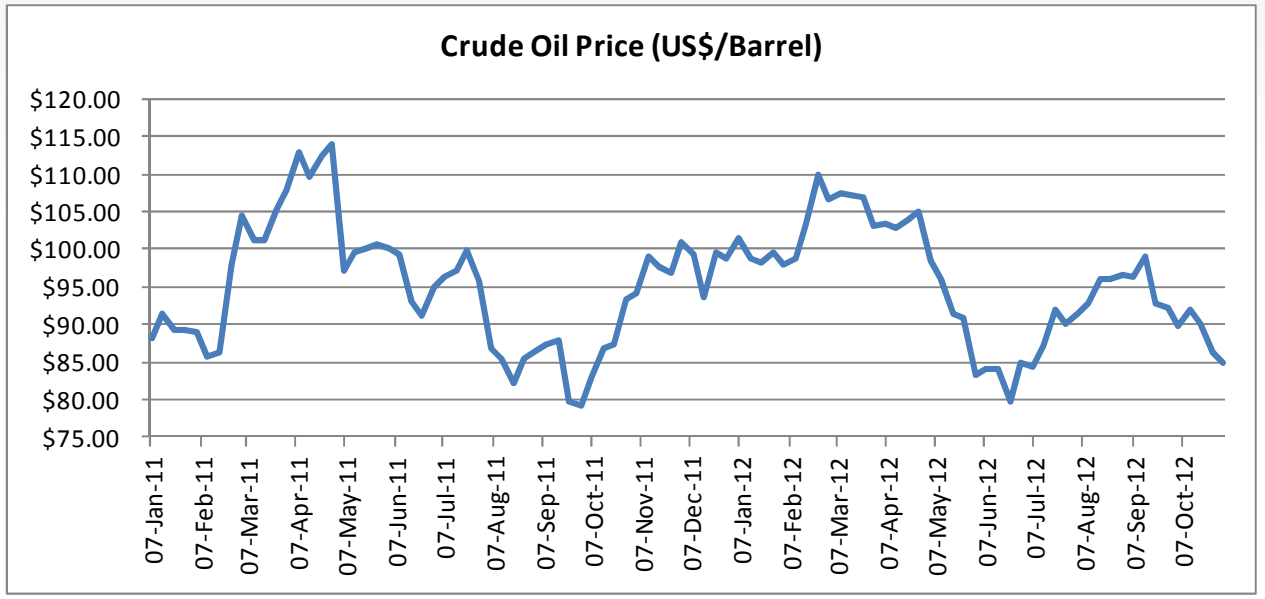
PET Resin Prices (US$/Metric Ton)

Source: http://www.recycleinme.com



Source: Eyre, C, "Tension as polymer price spiral continues", European Plastic News, October 3, 2012



Source: New York Mercantile Exchange (NYMEX)